



REGIONAL OFFICE,
M.P. POLLUTION CONTROL BOARD
17, BHARATPURI, UJJAIN

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S. No. 1075 /PCB/RO/2024.

Ujjain, Date 19/07/24

To,

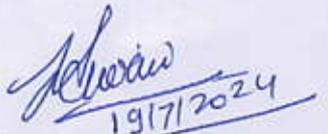
Smt. Parul Bhadoriya,
Advocate, Hon'ble N.G.T. (CZ)
Bhopal (M.P.)

Sub: Hon'ble NGT Original Application No.76/2024(CZ) (Rajendra Singh Thakur Vs State of M. P. & Ors.)".

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Please find enclosed Joint Committee Inspection Report in the Matter of Original Application No.76/2024(CZ) (Rajendra Singh Thakur Vs State of M. P. & Ors.) against Hon'ble NGT Central Bench Bhopal order dated 03 April 2024. The next hearing of case is scheduled on date 22 July 2024.

Encl:- As above


19/7/2024
(H. K. Tiwari)
Regional Officer

Joint Committee Inspection Report

In the Matter of

Original Application No.76/2024

‘Rajendra Singh Thakur V/s State of Madhya Pradesh&Ors.’

w.r.to

Hon`ble National Green Tribunal C`entral Bench

Bhopal order dated 3rd April, 2024



Date of Visit: 13th June, 2024

Location: Dewas (MP)

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Glossary

ATFD	Agitated Thin Film Dryer
BOD	Biochemical Oxygen Demand
CEMS	Continuous Emission Monitoring System
COD	Chemical Oxygen Demand
CPCB	Central Pollution Control Board
EPR	Extended Producer Responsibility
ETP	Effluent Treatment Plant
GPS	Global Positioning System
HPRO	High Pressure Reverse Osmosis
KLD	Kilo Liter Daily
MEE	Multiple Effect Evaporator
MW	Mega Watt
PTZ	Pan Tilt Zoom
RO	Reverse Osmosis
SOP	Standard Operating Procedure
STP	Sewage Treatment Plant
TDS	Total Dissolved Solid
TSDF	Treatment Storages Disposal Facility
ZLD	Zero Liquid Discharge

Joint Committee Inspection Report in the matter of
'Rajendra Singh Thakur V/s State of Madhya Pradesh &Ors.'

In the present case the applicant sent a letter petition to Hon'ble NGT Central Zone Bhopal and intimated about health & hygiene related issue and environmental pollution caused by M/s Sun Pharmaceutical Industries Dewas (MP). Hon'ble National Green Tribunal (CZ) took suo-moto cognizance and registered the case as O.A. no76/2024 'Rajendra Singh Thakur Vs State of Madhya Pradesh &Ors.' and directed vide its order dated 3.4.2024 as under vide para 1,6 and 7 :-

1. The issues raised in the abovesaid original application is use of polythene and poly bags, which are most harmful to the environment and used by the Sun Pharmaceutical Company Dewas in large quantity. The material is highly flammable product and there are misuse of electricity and untreated polluted water being discharge from the unit to the open land.

6. In view of the seriousness of the matter we constitute a Joint Committee consisting the following members to visit the site and submit the action taken report.

i. One representative from the Central Pollution Control Board (M.P.)

ii. One representative from the Madhya Pradesh State Pollution Control Board

iii. One representative from the District Magistrate Dewas (M.P.)

7. The Committee is directed to visit the place and submit the factual and action taken report within six weeks. The State PCB will be the nodal agency for coordination and logistic support.

In compliance with the Order dated 03.04.2024 of Hon'ble NGT (CZ) and based on the nominations received from the organizations concerned, Joint Committee has been constituted. The Committee was directed to ascertain verification of the violations and submit the factual report to the Hon'ble Tribunal. The committee comprising the following members:

1. Sh. Abhishek Sharma, City Magistrate District Dewas MP
2. Sh. H.K. Tiwari Regional Officer, M.P.P.C.B, Ujjain
3. Dr. Anoop Chaturvedi, Scientist 'B' CPCB, Bhopal

Terms of reference (ToR) to the Joint Committee:

The Terms of the Reference (ToR) to the Joint Committee referred therein the Order dated 03.04.2024 of Hon'ble NGT in the above matter inter-alia include the following:

1. Committee shall visit the site, collect relevant information and submit a factual report within before Central Zonal Bench at Bhopal.
2. To assess the alleged environmental issues as mentioned in petition, if any on the said area.

In compliance of the above direction, the joint committee visited area under question in Dewas, on 13.06.2024 to assess the factual status of allegation made in petition and present compliance status of use of polythene, safety precaution on handling of Potassium Clavulanate, electricity consumption, status of Zero liquid discharged, health & hygiene and duty hours of employees etc.

For better coordination in the investigation, the committee informed the applicant well in advance regarding the proposed visit. All the members of the Joint Committee were present and deliberated the TOR to the Committee and the issues involved therein. Sh.Rajender Singh Thakur(applicant) along with his other colleagues were present and discussed the issues mentioned in the petition. The representative of M/s Sun Pharma (further referred as unit)Sh. Vivek Bhargav, Sh. Shailesh Narkarwere also present and explained about technical operation of the unit and legal aspects of the case. The other officials present during the inspection are Dr. Deepak Kale, Scientist, Ms Nikita Barde District Env. Officer, MPPCB and Shri Neetesh Chaurasiya Jr. Engg. MPPCB.

The applicant Sh Rajendra Singh Thakur informed to the Committee that, he has not sent any complaint to the Hon'ble NGT or any other government department and the letter head and signature used in the application is fake and morphed by unknown person. Sh Thakur also told that when he came to know about this fraud, he immediately informed to police station on 14.03.2024 and the case was registered in Hon'ble NGT(CZ) on 21.3.2024, the intimation given to police station is enclosed as Annexure-01.

The applicant also submitted the affidavit before the Hon'ble NGT(CZ) Bhopal regarding fraudulent on the name of him, the copy of the affidavit is enclosed as Annexure-02.

However, to find out facts, as well as to know the extent of problem, the committee visited the plant premises and nearby area physically which are mentioned in petition and discussed the issue of waste water discharged in drain if any or any such instances in the recent past. The major observation of physical survey has been recorded in the form of Panchnama, which is enclosed as Annexure-03. After inspection of the site committee members again interacted with applicant and other local residents to provide further opportunities for providing any other information related to the application.

GPS location of the unit has been recorded using a mobile-based GPS application. The google map of the site and photographs were taken during the inspection are enclosed herewith. The geographical coordinates of unit and its surrounding area are $22^{\circ}92'79.35''N$, $76^{\circ}02'98.74''E$. To co-relate the visual observation, samples of nala passing through unit and outlet of RO and STP has been collected and later analysed by Regional lab. MPPCB, Ujjain for relevant parameters.



M/s Sun Pharma Dewas and nearby area

A brief on the industrial cluster & norms

M/s Sun Pharma Industries, Dewas (earlier known as Ranbaxy Ltd) was established in the year 1983 as formulation site at Dewas. This Plant conceptualized for handling Non sterile Semi synthetic penicillin's/ Cephalosporin's / General category products. The Plant has been built for supplying products to Domestic and International Regulated markets. The Bulk drugs Site established in the year 1992. Now this site is having 08 manufacturing plants of General API, Penem API (Sterile) & Intermediates.

The unit has Formulation and Bulk drug manufacturing plant in same premises and have valid Consent upto 30.04.2025 and 30.11.2024 respectively under Water (Prevention & Control of Pollution) Act, 1974 & Air (Prevention & Control of Pollution) Act, 1981 for the production of the same. The copy of the consents is enclosed as Annexure-04

The unit is also having valid authorisation under Hazardous and other Wastes (Management & Transboundary Movement) Rules, 2016 and valid upto 30.11.2026 and disposed all the hazardous waste as per condition given in authorisation.

The committee made the following observation on the issues as mentioned in petition during site visit: -

Issue No. 01: The use of polythene and polybags which are most harmful to the environment and are used in large quantity by the company. The company used more polythene and polybags than the entire city.

To verify the above fact the committee visited the raw material handling, drug packaging and waste collection yard area, observed that Plastic is widely used for the production of packaging systems in various section of unit, due to its characteristics of flexibility, mechanical strength and stability. One of the most obvious functions of pharmaceutical packaging is protection against physical damage as a product moves through the supply chain. As informed by the unit representative pharmaceutical products and plastic materials properties is essential to ensure the safety of the protected pharmaceutical products to reach its final destination.

The various type of plastic packaging i.e. LDPE, PP, PET is being used and same is generated as plastic packaging waste and as per Plastic waste

management Rules 2016 as amended unit has to dispose the plastic waste in accordance to 'Guidelines on Extended Producer Responsibility for Plastic Packaging'.

Extended Producers Responsibility (EPR) regime is under implementation as per Plastic Waste Management Rules, 2016, as amended according to which it is the responsibility of Importers and Brand-owners to ensure processing of their plastic packaging waste through recycling, re-use or end of life disposal. As per these guidelines, Producers, Importers and Brand Owners (PIBOs) shall have to register through the online centralized portal developed by the Central Pollution Control Board. PIBOs who are operating in more than two States shall be registered with CPCB in compliance of the rules the unit get registered on portal and registration certificate with annual plastic waste management target is enclosed as Annexure-05

Further, as per the information, available on the Centralized EPR Portal, 'Sun Pharmaceutical Industries Limited' is a Brand Owner and details of compliance with EPR Guidelines is as follows:

- It has registered on the above said portal on 03 June 2022 having EPR target for financial year 2022-23 of 2,024.18 tons [Rigid Plastic (Cat-I): 1477.52 MT and MLP (Cat-III): 546.66 MT].
- The unit has submitted the annual return for financial year 2022-23 on 25-11-2023 along with fulfilment of their EPR target which is enclosed as Annexure-06

Moreover, as per the information provided by the unit, the EPR target for financial year 2023-24 is determined as 3,772 tons [Rigid Plastic (Cat-I): 2208 MT, Flexible Plastic (Cat-II): 109 MT and MLP (Cat-III): 1455 MT], which needs to be fulfilled while submitting annual return for financial year 2023-24. For completion of plastic EPR targets the unit engaged M/s NEPRA Resource Pvt. Ltd. Ahmedabad. The committee randomly verify the documental proof of waste disposal which is submitted by the NEPRA on behalf of the unit which is enclosed as Annexure-07

Hence the committee has not observed discrepancy in plastic waste management as all the waste is being collected at centralised location of the unit and sent to authorised recycler for further disposal on daily basis in accordance to rules.

Issue No 02-The highly flammable product port Clave Potassium Clavinate is manufactured in the company which has cause fire several times. The company does not give information to government. This medicine manufactured in block A and Cof the company.Hundreds of labor are working here and fire accident that happened in crackers factory in Harda MP may occur here also.

As mentioned above the unit involved in production of Port Clave Potassium Calvinate in this regard the unit representative informed the committee that the unit is not manufacturing Potassium Calvinate however, for formulation purpose same is procured from outside and stored in cool and dry condition in isolated place with lock and key arrangement as per protocol. As per the requirement it is issued from the store and blended with other ingredient and binding agent to make drug in tablet form or in power form.

Clavulanic acid, also known by its potassium salt form clavulanate, is FDA approved for clinical use in conjunction with amoxicillin to treat certain bacterial infections. This can be based on the source of the infection, Gram stain, or culture and sensitivity results.

As per MSDS sheet of the Potassium Calvinate given by the unit is its flammability and reactivity are minimum hence the possibility of any explosion may not arise. The MSDS data sheet is enclosed as Annexure-08. The unit has also conducted the test of Potassium Calvinate powder from M/s GVS Cibatech Pvt Ltd. Which is fire testing laboratory based at Mumbai, the report also indicated that *'The material is not likely to be dust explosion hazard and has Minimum Ignition Energy (MIE) of more than 1000 mJ'*. The test report dated 29.12.2021 is enclosed as Annexure-09. The MIE is a safety characteristic in explosion protection and prevention which determines the ignition capability of fuel-air mixtures, where the fuel may be combustible vapor, gas or dust.

The committee member visited the storage and formulation area of Potassium Calvinate and observed no possibility of explosion hazard from that particular area.

The unit has also obtained the necessary manufacturing license No 25/18/23 in form 28 issued by Food and Drug Administration department of MP regarding use of Calvulanate Potassium and same is valid upto 8.3.2025 the manufacturing license is enclosed as Annexure-10

Issue No. 03-There is lot of misuse of electricity and need to charge 50% more bill by imposing special terrif in this company.

The unit representative informed that during last three years the energy consumption is gradually decreased because of various initiative taken by the unit i.e. Stoppage of dehumidifier in sterile block, installation of IE3 motors, energy efficient CT pump, installation of screw air pump etc. the cumulative effect is reduction of energy consumption as documental proof unit showed energy audit report and energy efficiency award of 2021 the efforts made by the unit is enclosed as Annexure-11 The document given by the unit reveled that the power index was 10.3 in 2021-22 and decreased 8.6 in 2023-24 (kwh per thousand-unit production) which is enclosed as Annexure-12 The unit also installed its own solar power plant of 30 MW capacity at Tarana near Ujjain and same is used for industrial purpose through grid. The unit is using approx. 50% solar power for its production, the power consumption during last three previous year given by the unit is enclosed as Annexure-13

Issue No 04- Dirty water containing chemicals is released into the drain at night in this company which is harmful to the environment.

The prime allegation in the application is discharging of waste water in night time by the unit causing water pollution, to verify this fact committee has been visited the entire adjacent area of the unit and pond but no such kind of activity of waste water discharge was observed by the committee. On the contrary the unit representative informed and it was also observed by committee a natural nala namely Rajeev Nagar nala passes through the unit which is entered from the back side of the unit and joins the Nagdhaman River, and mainly carrying domestic waste water of nearby residential area.

To assess the present status of water quality, samples of Rajeev Nagar nala before entering the unit and after leaving the unit has been collected and analyzed by Regional Lab. MPPCB, at Ujjain. The results of water analysis as given below:

Nala Water Analysis

S. No.	Parameters	Unit	Rajeev Nagar nala U/S Or before entering the unit	Rajeev Nagar nala D/S Or after leaving the unit
1	pH	pH Units	6.42	6.86
2	Chloride as Cl ⁻	mg/l	380	372
3	Total Solids	mg/l	1972	1924
4	Suspended Solids	mg/l	60	72
5	Total Dissolved Solids	mg/l	1912	1852
6	B.O.D.(3 Days 27°C)	mg/l	28	26
7	Chemical Oxygen Demand	mg/l	110	90
8	Phosphate as PO ₄ ³⁻ -P	mg/l	1.04	0.92

1. Based on the above analysis values of Rajeev Nagar nala it can be concluded that there is no reportable changes w.r.to pH, Chloride, COD and BOD values before entering and after leaving the unit premises. It indicated that no additional mixing of industrial effluent in the drain while passing through unit premises however if municipal corporation install the STP/in-situ type system of adequate capacity for the treatment of domestic waste water generated from Rajeev Nagar and nearby areas. It will also further improve the quality of waste water before mixing into Nagdahan River, a tributary of River Kshipra.

2. The effluent generated from the bulk drug and formulation plant, unit has provided ASP technology based ETP followed by MEE. The unit has full-fledged ETP/Zero Liquid Discharge (ZLD) facility equipped with RO, MEE for primary, secondary and tertiary treatment of effluent. The entire effluent load inclusive of process and domestic streams. Domestic waste water treated in SBT (Soil Bio-technology 250 KLD), and the same treated water is utilized for plantation.

Effluent segregated in to two streams High COD & Low COD. High COD stream is treated through Pre-treatment, MEE & ATFD. Condensate from MEE diverted to Low COD stream. Low COD stream treated through 1000 KLD ETP based on Aeration system (Activated Sludge Process) and further treated in RO. Treated effluent water finally yield good quality water which is recycled/ reused back to cooling tower, utilities and other area. During visit it was observed that the ETP was operated on 400 to 450 KLD capacity as bulk drug manufacturing unit operated on 40 % of its capacity due to market condition.

3. The effluent is collected from different collection pits provided in plants. The collection is done in equalization tank where the pH is adjusted if needed. The equalization tank is equipped with aeration mechanism for proper mixing. The effluent is transferred to primary clarifier where the coagulant dosing is done for sedimentation of suspended solids. The effluent goes into aeration tanks where the diffused aeration takes place. Thereafter it goes to secondary clarifier where again the flocculent dosing is done. The active sludge mass is recycled to aeration tanks to maintain the biomass.

4. The RO system is equipped with clarifier, Multigrade Filters, Basket Filters, Micron Filters and Ultra Filtration. The pre-treated water enters into the RO system for final polishing. RO system has three units of 700KLD, 300 KLD & 100 KLD HPRO. Two 300 KLD standby RO system also available to meet requirement in case of breakdown. The feed enters in 700 KLD RO & the reject goes into the 300 KLD RO, reject from 300 KLD RO goes into 100 KLD HPRO for further treatment. The reject is having high TDS and sent to MEE. The permeate water from RO plant recycled to cooling towers as a makeup water.

Units	Nos	Capacity
Collection tank	03 No.	900 KL x 3
Primary Clarifier	01 No.	45 KL
Clarifier with aeration tanks	03 No.	35 KL x 3
Final Clarifier	01 No.	192 KL
Clarifier before RO	01 No.	80 KL
Aeration tank-I	03 No.	246 KL x 2, 188 KL x 1
Aeration tank-II	03 No.	247 KL x 2, 228 KL x 1
Aeration tank-III	04 No.	500 KLx2, 300 KLx1, 400 KLx1
Ultra-Filtration (UF)	01 No.	400 KLD
RO plant -I	01 No.	700 KLD
RO plant -II	01 No.	300 KLD
RO plant -III (High pressure type)	01 No.	100 KLD
RO Plant (stand by)	02 No.	300 KLD x 2
Multiple Effect Evaporator and ATFD	01 No.	150 KLD

Multiple Effect Evaporator and ATFD (Standbysystem)	01 No.	150 KLD
Sludge dewatering Press Filter System	01 No.	6 M3/Hr.
Sludge dewatering-Decanter machine	01 No.	50 KLD
Sludge dewatering-Volute machine (Standby system)	01 No.	50 KLD
Soil bed technology (SBT) for sewage treatment	01 No.	250 KLD

5. The water balance of Formulation and Bulk drug plant with flow diagram of present treatment system is enclosed as Annexure-14

6. To assess the quality of RO, permeate and STP outlet water samples have been collected and the results as given below:

Outlet water analysis

S. No.	Parameters	Unit	RO permeate (being recycled)	SBT outlet (being used in horticulture)
1	pH	pH Units	7.11	7.26
2	Chloride as Cl ⁻	mg/l	24	114
3	Total Solids	mg/l	198	1038
4	Suspended Solids	mg/l	6	10
5	Total Dissolved Solids	mg/l	192	1028
6	B.O.D. (3 Days 27°C)	mg/l	1.2	8
7	Chemical Oxygen Demand	mg/l	20	40
8	Phosphate as PO ₄ ³⁻ -P	mg/l	ND	--
9	O & G	mg/l	ND	BDL
10	Cr6+	mg/l	ND	--
11	Lead (Pb)	mg/l	ND	--
12	Mercury (as Hg)	mg/l	ND	--

ND- Not Detected, BDL- Below Detectable Limit

7. On the basis of the analysis results of the RO permeate and STP outlet it can be concluded that none of the parameter is showing abnormal values and waste water treatment system work satisfactorily during visit.

8. The unit has installed continuous online monitoring system for measurement of pH, TSS, COD and BOD and also provided its connectivity to

MPPCB and CPCB server to monitor the treated water quality remotely on 24 X 7 basis. The unit has also installed the PTZ camera inside the ETP to monitor its operation and its access also provided to MPPCB. The online effluent monitoring system and the data displayed during visit was also in consonance of lab results. However as per consent condition the unit has to maintain the Zero Liquid Discharge status and unit found complied at the time of visit. The OCEMS data available on portal on the day of inspection is enclosed as Annexure-15 and the analysis report of collected water samples are enclosed as Annexure-16

9. The unit has maintained Zero Liquid Discharged condition at the time of visit and MEE and ATFD found operational. The unit has installed 02 MEE plant of 150 KLD each, one for operation and one standby. The MEE concentrates effluent by evaporating water content. MEE recovers about 95% of water, converting the remaining 5% into solid waste. ATFD is used for final drying of MEE concentrate, ATFD produces dry solids suitable for further disposal at TSDF. The above system is fulfilling the requirement of ZLD condition.

Issue No. 05-Male and female laborers working in the company are not even given time to wash their hands and face before going home every day. Dangerous antibiotic powder on hands which reached to there home, which is extreme fatal for small children's and elderly peoples.

To verify the above facts the committee visited the formulation and bulk drug manufacturing area and observed that due to compliance of stringent FDA rules SOPs of entering and exit made and each employee has to follow it for health and hygiene point of view. It was also observed that it is mandatory for everyone to follow the guidelines of entry and exit procedure. The SOP following by the unit is enclosed as Annexure-17

Issue No. 06 –Night duty of the company is for 2 days. Duty time is from 11.15 pm to 7.30 am due to which the quality of life saving medicines is hampered and health of the workers is also adversely affected.

The unit have continuous production type of manufacturing hence the unit is operating on 24 X 7 basis and as informed by the HR representative of the unit they have issued order in this regard and intimated all the concerned employees

through time office for their shift timings. This also pasted on the main gate and notice boards of the concerned section. The official order issued is enclosed as Annexure-18

Conclusion:

On the basis of present inspection, it was observed that the unit is maintaining Zero Liquid Discharged status through installation of MEE and ATFD with standby arrangement and no waste water found discharging during visit which is the main environmental contention of the petition.

The unit has installed CEMS system to monitor waste water treatment system on real time basis and also installed PTZ cameras to observe live activity remotely and all data transmitted on MPPCB portal.

The unit using plastic packaging for their product safety however unit has registered on CPCB plastic EPR portal and all necessary targets of plastic management has been completed in previous FY 2022-23 and compliance of the FY 2023-24 is under progress.

The other issues are mentioned in the petition are related to health, hygiene and service condition for that district administration may monitor the compliances through labour, food & safety department as per rules.

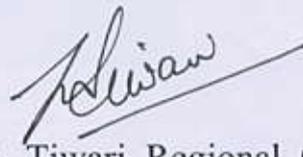
Hence, the facts mentioned in the letter petition are not in consonance with the factual position observed by the committee during site visit and no environmental violation were observed as alleged by petitioner, moreover the alleged applicant in formed the committee that it is the fake complaint and his name and letter head was mis-used by unknown person. However, for further betterment the following recommendations given by the committee.

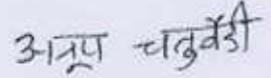
Recommendations

1. The municipal corporation of Dewas may install the STP of adequate capacity for the treatment of domestic waste water generated from Rajeev Nagar and nearby areas. Also, the Municipal Corporation should make arrangements to avoid the treated waste water entering into Sun Pharma premises through natural Nala which finally mixes into Nagdahan River, a tributary of River Kshipra.

2. The unit may fulfill the plastic EPR target in accordance to the PWM, Rules.
3. Annual health check-up camps may organise for all employee including contractual workers in association with local health authorities.
4. The functioning of CEQMS and PTZ camera shall have to be checked periodically and the strict surveillance and vigil shall have to be kept by MPPCB.
5. The unit shall have to strictly follow the Rules and guidelines issued by Labour Department regarding shift working hours and duration.
6. The log book of power consumption shall have to be maintained properly and the Unit authorities shall have to organize the meetings with Energy Department of MP Govt. to Conclude for minimize the power consumption w.r.to maximize the production capacity. And adopt new concepts of power saving technology.


Sh. Abhishek Sharma
City Magistrate , Dewas


Sh. H. K. Tiwari Regional Officer,
M.P. Pollution Control Board, Ujjain


Dr. Anoop Chaturvedi, Scientist 'B'
Regional Directorate, CPCB, Bhopal

Photograph of the committee visit



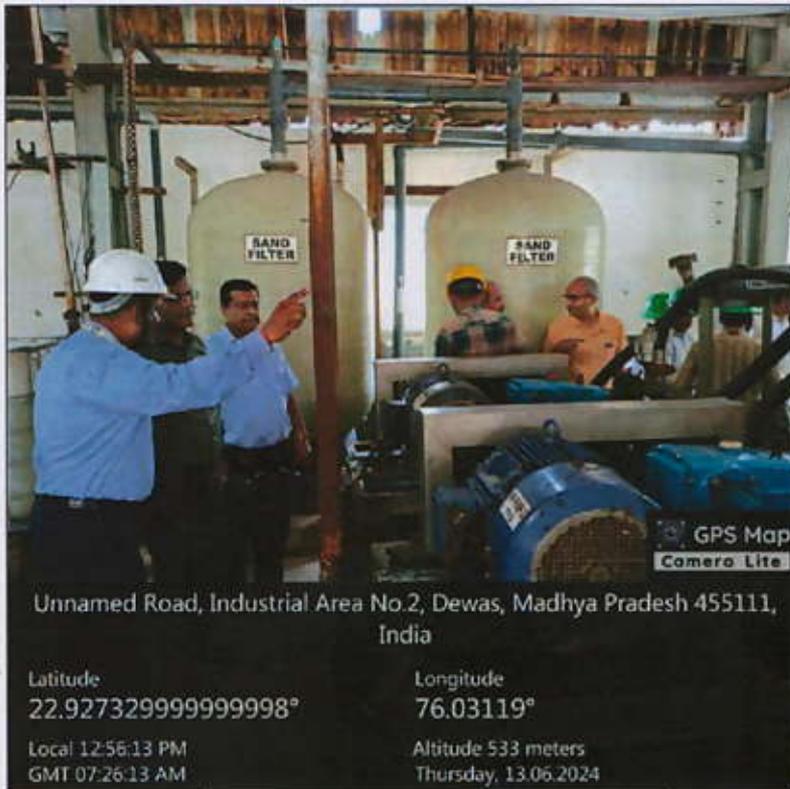
Committee meeting with applicant Sh Rajendra Singh Thakur



Committee visited the ETP area



Committee visits inside premises



Committee visited RO plant area



Rajeev Nagar nala before entering to plant premises



Rajeev Nagar nala after exit plant premises



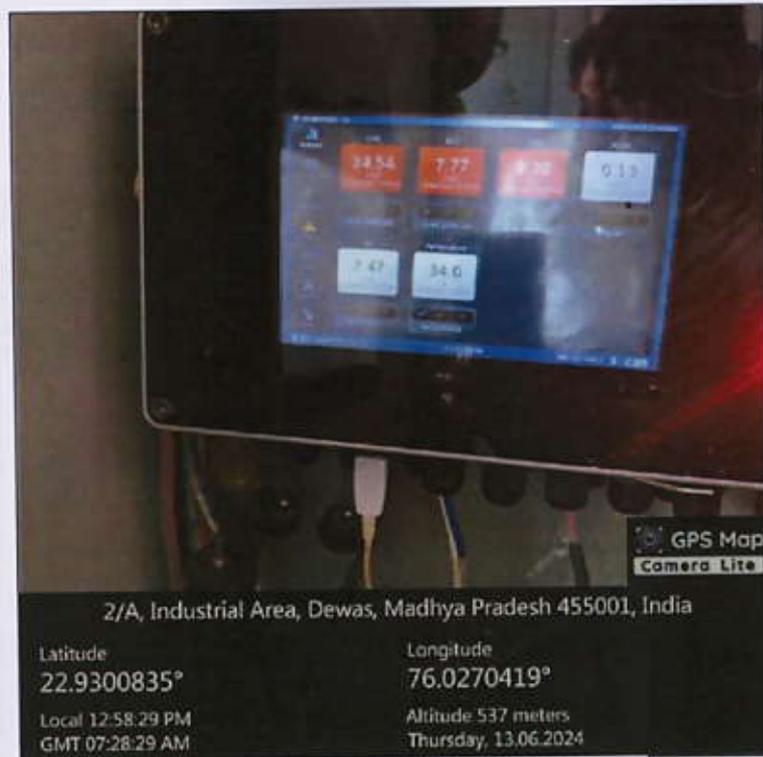
Inside view of process area with proper precaution as per SOP





Plastic waste generation, storage and collection area as per authorisation.





OCEMS installed at RO permeate



SBM based sewage treatment plant

“श्री”

रजि. क्र. 3304
मान्यता प्राप्त नं. 148 MPAIR
अनुमादित संघ नं. 64

ड्रग्स एण्ड फार्मास्यूटिकल्स एम्प्लॉयज यूनियन

क्रमांक 41/R/24 86, तुकोगंज रोड, देवास 455001 (म.प्र.), मो. 9826245521 दिनांक 15/03/24

अध्यक्ष शंकर सिंह बैस	<p>प्रति, श्रीमान थाना प्रमारी महोदय, थाना औद्योगिक क्षेत्र जिला देवास (म.प्र.)</p> <p>विषय- प्रतिनिधी संघ के लेटरहेड व संघ के प्रधानमंत्री के हस्ताक्षरित पत्र का दुरुपयोग करने बाबद।</p> <p>महोदय,</p> <p>उक्त विषयांतर्गत आपको सूचित हो कि हम प्रतिनिधी संघ राजस्व जिला देवास में ड्रग्स एवं फार्मास्यूटिकल उद्योग के मान्यता प्राप्त प्रतिनिधी संघ है।</p> <p>आपको विदित हो कि कुछ तथाकथित व्यक्तियों द्वारा हमारे संघ के लेटरहेड में फेरबदल कर युनियन के प्रधानमंत्री राजेन्द्र सिंह ठाकुर (अधोहस्ताक्षरकर्ता) के नाम से विभिन्न शासकीय कार्यालयों में झुठी एवं फर्जी शिकायत कर रहे हैं, जबकि हमारा की गई शिकायत से कोई संबंध नहीं है न ही हमारे द्वारा की गई है।</p> <p>मुझे अंदेशा है कि हमारे द्वारा श्रम एवं शासकीय कार्यालयों में विभिन्न पेशियों पर प्रत्युत्तर हेतू लेटरहेड का उपयोग होता है जिसकी प्रति विभाग द्वारा विपक्षी को भी दी जाती है उसी में छेड़-छाड़ कर मेरे नाम से झुठी शिकायतें सन फार्मास्यूटिकल इंडस्ट्रीज लिमिटेड देवास के विरुद्ध की गई हैं जिस शिकायत की प्रति पत्र के साथ संलग्न है।</p> <p>में प्रतिनिधी संघ का प्रधानमंत्री राजेन्द्रसिंह ठाकुर आपको अवगत कराते हुए ध्यान आकर्षित करना चाहता हूं कि झुठी शिकायत की प्रति को संज्ञान में लेकर उसकी बारीकी से जांच करें तो स्पष्ट होगा कि उक्त प्रति को कम्प्युटर</p>
उपाध्यक्ष योगेश पाटनकर	
प्रधानमंत्री राजेन्द्र सिंह ठाकुर	
मंत्री हिन्दुसिंह राजपुत	
कोषाध्यक्ष विजय शर्मा	
प्रचार मंत्री रामप्रसाद पटेल	

“श्री”

रजि. क्र. 3304

मान्यता प्राप्त नं. 148 MPAIR

अनुमादित संघ नं. 64

ड्रग्स एण्ड फार्मास्यूटिकल्स एम्पलाईज यूनियन

क्रमांक _____ 86, तुकोगंज रोड, देवास 455001 (म.प्र.), मो. 9826245521 दिनांक _____

अध्यक्ष
शंकर सिंह वैस

उपाध्यक्ष
योगेश पाटनकर

प्रधानमंत्री
राजेन्द्र सिंह ठाकुर

मंत्री
हिन्दुसिंह राजपुत

कोषाध्यक्ष
विजय शर्मा

प्रचार मंत्री
रामप्रसाद पटेल

द्वारा लेटरहेड में छेड़-छाड़ कर बनाया गया है। मेरे द्वारा सन फार्मास्यूटिकल इंडस्ट्रीज लिमिटेड देवास के विरुद्ध कोई झुठी शिकायत नहीं की गई है।

श्रीमान को अवगत कराना चाहते हूँ की तथाकथित व्यक्ति भविष्य में भी हमारे प्रतिनिधी संघ की छवि धुमिल करने के लिए विभिन्न षडयंत्र रच कर औद्योगिक शांति भंग करने का प्रयास कर सकते है।

अतः श्रीमान से निवेदन है कि हमारी शिकायत को त्वरित संज्ञान में लेकर उचित कार्यवाही कर घटना की तह तक पहुंचे।

भवदीय
राजेन्द्र सिंह ठाकुर
प्रधानमंत्री
ड्रग्स एण्ड फार्मास्यूटिकल्स एम्पलाईज यूनियन
देवास (म.प्र.)

प्रतिलिपी-

1. श्रीमान जिलाधीश महोदय, जिला देवास (म.प्र.)
2. श्रीमान पुलिस अधीक्षक महोदय, जिला देवास (म.प्र.)



14/03/2024

14/3/24
कामेश्वर ठाकुर
जोसेफ कार्यालय
जिला देवास (म.प्र.)

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नोट - मान्यता प्राप्त संघ होने के कारण पत्रों का उत्तर देना अनिवार्य है।

"श्री"

ड्रग्स एंड फार्मास्यूटिकल्स एम्प्लॉयज यूनियन

क्रमांक GEN

86, तुकोगंज रोड, देवास 455001 (म.प्र.), मो. 9826245521

दिनांक 22/4/2024

<p>अध्यक्ष शंकर सिंह बैस</p>	<p>प्रति, श्रीमान राजेश कुमार अग्रवाल साहब, रजिस्टार, नेशनल ग्रीन टिब्यूनल, सेंट्रल जोन बेंच, स्टेट कमीशन भवन, अरेरा हिल्स भोपाल (म.प्र.) 462011</p>
<p>उपाध्यक्ष योगेश पाटनकर</p>	<p>विषय: प्रतिनिधि संघ ड्रग्स एंड फार्मास्यूटिकल एम्प्लॉयज यूनियन राजस्व जिला देवास के लेटर पैड व संघ के प्रधानमंत्री के हस्ताक्षरित पत्र का दुरुपयोग करने के संदर्भ में सन्दर्भ: कतिपय व्यक्तियों द्वारा हमारे प्रतिनिधि संघ के लेटर हेड का दुरुपयोग करते हुए संघ के प्रधानमंत्री राजेंद्र सिंह ठाकुर के नाम से सन फार्मा कंपनी की झूठी शिकायत करने बाबत</p>
<p>प्रधानमंत्री राजेन्द्र सिंह ठाकुर</p>	<p>महोदय, उपरोक्त विषय अंतर्गत आपको सविनय सूचित हो कि हम प्रतिनिधि संघ "ड्रग्स एंड फार्मास्यूटिकल एम्प्लॉयज यूनियन" राजस्व जिला देवास में ड्रग्स एंड फार्मास्यूटिकल उद्योग के लिए मान्यता प्राप्त संघ (यूनियन) हैं</p>
<p>मंत्री हिन्दुसिंह राजपुत</p>	<p>निवेदन है की कतिपय व्यक्तियों द्वारा हमारे यूनियन के लेटर हेड में फेरबदल (cut-paste) करके यूनियन के प्रधानमंत्री राजेंद्र सिंह ठाकुर (अधोहस्ताक्षरकर्ता) के नाम से विभिन्न शासकीय विभागों में झूठी एवं मनगढ़ंत शिकायतें की गई है जबकि हमारे यूनियन का ऐसी शिकायतों से कोई संबंध नहीं है ना ही कोई शिकायत हमारे यूनियन एवं प्रधानमंत्री राजेंद्र सिंह ठाकुर द्वारा किसी भी सरकारी विभाग में की गई है</p>
<p>कोषाध्यक्ष विजय शर्मा</p>	<p>हमें ज्ञात हुआ है कि हमारी यूनियन के लेटर हेड में फेरबदल करके सन फार्मास्यूटिकल इंडस्ट्रीज लिमिटेड देवास (कंपनी) की आप श्रीमान के समक्ष भी झूठी एवं मनगढ़ंत शिकायत की गई है अतः इस पत्र के द्वारा हम निम्न स्पष्टीकरण प्रस्तुत करना चाहते हैं:</p>
<p>प्रचार मंत्री रामप्रसाद पटेल</p>	<p>1) यह कि जिस लेटर हेड पर झूठी शिकायत की गई है उसे पूरा बारीकी से जांच करेंगे तो आपको स्वयं स्पष्ट हो जाएगा की हमारी यूनियन के लेटर हेड को फेरबदल (cut-paste) करके झूठी एवं मनगढ़ंत शिकायत कर कंपनी सन फार्मा एवं हमारी यूनियन की छवि बिगड़ने के प्रयास किए गए हैं</p>
<p>2) यह कि हमें अदेशा है कि हमारे द्वारा श्रम एवं अन्य शासकीय कार्यालयों में विभिन्न पेशियों पर प्रतिउत्तर हेतु लेटर हेड का उपयोग किया गया है जिसकी छाया प्रति शासकीय कार्यालयों द्वारा विपक्षियों को भी दी जाती है उसी में छेड़छाड़ कर हमारे नाम से झूठी शिकायत कंपनी सन फार्मा के विरुद्ध की गई है जिस शिकायत की प्रति इस पत्र के साथ संलग्न है</p>	<p>3) यह कि उक्त संदर्भित झूठी शिकायत में कहा गया है कि पर्यावरण EHS को भारी नुकसान पहुंचाया जा रहा है जो की पूर्णतः असत्य है, यह मात्र हमारी यूनियन के नाम एवं पद का सहारा लेकर झूठी फर्जी शिकायत है, अतः निवेदन है की प्रथम दृष्टया ही</p>



Received
by

22-04-2024

नोट - मान्यता प्राप्त संघ होने के कारण पत्रों का उत्तर देना अनिवार्य है।

(10)

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“श्री”

रजि. क्र. 3304

मान्यता प्राप्त नं. 148 MPAIR

अनुमादित संघ नं. 64

ड्रग्स एण्ड फार्मास्यूटिकल्स एम्पलाईज यूनियन

क्रमांक _____

86, तुकोगंज रोड, देवास 455001 (म.प्र.), मो. 9826245521

दिनांक _____

अध्यक्ष शंकर सिंह बैस	इसे खारिज करें क्योंकि सन फार्मा कंपनी में किसी भी गलत तरीके से कार्य नहीं होता है तथा यहां पर्यावरण एवं सुरक्षा का भरपूर ध्यान रखा जाता है।
उपाध्यक्ष योगेश पाटनकर	4) यह कि उक्त झूठी शिकायत में कहा गया है कि पर्यावरण के लिए सबसे नुकसानदायक पॉलीथीन पॉलीबैग की थैलियां का बहुत ज्यादा उपयोग किया जाता है पॉलीबैग का ज्यादा वेस्टेज एवं उपयोग किया जाता है जो की पूर्णतः असत्य है, क्योंकि सन फार्मा में पॉलीबैग का इस्तेमाल फार्मा उद्योगों के नियम एवं मानकों के आधार पर ही होता है
प्रधानमंत्री राजेन्द्र सिंह ठाकुर	5) यह कि उक्त झूठी शिकायत में कहा गया है कि कंपनी में अत्यंत ज्वलनशील प्रोडक्ट पॉट क्लॉव का निर्माण किया जाता है जिसमें कई मर्तबा आग लग चुकी है यह संपूर्ण कथन पूर्णतः असत्य है क्योंकि कंपनी में सिर्फ जीवन रक्षक दवाइयों का निर्माण होता है, मैं स्वयं विगत 40 वर्षों से इसी उद्योग में कार्यरत हूँ परंतु आज दिनांक तक आग लगने जैसी कोई घटना नहीं हुई है और ना ही उक्त उत्पाद ज्वलनशील है यह जानकारी पूर्ण रूप से भ्रामक है एवं मात्र कंपनी एवं यूनियन को बदनाम करने हेतु एवं अनुचित स्वार्थ सिद्धि हेतु लिखा गया है। श्रीमान तथाकथित व्यक्तियों को इस बात का भी ज्ञान नहीं है कि हरदा जैसी घटना फार्मा उद्योग में किस प्रकार हो सकती है जो की जीवन रक्षक दवाइयों का निर्माण करते हैं ना कि किसी बारूद का, जो हरदा घटना हुई थी वह बारूद का कार्य करते थे जिससे दुर्घटना घटी, जिसका सन फार्मा कंपनी को उदाहरण बताना हास्य का विषय है।
मंत्री हिन्दुसिंह राजपुत	6) यह की उक्त झूठी शिकायत में कहा गया है कि बिजली का बहुत ज्यादा दुरुपयोग होता है, यह कथन पूर्णतः असत्य है तथा मेरी जानकारी के अनुसार ऐसा बिलकुल भी नहीं है और समय-समय पर विद्युत विभाग द्वारा जांच भी होती रहती है।
कोषाध्यक्ष विजय शर्मा	7) यह कि उक्त झूठी शिकायत में कहा गया है कि कंपनी में केमिकल युक्त गंदा पानी रात्रि में नाले में छोड़ दिया जाता है जो कि एकदम असत्य है और केवल कंपनी को बदनाम करने के उद्देश्य से कहा गया है, हमारी जानकारी के अनुसार सन फार्मा कंपनी में विशालकाय ट्रीटमेंट प्लांट लगा हुआ है जहां दूषित पानी को शुद्ध कर पुनः अन्य कार्यों में उपयोग में लाया जाता है।
प्रचार मंत्री रामप्रसाद पटेल	8) यह कि उक्त झूठी शिकायत में कहा गया है कि कंपनी में कार्यरत महिलाओं एवं मजदूरों को ड्यूटी के बाद घर जाते समय हाथ मुंह धोने का समय नहीं दिया जाता है, यह पूर्णतः गलत एवं झूठ है क्योंकि कंपनी में स्वास्थ्य संबंधी दवाइयों का ही निर्माण होता है और कंपनी में कार्य करते समय उचित सुरक्षा उपकरण प्रदान किये जाते हैं तथा कंपनी में बनने वाली दवाइयों की प्रक्रिया में शुरू से अंत तक कहीं भी दवाइयों को खुले हाथ से नहीं छुआ जाता है फिर भी कार्यरत श्रमिक कार्य समाप्ति पर पूरी तरह से हाथ-मुंह धोकर स्वच्छ रूप से घर जाते हैं इस हेतु कंपनी द्वारा चेंज रूम के अंदर उचित संसाधन दिए गए हैं।
	9) यह कि उक्त झूठी शिकायत में कहा गया है कि कंपनी रात्रिकालीन ड्यूटी 2 दिन रहती है, रात के 11:15 से सुबह के 7:30 तक ड्यूटी लेती है पूर्णतः गलत एवं झूठ है, श्रीमान को विदित हो कि पाली समय निर्धारण की पूरी समय सारणी स्वास्थ्य एवं सुरक्षा विभाग को कंपनी द्वारा कारखाना अधिनियम अनुसार दी जाती है तथा तथाकथित व्यक्तियों द्वारा गलत कहा गया है की रात्रि पाली दो दिन ही रहती है।

नोट – मान्यता प्राप्त संघ होने के कारण पत्रों का उत्तर देना अनिवार्य है।

(24)

“श्री”

रजि. क्र. 3304

मान्यता प्राप्त नं. 148 MPAIR

अनुमादित संघ नं. 64

ड्रग्स एण्ड फार्मास्यूटिकल्स एम्पलाईज यूनियन

क्रमांक _____ 86, तुकोगंज रोड, देवास 455001 (म.प्र.), मो. 9826245521 दिनांक _____

अध्यक्ष
शंकर सिंह बैस

अतः निवेदन है कि उक्त झूठी शिकायत द्वारा, जो कि कतिपय व्यक्तियों द्वारा, फर्जी तरह से, चारसौबीसी करके, मान्यता प्राप्त यूनियन के लेटर हेड में फेरबदल करके तथा विषयों को घुमाकर आप श्रीमान जी को गुमराह करने की कोशिश की गई है, उसपर कार्यवाही करने से पहले उसके संदर्भ में आप श्रीमान द्वारा हमें सर्वप्रथम अवगत कराना चाहिए था कि उक्त शिकायत हमारे द्वारा की गई है या नहीं? तो इससे आप श्रीमान जी का व्यस्तम समय इस तरह के अविचारणीय विषयों पर बर्बाद होने से बच सकता।

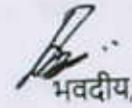
उपाध्यक्ष
योगेश पाटनकर

महोदय, हमारे प्रतिनिधि संघ द्वारा जिला कलेक्टर महोदय देवास, पुलिस अधीक्षक महोदय देवास एवं थाना औद्योगिक क्षेत्र देवास को भी इस झूठे पत्र के बाबत उचित कार्रवाई हेतु आवेदन प्रस्तुत किया गया है जिसकी प्रति इस पत्र के साथ संलग्न है।

प्रधानमंत्री
राजेन्द्र सिंह ठाकुर

मैं ड्रग्स एण्ड फार्मास्यूटिकल एम्प्लॉयज यूनियन राजस्व जिला देवास का प्रधानमंत्री राजेंद्र सिंह ठाकुर आपको अवगत कराना चाहता हूँ तथा आप श्रीमान नेशनल ग्रीन ट्रिब्यूनल एवं मध्य प्रदेश शासन को निवेदन करता हूँ कि इस तरह फेरबदल करके झूठी शिकायत करने वाले तथाकथित व्यक्तियों के विरुद्ध सख्त से सख्त दंडात्मक कार्रवाई करने की कृपा करें और मेरे नाम से की गई इस झूठी शिकायत को खारिज मानते हुए कार्रवाई को समाप्त करने का कष्ट करें।

मंत्री
हिन्दुसिंह राजपुत


भवदीय,

राजेन्द्रसिंह ठाकुर
प्रधानमंत्री

ड्रग्स एण्ड फार्मास्यूटिकल्स एम्प्लॉयज यूनियन
देवास (म. प्र.)

कोषाध्यक्ष
विजय शर्मा

प्रतिलिपि:

- डॉ ललित आर गभाने
डायरेक्टर जनरल नेशनल सेफ्टी काउंसिल आफ इंडिया
- डॉ राजीव सिंह रघुवंशी
ड्रग कंट्रोलर जनरल ऑफ इंडिया

प्रचार मंत्री
रामप्रसाद पटेल

संलग्न:

उपरोक्त अनुसार


राजेन्द्रसिंह ठाकुर
13/06/2024

(25)

नोट - मान्यता प्राप्त संघ होने के कारण पत्रों का उत्तर देना अनिवार्य है।



मध्य प्रदेश MADHYA PRADESH

CG 285560

शपथ-पत्र

मैं, राजेन्द्र सिंह ठाकुर पुत्र स्व० श्री बैरू सिंह ठाकुर आयु लगभग 61 वर्ष व्यवसाय सर्विस (सनफार्मा) निवासी-86 तुकोवन रोड़ देवास म.प्र. मो. 9826245521 का होकर शपथपूर्वक निम्न कथन करता हूँ कि:-

मैं सनफार्मा में सर्विस/मजदूर की हेसियत से सर्विस करता हूँ एवं इसके अलावा मैं यूनियन का लीडर हूँ एवं यूनियन में मेरी पोस्ट प्रधानमंत्री की है। मैं श्रमिकों का प्रतिनिधित्व करता हूँ।

मेरे नाम से एन.जी.टी. (न्यायालय नेशनल ग्रीन ट्रिब्यूनल) न्यायालय में किसी अन्य व्यक्ति द्वारा झूठी शिकायत की गई है एवं मेरे लेटर पेड एवं नाम का उपयोग किया गया है।

मेरे द्वारा एन.जी.टी. न्यायालय में कोई शिकायत दर्ज नहीं कराई गई है मैं यह शपथपत्र माननीय न्यायालय में मेरे द्वारा कोई शिकायत दर्ज नहीं कराई गई के संबंध में प्रस्तुत कर रहा हूँ।



[Signature]
शपथग्रहिता

सत्यापन

मैं, उपरोक्त शपथग्रहिता सत्यापित करता हूँ कि इस शपथपत्र के चरण क्रमांक 1 लगायत 3 में वर्णित तथ्य मेरे निजी ज्ञान एवं विश्वास के आधार पर सत्य एवं सही है।

सत्यापन आज दिनांक-22.04.2024 को किया गया।

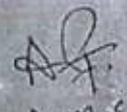
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Signature... *[Signature]*

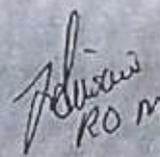
SWORN BEFORE ME, TH'
WITHEN NAMED
[Signature]
GHULAM NIZAMUDDIN
ANWAR SIDDIQUI
NOTARY ADVOCATE (M.P.)

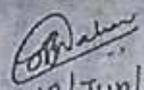
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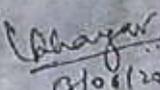
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13/06/2024

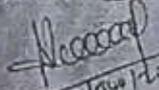
माननीय NCT प्रकल्प क्रमांक 76/2024 में पारित बादेश
 दिनांक 03/4/2024 द्वारा गठित समिति द्वारा आज दिनांक 13/6/2024
 को मे. स. ज. प्रकल्प प्रकल्प एडमिनिस्ट्रेशन लि. देवाह मा एनल सिरीजन
 किया गया। सिरीजन के दौरान समिति के सदस्य श्री अशोकेश शर्मा
 सिरीजन, देवाह, श्री एन. के. तिवारी क्षेत्रीय प्रशासकीय आ. प्र. स. नि.
 लोई, उज्जैन एवं श्री प्रकल्प प्रकल्प वेतारिक केन्द्रीय प्रशासकीय
 लोई, भोपाल एवं मे. स. ज. प्रकल्प प्रकल्प एडमिनिस्ट्रेशन लि. देवाह के
 श्री शैलेष नारकर एनोट टेड अलक इण्ड इण्ड एवं अलक
 प्रतिनिधि उपस्थित रहे। सिरीजन दौरान मानिसा मती श्री राजेश्वर शि
 वाकुट भी उपस्थित थे। मानिसा मती द्वारा समिति को बताया
 करवाया गया कि यह सिमागत मेरे द्वारा नहीं की गई है
 एवं दल संबंध मे मेरे द्वारा रजिस्टार NCT सेन्डल बैंक
 भोपाल को मय शपथ पत्र के साथ इच्छित किया है। लोई
 समिति द्वारा सिरीजन के दौरान अलक इण्ड द्वारा नए
 एमिनित किए गए।


 Anup, CPEB


 RO MPPCB Ujjain


 13/06/2024
 Shaillesh Narkar
 (Site-Head)


 13/06/2024
 Vinak Shargare
 97555 55112


 13/06/2024
 Anil Kumar
 (919732313)



Consent Order

M.P. Pollution Control Board
E-5, Arera Colony
Paryavaran Parisar, Bhopal - 16 MP
Tele : 0755-2466191, Fax-0755-2463742

ORANGE-LARGE

CCA-RENEWAL

CONSENT NO: ***

PCB ID: 19453

Outward No:-117003,18/12/2022

Consent No:AW-57205

To,
The Occupier,
M/s. Sun Pharmaceutical Industries Limited (Formulation Plant),
Industrial area, A.B. Road,
Distt. Dewas- 455001 (M.P.)

Subject: Grant of Renewal of Consent under section 25 of the Water (Prevention & Control of Pollution) Act, 1974 and under section 21 of the Air (Prevention & Control of Pollution) Act, 1981.

Ref: Your Application Receipt no. 1245698 Dt. 25/11/2022.

With reference to above, your application for renewal of consent has been considered under the aforesaid Acts and existing rules therein. The M. P. Pollution Control Board has agreed to grant renewal of consent up to **30/04/2025**, subject to the fulfilment of the terms & conditions, enclosed with this letter.

SUBJECT TO THE FOLLOWING CONDITIONS :-

- a. Location: Industrial area, A.B.Road, Distt. Dewas- 455 001 (M.P.)
b. Capital investment in Lakhs: Rs. 62895.00
c. Product & Production Capacity:

Product	Production Quantity/Year
Capsules	600 MT
Dry Capsules	1000 MT
Injectable Ampoules	300 MT
Injectable Vials	200 MT
Liquids	10,00,000 Liters
Ointments and Creams	150 MT
Tablets	1200 MT

Note:- For any change in above industry shall obtain fresh consent from the Board.

The validity of the consent shall be up to **30/04/2025** and has to be renewed before expiry of consent validity. Online application through XGN with annual license fees in this regard shall be submitted to this office 6 months before expiry of the consent. Board reserves the right to amend/cancel / revoke the above condition in part or whole as and when required.

Enclosures:-

- Conditions under Water Act, 1974
- Conditions under Air Act, 1981
- General conditions

By the order of Chairman, MPPCB

e-Sign
Digitally Sign with Aadhaar

(Organic Authentication on AADHAR from UIDAI Server)
TPAV # O45A4VN9M1

Signature Not Verified
Digitally Signed by : Chandra
Mohan Thakur, AS
Date: 18/12/2022 08:17:15 PM

Chandra Mohan Thakur (28)
CHANDRA MOHAN THAKUR
Member Secretary



Consent Order

M.P. Pollution Control Board
E-5, Arera Colony
Paryavaran Parisar, Bhopal - 16 MP
Tele : 0755-2466191, Fax-0755-2463742

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Consent No:AW-57205



Consent Order

M.P. Pollution Control Board
E-5, Arera Colony
Paryavaran Parisar, Bhopal - 16 MP
Tele : 0755-2466191, Fax-0755-2463742

CONDITIONS PERTAINING TO WATER (PREVENTION & CONTROL OF POLLUTION) ACT 1974 :-

1. The daily quantity of trade effluent of the unit shall not exceed 230.000 KL/day, and the daily quantity of sewage of the unit shall not exceed 90.000 KL/day.

2. Trade Effluent Treatment:- The applicant shall operate and maintain Effluent Treatment System to achieve following standards-

pH	Between	6.5 - 8.5	Chlorobenzene	Not exceed	0.2 mg/l
Suspended Solids	Not exceed	100 mg/l.	Phosphates as P	Not exceed	5 mg/l
BODs Days 27°C	Not exceed	30 mg/l.	Sulphides as S	Not exceed	2 mg/l
COD	Not exceed	250 mg/l.	Phenolic Compounds	Not exceed	1 mg/l
Oil and grease	Not exceed	10 mg/l.	Zinc	Not exceed	5 mg/l
TDS	Not exceed	2100 mg/l.	Copper	Not exceed	3 mg/l
Chlorides	Not exceed	1000 mg/l.	Total Chromium	Not exceed	2 mg/l
Bio - Assay Test	90% Survival of Fish after first 96 hours in 100% effluent		Hexavalent Chromium (Cr ⁶⁺)	Not exceed	0.1 mg/l
Benzene	Not exceed	0.1 mg/l	Cyanide (as HCN)	Not exceed	0.1 mg/l
Xylene	Not exceed	0.12 mg/l	Arsenic	Not exceed	0.2 mg/l
Methylene Chloride	Not exceed	0.9 mg/l	Mercury	Not exceed	0.01 mg/l
			Lead	Not exceed	0.1 mg/l

For other parameters general standards of discharge as notified under EP Act 1986 shall be applicable.

3. Sewage Treatment :- The applicant shall operate and maintain Sewage Treatment System to achieve following standards-

pH	Between	5.5 - 9.0
Suspended Solids	Not exceed	100 mg/l.
BODs Days 27°C	Not exceed	30 mg/l.
COD	Not exceed	250 mg/l.
Oil and grease	Not exceed	10 mg/l.

Sr.	Water Code (Quantity in Kilo Liter per Day)	WC : 650.000	WWG : 320.000	Water Source
1.	Boiler Feed	120.000	50.000	Recycled
2.	Cooling Water	340.000	80.000	Recycled
3.	Domestic Purpose	90.000	90.000	Local Body
4.	Mnfg Process	100.000	100.000	Local Body

4. The effluent shall be treated up to prescribed Standards and reuse in the process, for cooling and for green belt devolvement/gardening within premises. Hence zero discharge condition shall be practiced. In no case treated effluent shall be discharged outside of industry/unit premises.

5. Water meter preferably electromagnetic/ultrasonic type with digital flow recording facilities shall be installed separately for category wise consumption of water for Industrial cooling/boiler feed, mine spray, process & domestic purposes and data shall be submitted online through XGN monthly patrak/statements. The industry/unit shall also monitor the treated wastewater flow and report the same online through monthly patrak/statements.

6. Any change in production capacity, process, raw material used etc. and for any enhancement of the above prior permission of the Board shall be obtained. All authorized discharges shall be consistent with terms and conditions of this consent. Facility expansions, production increases or process modifications which result new or increased discharges of pollutants must be reported by submission of a fresh consent application for prior permission of the Board

7. All treatment/control facilities/systems installed or used by the applicant shall be regularly maintained in good working order and operate effectively/efficiently to achieve compliance of the terms and conditions of this consent

8. The specific effluent limitations and pollution control systems applicable to the discharge permitted herein are set forth as above conditions.

9. Compilation of Monitoring data-

Consent No:AW-57205

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Consent Order

M.P. Pollution Control Board
E-5, Arera Colony
Paryavaran Parisar, Bhopal - 16 MP
Tele : 0755-2466191, Fax-0755-2463742

- i. Samples and measurements taken to meet the monitoring requirements specified above shall be representative of the volume and nature of monitored discharge.
- ii. Following promulgation of guidelines establishing test procedures for the analysis of pollutants, all sampling and analytical methods used to meet the monitoring requirements specified above shall conform to such guidelines unless otherwise specified sampling and analytical methods shall conform to the latest edition of the Indian Standard specifications and where it is not specified the guidelines as per standard methods for the examination of Water and Waste latest edition of the American Public Health Association, New York U.S.A. shall be used.
- iii. The applicant shall take samples and measurement to meet the monthly requirements specified above and report online through XGN the same to the Board.

10. Recording of Monitoring Activities & Results-

i. The applicant shall make and maintain online records of all information resulting from monitoring activities by this Consent.

ii. The applicant shall record for each measurement of samples taken pursuant to the requirements of this Consent as follows:

- (i) The date, exact place and time of sampling
- (ii) The dates on which analysis were performed
- (iii) Who performed the analysis?
- (iv) The analytical techniques or methods used and
- (v) The result of all required analysis

iii. If the applicant monitors any Pollutant more frequently as is by this Consent he shall include the results of such monitoring in the calculation and reporting of values required in the discharge monitoring reports which may be prescribed by the Board. Such increased frequency shall be indicated on the Discharge Monitoring Report Form.

iv. The applicant shall retain for a minimum of 3 years all records of monitoring activities including all records of Calibration and maintenance of instrumentation and original strip chart regarding continuous monitoring instrumentation. The period of retention shall be extended during the course of any unresolved litigation regarding the discharge of pollutants by the applicant or when requested by Central or State Board or the court.

11. Reporting of Monitoring Results:-

Monitoring Information required by this Consent shall be summarized and reported by submitting a Discharge Monitoring report on line to the Board.

12. Limitation of discharge of oil Hazardous Substance in harmful quantities:-

The applicant shall not discharge oil or other hazardous substances in quantities defined as harmful in relevant regulations into natural water course. Nothing in this Consent shall be deemed to preclude the institution of any legal action nor relieve the applicant from any responsibilities, liabilities, or penalties to which the applicant is or may be subject to clauses.

13. Limitation of visible floating solids and foam:

During the period beginning date of issuance the applicant shall not discharge floating solids or visible foam.

14. Disposal of Collected Solid waste/sludge-

All hazardous waste/sludge shall be disposed of as per the Authorization issued under Hazardous & other waste (M&TM) Rules 2016. And/other Solids Sludges, dirt, silt or other pollutant separated from or resulting from treatment shall be disposed of in such a manner as to prevent any pollutant from such materials from entering any such water Any live fish, Shall fish or other animal collected or trapped as a result of intake water screening or treatment may be returned to eaters body habitat.

15. Provision for Electric Power Failure-

The applicant shall assure to the consent issuing authority that the applicant has installed or provided for an alternative electric power source sufficient to operate all facilities utilized by the applicant to maintain compliance with the terms and conditions of the Consent.

16. Prohibition of Bypass system of treatment facilities-

The diversion or by-pass of any discharge from facilities utilized by the applicant to maintain compliance with the terms and conditions of this Consent is prohibited except:

- i. where unavoidable to prevent loss of life or severe property damage, or
- ii. Where excessive storm drainage or run off would damage any facilities necessary for compliance with the terms and conditions of this Consent. The applicant shall immediately notify the consent issuing authorities in writing of each such diversion or by-pass in accordance with the procedure specified above for reporting non-compliance.

17. Industry management shall submit the information online through XGN in reference to compliance of consent conditions.

Consent No:AW-57205



Consent Order

M.P. Pollution Control Board
E-5, Arera Colony
Paryavaran Parisar, Bhopal - 16 MP
Tele : 0755-2466191, Fax-0755-2463742

18. Industry shall treat the wastewater in API division with UF, RO, MEE and ATFD to maintain ZLD condition.
19. The industry shall make all possible protection arrangements for control of pollution in nearby nallah/water resources from the industry.
20. Industry shall be make the arrangement for conducting Bioassay test and submit Bioassay test report to the Board.
21. In case of any discharge found outside of unit premises the unit may be liable to pay environmental compensation and the industry shall be punishable or court case may be filed by the Board as per provisions of the Water (Prevention & Control of Pollution) Act, 1974.

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Consent No:AW-57205



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CONDITIONS PERTAINING TO AIR (PREVENTION & CONTROL OF POLLUTION) ACT 1981 :-

1. The applicant shall operate and maintain Air Pollution Control System to achieve the level of pollutants to the following standards:-

Name of section	Capacity	Stack height (mtrs)	Fuel	Control equipment installed	P.M, SO _x , NO _x (mg/Nm ³)
Boiler(stand by)	2 X 5 TPH	40	LNG - 333 SCM/hr (FO as an alternate)	Cyclone	PM - 150
D.G. Sets	2 X 1250 KVA	30	Diesel - 250 lit./hr	Acoustic enclosure	As per MoEF&CC/CPCB notification
D.G. Sets	1500 KVA	30	Diesel - 300 lit./hr		
D.G. Sets	1250 KVA	8	Diesel - 250 lit./hr		
D.G. Sets	1250 KVA	9	Diesel - 250 lit./hr		
D.G. Sets	1000 KVA	8	Diesel - 200 lit./hr		
D.G. Sets	1000 KVA	10	Diesel - 200 lit./hr		
D.G. Sets	750 KVA	8	Diesel - 100 lit./hr		
D.G. Sets	437.5 KVA	8	Diesel - 100 lit./hr		

2. Ambient air quality at the boundary of the industry/unit premises shall be monitored and reported to the Board regularly on quarterly basis. The Ambient air quality norms are prescribed in MoEF&CC gazette notification no. GSR/826(E), dated: 16/11/2009. Some of the parameters are as follows:

- Particulate Matter (less than 10 micron) - 100 µg/m³ (PM10 µg/m³ 24 hrs. basis)
- Particulate Matter (less than 2.5 micron) - 60 µg/m³ (PM2.5 µg/m³ 24 hrs. basis)
- Sulphur Dioxide [SO₂] (24 hrs. Basis) - 80 µg/m³
- Nitrogen Oxides [NO_x] (24 hrs. Basis) - 80 µg/m³
- Carbon Monoxide [CO] (8 hrs. Basis) - 2000 µg/m³

3. The industry shall take adequate measures for control of noise level generated from industrial activities within the premises less than 75 dB(A) during day time and 70 dB(A) during night time.

4. Industry/Unit shall provide with each stack port hole with safe platform of 1 meter width with support & spiral ladder/ Stepped ladder with hand rail up to monitoring platform as per specifications given in part-III emission regulation of CPCB. In no case monkey ladder shall be allowed as stack monitoring facility.

5. The industry/unit shall make the necessary arrangements for control of the fugitive emission from any source of emission/section/activities.

6. All other fugitive emission sources such as leakages, seepages, spillages etc shall be ensured to be plugged or sealed or made airtight to avoid the public nuisance.

7. The industry/ unit shall ensure all necessary arrangements for control of odour nuisance from the industrial activities or process within premises

8. All the internal roads shall be made pucca to control the fugitive emissions of particulate matter generated due to transportation and internal movements. Good housekeeping practices shall be adopted to avoid leakages, seepages, spillages etc.

9. Industry shall take effective steps for extensive tree plantation preferably of the local tree species within or around the industry/unit premises for general improvement of environmental conditions.

10. Industry shall write name of the industry on stack with heat resistant paint.



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GENERAL CONDITIONS:

1. The non hazardous solid waste arising in the industry/unit/unit premises sweeping, etc. be disposed off scientifically so as not to cause any nuisance/pollution. The applicant shall take necessary permission from civic authorities for disposal to dumping site. If required.

Non Hazardous Solid wastes:-

Type of waste	Quantity	Disposal
Paper/ Cardboards	50 MT	Re-use/Sale to authorized party/As Per CPCB/MoEF&CC Guidelines / Others.
Plastic	22 MT	
Metal	25 MT	
Glass	5 MT	
Wood	5 MT	

2. The applicant shall allow the staff of Madhya Pradesh Pollution Control Board and/or their authorized representative, upon the representation of credentials:

- To inspect raw material stock, manufacturing processes, reactors, premises etc to perform the functions of the Board.
- To enter upon the applicant's premises where an effluent source is located or in which any records are required to be kept under the terms and conditions of this Consent.
- To have access at reasonable times to any records required to be kept under the terms and conditions of this Consent.
- To inspect at reasonable times any monitoring equipment or monitoring method required in this Consent: or,
- To sample at reasonable times any discharge or pollutants.

3. This consent is transferable in nature, in case of any change in ownership / management, the new owner / partner / directors / proprietor shall immediately apply for the consent with new requisite information.

4. The issuance of this Consent does not convey any property rights in either real or personal property or any exclusive privileges, nor does it authorise any invasion of personal rights, nor any infringement of Central, State or local laws or regulations.

5. Industry shall install separate electric metering arrangement for running of pollution control devices and this arrangement shall be made in such fashion that any non-functioning of pollution control devices shall immediately stop electric supply to the production and shall remain tripped till such time unless the pollution control device/devices are made functional. The record of electricity consumption for running of pollution control equipment shall be maintained and submitted to the Board every month

6. This consent is granted in respect of Water pollution control Act 1974 or Air Pollution Control act, 1981 only and does not relate to any other Department/Agencies. License required from other Department/Agencies have to be obtained by the unit separately and have to comply separately as per there Act / Rules.

7. Balance consent/authorisation fee, if any shall be recoverable by the Board even at a later date.

8. The applicant shall submit such information, forms and fees as required by the board not later than 180 day prior to the date of expiration of this consent/authorisation

9. The industry/unit shall establish a separate environmental cell, headed by senior officer of the unit for reporting the environmental compliances. The industry/ Unit shall submit environmental statement for the previous year ending 31st March on or before 30th September every year to the Board.

10. Industry shall obtain membership of Emergency Response Center of the Board if needed.

11. Knowingly making any false statement for obtaining consent or compliance of consent conditions shall result in the imposition of criminal penalties as provided under the section 42(g) of the Water Act or section 38 (g) of the Air Act.

12. After notice and opportunity for the hearing, this consent may be modified, suspended or revoked by the Board in whole or in part during its term for cause including, but not limited to, the following:

- Violation of any terms and conditions of this Consent.
- Obtaining this Consent by misrepresentation of failure to disclose fully all relevant facts.
- A change in any condition that requires temporary or permanent reduction or elimination of the authorized discharge.

13. On violation of any of the above-mentioned conditions the consent granted will automatically be taken as cancelled and necessary action will be initiated against the industry.

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Consent Order

M.P. Pollution Control Board
E-5, Arera Colony
Paryavaran Parisar, Bhopal - 16 MP
Tele : 0755-2466191, Fax-0755-2463742

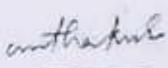
14. The industry shall ensure the arrangements for disposal of above Non Hazardous solid waste generated from the unit to the authorized vendors only.

15. The industry shall maintain the record of generation and disposal of the non hazardous wastes and same shall be produced before the officers of Pollution Control Board during inspection or visit.

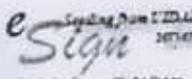
Renewal of Consent as required under the Water (Prevention & Control of Pollution) Act, 1974 and The Air (Prevention & Control of Pollution) Act, 1981 is granted to your industry subject to fulfillment of all the conditions mentioned above. For renewal purpose you shall have to make an application to this Board through XGN at least Six months before the date of expiry of this consent. The applicant without valid consent (for operation) of the Board shall not bring in to use any outlet for the discharge of effluent and gaseous emission.

For and on behalf of
M.P. Pollution Control Board

By the order of Chairman, MPPCB

 (35)

CHANDRA MOHAN THAKUR
Member Secretary


Digitally signed with Aadhaar

(Organic Authentication on AADHAR from UIDAI Server)
TPAV # 045A4VN9M1

Consent No:AW-57205



Consent Order

M.P. Pollution Control Board
E-5, Arera Colony
Paryawaran Parisar, Bhopal - 16 (M.P.)
Tele : 0755-2466191, Fax-0755-2463742

RED - LARGE
Outward No:114042,24/11/2021

CCA-Expansion &
Hazardous authorization and Authorization under
Solid Waste

CONSENT NO: ***
Consent No:AWHS-54677

PCB ID: 19526

To,

The Occupier,
M/s Sun Pharmaceutical Industries Limited (Bulk Drug Unit)
Industrial area No.3, A.B. road, City-Dewas,
Tehsil & District-Dewas (M.P.)

Sub: Grant of consent to operate for change in products mix under section 25 of the Water (Prevention & Control of Pollution) Act, 1974 & under Section 21 of the Air (Prevention & Control of Pollution) Act, 1981 and Authorization under Hazardous and Other Wastes (Management and Trans-boundary Movement) Rules, 2016 and Authorization under Solid Waste (Management) Rules, 2016 - reg.

Ref: Your application receipt no. CCA-Expansion-1099759-21/10/2021-AWHS.

With reference to your above application for consent to operate and authorization has been considered under the aforesaid Acts and existing rules therein. The M. P. Pollution Control Board has agreed to grant consent up to 30/11/2022, & hazardous authorization up to 30/11/2026 and solid waste authorization up to 30/11/2022 subject to the fulfillment of the terms & conditions, enclosed with this letter.

SUBJECT TO THE FOLLOWING CONDITIONS:-

- Location: Industrial area No.3, A.B. road, City-Dewas, Tehsil & District-Dewas (M.P.)
- The capital Investment: Rs. 609.90 Crores
- Product and Production Capacity: Detailed products list is given on page no. 13 of this letter.

Note: -For any change in above Product and Production Capacity industry shall obtain fresh consent from the Board.

The validity of the consent is up to 30/11/2022 & hazardous authorization up to 30/11/2026 and solid waste authorization up to 30/11/2022 has to be renewed before expiry of consent validity. Online application through XGN with annual license fees in this regard shall be submitted to this office 6 months before expiry of the consent. Board reserves the right to amend/cancel / revoke the above condition in part or whole as and when required.

Enclosures:-

- Conditions under Water Act
- Conditions under Air Act
- Conditions under Hazardous and Other Wastes (Management and Trans boundary Movement) Rules, 2016
- Conditions under Solid Waste Management Rules, 2016
- General conditions

Copy to:

- 1) Regional Officer, M.P. Pollution Control Board, Dewas for information.
- 2) Collector, District Dewas for information please.

e-Signing from 12345
Sign
Digitally signed by A. A. Mishra

(Organic Authentication on AADHAR from UIDAI Server)
TPAV # 78D3NXJE91

Validity unknown

Digitally Signed by A. A.
Mishra, Member Secretary
Date: 24/11/2021 08:42:06 AM

Achyut Anand Mishra
Member Secretary



Consent Order

M.P. Pollution Control Board
 E-5, Arera Colony
 Paryawaran Parisar, Bhopal - 16 (M.P.)
 Tele : 0755-2466191, Fax-0755-2463742

CONDITIONS PERTAINING TO WATER (PREVENTION & CONTROL OF POLLUTION) ACT 1974:-

- The quantity of trade effluent of the unit shall not exceed 605.000 KL/day and the daily quantity of sewage of the unit shall not exceed 120.000 KL/day.
- Trade Effluent Treatment:-**

The applicant shall maintain effluent treatment plant to achieve following standards-

✓	pH	Between	6.5 - 8.5
	Suspended Solids	Not exceed	100 mg/l.
	BOD ₅ Days 27°C	Not exceed	30 mg/l.
	COD	Not exceed	250 mg/l.
	Oil and grease	Not exceed	10 mg/l.
	Chromium (Cr ⁶⁺)	Not Exceed	0.10 mg/l.
	Lead	Not exceed	0.10 mg/l.
	Cyanide	Not Exceed	0.10 mg/l.
	TDS	Not exceed	2100 mg/l.
	Chlorides	Not exceed	1000 mg/l.
	Mercury	Not exceed	0.01 mg/l.
	Arsenic	Not Exceed	0.20
	Phenolics (C ₆ H ₅ OH)	Not exceed	1.0 mg/l.
	Sulphides (as S)	Not exceed	2.0 mg/l.
	Phosphate (as P)	Not exceed	5.0 mg/l.

For other parameters general standards of discharge as notified under EP Act 1986 shall be applicable.

- Sewage Treatment:-** The applicant shall maintain sewage treatment system to achieve following standards-

	pH	Between	5.5 - 9.0
	Total Suspended Solids	Not exceed	100 mg/l.
	BOD ₅ Days 27°C	Not exceed	30 mg/l.
	COD	Not exceed	250 mg/l.
	Oil and grease	Not exceed	10 mg/l.
	Fecal Coliform (MPN/100ml)	Not exceed	1000

For other parameters general standards of discharge as notified under EP Act 1986 shall be applicable.

Sr.	Water Code (Qty in KLPD - Kilo Ltr per Day)	WC : 2150.000 (Fresh- 1450KLD +Recycled700 KLD)	WWG : 700.00	Water Source
1	Boiler Feed	150.000	15.000	Local Body Tankers
2	Cooling Water	650.000	90.000	
3	Domestic Purpose	50.000	45.000	
4	Domestic Purpose	50.000	50.000	
5	Mnfg Process	750.000	500.000	
6	Others.....	500.000	0.000	

- The combined effluent shall be treated up to prescribed Standards and reuse in the process, for cooling and for green belt development/gardening within premises. Hence zero discharge condition shall be practiced. In no case treated effluent shall be discharged outside of industry/unit premises.
- Water meter preferably electromagnetic/ultrasonic type with digital flow recording facilities shall be properly maintained for category wise consumption of water for Industrial cooling/boiler feed, process & domestic purposes and data shall be submitted online through XGN monthly. The industry/unit shall also monitor the treated wastewater flow and report the same online through monthly patrak/statements.

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Consent No:AWHS-54677

e-Signed (Physical Signature NOT requires)



Consent Order

M.P. Pollution Control Board
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6. Any change in production capacity, process, fuel used etc. and for any enhancement of the above prior permission of the Board shall be obtained. All authorized discharges shall be consistent with terms and conditions of this consent. Facility expansions, production increases or process modifications which result new or increased discharges of pollutants must be reported by submission of a fresh consent application for prior permission of the Board.
7. All treatment/control facilities/systems installed or used by the applicant shall be regularly maintained in good working order and operate effectively/efficiently to achieve compliance of the terms and conditions of this consent.
8. The specific effluent limitations and pollution control systems applicable to the discharge permitted herein are set forth as above conditions.
9. **Compilation of Monitoring data:-**
 - i. Samples and measurements taken to meet the monitoring requirements specified above shall be representative of the volume and nature of monitored discharge.
 - ii. Following promulgation of guidelines establishing test procedures for the analysis of pollutants, all sampling and analytical methods used to meet the monitoring requirements specified above shall conform to such guidelines unless otherwise specified sampling and analytical methods shall conform to the latest edition of the Indian Standard specifications and where it is not specified the guidelines as per standard methods for the examination of Water and Waste latest edition of the American Public Health Association, New York U.S.A. shall be used.
 - iii. The applicant shall take samples and measurement to meet the monthly requirements specified above and report online through XGN the same to the Board.
10. **Recording of Monitoring activities and results:-**
 - i. The applicant shall make and maintain online records of all information resulting from monitoring activities by this Consent.
 - ii. The applicant shall record for each measurement of samples taken pursuant to the requirements of this Consent as follows:
 - (i) The date, exact place and time of sampling
 - (ii) The dates on which analysis were performed
 - (iii) Who performed the analysis?
 - (iv) The analytical techniques or methods used
 - (v) The result of all required analysis
 - iii. If the applicant monitors any Pollutant more frequently as is by this Consent he shall include the results of such monitoring in the calculation and reporting of values required in the discharge monitoring reports which may be prescribed by the Board. Such increased frequency shall be indicated on the Discharge Monitoring Report Form.
 - iv. The applicant shall retain for a minimum of 3 years all records of monitoring activities including all records of Calibration and maintenance of instrumentation and original strip chart regarding continuous monitoring instrumentation. The period of retention shall be extended during the course of any unresolved litigation regarding the discharge of pollutants by the applicant or when requested by Central or State Board or the court.
11. **Reporting of Monitoring Results:-**

Monitoring Information required by this Consent shall be summarized and reported by submitting a Discharge Monitoring report on line to the Board.
12. **Limitation of discharge of oil Hazardous Substance in harmful quantities:-**

The applicant shall not discharge oil or other hazardous substances in quantities defined as harmful in relevant regulations into natural water course. Nothing in this Consent shall be deemed to neither preclude the institution of any legal action nor relive the applicant from any responsibilities, liabilities, or penalties to which the applicant is or may be subject to clauses.



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13. Limitation of visible floating solids and foam:-

During the period beginning date of issuance the applicant shall not discharge floating solids or visible foam.

14. Disposal of Collected Solid waste/sludge:-

All hazardous waste/sludge shall be disposed of as per the Authorization issued under Hazardous and Other Waste (Management and Transboundary Movement) Rules, 2016 and other solids sludge, dirt, silt or other pollutant separated from or resulting from treatment shall be disposed of in such a manner as to prevent any pollutant from such materials from entering any such water. Any live fish, shell fish or other animal collected or trapped as a result of intake water screening or treatment may be returned to its natural body habitat.

15. Provision for Electric Power Failure:-

The applicant shall assure to the consent issuing authority that the applicant has installed or provided for an alternative electric power source sufficient to operate all facilities utilized by the applicant to maintain compliance with the terms and conditions of the Consent.

16. Prohibition of Bypass of technical facilities:-

The diversion or by-pass of any discharge from facilities utilized by the applicant to maintain compliance with the terms and conditions of this Consent is prohibited except:

- i. Where unavoidable to prevent loss of life or severe property damage, or
- ii. Where excessive storm drainage or run off would damage any facilities necessary for compliance with the terms and conditions of this Consent. The applicant shall immediately notify the consent issuing authorities in writing of each such diversion or by-pass in accordance with the procedure specified above for reporting non-compliance.

17. Industry shall submit the information online through XGN in reference to compliance of consent conditions.

Additional Water condition (if any):-

1. The industry shall maintain flow meters at raw water consumption, RO feed, RO permeate, RO reject, MEE feed, MEE condensate, Water recycling point etc. and report the same to the Board.
2. The industry shall install advance process technologies for reduction of effluent and waste generation from the unit.
3. The industry shall continue to re-utilize the MEE condensate completely in process/ utility.
4. Treatment of other effluents such as plant washing, leakages, boiler blow down, softener regeneration, DM plant, regeneration, plate heat exchangers cleaning etc in the ETP and use for process/utilities.
5. The industry shall make all possible protection arrangements for control of pollution in nearby nallah/water resources from the industry.
6. Industry shall be make the arrangement for conducting Bioassay test and submit Bioassay test report to the Board.



Consent Order

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CONDITIONS PERTAINING TO AIR (PREVENTION & CONTROL OF POLLUTION) ACT 1981:-

1. The applicant shall operate & maintain air pollution control facility continuously so as to achieve the level of pollutants.

Name of section	Capacity	Stack height(m)	Fuel	Consp-Unit	Control equipment to be installed	P.M, SO _x , NO _x (mg/Nm ³)
D.G. Sets	7X1250 KVA	30	Diesel	250 LPH/DG set	Acoustic enclosure	As per CPCB/MoEFCC norms.
D.G. Set	1000 KVA	10	Diesel	200 LPH	Acoustic enclosure	
D.G. Set	750 KVA	10	Diesel	100 LPH	Acoustic enclosure	
Boiler	14TPH	40	Agro Waste	35 Liter/Hrs	Bag filter, Green Belt, Muffler	PM-150
Boiler	5 TPH	43	L.N. Gas	20 Liter/Hrs	Cyclone, Green Belt	
Boiler	5 TPH	43	L.N. Gas	250 Kg/Hrs	Cyclone, Green Belt	
Boiler	10 TPH	52	L.N. Gas	250 Kg/Hrs	Cyclone, Green Belt	
Reaction Vessels	Process Scrubber X 17	12	--	--	Scrubber	--

Note- Industry shall inform to the Board for any addition or removal of source of air/water pollution and control equipment.

2. Ambient air quality at the boundary of the industry/unit premises shall be monitored and reported to the Board regularly on quarterly basis: The Ambient air quality norms are prescribed in MoEF gazette notification no. GSR/826(E), dated: 16/11/09. Some of the parameters are as follows:

- Particulate Matter (less than 10 micron) - 100 µg/m³ microgram/cubic meter (PM₁₀ µg/m³ 24 hrs. basis)
 - Particulate Matter (less than 2.5 micron) - 60 µg/m³ (PM_{2.5} µg/m³ 24 hrs. basis)
 - Sulphur Dioxide [SO₂] (24 hrs. Basis) - 80 µg/m³
 - Nitrogen Oxides [NO_x] (24 hrs. Basis) - 80 µg/m³
 - Carbon Monoxide [CO] (8 hrs. Basis) - 2000 µg/m³
- The industry shall take adequate measures for control of noise level generated from industrial activities within the premises less than 75 dB (A) during day time and 70 dB(A) during night time.
 - Industry shall maintain each stack port hole with safe platform of 1 meter width with support & spiral ladder/ Stepped ladder with hand rail up to monitoring platform as per specifications given in part-III emission regulation of CPCB.
 - The industry shall make and maintain the necessary arrangements for control of the fugitive emission from any source of emission/section/activities.
 - All other fugitive emission sources such as leakages, seepages, spillages etc shall be ensured to be plugged or sealed or made airtight to avoid the public nuisance.
 - The industry shall ensure all necessary arrangements for control of odour nuisance from the industrial activities or process within premises.
 - All the internal roads shall be maintained in good condition to control the fugitive emissions of particulate matter generated due to transportation and internal movements. Good housekeeping practices shall be adopted to avoid leakages, seepages, spillages etc.
 - Industry shall take effective steps for extensive tree plantation within or around the industry/unit premises for general improvement of environmental conditions and as stated in additional condition.



Consent Order

M.P. Pollution Control Board
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CONDITIONS PERTAINING TO HAZARDOUS AND OTHER WASTES (MANAGEMENT AND TRANS-BOUNDARY MOVEMENT) RULES, 2016:-

FORM-2

[See rule 6(2)]

FORM FOR GRANT OR RENEWAL OF AUTHORISATION BY STATE POLLUTION CONTROL BOARD TO THE OCCUPIERS, RECYCLERS, REPROCESSORS, REUSERS, USER AND OPERATORS OF DISPOSAL FACILITIES

1. Number of authorization and date of issue: Please refer in red ink at bottom of page.
2. Reference of application (No. and date): CCA-Expansion-1099759-21/10/2021-AWHS
3. The Occupier of M/s Sun Pharmaceutical Industries Limited (Bulk Drug Unit) is hereby granted an authorization based on the enclosed signed inspection report for generation, collection, reception, storage, transport, reuse, recycling, recovery, pre-processing, co-processing, utilization, treatment, disposal or any other use of hazardous or other wastes or both on the premises situated at Industrial area No.3, A.B. road, City-Dewas, Tehsil & District-Dewas (M.P.)

Details of Authorization

S.No.	Category of Hazardous Waste as per the Schedules I, II and III of these rules	Authorised mode of disposal or recycling or utilization or co-processing, etc.	Quantity (per annum)
1	Used or Spent Oil I -5.1	Disposal-TSDF, Pre-processing, Sale to authorize recycler, Storage, Thru authorized recycler,	15.000-M.T
2	Distillation Residues I -20.3	Co-processing, Disposal-TSDF, Pre-processing, Processing, Thru authorized recycler,	80.000-M.T
3	Process Residue and wastes I -28.1	Co-processing, Disposal-TSDF, Pre-processing, Processing,	300.000-M.T
4	Spent carbon I -28.3	Co-processing, Disposal-TSDF, Generation, Pre-processing, Thru authorized recycler,	120.000-M.T
5	Spent Catalyst I -28.2	Co-processing, Disposal-TSDF, Pre-processing, Thru authorized recycler, Processing, Recycling	10.000-M.T
6	Date-expired products I -28.5	Co-processing, Disposal-TSDF, Pre-processing, Processing,	195.000-M.T
7	Empty barrels/containers/liners contaminated with hazardous chemicals /wastes I -33.1	Pre-processing, Sale to authorize recycler, Thru authorized recycler,	116.000-M.T
8	Chemical sludge from waste water treatment I -35.3	Co-processing, Disposal-TSDF, Pre-processing, Thru authorized recycler,	500.000-M.T
10	Spent Solvents -28.6	Co-processing, Thru authorized recycler, Disposal-TSDF, Pre-processing, Recycling, Reuse, Sale to authorize recycler, Disposal-Sale, Processing	600.000-M.T
11	Contaminated aromatic, aliphatic or naphthenic solvents may or may not be fit for reuse. -20.1	Co-processing, Thru authorized recycler, Disposal-TSDF, Pre-processing, Recycling, Reuse, Sale to authorize recycler, Disposal-Sale, Processing	390.000-M.T

- (1) The authorization is valid for a period of five years i.e. from dated 01/12/2021 to 30/11/2026.
- (2) The authorization is subject to the following general and specific conditions:

A. General conditions of authorisation:

1. The authorized person shall comply with the provisions of the Environment (Protection) Act, 1986, and the rules made there under.
2. The authorization or its renewal shall be produced for inspection at the request of an officer authorized by the State Pollution Control Board.

Consent No:AWHS-54677

e-Signed (Physical Signature NOT requires)

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3. The person authorized shall not rent, lend, sell, transfer or otherwise transport the hazardous and other wastes except what is permitted through this authorization.
4. Any unauthorized change in personnel, equipment or working conditions as mentioned in the application by the person authorized shall constitute a breach of his authorization.
5. The person authorized shall implement Emergency Response Procedure (ERP) for which this authorization is being granted considering all site specific possible scenarios such as spillages, leakages, fire etc. and their possible impacts and also carry out mock drill in this regard at regular interval of time;
6. The person authorized shall comply with the provisions outlined in the Central Pollution Control Board guidelines on "Implementing Liabilities for Environmental Damages due to Handling and Disposal of Hazardous Waste and Penalty"
7. It is the duty of the authorized person to take prior permission of the State Pollution Control Board to close down the facility.
8. The imported hazardous and other wastes shall be fully insured for transit as well as for any accidental occurrence and its clean-up operation.
9. The record of consumption and fate of the imported hazardous and other wastes shall be maintained.
10. The hazardous and other waste which gets generated during recycling or reuse or recovery or pre-processing or utilization of imported hazardous or other wastes shall be treated and disposed of as per specific conditions of authorization.
11. The importer or exporter shall bear the cost of import or export and mitigation of damages if any.
12. An application for the renewal of an authorization shall be made as laid down under these Rules.
13. Any other conditions for compliance as per the Guidelines issued by the Ministry of Environment, Forest and Climate Change or Central Pollution Control Board from time to time.
14. Annual return shall be filed by June 30th for the period ensuring 31st March of the year.

B. Specific conditions:

1. The industry shall display the information on hazardous waste generated on notice board of size 6' x 4' (in Hindi & English) outside the unit main gate along with quantity and nature of hazardous chemicals being handled in the plant, including wastewater, air emission and hazardous wastes.
2. The Industry shall maintain the records of hazardous wastes as per the Form-3 of rule 6(5) and should online submit the annual return in Form No.4 as per the rule 6(5) to this office on or before 30th day of June of every year for the preceding period April to March.
3. In the event of any accident due to handling of hazardous wastes, the authorized person must inform immediately to the Regional Office & Head office of the board on Fax/telephone/emailit_mppcb@rediffmail.com about the incident and detail report should be sent in Form No. 10 as per rule -22 of Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016.
4. **Packing, Labeling & Transportation of Hazardous wastes:-**
 - (i) The occupier or operator of the Treatment, Storage and Disposal Facility or recycler shall ensure that the hazardous waste are packaged and labeled, based on the composition in a manner suitable for safe handling, storage and transport as per the guidelines issued by the Central Pollution Control Board vide - October 2004 & conditions issues from time to time.
 - (ii) The labeling and packaging shall be easily visible and be able to withstand physical conditions and climate factors.
 - (iii) The transport of the hazardous wastes shall be in accordance with the provision of these rules and the rules made by the Central Govt. under the Motor Vehicle Act 1988 and other guidelines issued from time to time in this regard.
 - (iv) In case of transportation of hazardous wastes through a State other than the State of origin or destination, the Occupier shall intimate the concerned State Pollution Control Board before he hands over the hazardous wastes to the transporter.
 - (v) The occupier shall provide the transporter with seven copies of the manifest as per the color codes as per rule 19(1).
 - (vi) The occupier shall forward copy 1 (white) to the State Pollution Control Board and in case the hazardous wastes is likely to be transported through any transit State, the occupier shall prepare an additional copy each for intimation to such State and forward the same to the concerned SPCB before he hands over the hazardous wastes to the transporter.
 - (vii) No transporter shall accept hazardous wastes from an occupier for transport unless copies 3 to 7 of the manifest accompany it.



Consent Order

M.P. Pollution Control Board
E-5, Arera Colony
Paryawaran Parisar, Bhopal - 16 (M.P.)
Tele : 0755-2466191, Fax-0755-2463742

- (viii) The transporter shall submit copies 3 to 7 of the manifest duly signed with date to the operator of the facility along with the waste consignment.
- (ix) The industry shall ensure the transportation of the hazardous waste through the MPPCB authorized trucks/tankers provided with the GPS system, Blue colored with white strip painted as hazardous waste, driver with tenth passed etc as per CPCB guidelines issued in year 2005-06.
5. The occupiers of facilities may store the hazardous and other wastes for a period not exceeding ninety days and shall maintain a record of sale, transfer, storage, recycling, recovery, pre-processing, co-processing and utilization of such wastes and make these records available for inspection.
6. The transport of the hazardous wastes shall be in accordance with the provision of these rules and the rules made by the Central Govt. under the Motor Vehicle Act 1988 and other guidelines issued from time to time in this regard.
7. If the industry comes in such a category where insurance under Public Liability Insurance Act, is necessary, the industry shall comply with provision and submit a copy of the policy to the Board.
8. The information regarding quantity of hazardous wastes generated and its analysis report should be sent to the Board online quarterly.
9. Hazardous Waste Storage Site & Danger signboard shall be provided with all fire safety & emergency safety devices at the storage site.
10. The authorized person should inform the name and address of the contact person responsible for hazardous waste management.
11. The industry shall make arrangements for store of hazardous waste/non hazardous solid waste in cover shed with pucca floor area.



Consent Order

M.P. Pollution Control Board
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GRANT OF AUTHORISATION UNDER SOLID WASTE MANAGEMENT RULES 2016

Form II

Ref: Your application CCA-Expansion-1099759-21/10/2021-AWHS.

To,

**The Occupier,
M/s Sun Pharmaceutical Industries Limited (Bulk Drug Unit)
Industrial area No.3, A.B. road, City-Dewas,
Tehsil & District-Dewas (M.P.)**

- Authorization shall be valid for a period of Five year i.e. from 01/12/2021 to 30/11/2026.
- Authorization For: **Operator of Waste Processing Facility**
- The MP Pollution Control Board, after examining the proposal hereby authorizes **M/s Sun Pharmaceutical Industries Limited (Bulk Drug Unit)** having administrative office and waste processing/ recycling facility at **Industrial area No.3, A.B. road, City-Dewas, Tehsil & District-Dewas (M.P.)**.
- The authorization is hereby granted to operate facility for processing and recycling of solid waste.
- The authorization is subject to the terms and conditions stated below and such conditions as may be otherwise specified in these rules and the standards laid down in Schedule I & II under these rules.
- The MP Pollution Control Board may, at any time, revoke any of the conditions applicable under the authorization and shall communicate the same in writing. Any violation of the provision of the Solid Waste Management Rules, 2016 will attract the penal provisions of Environment (Protection) Act, 1986 (29 of 1986).

Terms & Conditions of Authorization:

1. The operator of the solid Waste Processing and recycling facility shall comply with the provisions of the Solid Waste Management Rules, 2016.
2. The operator of the facility shall comply with the standards of Processing & Treatment of Solid Waste as given in **Schedule I & Schedule II** of the Solid Waste Management Rules, 2016.
3. The operator of the facility shall ensure the safe collection, segregation, storage, transportation, processing and disposal of MSW with all safety to avoid any environmental/ health problems in surrounding area due to activities of facility. Efforts shall be made to ensure complete treatment and disposal by recycling/ reuse/ sale of waste received at the site.
4. In order to prevent pollution problems from the facility operations, the provisions shall be made for storm water drain shall be designed and constructed in such a way that the surface runoff water is diverted from the site and leachates from solid wastelocations do not get mixed with the surface runoff water. Provisions for diversion of storm water discharge drains shall be made to minimize leachate generation and prevent pollution of surface water and also for avoiding flooding and creation of marshy conditions.
5. The operator of the facility shall comply with the provisions of Rule 25 of SWM Rules, regarding immediate reporting of accidents at solid waste processing or treatment or disposal facility or landfill site to the local body and MPPCB in Form - VI and the local body shall review and issue instructions if any, to the incharge of facility.



Consent Order

M.P. Pollution Control Board
E-5, Arera Colony
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6. The operator of the facility shall comply with the provisions of Rule 24 for submission of annual report in Form-III to the local body with a copy to the MPPCB, every year on or before 30th day of April every year.
7. The management of facility shall take all necessary steps to strictly comply with the duties mentioned in Rule 19 regarding setting up of solid waste processing and treatment facility in accordance to the technical guidelines issued by CPCB in this regard from time to time and the manual on Solid Waste Management prepared by the Ministry of Urban Development.
8. The Operator of the facility shall ensure safe and environmentally sound operations of the solid waste processing and treatment facilities as per the above guidelines / manual.
9. The Ambient Air Quality at the facility site and the vicinity shall be regularly monitored and shall meet the Standards prescribed in air consent issued under Air (Prevention & Control of Pollution) Act, 1981.
10. The operator of the facility shall take all preventive and other control measures to avoid odour nuisance for general public in surrounding areas during management of the MSW.
11. The operator of the facility shall constitute an Environmental Management Cell headed by the Senior Executive to keep the record and carry out the works related compliance of provisions of the SWM Rules, Preferably the work should be supervised by a qualified and experienced Environmental Engineer who understand the technicality of the subject.
12. Afforestation, roadside plantation, plantations on suitable vacant land, plantation on barren land shall be carried out for generation improvement of the environmental and a buffer zone of suitable width shall be developed in consultation with Local body and SPCB as per site conditions.
13. The operator of the facility shall carry out the public awareness programs throughout the year under intimation to MPPCB amongst the citizens in vicinity for proper management of Solid Waste.
14. The facility operator, any stake holders who violates or fails to comply with the provisions of Solid Waste Management Rules - 2016 shall be liable for penal action in accordance with Section - 15 of the Environment (Protection) Act, 1986 and shall also be liable to pay environmental compensation in terms of Sections 15 & 17 of the National Green Tribunal Act, 2010.
15. The management of facility shall comply all the conditions stipulated in consent and Authorization issued under Water Act 1974, Air Act 1981.
16. The management of facility shall install, operate & maintain Outdoor HD Industrial grade IP (Internet Protocol) Cameras with pan-Tilt-Zoom (PTZ) feature, minimum focal length 30X with night vision facility and temper proof mechanism at suitable locations to display all activities of processing facility, emission sources and effluent discharge point and connect the same with Environment Surveillance Centre, MP Pollution control board Bhopal for remote surveillance.
17. The operator of the facility shall be responsible for the safe and environmentally sound operations of the facility as per the guidelines issued by CPCB from time to time and the manual on Municipal Solid Waste Management published by the Ministry of Urban Development and updated from time to time.
18. The Board reserves the rights to amend/cancel any of the terms and conditions and or revoke the authorization as and when deemed necessary.

MPPCB

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Consent Order

M.P. Pollution Control Board
E-5, Arera Colony
Paryawaran Parisar, Bhopal - 16 (M.P.)
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19. Municipal solid waste shall not be burnt at disposal site.
20. The waste needs to be stored at site by earmarking the cells in the dumpsite instead of indiscriminate dumping and the older cells need to be covered as per guidelines of CPCB/Manual of urban development department to prevent burning.
21. Standard operating plan including Fire Prevention Plan should be framed to avoid instances of fire at site.
22. Safety and health issues of the people at facility site must be properly monitored and all safety equipment and PPEs shall be made available.
23. Facility shall ensure to segregate inert, C&D Waste, E-Waste, Bio Medical Waste, Hazardous Waste if any at source/ collection point and its disposal in accordance with the relevant rules notified by Govt. of India.
24. The inert waste remaining after the processing of the Solid Waste shall be disposed in the land fill being operated by the Local Body i.e. Indore Municipal Corporation or any operator entrusted for the purpose by the local body, and the record for the same shall be provided and shall be made available to the authorized officers of the MPPCB.

GENERAL CONDITIONS:-

1. The non-hazardous solid waste arising in the industry/unit/unit premises sweeping, etc. be disposed off scientifically so as not to cause any nuisance/pollution. The applicant shall take necessary permission from civic authorities for disposal to dumping site. If required.

Non Hazardous Solid Waste:-

Type of waste	Quantity(M.T./Month)	Disposal
Horticulture Waste	13.000	As per CPCB, MoEF&CC guidelines
Paper/Card boards	50.000	
Glass	5.000	
Wood	5.000	
Plastic	22.000	
Metal	25.000	
Wood	5.000	
Domestic Waste	5.000	
Ash from Bio briquette Boiler (Proposed)	366.000	
Street Sweeping waste	15.000	

2. The applicant shall allow the staff of Madhya Pradesh Pollution Control Board and/or their authorized representative, upon the representation of credentials:
 - a. To inspect raw material stock, manufacturing processes, reactors, premises etc to perform the functions of the Board.
 - b. To enter upon the applicant's premises where an effluent source is located or in which any records are required to be kept under the terms and conditions of this Consent.
 - c. To have access at reasonable times to any records required to be kept under the terms and conditions of this Consent.
 - d. To inspect at reasonable times any monitoring equipment or monitoring method required in this Consent: or,
 - e. To sample at reasonable times any discharge or pollutants.
3. This consent/authorization is transferable, in case of change of ownership/management and addresses of new Owner/partner/Directors/proprietor should immediately apply for the same.
4. The issuance of this Consent does not convey any property rights in either real or personal property or any exclusive privileges, nor does it authorize any invasion of personal rights, nor any infringement of Central, State or local laws or regulations.



Consent Order

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5. Industry shall maintain separate electric metering arrangement for running of pollution control devices and this arrangement shall be made in such fashion that any non-functioning of pollution control devices shall immediately stop electric supply to the production and shall remain tripped till such time unless the pollution control device/devices are made functional. The record of electricity consumption for running of pollution control equipment shall be maintained and submitted to the Board every month.
6. This consent is granted in respect of Water pollution control Act 1974 or Air Pollution Control act, 1981 or Authorization under the provisions of Hazardous and Other Waste (Management and Transboundary movement) Rules, 2016, only and does not relate to any other Department/Agencies. License required from other Department/Agencies have to be obtained by the unit separately and have to comply separately as per there Act / Rules.
7. Balance consent/authorization fee, if any shall be recoverable by the Board even at a later date.
8. The applicant shall submit such information, forms and fees as required by the board not later than 180 day prior to the date of expiration of this consent/authorization.
9. Knowingly making any false statement for obtaining consent or compliance of consent conditions shall result in the imposition of criminal penalties as provided under the section 42(g) of the Water Act or section 38 (g) of the Air Act.
10. After notice and opportunity for the hearing, this consent may be modified, suspended or revoked by the Board in whole or in part during its term for cause including, but not limited to the following:-
 - (a) Violation of any terms and conditions of this Consent.
 - (b) Obtaining this Consent by misrepresentation of failure to disclose fully all relevant facts.
 - (c) A change in any condition that requires temporary or permanent reduction or elimination of the authorized discharge.
11. On violation of any mentioned conditions the consent granted will automatically be taken as canceled and necessary action will be initiated against the industry.

Additional Conditions:-

1. The industry shall comply with the updated norms/directions/acts/rules/guidelines issued by the Hon'ble Courts/Tribunals/MoEFCC /MPPCB time to time.
2. The industry shall ensure the arrangements for disposal of above Non Hazardous solid waste generated from the unit to the authorized vendors only.
3. The industry shall maintain the record of generation and disposal of the non hazardous wastes and same shall be produced before the officers of Pollution Control Board during inspection or visit.
4. **The industry shall submit contract document with unit for accepting hazardous waste for Co-processing and Pre-processing before sending hazardous waste.**
5. **The industry shall submit valid consent and hazardous waste authorization of unit which will Pre-Process / Co-process hazardous waste before sending hazardous waste.**
6. **The industry shall submit details of vehicle to be used in transportation of hazardous waste before sending hazardous waste for Co-Processing and Pre-Processing.**
7. **The industry shall intimate in advance to MPPCB and other PCB/PCC, if hazardous waste has to be transported through other state or has to be transported other state for Pre-processing/ Co-Processing.**
8. This consent is granted in respect of Water pollution control Act, 1974 & Air Pollution Control act, 1981 or Authorization under the provisions of The Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 only and does not relate to any other Department/Agencies. License/NOC required from other Department/Agencies have to be obtained by the unit separately and have to comply separately as per their Act / Rules.



Consent Order

M.P. Pollution Control Board
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Details of Products and Production Capacity

Existing & Proposed Products			
S. No.	Products	Existing Qty	Total Proposed Qty
1	4,7 Di Chloro Quinoline	--	40.000 MT
2	Anti-hypertension Sartans (Irbesartan, Valsartan, Candesartan, Telmesartan, Losartan)	--	240.00 MT
3	Dipropyl Diethyl Malonate	--	100.00 MT
4	Doripenem	--	2.000 MT
5	Ertapenem	--	2.000 MT
6	Esmoprozole	--	10.000 MT
7	Levitracetam	--	240.00 MT
8	Mephentermine	--	15.000 MT
9	Meropenem	--	26.000 MT
10	Metadoxin	--	15.000 MT
11	Orlistat	--	30.000 MT
12	Oxetacaine	--	70.000 MT
13	Pentoxifylline	--	50.000 MT
14	Piroxicam Betacyclodextrin	--	5.000 MT
15	Sodium bicarbonate sterile	--	2.000 MT
16	Sodium carbonate sterile	--	5.000 MT
17	Sodium Valporate	--	60.000 MT
18	T-3811 A03 Toyama	--	20.000 MT
19	R&D Products Validation	--	20.000 MT
20	antibiotic cilastatin	10.000 MT	20.000 MT
21	Antibiotic Imipenem	10.000 MT	20.000 MT
22	Ciprofloxacin and salts	250.000 MT	250.000 MT
23	gancyclovir/ valacyclovir/ ganvalacyclovir	50.000 MT	30.000 MT
24	macrolide, clarithromycin	100.000 MT	100.000 MT
	Total		1372 TPA

Consent and authorization as required under the Water (Prevention & Control of Pollution) Act, 1974, The Air (Prevention & Control of Pollution) Act, 1981 and the Authorization under Hazardous and Other Waste (Management and Transboundary Movement) Rules, 2016 & Solid Waste Management Rules, 2016 is granted to your industry subject to fulfillment of all the conditions mentioned above. **For renewal purpose you shall have to make an application to this Board through XGN at least Six months before the date of expiry of this consent and authorization.** The applicant without valid consent (for operation) of the Board shall not bring in to use any outlet for the discharge of effluent and gaseous emission.

e-Signing from UIDAI Server
Digitally signed with Aadhaar

(Organic Authentication on AADHAR from UIDAI Server)
TPAV # 78D3NXJE91

Achyut Mishra

ACHYUT ANAND MISHRA
Member Secretary

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Consent No:AWHS-54677

e-Signed (Physical Signature NOT required)



Central Pollution Control Board
 (Ministry Of Environment, Forest and Climate
 Change, Govt. of India)
 Parivesh Bhawan, East Arjun Nagar
 Delhi-110032

Regn. No.
 BO-03-000-06-AADCS3124K-22

Date:
 20/06/2022 03:24 PM

RENEWAL OF REGISTRATION CERTIFICATE FOR BRAND OWNER
 (Under Rule-13(2) of the Plastic Waste Management Rules, 2016, as amended)

To,
SUN
PHARMACEUTICAL
INDUSTRIES LIMITED,
 SPARC, Tandalja

With reference to the application dated **03/05/2022** regarding registration as a **Brand Owner**, this is to inform that your application has been processed and found in order. Now, therefore, Central Pollution Control Board Board is pleased to grant the registration in favour of **SUN PHARMACEUTICAL INDUSTRIES LIMITED**, vide registered office address **SPARC, Tandalja**, as a Brand Owner, for disposal of MLP & other plastic waste generated due to their products as per the EPR Action Plan given below:

Sl. No	Financial Year	2022-23			
	State/UT	Cat-I	Cat-II	Cat-III	Cat-IV
1	CPCB	1477.52	0.00	546.66	0.00
TOTAL		1477.52	0.00	546.66	0.00
Grand Total		2024.18 TPA			

This certificate of registration shall be valid for a period of **Three years** from the expiry date of previous registration i.e. 10/04/2020 unless revoked, suspended or cancelled. The Registration is granted subject to the following terms & conditions: -

1. The Brand Owner shall fulfil the categorize EPR Targets for the year 2022-23 as specified in the above table. For the subsequent years, EPR Target shall be calculated based on the information provided in the Annual report, the format of which shall be specified by CPCB.
2. The Brand Owner shall provide certificate only from registered plastic waste processors as evidence of fulfilling their EPR obligation. The PIBO can meet the EPR obligation under a category by providing EPR certificates from other PIBOs of the same category.
3. Exchange of EPR credit between PIBOs and Plastic Waste Processors (PWP) to be done as per mechanism provided by CPCB.
4. The Brand Owner shall not deal with any entity not registered through on-line centralized portal developed by Central Pollution Control Board. .
5. The Brand Owner shall not engage in manufacture, stocking, distribution, selling of banned SUP items as listed in Amendment to PWM Rules dated August 12, 2021
6. In case, it is found or determined that any PIBO registered on the on-line portal has provided false information or has willfully concealed information or there is any irregularity or deviation from the conditions stipulated while obtaining registration under Extended Producer Responsibility guidelines, then the registration of such an entity would be revoked for a one - year period after giving an opportunity to be heard. The entities whose registration has been revoked shall not be able to register afresh for the period of revocation.
7. The Brand Owner should ensure compliance with provisions of the PWM Rules, 2016, as amended. Action, as deemed fit, including revocation of registration, closure of unit, levying Environmental Compensation charges, shall be taken against violators of PWM Rules.
8. CPCB reserves the right to take such action as deemed fit under Environment (Protection) Act, 1986 for violation of PWM Rules, 2016, as amended, if any, by the concerned PIBO for the period prior to grant of registration.

Div. Head, UPC-II



Signed
by: Divya Sinha
Date:
2022.06.20
15:26:08
+05:30

Annexure B

Select year for annual report data :

2022-23

Annexure-06

Annual Return Filing

Annual Report Filing Part - A

1. Name of Unit	SUN PHARMACEUTICAL INDUSTRIES LIMITED
2. Filing for Year	2022-23
3. Category	BRAND OWNER

4. Annual Report (2022-23)

Category	Procurement (Tons)	Sales (Tons)	Export (Tons)	Reuse (Tons)	UREP (Tons)
Cat I	10905.215487020...	2089.2500	5757.8500	0.0000	0
Cat II	1082.0072856601...	206.6000	571.3900	NA	0
Cat III	2811.386647720821	2051.8300	134.9400	NA	0
Cat IV	NA	0.0000	0.0000	NA	0

5. Compliance Status of Fulfilment of EPR Targets

Category	Target	Achieved	Available Potential	Remarks
Cat 1 - Recycling and End of Life ...	1478	1478	0	Close
Cat 2 - Recycling and End of Life...	0	0	0	Close
Cat 3 - Recycling and End of Life...	547	547	0	Close
Cat 4 - Recycling and End of Life...	0	0	0	Close
Cat 1 - Mandated Use of Recycle...	NA	0	0	Close
Cat 2 - Mandated Use of Recycl...	NA	0	0	Close
Cat 3 - Mandated Use of Recycl...	NA	0	0	Close
Cat 1 - Reuse of Plastic (Contain...	NA	0	0	Close
CAT 1 - Reuse of Plastic (Contain...	NA	0	0	Close

Annual Report Part - B (EPR Target for 2023-24)

7. Next year Targets (2023-24)

Category	Target
Cat 1 - Recycling and End of Life Plastic	2208
Cat 2 - Recycling and End of Life Plastic	109
Cat 3 - Recycling and End of Life Plastic	1455
Cat 4 - Recycling and End of Life Plastic	0
Cat 1 - Mandated Use of Recycled Plastic	NA
Cat 2 - Mandated Use of Recycled Plastic	NA
Cat 3 - Mandated Use of Recycled Plastic	NA
Cat 1 - Reuse of Plastic (Containers> 0.9 L & < 4.9 L)	
CAT 1 - Reuse of Plastic (Containers> 4.9 L)	

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NEPRA

No : B-2023040852

Annexure-07

ALLOCATION DETAILS
Extended Producer Responsibility (EPR) Activity for : Sun Pharmaceutical Industries Ltd.
Dispatch Duration : 04-Jul-2023 to 08-Jul-2023

M/s NEPRA Resource Management Pvt. Ltd., on behalf of **M/s. Sun Pharmaceutical Industries Ltd.**, has collected Post Consumer Rigid Plastic (Cat-I) Waste from the following state as a part of EPR Activity.

State	Collection Center - Name & Address	ULB Name	Type of Plastic	Assigned Qty (MT)	Mode of Disposal	Plastic Waste Processing Facility (PWPF)
Madhya Pradesh	Balaji Scrap Traders - Morena, Madhya Pradesh - 476001.	Municipal Corporation Morena	Rigid Plastic (Cat-I)	25.545	Recycling	RPG Industrial Product Pvt. Ltd. - RPG Industrial PVT Ltd - Uttar Pradesh
Total (MT)				25.545		

The collected quantity of Rigid Plastic (Cat-I) has been sent to above mentioned (PWPF) for recycling to ensure EPR compliance as per Plastic Waste Management Rules, 2016 and amended there after.

We confirm that quantities as per annexure-1 have been allocated only to **M/s. Sun Pharmaceutical Industries Ltd.** by us.

For NEPRA Resource Management Pvt. Ltd.

Sarrah Doola

Date of Allocation : 31-Jul-2023

NEPRA Resource Management Pvt. Ltd.

708, 7th Floor, Noble Trade Center, Opp. B.D.Rao Hall, Nr. Bhuyangdev Cross Road, Memnagar, Ahmedabad 380052.

+91-79-40050400

info@nepra.co.in

www.jetsrecycle.in

CIN: U90001GJ2008PTC049227


NEPRA
ANNEXURE 1

Sr No.	Vehicle No	Dispatch Date	Weight at the Loading Point (MT)	Weight at the Unloading Point (MT)	Qty. to be Allocated to PIBO (MT)	Assigned Qty. to PIBO (MT)
1	HR 55 V 0577	04-Jul-2023	12.440	12.380	12.380	12.380
2	UP 14 KT 4817	05-Jul-2023	9.480	9.640	9.480	9.480
3	UP 37 T 9760	08-Jul-2023	10.050	9.950	9.950	3.685
Total (MT)			31.970	31.970	31.810	25.545

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NEPRA Resource Management Pvt. Ltd.

708, 7th Floor, Noble Trade Center, Opp. B.D.Rao Hall, Nr. Bhuyangdev Cross Road, Memnagar, Ahmedabad 380052.

+91-79-40050400

info@nepra.co.in

www.letsrecycle.in

CIN: U90001GJ2006PTC049227

CLAVULANIC ACID, POTASSIUM SALT

SUN Pharmaceutical Industries Ltd

Chemwatch: 4019-91
Version No. 5.1.1.1
Safety Data Sheet

Chemwatch Hazard Alert Code: 1

Issue Date: 01/01/2013
Print Date: 20/08/2016
S.GHS.IND.EN**SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING****Product Identifier**

Product name	CLAVULANIC ACID, POTASSIUM SALT
Chemical Name	clavulanic acid, potassium salt
Synonyms	4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 3-(2-hydroxyethylidene)-7-oxo-, monopotassium salt, (2R-(2alpha,3Z,5alpha)-, BRL 14151K, C8-H8-N-O5.K, antibacteraf antibiotic, potassium clavulanate
Chemical formula	C8-H9-N-O5 .K
Other means of identification	Not Available
CAS number	51177-45-5

Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Clavulanic acid has negligible intrinsic antimicrobial activity, despite sharing the beta-lactam ring that is characteristic of beta-lactam antibiotics. However, the similarity in chemical structure allows the molecule to interact with the enzyme beta-lactamase secreted by certain bacteria to confer resistance to beta-lactam antibiotics. Clavulanic acid is a suicide inhibitor, covalently bonding to a serine residue in the active site of the beta-lactamase. This restructures the clavulanic acid molecule, creating a much more reactive species that is attacked by another amino-acid in the active site, permanently inactivating it, and thus inactivating the enzyme. Given with beta-lactam antibiotics as an antibacterial. The acid is produced by cultures of Streptomyces clavuligeris and has a beta-lactam structure resembling that of the penicillin nucleus except that the fused thiazolidine ring of the penicillin is replaced by an oxazolidine ring. The acid and its salts generally display only weak antibacterial activity but are potent progressive inhibitors of beta-lactamases produced by gram-negative bacteria and Staphylococcus aureus. Clavulanic acid permeates bacterial cell walls and inactivates both extracellular enzymes and those bound to the cell. Generally acts as competitive, irreversible, inhibitor. Enhances the activity of penicillin and cephalosporin antibiotics against many resistant strains of bacteria. Given by mouth.
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Details of the supplier of the safety data sheet

Registered company name	SUN Pharmaceutical Industries Ltd
Address	Plot: A7/8,MIDC, Ahmednagar Maharashtra 414 111 India
Telephone	0241 2777330
Fax	02412777231
Website	www.sunpharma.com
Email	safetynagar@sunpharma.com

Emergency telephone number

Association / Organisation	Not Available
Emergency telephone numbers	024126513060
Other emergency telephone numbers	02412777330

SECTION 2 HAZARDS IDENTIFICATION**Classification of the substance or mixture****CHEMWATCH HAZARD RATINGS**

	Min	Max
Flammability	1	■
Toxicity	0	
Body Contact	0	
Reactivity	1	■
Chronic	0	

0 = Minimum
1 = Low
2 = Moderate
3 = High
4 = Extreme

NFPA 704 diamond

Note: The hazard category numbers found in GHS classification in section 2 of this SDS are NOT to be used to fill in the NFPA 704 diamond. Blue = Health Red = Fire Yellow = Reactivity White = Special (Oxidizer or water reactive substances)

CANADIAN WHMIS SYMBOLS

Classification	Not Applicable
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Label elements

GHS label elements	Not Applicable
SIGNAL WORD	NOT APPLICABLE

Continued...

5A

CLAVULANIC ACID, POTASSIUM SALT

Hazard statement(s)

Not Applicable

Supplementary statement(s)

Not Applicable

Precautionary statement(s) Prevention

Not Applicable

Precautionary statement(s) Response

Not Applicable

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

Not Applicable

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

Substances

CAS No	%[weight]	Name	Classification
61177-45-5	>98	clavulanic acid, potassium salt	Not Applicable

Mixtures

See section above for composition of Substances

SECTION 4 FIRST AID MEASURES

Description of first aid measures

Eye Contact	<p>If this product comes in contact with eyes:</p> <ul style="list-style-type: none"> Wash out immediately with water. If irritation continues, seek medical attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	<p>If skin or hair contact occurs:</p> <ul style="list-style-type: none"> Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.
Inhalation	<ul style="list-style-type: none"> If dust is inhaled, remove from contaminated area. Encourage patient to blow nose to ensure clear passage of breathing. If irritation or discomfort persists seek medical attention.
Ingestion	<ul style="list-style-type: none"> Immediately give a glass of water. First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 FIREFIGHTING MEASURES

Extinguishing media

- Water spray or fog.
- Foam.
- Dry chemical powder.
- BCF (where regulations permit).

Special hazards arising from the substrate or mixture

Fire Incompatibility	<ul style="list-style-type: none"> Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
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Advice for firefighters

Fire Fighting	<ul style="list-style-type: none"> Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves. Prevent, by any means available, spillage from entering drains or water courses. Use water delivered as a fine spray to control fire and cool adjacent area.
Fire/Explosion Hazard	<ul style="list-style-type: none"> Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions. Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions). Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard: accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited - particles exceeding this limit will generally not form flammable dust clouds; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion. Combustion products include: carbon monoxide (CO) carbon dioxide (CO2) nitrogen oxides (NOx) sulfur oxides (SOx) other pyrolysis products typical of burning organic material

SECTION 6 ACCIDENTAL RELEASE MEASURES

CLAVULANIC ACID, POTASSIUM SALT

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	<ul style="list-style-type: none"> ▶ Clean up waste regularly and abnormal spills immediately. ▶ Avoid breathing dust and contact with skin and eyes. ▶ Wear protective clothing, gloves, safety glasses and dust respirator. ▶ Use dry clean up procedures and avoid generating dust.
Major Spills	<ul style="list-style-type: none"> ▶ Clear area of personnel and move upwind. ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Control personal contact with the substance, by using protective equipment and dust respirator. ▶ Prevent spillage from entering drains, sewers or water courses.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling

Safe handling	<ul style="list-style-type: none"> ▶ Limit all unnecessary personal contact. ▶ Wear protective clothing when risk of exposure occurs. ▶ Use in a well-ventilated area. ▶ Avoid contact with incompatible materials. ▶ Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions) ▶ Minimise airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame. ▶ Establish good housekeeping practices. ▶ Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds.
Other information	<ul style="list-style-type: none"> ▶ Store in original containers. ▶ Keep containers securely sealed. ▶ Store in a cool, dry area protected from environmental extremes. ▶ Store away from incompatible materials and foodstuff containers.

Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> ▶ Lined metal can, lined metal pall/ can. ▶ Plastic pail. ▶ Polyliner drum. ▶ Packing as recommended by manufacturer. ▶ Glass container is suitable for laboratory quantities.
Storage incompatibility	<p>Avoid contamination of water, foodstuffs, feed or seed.</p> <ul style="list-style-type: none"> ▶ Avoid reaction with oxidising agents

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

OCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA

Not Available

EMERGENCY LIMITS

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
CLAVULANIC ACID, POTASSIUM SALT	Not Available	Not Available	Not Available	Not Available
Ingredient	Original IDLH	Revised IDLH		
clavulanic acid, potassium salt	Not Available	Not Available		

Exposure controls

Appropriate engineering controls	<p>Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation.</p> <p>HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours.</p> <p>Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.</p> <p>A fume hood or vented balance enclosure is recommended for weighing/ transferring quantities exceeding 500 mg.</p>
Personal protection	

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CLAVULANIC ACID, POTASSIUM SALT

Eye and face protection	When handling very small quantities of the material eye protection may not be required. For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs: <ul style="list-style-type: none"> Chemical goggles. Face shield. Full face shield may be required for supplementary but never for primary protection of eyes.
Skin protection	See Hand protection below
Hands/feet protection	The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application. The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice. Suitability and durability of glove type is dependent on usage. <ul style="list-style-type: none"> Rubber gloves (nitrile or low-protein, powder-free latex, latex/nitrile). Employees allergic to latex gloves should use nitrile gloves in preference. Double gloving should be considered. PVC gloves. Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present. <ul style="list-style-type: none"> polychloroprene. nitrile rubber. butyl rubber.
Body protection	See Other protection below
Other protection	<ul style="list-style-type: none"> For quantities up to 500 grams a laboratory coat may be suitable. For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs. For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
Thermal hazards	Not Available

Respiratory protection

Particulate, (AS/NZS 1718 & 1715, EN 143.000 & 149.001, ANSI Z88 or national equivalent)

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	P1 Air-line*	-	PAPR-P1
up to 50 x ES	Air-line**	P2	PAPR-P2
up to 100 x ES	-	P3 Air-line*	-
100+ x ES	-	Air-line**	PAPR-P3

* - Negative pressure demand ** - Continuous flow

A (All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

- Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.
- Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- Use approved positive flow mask if significant quantities of dust becomes airborne.
- Try to avoid creating dust conditions.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Solid, mixes with water.		
Physical state	Divided Solid	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Applicable	Decomposition temperature	Not available.
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Applicable
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	237.27
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Applicable	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not available.	Surface Tension (dyn/cm or mN/m)	Not Applicable
Lower Explosive Limit (%)	Not Available	Volatile Component (Nvol)	Negligible

CLAVULANIC ACID, POTASSIUM SALT

Vapour pressure (kPa)	Negligible	Gas group	Not Available
Solubility in water (g/L)	Miscible	pH as a solution (1%)	5.5-8.0
Vapour density (Air = 1)	Not Applicable	VOC g/L	Not Available

SECTION 10 STABILITY AND REACTIVITY

Reactivity	See section 7
Chemical stability	Product is considered stable and hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 TOXICOLOGICAL INFORMATION

Information on toxicological effects

Inhaled	The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled. If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.
Ingestion	Although ingestion is not thought to produce harmful effects (as classified under EC Directives), the material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g. liver, kidney) damage is evident. The use of clavulanic acid with penicillins has been associated with an increased incidence of cholestatic jaundice and acute hepatitis during therapy or shortly after, in particular, in men and those over the age of 55. The associated jaundice is usually self-limiting and very rarely fatal. The UK Committee on Safety of Medicines (CSM) recommends that treatments such as amoxicillin/clavulanic acid preparations be reserved for bacterial infections likely to be caused by amoxicillin-resistant beta-lactamase-producing strains, and that treatment should not normally exceed 14 days. Allergy has been reported.
Skin Contact	The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting. Open cuts, abraded or irritated skin should not be exposed to this material. Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.
Eye	Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result.
Chronic	Long-term exposure to the product is not thought to produce chronic effects adverse to the health (as classified by EC Directives using animal models); nevertheless exposure by all routes should be minimised as a matter of course. Long term exposure to high dust concentrations may cause changes in lung function (i.e. pneumoconiosis, caused by particles less than 0.5 micron penetrating and remaining in the lung).

clavulanic acid, potassium salt	TOXICITY	IRRITATION
	Oral (rat) LD50: 7936 mg/kg ⁽²⁾	Nil reported

Legend: 1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

CLAVULANIC ACID, POTASSIUM SALT
Animal studies failed to reveal any evidence of amoxicillin-clavulanate teratogenicity. There are no controlled data in human pregnancies. The results of a study suggest an increased risk of necrotising enterocolitis in neonates if amoxicillin-clavulanate is given prophylactically to women with premature rupture of membranes. Amoxicillin-clavulanate should only be given during pregnancy when need has been clearly established. Somnolence, dyspnea, altered sleep time, dermatitis after systemic exposure, specific developmental abnormalities (musculoskeletal system), effects on newborn, foetotoxicity, maternal effects recorded.

Acute Toxicity	X	Carcinogenicity	⊖
Skin Irritation/Corrosion	⊖	Reproductivity	⊖
Serious Eye Damage/Irritation	⊖	STOT - Single Exposure	⊖
Respiratory or Skin sensitisation	⊖	STOT - Repeated Exposure	⊖
Mutagenicity	⊖	Aspiration Hazard	⊖

Legend: X - Data available but does not fill the criteria for classification
⊖ - Data required to make classification available
⊕ - Data Not Available to make classification

SECTION 12 ECOLOGICAL INFORMATION

Toxicity	Ingredient	Endpoint	Test Duration (hr)	Species	Value	Source
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Continued...

CLAVULANIC ACID, POTASSIUM SALT

Not Available	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Legend:	Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological information - Aquatic Toxicity 3. EPIWIN Suite V3.12 - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data				

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
	No Data available for all ingredients	No Data available for all ingredients

Bioaccumulative potential

Ingredient	Bioaccumulation
	No Data available for all ingredients

Mobility in soil

Ingredient	Mobility
	No Data available for all ingredients

SECTION 13 DISPOSAL CONSIDERATIONS

Waste treatment methods

Product / Packaging disposal	<p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.</p> <p>A Hierarchy of Controls seems to be common - the user should investigate:</p> <ul style="list-style-type: none"> • Reduction • Reuse • Recycling • Disposal (if all else fails) <p>This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use.</p> <ul style="list-style-type: none"> • DO NOT allow wash water from cleaning or process equipment to enter drains. • It may be necessary to collect all wash water for treatment before disposal. • In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. • Where in doubt contact the responsible authority • Recycle wherever possible. • Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified. • Dispose of by: burial in a land-fill specifically licenced to accept chemical and / or pharmaceutical wastes or incineration in a licenced apparatus (after admixture with suitable combustible material) • Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.
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SECTION 14 TRANSPORT INFORMATION

Labels Required

Marine Pollutant	NO
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Land transport (UN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

SECTION 15 REGULATORY INFORMATION

Safety, health and environmental regulations / legislation specific for the substance or mixture

CLAVULANIC ACID, POTASSIUM SALT(61177-45-5) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Not Applicable

National Inventory	Status
Australia - AICS	N (clavulanic acid, potassium salt)
Canada - DSL	N (clavulanic acid, potassium salt)
Canada - NOSL	N (clavulanic acid, potassium salt)
China - IECSC	N (clavulanic acid, potassium salt)
Europe - ENEC / ELINCS / NLP	Y
Japan - ENCS	N (clavulanic acid, potassium salt)
Korea - KECI	N (clavulanic acid, potassium salt)
New Zealand - NZIoC	Y

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CLAVULANIC ACID, POTASSIUM SALT

Philippines - PICCS	N (clavulanic acid, potassium salt)
USA - TSCA	N (clavulanic acid, potassium salt)
Legend:	Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing (see specific ingredients in brackets)

SECTION 16 OTHER INFORMATION

Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

A list of reference resources used to assist the committee may be found at:

www.chemwatch.net

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

- PC - TWA: Permissible Concentration-Time Weighted Average
- PC - STEL: Permissible Concentration-Short Term Exposure Limit
- IARC: International Agency for Research on Cancer
- ACGIH: American Conference of Governmental Industrial Hygienists
- STEL: Short Term Exposure Limit
- TEEL: Temporary Emergency Exposure Limit
- IDUH: Immediately Dangerous to Life or Health Concentrations
- OSF: Odour Safety Factor
- NOAEL: No Observed Adverse Effect Level
- LOAEL: Lowest Observed Adverse Effect Level
- TLV: Threshold Limit Value
- LOD: Limit Of Detection
- OTV: Odour Threshold Value
- BCF: BioConcentration Factors
- BEI: Biological Exposure Index

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TEL (+61 3) 9572 4700.

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TEST REPORT

REPORT NO.: FTL/R5262112

Date: 29/12/2021

PAGE No. : 1 OF 2

SAMPLE NAME : *PDT.CLAV+MCC91:1_DIL.IP*

BATCH NO. : -

SAMPLE DESCRIPTION : *Powder*

SAMPLE SOURCE : *Sun Pharmaceuticals Industries Ltd,
Mumbai - Agra National Hwy,
Industrial Area No. 3,
Dewas-455001.*

Mr. Hariom Maurya

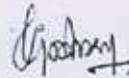
TESTS REQUESTED : *Powder Resistivity.*

DATE OF SAMPLE RECEIPT : *08/12/2021*

SAMPLE REFERENCE NO. : *S5252112*

DATE OF TESTING : *28/12/2021*

REMARK : -


Authorised Signatory
J. Ganeshkumar
Vice President-Technical

REPORT NO.: FTL/R5262112

TEST RESULT

SPECIFIC POWDER (BULK) RESISTIVITY:

Test Method: FTL/SOP/12, Test Method: ASTM D257, IEC 62631-3-1.

Description: Sample is dried at 50°C under vacuum, sieved through 250 μ sieve. The sample is filled in the test cell to form a layer of 10 mm thickness. A current is passed through the sample at 100volts. The resistance of the sample is directly measured on megohmmeter.

Observation (Resistivity)	Inference
<10 ⁸ ohm.m	Conductive
10 ⁸ -10 ¹⁰ ohm.m	Moderately Conductive
>10 ¹⁰ ohm.m	Resistive

Result:

Specific Powder Resistivity: > 1 x 10¹² Ohm-m

Measured Temperature: 25°C

Measured Humidity: 50%

Analyst

Analyst

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SAMPLE REFERENCE NO.: S5252112

Comments:

1. *The material shows first exothermic decomposition onset at 145 °C and second exothermic decomposition onset at 186 °C in presence of fresh air stream, this decomposition leads to auto ignition.*
2. *The material is not likely to be dust explosion hazard and has a Minimum Ignition Energy (MIE) of more than 1000 mJ.*
3. *Static electricity is not critical, provided the powder is processed in grounded equipment.*
4. *As the sample is having Specific Powder resistivity more than that of 10^{12} Ohm-m, it can be considered as Resistive.*
5. *For more clarity on implication contact our Firex Testing Laboratory.*

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OFFICE OF THE CONTROLLER FOOD AND DRUGS ADMINISTRATION
MADHYA PRADESH

No. V/28/Ren/Sun-16/2020 / 2700

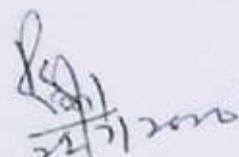
Bhopal Dated: 22/7/2020

TO WHOM IT MAY CONCERN

M/s. Sun Pharmaceutical Industries Limited, Plot no. 2 & 2A, Industrial Area No. 03, Dewas 455001 (Madhya Pradesh) India is holding Drugs Manufacturing License No.: 28/15/83 in Form 28 valid up to 08.03.2020. The licensee has deposited requisite online fee for retention of license(s) as per this office record vide Form-27 application no. DWX1928R730 dated 10-02-2020 along with list of drugs items specified in Schedule C and C(1) [excluding those specified in [part XB and] Sch. X] submitted by the licensee.

In view of above and as per Gazette Notification no.: GSR 1337 (E) dated 27.10.2017 of Ministry of Health & Family Welfare, Government of India, the above mention license(s) is deemed to be valid for a period of next 5 years i.e. from 09-03-2020 to 08.03.2025, subject to the condition of deposition of item-wise fees.




Licensing Authority
Food & Drugs Administration
Madhya Pradesh

To,
M/s Sun Pharmaceutical Industries Limited
Plot No.2, & 2A, Industrial Area No. 03,
Dewas 455 001 (Madhya Pradesh) India

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Sr. No.	Name of Product	Product composition
b	Co-amoxiclav Tablets 375mg For Export Only	Each filmcoated tablet contains: Amoxicillin Trihydrate Ph.Eur. equivalent to Amoxicillin 250mg Potassium Clavulanate Ph. Eur. Equivalent to Clavulanic Acid 125mg
c	Co-amoxiclav Tablets BP 375mg For Export Only	Each film coated tablet contains: Amoxicillin Trihydrate Ph.Eur. equivalent to Amoxicillin 250mg Potassium Clavulanate Ph. Eur. Equivalent to Clavulanic Acid 125mg
d	Amoxicillin and Clavulanate Potassium Tablets (Amoxicilina-ac. Clavulanico cinfa 250/125 mg) For export only	Each film coated tablet contains: Amoxicillin equivalent to anhydrous Amoxicillin 250 mg Clavulanate Potassium equivalent to Clavulanic Acid 125 mg
e	Amoxicillin & Clavulanate Potassium Tablets (adco-amoclav 375 mg Tablets) (For export only)	Each tablet contains : Amoxicillin Trihydrate equivalent to Amoxicillin 250 mg Potassium Clavulanate equivalent to Clavulanic acid 125 mg Butylated hydroxy toluene (as antioxidant) 0.46 % m/m
f	Co-amoxiclav Tablets BP (Bellmentin 250/125 mg Tablets) For Export only	Each film coated tablet contains : Amoxicillin Trihydrate Ph.Eur. equivalent to Amoxicillin 250 mg Diluted Potassium Clavulanate Ph. Eur. Equivalent to Clavulanate Acid 125 mg
g	Amoxicillin and Clavulanate Potassium Tablets USP (Enhancin 250mg-125mg) (For export only)	Each Film Coated tablet contains: Amoxicillin USP equivalent to anhydrous Amoxicillin 250 mg Clavulanate Potassium equivalent to Clavulanic Acid 125 mg
h	Amoxicillin and Clavulanate Potassium Tablets USP 375 mg (Enhancin Tablets 375mg) For Export Only	Each film coated tablet contains: Amoxicillin USP equivalent to anhydrous Amoxicillin 250mg Clavulanate Potassium equivalent to Clavulanic Acid 125mg



Conditions:

- Pursuant to the directions contained in Govt. of India, Ministry of Health & Family Welfare, New Delhi letter no.: X11011/1/2011-DPCD dated 1-Oct-2012 the trade names of the products are deleted
- The licensee shall submit data on safety and efficacy of those permitted items of F.D.C. which do not appear in list of items approved by D.C.G.I. New Delhi, within eighteen months w.e.f. 15-01-2013
- The Licensee shall not manufacture any drug formulation which is prohibited by the Govt. of India U/L. 26-A of the Drugs and Cosmetics Act, 1940 from time to time
- Content of Paracetamol changed from 500 to 325 mg as per the DCGI letter no.: 18-06/2011-OC dated 23-09-2011

24 APR 2015

(Signature)
Licensing Authority
Food & Drugs Administration
Madhya Pradesh

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E-8 MAR 2020

Sr. No.	Name of Product	Product composition
i	Amoxycillin and Potassium Clavulanate Tablets IP 375mg (Enhancin Tablets 375mg)	Each film coated tablet contains: Amoxycillin Trihydrate IP equivalent to Amoxycillin 250mg Potassium Clavulanate Diluted BP equivalent to Clavulanic Acid 125 mg
j	Amoxicillin and Clavulanic Acid 250/125 mg Tablets (Enhancin 250 / 125 Tablets) For export only	Each film coated tablet contains : Amoxycillin Trihydrate equivalent to anhydrous Amoxycillin 250mg Potassium Clavulanate Equivalent to Clavulanic Acid 125mg
k	Co-amoxiclav Tablets BP (Enhancin Tablets 375 mg) (for export only)	Each film coated tablet contains : Amoxicillin Trihydrate Ph.Eur. equivalent to Amoxicillin 250 mg Potassium Clavulanate Ph.Eur. equivalent to Clavulanic Acid 125 mg
l	Co-amoxiclav Tablets (Enhancin Tablets 375 mg) (for export only)	Each film coated tablet contains : Amoxicillin Trihydrate Ph.Eur. equivalent to Amoxicillin 250 mg Potassium Clavulanate equivalent to Clavulanate Acid 125 mg
m	Co-amoxiclav Tablets (Enhancin Tablets 375 mg) (for export only)	Each film coated tablet contains : Amoxicillin Trihydrate Ph.Eur. equivalent to Amoxicillin 250 mg Potassium Clavulanate Ph. Eur. Equivalent to Clavulanate Acid 125 mg
n	Co-Amoxiclav Tablets BP 375 mg (Enhancin Tablets 375mg)	Each film coated tablet contains: Amoxycillin Trihydrate IP equivalent to Amoxycillin 250mg Diluted Potassium Clavulanate BP Equivalent to Clavulanic Acid 125mg
o	Co-Amoxiclav Tablets BP 375 mg (Enhancin Tablets 375mg) For Export Only	Each film coated tablet contains: Amoxycillin Trihydrate BP equivalent to Amoxycillin 250mg Potassium Clavulanate equivalent to Clavulanic Acid 125mg



Conditions:

- Pursuant to the directions contained in Govt. of India, Ministry of Health & Family Welfare, New Delhi letter no.: X11011/1/2011-DPCO dated 1-Oct-2012 the trade names of the products are deleted
- The licensee shall submit data on safety and efficacy of those permitted items of F.D.C. which do not appear in list of items approved by D.C.G.I, New Delhi, within eighteen months w.e.f. 15-01-2013
- The Licensee shall not manufacture any drug formulation which is prohibited by the Govt. of India U/s. 26-A of the Drugs and Cosmetics Act, 1940 from time to time
- Content of Paracetamol changed from 500 to 325 mg as per the DCGI letter no.: 18-06/2011-DC dated 23-09-2011

(Signature)
Licensing Authority
Food & Drugs Administration
Madhya Pradesh

24 APR 2015

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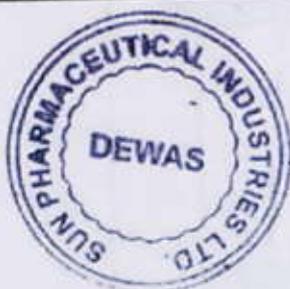
Energy Saving Idea Details			Savings in Lac KWh
Sr. no	Idea Name		
1	Replacement of Air Compressor.		3.51
2	Auto tube cleaning system to be installed for chiller condenser		3.57
3	Replacement of Chilled water Pumps		1.036
4	Chiller Power saving by optimization of set point as per requirement of plant load		1.49
5	PDL area Closer as not in use		2.59
6	Training & EHS office closer		0.2
7	Reduction in Ceiling Height in Low RH area : Block A		1.99
8	Dust Collector operation interlock with respective M/c		2.2
9	ON/OFF Mode implemented for WH 24 Hrs. AHU		0.3
10	Block C FG store AC load shifting From Split AC to AHU		0.92
11	Stop operation of small air compressor at Block B and laod given on centralised air compressor		0.42
12	Old CT & Pump Replacement with energy efficient CT & Pump	4	
13	Micro HVAC shifting from DX to centerlised Chilled water system		1.2
14	Modulation of Compressed air pressure during holiday / non-working days.		1.59
15	Rh Limit To Be Revised In Liquid Preparation Area (Redimix)		0.06
16	In block C warehouse supply of Room No. C426 to be cater with room no C404 instead of AHU of dispensing Room		0.5
17	VFD to be installed in AHU of HVAC system where not in place		0.7
18	Motion sensor: for Lighting to be install in storage areas in Block B		0.08
19	Replacement of Existing Cooling Tower Fan with High Efficiency Aerodynamic Fans		0.86
20	Air Dryer: Energy efficient Zero Purge External Heat Reactivated type Air Dryer for Block B.		3.02
21	Motion Sensor: for Lighting to be installed at Service Floor of Penem Block		0.096
22	Installation of Energy efficient Zero Purge External Heat Reactivated type Air Dryer for Block C.		0.55
23	Replacenet of Drinking RO High Pressure pump with Energy Efficient pump and with IE3 motor		0.11
24	Energy Saving by Optimizing Condenser and Chilled water pump operation at Chiller Plant Block- 'B'		1.37
25	Energy Saving by arresting air ingress in Economizer of Briquette Boiler		0.93
26	Energy Saving by using Variable frequency drive (VFD) at secondary Pumps of Chillers (Block- Utility)		0.57



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SUN PHARMA - DEWAS BULK DRUG ENERGY INITIATIVES

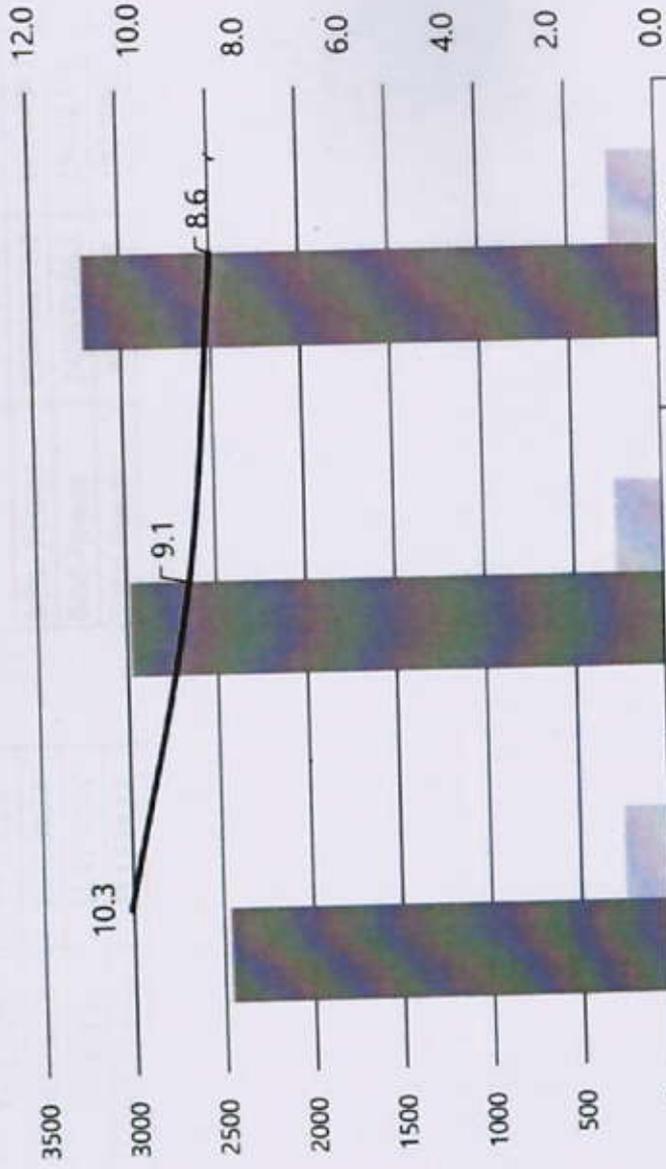
Sr. No.	Description
1	Stoppage of dehumidifier in sterile block
2	125 HP Energy Efficient IE3 Motors (03nos) for Brine Compressors....
3	Auto Tube Cleaning system installed for chillers condensers (11nos chillers)
4	Compressed air demand side Master Air Control (MAC)
5	Replacement of Cooling Tower Solid Aluminium fan blade by hollow FRP Fan blade
6	Energy Efficient CT pump-
7	Screw Air Compressor against reciprocating old air compressors
8	Reduce Ceiling Height for PP/FG wherever required, identified area Plant 2,3 & 4 PP/FG area.



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Power Index Improvement Year on Year



	FY 21-22	FY 22-23	FY 23-24
Production (Mio.)	2466	2980	3214
Power (Lac- kwh)	255	271	275
Index (kwh per thousand unit production)	10.3	9.1	8.6



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Annexure-13

Power Source	Sun Pharma Dewas Bulk Drug		
	FY 21-22	FY 22-23	FY 23-24
Solar Power	15830171.2	16344941	15467736
Grid Power	24093776.8	23431756	18535306
Total Power	39923948	39776697	34003042

Power Source	Sun Pharma Dewas Formulation		
	FY 21-22	FY 22-23	FY 23-24
Solar Power	16211598	16729260	15753172
Grid Power	14181598	13837189	15379255
Total Power	30393196	30566449	31132427



SUN PHARMACEUTICAL INDUSTRIES LIMITED DEWAS
FORMULATION WATER BALANCE

X

WATER CONSUMPTION		
Water code	Qty. as per CCA	Daily consumption Qty.
	KLD	KLD
Boiler	120	60
Cooling tower	340	242
Domestic	90	59
Manufacturing	100	93
Total	650	454

Water consumption (KLD)	454.0
Effluent Generations (KLD)	162.0
Cooling tower evaporation losses (KLD)	292.0

Fresh Water for Cooling tower	Recycle water for Cooling tower	Total
(KLD)	(KLD)	(KLD)
242	87	329

EFFLUENT GENERATIONS		
Type of Effluent	Qty. as per CCA in KLD	Qty. in KLD
Mfg. process	100	60
Cooling Tower	80	37
Boiler Blowdown	50	25
Domestic	90	40
Total	320	162

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SUN PHARMACEUTICAL INDUSTRIES LIMITED DEWAS
BULK DRUG WATER BALANCE

WATER CONSUMPTION		
Water code	Qty. as per CCA	Daily consumption Qty.
	KLD	KLD
Boiler	150	113
Cooling tower	650	186
Domestic	100	60
Manufacturing	750	175
Others	500	42
Total	2150	576

Water consumption (KLD)	576
Effluent Generations (KLD)	254
Total losses (KLD)	322

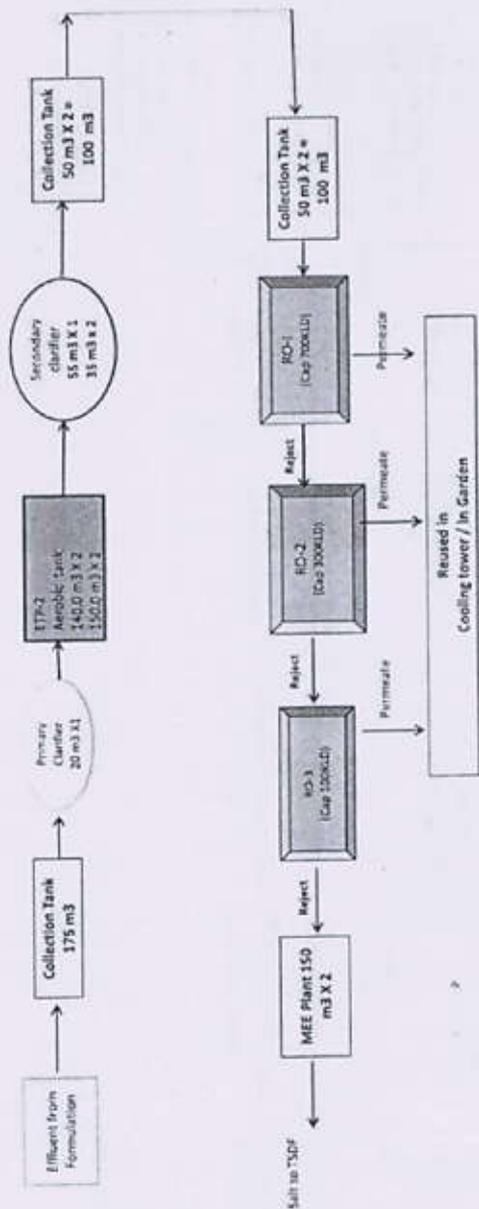
Fresh Water for Cooling tower	Recycle water for Cooling tower	Total
(KLD)	(KLD)	(KLD)
186	120	306

EFFLUENT GENERATIONS		
Type of Effluent	Qty. as per CCA in KLD	Qty. in KLD
Mfg. process	500	168
Cooling Tower	90	20
Boiler Blowdown	15	8
Domestic	95	58
Other	0.0	0.0
Total	700	254

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SUN PHARMACEUTICAL INDUSTRIES LIMITED, DEWAS

FLOW CHART OF ZLD FORMULATION PLANT (CAP-250KLD)

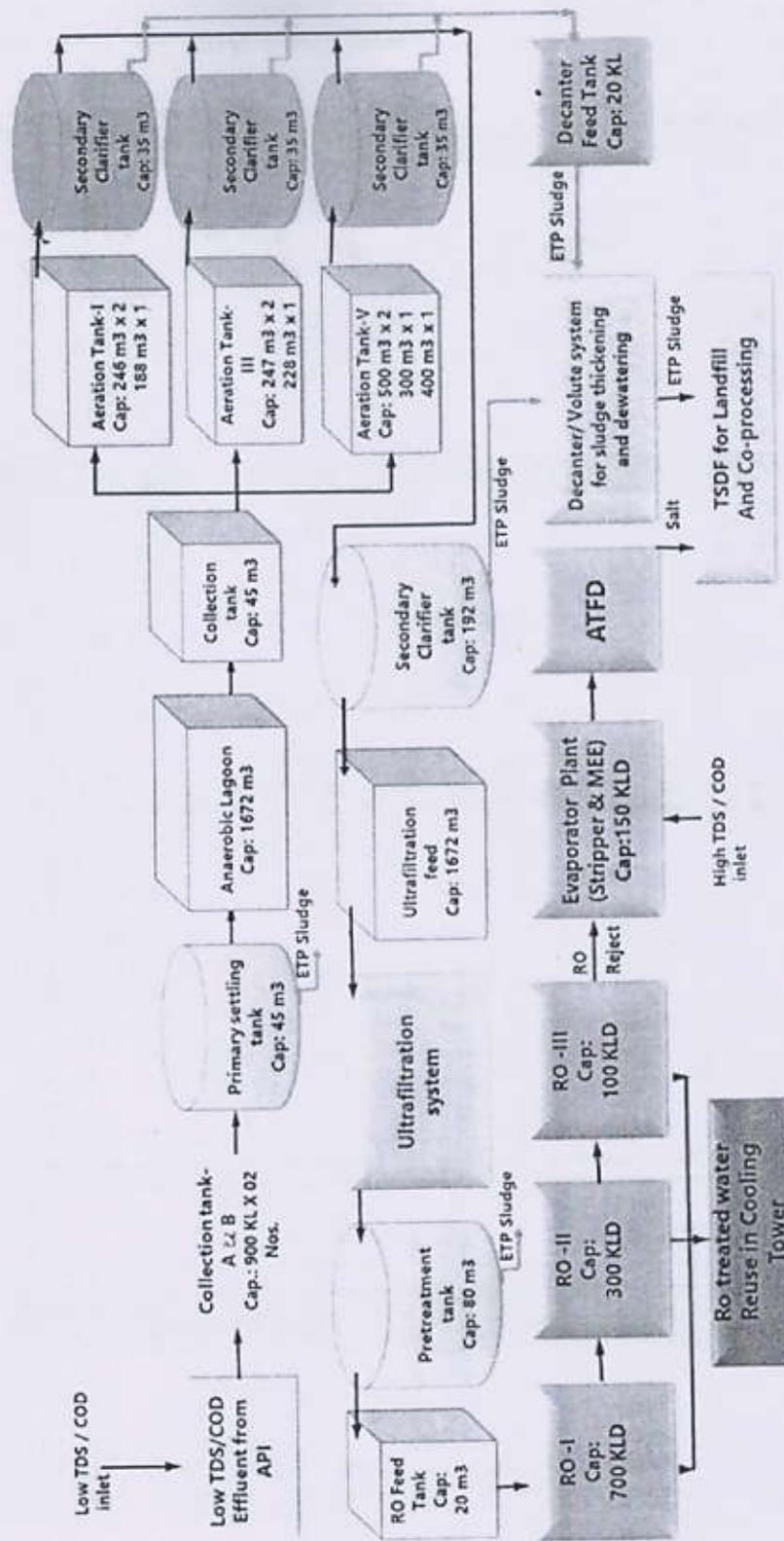


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Sun Pharmaceutical Industries Limited - Bulk drug

FLOW CHART OF ZERO LIQUID DISCHARGE PLANT



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Online Continuous Emission Monitoring System Report

Report Type: Single Industry Single Station Report

State: Madhya Pradesh

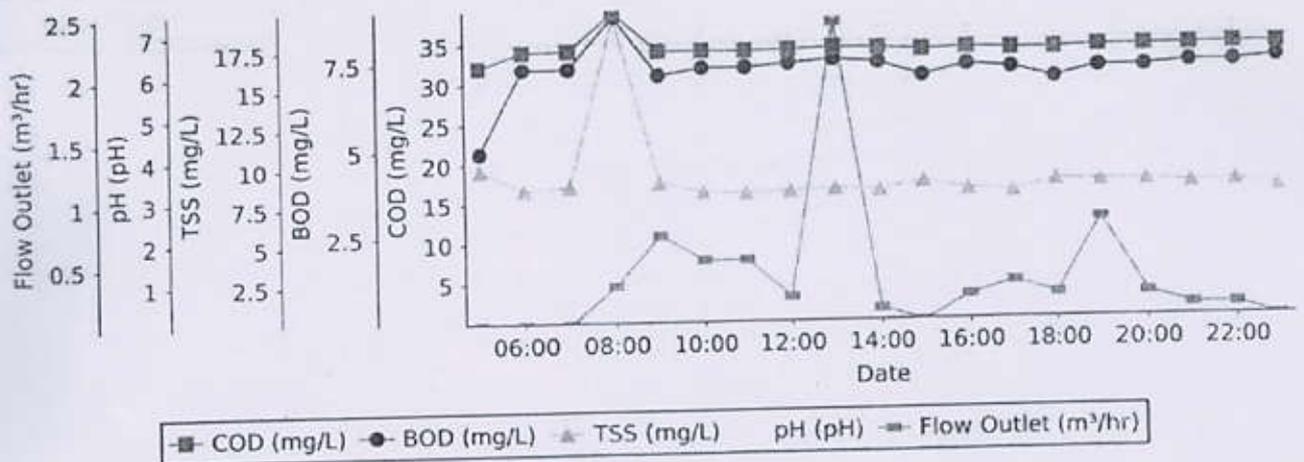
Category: Pharma

Industry	Address	Monitoring Station	Parameters	Period From	Period To	Averaging Interval	Aggregation
Sun Pharmaceuticals Industries Ltd.-Dewas	Industrial Area No. 3, A.B. Road, Dewas, Madhya Pradesh 455001	12MP325_ETP_SUN_Dewas	BOD, Flow Outlet, TSS, pH, COD	13-Jun-2024 00:00	13-Jun-2024 23:59	hourly	Average/Mean

Alert Thresholds

Station	Parameter	Min	Max
12MP325_ETP_SUN_Dewas	COD	N/A	250 mg/L
12MP325_ETP_SUN_Dewas	BOD	N/A	30 mg/L
12MP325_ETP_SUN_Dewas	TSS	N/A	100 mg/L
12MP325_ETP_SUN_Dewas	pH	6 pH	8.5 pH

Chart



Report Data

Datetime	COD (mg/L)	BOD (mg/L)	TSS (mg/L)	pH (pH)	Flow Outlet (m³/hr)
13-Jun-2024 05:30:00:000	32.1	4.9	9.8	7.4	0.0
13-Jun-2024 06:30:00:000	34.0	7.3	8.5	7.4	0.0
13-Jun-2024 07:30:00:000	34.1	7.3	8.7	7.4	0.0
13-Jun-2024 08:30:00:000	38.9	8.8	19.4	7.4	0.3
13-Jun-2024 09:30:00:000	34.0	7.1	8.9	7.4	0.7

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Datetime	COD (mg/L)	BOD (mg/L)	TSS (mg/L)	pH (pH)	Flow Outlet (m ³ /hr)
13-Jun-2024 10:30:00:000	34.0	7.3	8.3	7.5	0.5
13-Jun-2024 11:30:00:000	33.9	7.3	8.2	7.5	0.5
13-Jun-2024 12:30:00:000	34.0	7.4	8.3	7.5	0.2
13-Jun-2024 13:30:00:000	34.2	7.5	8.4	7.4	2.4
13-Jun-2024 14:30:00:000	34.1	7.4	8.3	7.4	0.1
13-Jun-2024 15:30:00:000	33.8	7.0	8.8	7.4	0.0
13-Jun-2024 16:30:00:000	34.0	7.3	8.3	7.3	0.2
13-Jun-2024 17:30:00:000	33.8	7.2	8.1	7.3	0.3
13-Jun-2024 18:30:00:000	33.8	6.9	8.8	7.4	0.2
13-Jun-2024 19:30:00:000	34.0	7.2	8.7	7.4	0.8
13-Jun-2024 20:30:00:000	34.0	7.2	8.7	7.4	0.2
13-Jun-2024 21:30:00:000	34.0	7.3	8.5	7.3	0.1
13-Jun-2024 22:30:00:000	34.1	7.3	8.6	7.3	0.1
13-Jun-2024 23:30:00:000	34.0	7.4	8.2	7.3	0.0

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REGIONAL LABORATORY
M. P. POLLUTION CONTROL BOARD, UJJAIN (M.P.)
17, BHARAT PURI, UJJAIN-456001
Phone-0734-2510984, E-mail- rlmppcbujain@gmail.com

Annexure-16

TEST REPORT
ANALYSIS REPORT FOR WATER / WASTE WATER SAMPLE

Report No. 270/2024
Date of Issue: 21-06-2024

Sample from : :- M/s Sun Pharmaceutical Industries Ltd., Dewas
Description of Sample: :- Treated water from RO
Sampling Method: :- APHA 24 th edi. 2023

Date of Collection :	13-06-24	Sample Volume - 2+1 Litre
Date of Receipt :	13-06-24	Plastic bottle & Glass bottle - Plastic bottle & Glass Bottle
Start of Analysis :	13-06-24	Collected by :- Dr. Anoop Chaturvedi, Scientist- B, CPCB Bhopal & Joint Team
Date of Completion of Analysis:	21-06-24	Analysed by :- Mr. Vishal Solanki, Chemist

Environmental condition during sampling :

Preservation Status : As per Protocol

Visual Observations :

- 1 Colour : Colourless
- 2 Appearance : Clear
- 3 Odour : Odourless

S.No.	Parameters	Unit	Test Method	Result
1	pH	pH Units	APHA 24 th edi. 2023, Electrometric Method 4500-H+B,	7.11
2	Chloride as Cl	mg/l	APHA 24 th edi. 2023, Argentometric Method 4500-Cl-B	24
3	Total Solids	mg/l	APHA 24 th edi. 2023, Gravimetric Method 2540 B	198
4	Suspended Solids	mg/l	APHA 24 th edi. 2023, Gravimetric Method 2540 D	6
5	Total Dissolved Solids	mg/l	APHA 24 th edi. 2023, Gravimetric Method 2540 C	192
6	B.O.D.(3 Days 27°C)	mg/l	IS 3025, Part-44, 2023 (3-Day B.O.D. Test)	1.2
7	Chemical Oxygen Demand	mg/l	APHA 24 th edi. 2023, Open Reflux Method 5220 B	20
8	Phosphate as PO ₄ ³⁻ -P	mg/l	APHA 24 th edi. 2023, Method 4500-PO-Stannous Chloride	ND
9	Oil & Grease	mg/l	APHA 24 th edi. 2023, Gravimetric Method 5520 B	ND
10	Hexavalent Chromium	mg/l	-	ND
11	Lead (as pb)	mg/l	APHA 24 th edi. 2023, Standard Method 3111 B	ND
12	Mercury (as Hg)	mg/l	-	ND

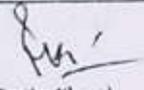
INDICATION () PARAMETER DOES NOT CONFIRM TO:

- 1 Standards prescribed by M.P.P.C.B. in M.P. Gazette notification, dated 25-03-1988.
- 2 Standards prescribed in Environment (Protection) Rules 1986.
- 3 ND- Not Detected, BDL- Below Detectable Limit

Note:-

- (1) The report shall not be reproduced except in full, without permission of Regional Laboratory, M.P. Pollution Control Board, Ujjain.
- (2) No Statutory liability accepted for samples not collected by M.P.P.C.B.
- (3) The result relate only to the sample tested.
- (4) Sample received in sealed condition.

End of Test Report


(Pratim Khare)
Authorized Signatory
Scientist

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REGIONAL LABORATORY
M. P. POLLUTION CONTROL BOARD, UJJAIN (M.P.)
17, BHARAT PURI, UJJAIN-456001
Phone -0734-2510984, E-mail- rlmppcbujain@gmail.com

TEST REPORT
ANALYSIS REPORT FOR WATER / WASTE WATER SAMPLE

Report No. 271/2024
Date of issue: 21-06-2024

Sample from : M/s Sun Pharmaceutical Industries Ltd., Dewas
Description of Sample: Treated Domestic waste water at SBT outlet before reuse in gardening
Sampling Method: APHA 24 th edn. 2023

Date of Collection :	13-06-24	Sample Volume - 2+1 Litre
Date of Receipt :	13-06-24	Plastic bottle & Glass bottle - Plastic bottle & Glass Bottle
Start of Analysis :	13-06-24	Collected by :- Dr. Anoop Chaturvedi, Scientist- B, CPCB Bhopal & Joint Team
Date of Completion of Analysis:	21-06-24	Analysed by :- Mr. Vishal Solanki, Chemist

Environmental condition during sampling :

Preservation Status : As per Protocol

Visual Observations :

- 1 Colour : Colourless
- 2 Apperance : Clear
- 3 Odour : Odourless

S.No.	Parameters	Unit	Test Method	Result
1	pH	pH Units	APHA 24 th edn. 2023, Electrometric Method 4500-H-B,	7.26
2	Chloride as Cl ⁻	mg/l	APHA 24 th edn. 2023, Argentometric Method 4500-Cl-B	114
3	Total Solids	mg/l	APHA 24 th edn. 2023, Gravimetric Method 2540 B	1038
4	Suspended Solids	mg/l	APHA 24 th edn. 2023, Gravimetric Method 2540 D	10
5	Total Dissolved Solids	mg/l	APHA 24 th edn. 2023, Gravimetric Method 2540 C	1028
6	B.O.D. (3 Days 27°C)	mg/l	IS 3025, Part-44, 2023 (3 Day B.O.D. Test)	8
7	Chemical Oxygen Demand	mg/l	APHA 24 th edn. 2023, Open Reflux Method 5220-B	40
8	Fecal Coliform	MPN/100ml	APHA 24 th edn. 2023, Standard Method	120
9	Oil & Grease	mg/l	APHA 24 th edn. 2023, Gravimetric Method 5520 B	BDL

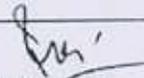
INDICATION : □ PARAMETER DOES NOT CONFIRM TO-

- 1 Standards prescribed by M.P.P.C.B. in M.P. Gazette notification, dated 25-03-1988.
- 2 Standards prescribed in Environment (Protection) Rules 1986
- 3 ND- Not Detected, BDL- Below Detection Limit, Oil & Grease Detection Limit 2 mg/l.

Note:-

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- (2) No Statutory liability accepted for samples not collected by M.P.P.C.B.
- (3) The result relate only to the sample tested.
- (4) Sample received in sealed condition.

End of Test Report


(Pratim Khare)
Authorized Signatory
Scientist



REGIONAL LABORATORY
M. P. POLLUTION CONTROL BOARD, UJJAIN (M.P.)
17, BHARAT PURI, UJJAIN-456001
Phone -0734-2510284, E-mail-rlmppcbujain@gmail.com

TEST REPORT
ANALYSIS REPORT FOR WATER / WASTE WATER SAMPLE

Report No. 272/2024
Date of issue: 21-06-2024

Sample from : :- Nallah water before entering in M/s Sun Pharmaceutical Industry Ltd.
Dewas Premises near Rajiv Nagar, Dewas

Description of Sample: :- Nallah water
Sampling Method: :- APHA 24 th edi. 2023

Date of Collection :	13-06-24	Sample Volume - 2+1 Litre
Date of Receipt :	13-06-24	Plastic bottle & Glass bottle - Plastic bottle & Glass Bottle
Start of Analysis :	13-06-24	Collected by :- Dr. Anoop Chaturvedi, Scientist- B, CPCB Bhopal & Joint Team
Date of Completion of Analysis:	21-06-24	Analysed by :- Mr. Vishal Solanki, Chemist

Environmental condition during sampling :

Preservation Status : As per Protocol

Visual Observations :

1 Colour : Turbid

2 Apperance : --

3 Odour : Unpleasant

S.No.	Parameters	Unit	Test Method	Result
1	pH	pH Units	APHA 24 th edi. 2023, Electrometric Method 4500-H+B.	6.42
2	Chloride as Cl ⁻	mg/l	APHA 24 th edi. 2023, Argentometric Method 4500-Cl-B	380
3	Total Solids	mg/l	APHA 24 th edi. 2023, Gravimetric Method 2540 B	1972
4	Suspended Solids	mg/l	APHA 24 th edi. 2023, Gravimetric Method 2540 D	60
5	Total Dissolved Solids	mg/l	APHA 24 th edi. 2023, Gravimetric Method 2540 C	1912
6	B.O.D. (3 Days 27°C)	mg/l	IS 3025, Part-44, 2023 (3-Day B.O.D. Test)	28
7	Chemical Oxygen Demand	mg/l	APHA 24 th edi. 2023, Open Reflux Method 5220-B	110
8	Phosphate as PO ₄ ³⁻ -P	mg/l	APHA 24 th edi. 2023, Method 4500-PO-Stannous Chloride	1.04

INDICATION : () PARAMETER DOES NOT CONFIRM TO-

1 Standards prescribed by M.P.P.C.B. in M.P. Gazette notification, dated 25-03-1988.

2 Standards prescribed in Environment (Protection) Rules 1986.

3 ND- Not Detected, BDL- Below Detectable Limit

Note:-

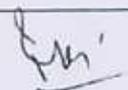
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(2) No Statutory liability accepted for samples not collected by M.P.P.C.B.

(3) The result relate only to the sample tested.

(4) Sample received in sealed condition.

End of Test Report


(Pratim Khare)
Authorized Signatory
Scientist

76

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REGIONAL LABORATORY
M. P. POLLUTION CONTROL BOARD, UJJAIN (M.P.)
17, BHARAT PURI, UJJAIN-456001
Phone -0734-2510984, E-mail- rimppcbujjain@gmail.com

TEST REPORT
ANALYSIS REPORT FOR WATER / WASTE WATER SAMPLE

Report No. 273/2024
Date of Issue: 21-06-2024

Sample from : :- Nallah water collected outside premises of M/s Sun Pharmaceutical Industry Ltd. Dewas before mixing to Nagdhaman Nallah

Description of Sample: :- Nallah water

Sampling Method: :- APHA 24 th ed. 2023

Date of Collection :	13-06-24	Sample Volume - 2+1 Litre
Date of Receipt :	13-06-24	Plastic bottle & Glass bottle - Plastic bottle & Glass Bottle
Start of Analysis :	13-06-24	Collected by :- Dr. Anoop Chaturvedi, Scientist- B, CPCB Bhopal & Joint Team
Date of Completion of Analysis:	21-06-24	Analysed by :- Mr. Vishal Solanki, Chemist

Environmental condition during sampling :

Preservation Status : As per Protocol

Visual Observations :

- 1 Colour : Turbid
- 2 Appearance : --
- 3 Odour : Unpleasant

S.No.	Parameters	Unit	Test Method	Result
1	pH	pH Units	APHA 24 th ed. 2023, Electrometric Method 4500-H+B.	6.86
2	Chloride as Cl	mg/l	APHA 24 th ed. 2023, Argentometric Method 4500-Cl-B	372
3	Total Solids	mg/l	APHA 24 th ed. 2023, Gravimetric Method 2540 B	1924
4	Suspended Solids	mg/l	APHA 24 th ed. 2023, Gravimetric Method 2540 D	72
5	Total Dissolved Solids	mg/l	APHA 24 th ed. 2023, Gravimetric Method 2540 C	1852
6	B.O.D. (3 Days 27°C)	mg/l	IS 3025, Part-44, 2023 (3-Day B.O.D. Test)	26
7	Chemical Oxygen Demand	mg/l	APHA 24 th ed. 2023, Open Reflux Method 5220-B	90
8	Phosphate as PO ₄ ³⁻ -P	mg/l	APHA 24 th ed. 2023, Method 4500-PO-Stannous Chloride	0.92

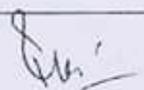
INDICATION : PARAMETER DOES NOT CONFIRM TO-

- 1 Standards prescribed by M.P.P.C.B. in M.P. Gazette notification, dated 25-03-1988.
- 2 Standards prescribed in Environment (Protection) Rules 1986.
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- (3) The result relate only to the sample tested.
- (4) Sample received in sealed condition.

End of Test Report


(Pratim Khare)
Authorized Signatory
Scientist

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Sun Pharmaceutical Industries Ltd, Dewas

Title: Entry and Exit procedure for Employees and Visitors in Production area

- Follow the procedure of gowning/de-gowning to enter/exit respective area.
- Persons working in the process area shall remove their wristwatch and personal belongings, jewellery, stick bindies and keep them in their lockers before entering process area.
- Dispose-off the used hand gloves, nose masks and used shoe covers into the collection bin/waste bin.
- Whenever a person needs to handle product he/ she shall wear an additional pair of gloves over the gloves already worn. After the completion of work the additional pair of gloves shall be removed and disposed-off in collection bin/waste bin.
- Employee/ Visitor can also put on the Beard Mask if required.
- Persons working in process area should put on hand gloves to cover maximum hand area, before entering core process room.
- Long length hand gloves shall be used in the process area to avoid squeezing/gliding of hand gloves while performing the process area activities.
- Never go out of the process area without removing the process area uniform.

ENTRY PROCEDURE TO THE PRODUCTION AREA.

- Enter into the air lock by pressing/touching the door inter lock button/Sensor.
- Enter into change room (street wear gowning / de-gowning area).
- Remove street footwear and street clothes. Put them in respective Lockers/Rack/Almirah.
- Press the door release push button and enter into gowning area (wherever applicable).
- Cross the cross over bench (Wherever available).
- Put on factory footwear available in racks beneath cross over bench/designated place.
- Wash the hands using soap solution and dry hands using hand drier.
- Put on factory uniform available in Amirah in Below order,
 - a. Hood/Cap.
 - b. Wear shirt
 - c. Trouser.
- Check for proper gowning by seeing into the mirror.
- Disinfect the hands using 70 % v/v IPA Solution.
- Rub the hands and in between fingers thoroughly till IPA is dried.
- Press/touch/ show hand to hand type sensor plates on door inter lock button.
- Enter into the airlock where ever applicable or enter production area.

EXIT PROCEDURE FROM THE PRODUCTION AREA

- Press/touch/ show hand to hand type sensor plates on door inter lock button.
- Enter into the airlock where ever applicable.
- Press/touch/ show hand to hand type sensor plates on door inter lock button (wherever applicable).
- Enter into the change room.

(80)

(81)

- Remove factory footwear and keep them in racks beneath cross over bench/designated place, cross the cross over bench (wherever applicable).
- Remove factory uniform in sequence,
- Trouser.
- Shirt.
- Hood/Cap
- Dispose them in used Linen collection bag/designated place.
- For Block A and C Open the door of air flushing tunnel.
- Enter into the Air flushing tunnel.

EXIT PROCEDURE FROM PROCESSING ROOM AT SHIFT END.

- Remove hand gloves, Nose mask, Tertiary Gown (Hood attached) / Antistatic gown and additional pair of Brown shoe cover near the demarcated area (yellow safe zone) in Process room and discard in designated place with in processing room.
- De-gowning shall be done in such a way that the person stands closer to the yellow safe zone (taking care not to enter in the yellow safe zone) remove the hand gloves, head gear/snood, mask, followed by the tertiary gown. Care should be taken to remove the bootie one by one and stepping over the yellow safe zone, thus preventing dust falling into this yellow safe zone.

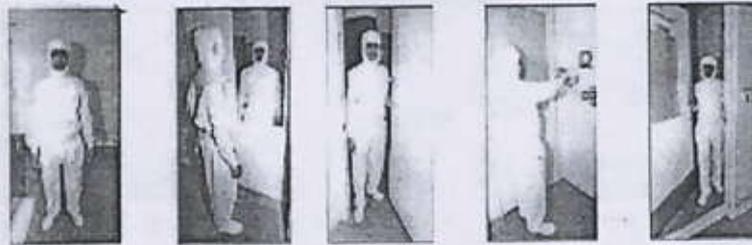
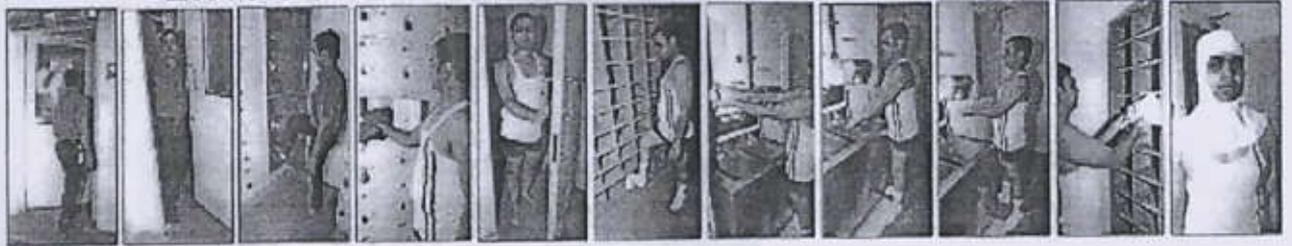
EXIT PROCEDURE FROM PROCESS AREA

- Press/touch/show hand to hand type sensor plates on door inter lock button of process area change room and enter process area change room.
- Remove pair of shoe covers while swinging over the cross over bench and dispose them collection bag. Press/touch/show hand to hand type sensor plates on door inter lock button and exit from the process area change room.



ENTRY AND EXIT PROCEDURE TO THE PRODUCTION AREA - FOR EMPLOYEES (GENTS CHANGE ROOM)

ENTRY PROCEDURE TO THE PRODUCTION AREA



EXIT PROCEDURE FROM THE PRODUCTION AREA



SOP024925

ENTRY AND EXIT PROCEDURE TO THE PRODUCTION AREA - FOR EMPLOYEES (LADIES CHANGE ROOM)

ENTRY PROCEDURE TO THE PRODUCTION AREA



EXIT PROCEDURE FROM THE PRODUCTION AREA



SOP024075

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ENTRY - EXIT PROCEDURE TO PROCESS AREA FOR EMPLOYEES AND VISITORS

PROCEDURE TO PROCESS AREA

ENTRY PROCEDURE



EXIT PROCEDURE



IMAGE FOR OIL RESPONSE

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दिनांक : 24/12/2021

सूचना

सभी कर्मचारियों को सूचित किया जाता है कि दिनांक 01/01/2022 से देवास साइट पर स्थित सभी कर्मचारियों पर निम्नलिखित शिफ्ट परिवर्तन लागू होंगे-

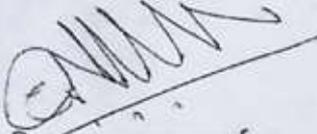
1. निम्नलिखित संशोधित शिफ्ट का समय सभी एस.जी.ओ. (SGO) आधारित कर्मचारियों के लिए दिनांक 01/01/2022 से लागू होगा।

Shift Timings	A Shift		B Shift		C Shift		G Shift	
	Start	End	Start	End	Start	End	Start	End
Existing	07:00	15:30	15:15	23:45	23:45	07:00	09:00	17:30
New	07:15	15:30	15:15	23:30	23:15	07:30	09:00	17:30

2. निम्नलिखित संशोधित शिफ्ट का समय सभी ए.पी.आई. (API) आधारित कर्मचारियों के लिए दिनांक 01/01/2022 से लागू होगा।

Shift Timings	A Shift		B Shift		C Shift		G Shift	
	Start	End	Start	End	Start	End	Start	End
Existing	06:00	14:00	14:00	22:00	22:00	06:00	09:00	17:30
New	06:00	14:15	14:00	22:15	22:00	06:15	09:00	17:30

वास्ते सन फार्मास्युटिकल इंडस्ट्रीज लिमिटेड, देवास


 अधिकृत हस्ताक्षरकर्ता