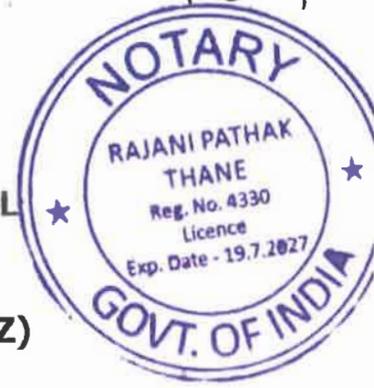


489

BEFORE THE HON'BLE NATIONAL GREEN TRIBUNAL
WESTERN BENCH, PUNE
ORIGINAL APPLICATION NO. 31 OF 2023 (WZ)



IN THE MATTER OF:

Prasad M. Mulye

..... Applicant

Versus

M/s. Bharat Serums and Vaccines Ltd. & Ors.

..... Respondents

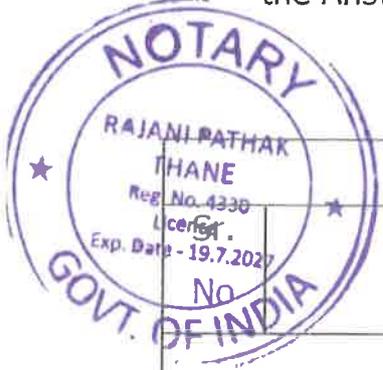
AFFIDAVIT IN REJOINDER ON BEHALF OF M/S. BHARAT SERUMS AND VACCINES LTD. / RESPONDENT NO. 1 TO THE AFFIDAVIT FILED BY THE RESPONDENT NO. 5 DIRECTOR OF INDUSTRIAL SAFETY AND HEALTH

MOST RESPECTFULLY SHOWETH:

I, Mrs. Anupama Pai, W/o Mr. Diwakar Pai, Authorized Representative of the Respondent No. 1: having office at 3rd Floor, Liberty Tower, Plot No. K-10. Behind Thane-191, Kalwa Industrial Estate, Airoli Navi Mumbai – 400708 do solemnly affirm and state as under :

1. I am the authorized Representative of the Respondent No. 1 and am fully acquainted with the facts of the present case and am duly authorized to file the present Affidavit in Rejoinder on behalf of the Respondent No. 1. I state that the filing of the Present Rejoinder Affidavit is necessitated in order to controvert certain allegations and averments made in the Affidavit in Reply filed by the Respondent No. 5.

2. The Respondent No. 1 states and submits that the contentions and averments made by the Respondent No. 5 in their reply are denied as the Authorities have not mentioned the true and correct facts in their Affidavit in Reply and have failed to bring on record the actual sequence and chronology of events pertaining to the visit of the authorities at the R and D Facility of the answering Respondent at Airoli.
3. The Research and Development unit of the Answering Respondent is registered under the Shops & Establishments Act and a valid license is obtained in adherence to the provisions of the Act. In fact, the Summary and Chronology of the Events that took place at the R and D Facility of the Answering Respondent are mentioned in a tabular form as under :



Summary			
No	Event	Date of Event	Date of Receipt
R & D Facility of Answering Respondent at Airoli			
1	Inspection Visit by Respondent No. 5	28.11.2022	
2	Visit Note of Respondent No. 5	15.12.2022	27.12.2022
3	Show Cause Notice issued by Res. 5	16.12.2022	27.12.2022
3	Answering Respondent's reply to Show Cause Notice & Visit Note	02.02.2023	03.02.2023

It is most humbly stated that the Answering Respondent has filed a detailed reply to the Show Cause Notice and Visit Note of the Respondent No. 5 and has exhaustively dealt with each and every aspect of the Show Cause Notice and the same has been duly received by the Authorized officer of the Respondent No. 5 on 3rd February 2023. A copy of the Show Cause Notice dated 15.12.2022

and the Reply filed by the Answering Respondent dated 2nd February 2023 are annexed hereto and marked as **Annexure P-1** to this Affidavit.

4. The Answering Respondent further submits that it was disingenuous on the part of the Respondent No. 5 to not bring the true and correct facts before this Honourable Tribunal by not mentioning the detailed reply to the visit note and show cause notice filed by the Answering Respondent and not file the same on record. In fact, there has been no further communication by the Respondent No. 5 nor any action taken pursuant to the reply filed by the Answering Respondent dated 2nd February 2023 and therefore, the Answering Respondent had legitimately believed that the issue at hand was satisfactorily resolved and there would be a quietus to the issue. At this point, it is pertinent to mention that there is not a single allegation with respect to any form of pollution or any other allegation that would fall within the jurisdiction of this Honourable Tribunal to decide on the subject matter in issue and the affidavit filed by the Respondent No. 5 is disingenuous as it seeks to bring forth certain averments which would not even fall within the jurisdiction of this Honourable Tribunal, much less when there has not been a single averment in the affidavit with respect to any pollution or harm caused by the activities of the Answering Respondent to the public at large

5. The Answering Respondent further reiterates that there is not a single provision of any act, much less, the Factories Act that has been breached by the Answering Respondent and not a single document or any notice/summons of any court or any legal proceeding has been served

on the Answering Respondent till date and therefore, the allegations

made with respect to breach of the provisions of the Factories Act are

unfounded and ought not be countenanced by this Hon'ble Tribunal.



6. The Answering Respondent craves leave of this Honourable Tribunal to file any further rejoinder and produce any other important documents at the time of hearing of this matter, in case the said are critical for fair adjudication of the matter.

Solemnly affirmed at Thane on this 1st day of August 2023.

Anupama Pai D



Authorized Representative of the RESPONDENT NO. 1

VERIFICATION

Verified on this 1st day of August 2023 that the contents of the above Affidavit in Rejoinder are true and correct to the best of my knowledge and belief and nothing material is concealed herefrom.

BEFORE ME

Rajani Pathak

B.Sc., LL.M.

NOTARY & ADVOCATE

Ground Floor, Medha House,
Opp. Aadarsh Sanskar Kendra/Garden,
Rationing Office, Court Naka, Thane.
Mob. No. 9930538766 / 9821138766



Anupama Pai D

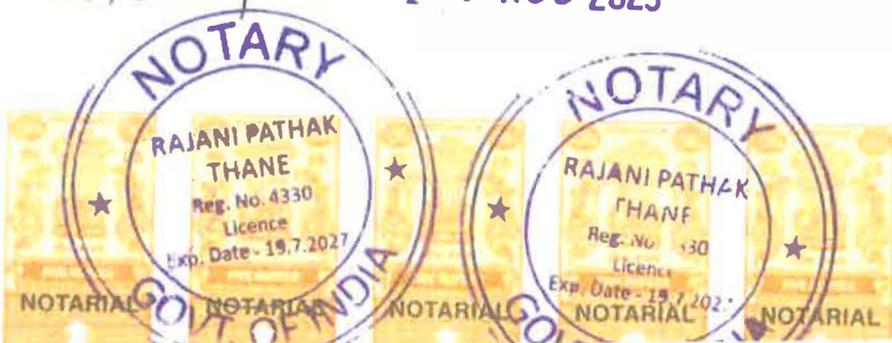


Authorized Representative of the RESPONDENT NO. 1

NOTED & REGISTERED

A8465/2023

- 1 AUG 2023





Government of Maharashtra
Directorate of Industrial Safety and Health



Office of Joint Director, Industrial Safety and Health 2nd Floor, Vardan Building,
Wagle Estate, Thane (W), 400606, Dist- Thane. Email- jddish.tha-mh@gov.in

RPAD No. Jt. D.I.S.H./Visit/PLP/2022/ 1258 /Thane Date 15 DEC 2022

M/s. BHARAT SERUMS AND VACCINES LIMITED
3rd Floor, Liberty Tower, Plot No. K-10,
Behind Reliable Plaza Kalwa Industrial Estate,
Airoli, Navi Mumbai, Thane 400 708.

1. Visited the premises for amenability check on 28.11.2022 and found it working.
2. Shri. Hemendra Rahate (Head-Facilities and Administration) was present and accompanied me during my visit in the premises.
3. I have obtained signed copies of list of products manufactured in this premises, along with list of raw materials used and flow chart for manufacturing process.
4. In this premises activity of making of medicines is being carried out. These includes medicines such as a. Luprodex 3.75 mg, 11.25 mg, b. Liposomal Amphotericin B Injection 50 mg, c. Ceftaroline fosamil powder for infusion 600 mg, d. Ceftazidime 2gm and avibactam 0.5g powder injection, e. Dydrogesterone tablets 10mg, f. Anti-T Lymphocyte Immunoglobulin, g. Snake Venom Antiserum, h. Rabies Antiserum i. Recombinant anti rho d immunoglobulin, j. Recombinant human follicle stimulating hormone, k. Human chorionic gonadotropin (recombinant). The list of products made in this premises obtained during my visit is attached herewith.
5. Making of medicines is a '**Manufacturing Process**' as per section 2(k) (i) of Factories Act 1948.
6. I have obtained signed copy of list of around 63 workers who are normally employed in or in connection with this manufacturing process in said premises. The nature of work/designation and in time of each worker is mentioned on it. The list of workers obtained during visit is attached herewith. These persons engaged in making of medicines are '**workers**' as per section 2(l) of Factories Act 1948.
7. This Manufacturing was being carried out with the aid of power in the form of electricity, this premises therefore constitutes a '**factory**' as per section 2(m)(i) of Factories Act 1948 as the Manufacturing process was being carried out in this premises with more than 20 workers & with the aid of power in the form of electricity.
8. I have also obtained signed copy of list of machines/equipments found installed in the factory and were being used to carry out the manufacturing process.
9. The occupier of the said factory ought to have obtained a license under rule 6 of Maharashtra Factories Rules, 1963 from the Chief Inspector of Factories (i.e. Director Industrial Safety and Health, Mumbai, Maharashtra State) as per provision of clause (4) of Rule 4 of Maharashtra Factories Rules 1963 before using the said premises as a factory. **At the time of my visit on 28.11.2022 occupiers were actually found using the premises as a 'factory' without having valid factory license. Therefore the occupiers of the factory has contravened the provision of clause (4) of Rule 4 of Maharashtra Factories Rules 1963.**

10. Also, the occupier of the said factory ought to have obtained approval plans from Joint Director Industrial Safety and Health, Thane in respect of the following
- The site plan on which the factory is situated
 - Building and extension used for the purpose of manufacturing process
 - The layout of plant and machinery, including the storages for raw materials and finished products before using said premises as a factory.

At the time of my visit on 28.11.2022 I found that, the occupier of the said factory has not submitted & got the factory plans approved from Joint Director Safety & Health, Thane in respect of the following

- The site plan on which the factory is situated**
 - Building and extension used for the purpose of manufacturing process**
 - The layout of plant and machinery, including the storages for raw materials and finished products. Thus the occupier has contravened the provision of clause (1)(a)(b)(c) of Rule 4 of Maharashtra Factories Rules 1963.**
11. Shri. Hemendra Rahate (Head-Facilities and Administration) had also produced before me Xerox copy of registration of Shops and Establishment i.e. नमुना "ब".
12. From the records of registrar of companies through its website it was revealed that following are the directors of company M/s. BHARAT SERUMS AND VACCINES LIMITED -

DIN/PAN	Director Name	Appointment Date
00291675	Smt. Shweta Jalan	22/09/2021
00480341	Shri. Bhaskar Vemban Iyer	22/09/2021
00555052	Shri. Jayesh Tulsidas Merchant	22/09/2021
APZPM8565J	Shri. Chirag Ashokbhai Mehta	22/09/2021
02924640	Shri. Sanjiv Hari Navangul	06/02/2020
ACFPP7829K	Shri. Anupama Diwakar Pai	22/09/2021
08206620	Shri. Pankaj Patwari	06/02/2020
08610857	Shri. Abhijit Mangalmoy Mukherjee	22/09/2021

13. As per Section 2(n) of Factories Act 1948 "occupier" of a factory means the person who has ultimate control over the affairs of the factory. Also as per section 2(n) (ii) in the case of a company, any one of the directors shall be deemed to be the occupier. Hence, these directors are deemed occupiers of factory.
14. The occupiers of said factory may explain within 7 days from the receipt of these remarks as to why legal action shall not be considered against them for the contraventions mentioned above.

(P. L. Patil)

Deputy Director
Industrial Safety & Health, Thane

Bharat Serums and Vaccines Limited

Attendance Intime/Outtime Report date from '2022-11-28 12:00:00 AM' to '2022-11-28 12:00:00 AM'

Emp Code	Employee Name	Designation	Date	Intime	Outtime
AIROLI R&D					
R&D					
1000179	Aldon Fernandes	Vice President	28-11-2022	28-11-2022	07:36:18
1004759	Sunil Pandey	Senior General Manager	28-11-2022	28-11-2022	09:37:23
1001718	Aditee Kambli	Deputy General Manager	28-11-2022	28-11-2022	09:01:28
1004467	Shraddha Bhatlode	Scientist	28-11-2022	28-11-2022	09:05:21
1005778	Ruchira Pradeep Koltarkar	Senior Research Associate	28-11-2022	28-11-2022	09:13:33
1000603	Mahesh Gavasane	General Manager	28-11-2022	28-11-2022	09:34:33
1002863	Pranav Gupte	Principal Scientist	28-11-2022	28-11-2022	08:54:36
1004823	Tushar Bhabal	Scientist	28-11-2022	28-11-2022	09:38:40
1001008	Prashant Kumar	General Manager	28-11-2022	28-11-2022	10:15:50
1005353	Preethi Ravindran	Senior Scientist	28-11-2022	28-11-2022	09:14:07
1004810	Eknath Raut	Assistant	28-11-2022	28-11-2022	09:00:39
1006172	Prasanna Krishna Parab	Senior Research Associate	28-11-2022	28-11-2022	09:03:12
1001053	Kripa Murzello	General Manager	28-11-2022	28-11-2022	08:24:18
1005822	Sneha Vaidyanathan Iyer	Senior Research Associate	28-11-2022	28-11-2022	09:22:19
1003346	Abhay Parab	Lab Associate	28-11-2022	28-11-2022	08:37:12
1005514	Pooja Shrikant Patil	Senior Research Associate	28-11-2022	28-11-2022	08:32:59
1006139	Poojadevi Prashant	Senior Research Associate	28-11-2022	28-11-2022	08:45:28
11244	Prasenjeet Chahande	Deputy General Manager	28-11-2022	28-11-2022	08:38:17
5157	Niraj Rameshwarnath	Principal Scientist	28-11-2022	28-11-2022	10:00:38
1001196	Nilesh Bawaskar	Senior Principal Scientist	28-11-2022	28-11-2022	08:59:09
1003552	Remya Nair	Senior Scientist	28-11-2022	28-11-2022	09:17:48
1001763	Amar Mhase	Principal Scientist	28-11-2022	28-11-2022	09:04:22
1003185	Swapnil Mundhe	Senior Scientist	28-11-2022	28-11-2022	09:20:22
1005491	Rajendra Ganpat Gadhave	Senior Research Associate	28-11-2022	28-11-2022	09:06:10
1004097	Nilesh Dighe	Senior Technician	28-11-2022	28-11-2022	07:56:47
1004101	Sadashiv Narvekar	Semi Skilled	28-11-2022	28-11-2022	08:38:15
1004459	Sudhir Pednekar	Semi Skilled	28-11-2022	28-11-2022	06:57:51
1001756	Rupesh Shinde	Junior Technician	28-11-2022	28-11-2022	07:44:34
1004102	Nayan Jolil	Worker	28-11-2022	28-11-2022	07:53:25
1000056	Ashok Shinde	Skilled Staff	28-11-2022	28-11-2022	08:00:49
1000188	Rajendra Shinde	Skilled Staff	28-11-2022	28-11-2022	08:08:11
1000290	Ravindra Bane	Skilled Staff	28-11-2022	28-11-2022	07:22:03
1004456	Ganesh Phate	General Worker	28-11-2022	28-11-2022	08:04:29
1005421	Sanjay Sitaram Patere	Semi Skilled	28-11-2022	28-11-2022	07:52:11
1004100	Mangesh Gaikwad	Worker	28-11-2022	28-11-2022	09:57:44
1004457	Anil Shinde	Worker	28-11-2022	28-11-2022	07:46:00
1004937	Ganesh Gaikwad	Worker	28-11-2022	28-11-2022	07:07:57
1004938	Shridhar Nathu Pawar	Worker	28-11-2022	28-11-2022	11:06:32
1000210	Sunilkumar Tiwari	Worker	28-11-2022	28-11-2022	08:53:38
1006678	Trushna Rathnakara	Senior Research Associate	28-11-2022	28-11-2022	08:51:54
16921	Nilesh Ashok Yadav	Semi Skilled	28-11-2022	28-11-2022	09:14:04
1006922	Yatin Satam	Semi Skilled	28-11-2022	28-11-2022	08:51:52
1007203	Jaby Jacob	Senior President	28-11-2022	28-11-2022	08:47:42
1007220	Deep Sankar Ghosh	Senior Research Associate	28-11-2022	28-11-2022	08:54:46
1007262	Sai Dilip Tainikar	Lab Associate	28-11-2022	28-11-2022	09:43:16
1007276	Moksha Chitrang Pathan	Lab Associate	28-11-2022	28-11-2022	09:36:45
1007387	Akshay Pandurang	Lab Associate	28-11-2022	28-11-2022	09:00:01
1007407	Avikumar Hemraj	Senior Research Associate	28-11-2022	28-11-2022	08:39:16
1007519	Anil Manik Waghmode	Senior Scientist	28-11-2022	28-11-2022	09:05:18
1007538	Rohit Pralhad Awale	Senior Scientist	28-11-2022	28-11-2022	09:41:38
1007545	Amit Appasaheb Pawase	Senior Scientist	28-11-2022	28-11-2022	09:17:52
1007626	Suresh Kumar	Senior Principal Scientist	28-11-2022	28-11-2022	08:55:31
1007751	Latika Pradeep Anchan	Lab Associate	28-11-2022	28-11-2022	09:16:36
1007855	Chintan Prakashchandra	Deputy General Manager	28-11-2022	28-11-2022	10:23:22
1007947	Sagar Laxmiprasad Uniyal	Management Trainee	28-11-2022	28-11-2022	09:23:39
1007964	Chaitanya Pravin	Lab Associate	28-11-2022	28-11-2022	08:40:02
1007983	Dhiraj Mahendra	Senior Scientist	28-11-2022	28-11-2022	09:22:17
1008018	Gargi Mahendra Indurkar	Manager - Project Management	28-11-2022	28-11-2022	09:03:37
1008083	Lilesh Vaman Bhise	Principal Scientist	28-11-2022	28-11-2022	09:20:37
1008107	Komal Manohar Kamthekar	Research Associate	28-11-2022	28-11-2022	09:28:32
1008085	Saurav Madhav Sakunde	Lab Associate	28-11-2022	28-11-2022	09:05:15
1008150	Jullii Kiran Narkar	Lab Associate	28-11-2022	28-11-2022	08:57:23
1008184	Prathyusha Srinivas Thatipamula	Lab Associate	28-11-2022	28-11-2022	08:07:16

Handwritten signature and date: 28/11/2022

Handwritten text: Hemendra Bahate Head - Facilities & Administration

Handwritten text: 28/11/2022, उप सं-चौक, 2022, प्रतिष्ठा संस्थान

List of Products at NDDS Department (R&D)

Sr. No.	List of Products
1	Liposomal Amphotericin B Injection 50 mg
2	Luprodex 3.75 mg, 11.25 mg
3	Ceftaroline fosamil powder for infusion 600 mg
4	Ceftazidime 2 g & Avibactam 0.5 g Powder for infusion
5	Dydrogesterone Tablet 10 mg

(N) 26/11/2022

Nemendra Bahale

Head - Vaccines & Administration

(प्रविण पाटील)
 28/11/2022
 उप संचालक
 डॉ. सु. व. आ. ठाणे

BHARAT SERUMS AND VACCINES LIMITED
 (formerly known as Aksipro Diagnostics P Limited)

Corporate Office
 3rd Floor, Liberty Tower, Airoli,
 Navi Mumbai- 400708,
 Maharashtra, India
 Tel.: +91-22-4504 3456
 Fax: +91-22-4504 3200

Registered Office
 17th Floor, Hoechst House,
 Nariman Point, Mumbai- 400021,
 Maharashtra, India
 CIN: U74110MH1993PLC075088

R & D Centre
 3rd Floor, Liberty Tower,
 Airoli, Navi Mumbai- 400708
 Maharashtra, India
 Tel.: +91-22-4504 3000
 Fax: +91-22-4504 3200

Ambernath Factory
 Plot No. K-27, Anand Nagar, Additional
 M.I.D.C., Ambernath East- 421501
 Tel.: +91-251-262 7000
 Fax: +91-251-262 7008

497



List of Products at Equine Department (R&D)

Sr. No.	List of Products
1	Anti-T Lymphocyte Immunoglobulin For Human Use, Animal
2	Snake Venom Antiserum
3	Rabies Antiserums - Equine

28/11/2022

Neerajra fashale
Head - Facilities & Administration

प्राविण

28/11
2022
(प्राविण पारील)
उप संचालक
अ. सु. व आ. ढाणे

BHARAT SERUMS AND VACCINES LIMITED
(formerly known as Aksipro Diagnostics P Limited)

Corporate Office
3rd Floor, Liberty Tower, Airoli,
Navi Mumbai- 400708,
Maharashtra, India
Tel.: +91-22-4504 3456
Fax: +91-22-4504 3200

Registered Office
17th Floor, Hoechst House,
Nariman Point, Mumbai- 400021,
Maharashtra, India
CIN: U74110MH1993PLC075088

R & D Centre
3rd Floor, Liberty Tower,
Airoli, Navi Mumbai- 400708
Maharashtra, India
Tel.: +91-22-4504 3000
Fax: +91-22-4504 3200

Ambernath Factory
Plot No. K-27, Anand Nagar, Additional
M.I.D.C., Ambernath East- 421501
Tel.: +91-251-262 7000
Fax: +91-251-262 7008

498



List of Products at Biotech Department (R&D)

Sr. No.	List of Products
1	Recombinant Anti Rho-D Immunoglobulin
2	Recombinant human Follicle stimulating hormone
3	Human Chorionic Gonadotropin (Recombinant)

28/11/2022

Manojna Patil

Head - Facilities & Administration

28/11/2022

(प्रविण फारीक)

उप संचालक

ऑ. सु. व आ. वणे.

BHARAT SERUMS AND VACCINES LIMITED (formerly known as Aksipro Diagnostics P Limited)

Corporate Office
3rd Floor, Liberty Tower, Airoli,
Navi Mumbai- 400708,
Maharashtra, India
Tel.: +91-22-4504 3456
Fax: +91-22-4504 3200

Registered Office
17th Floor, Hoechst House,
Nariman Point, Mumbai- 400021,
Maharashtra, India
CIN: U74110MH1993PLC075088

R & D Centre
3rd Floor, Liberty Tower,
Airoli, Navi Mumbai- 400708
Maharashtra, India
Tel.: +91-22-4504 3000
Fax: +91-22-4504 3200

Ambarnath Factory
Plot No. K-27, Anand Nagar, Additional
M.I.D.C., Ambarnath East- 421501
Tel.: +91-251-262 7000
Fax: +91-251-262 7008

499 o/c.



February 02, 2023

The Government of Maharashtra
Directorate of Industrial Safety and Health
Office of Joint Director, Industrial Safety & Health,
2nd Floor, Vardan Building, Wagle Estate,
Thane (West),
Mumbai - 400 606.

Dear Sir,

This has reference to your notice bearing no. JT.DISH/VISIT/PLP/2022/1258/THANE addressed to the Company dated 15.12.2022.

By the said notice, it has been contended that the activities carried out by the Company at its R&D Unit located at Liberty Tower, Plot No. K-10, Behind Reliable Plaza, Kalwa Industrial Estate, Airoli, Navi Mumbai - 400 708, amounts to a manufacturing process as defined under the provisions of the Factories Act, 1948.

At the very outset, we would like to submit that the Company is engaged in the activities of manufacturing bulk and finished formulations medicines which activity is carried at the Ambernath Plant. The said Ambernath Plant is registered as a factory as defined under the Factories Act, 1948 and this facility is FDA certified facility for manufacture of bulk drugs.

The Company has been carrying out its Research & Development (R&D) activities at its Airoli establishment. The said establishment is registered under the provisions of the Maharashtra Shops & Establishment Act & Rules (S&E Law). The activities carried out in the said establishment are in no way connected with the manufacturing process of a factory nor are they incidental to the manufacturing process of a factory and hence the R&D establishment is governed by the provisions of the S&E Law. Annexed hereto and marked Annexure-A are the workflow and process flow for all products development in the Company's R&D Division. The workflows and the process flows are meant only for R&D process and not for manufacturing the products of the Company.

BHARAT SERUMS & VACCINES LIMITED

Corporate Office
3rd Floor, Liberty Tower,
Airoli, Navi Mumbai - 400708,
Maharashtra, India
Tel : +91 22 4504 3456
Fax: +91 22 4504 3200

Registered Office
17th Floor, Hoechst House,
Nariman Point, Mumbai - 400021,
Maharashtra, India
CIN : U24230MH1971PLC015134

R & D Centre
3rd Floor, Liberty Tower,
Airoli, Navi Mumbai - 400708,
Maharashtra, India
Tel : +91 22 4504 3000
Fax : +91 22 4504 3200

Ambernath Factory
Plot No. K-27, Anand Nagar,
Additional M.I.D.C., Ambernath East - 421501,
Maharashtra, India
Tel : +91 251 262 7000
Fax : +91 251 262 7008



Further, based on a mandate issued by the Department of Scientific and Industrial Research (DSIR) which is a part of Ministry and Science and Technology, the DSIR has been mandated to carry out activities relating to promotion of indigenous technology, development, utilization etc. The DSIR has been carrying out its activities to promote R&D by the industries, support a larger cross section of small & medium industrial units to develop state of the art global competitive technologies of high commercial potential. The R&D centre at Airoli is DSIR approved R&D Centre.

With reference to the inspection visit carried out by your goodself on 28.11.2022, the Company shall now briefly deal with the contents of the inspection visit remarks as contained in the letter dated 15.12.2022.

With reference to Para 3 of the show-cause notice, it is reiterated that no products are manufactured for commercial purposes in the premises at Airoli, Navi Mumbai. The manufacturing activities of products are carried out by the Company in its premises located at Ambernath which manufactures bulk and finished formulations medicines for commercial purposes. It is further submitted that as far as R&D activities are concerned, the Company is referring to and relying upon the workflow and process flows for all the products relating to the Research and Development. The said workflow and process flows are only for R&D purposes and not used for manufacturing of the products.

With reference to Para 4 of the show-cause notice, a reference has been made to certain products as stated therein. We wish to submit that the said products are chemicals used in R&D process. The same are not used for any manufacturing activities for commercial purposes. For the purposes of manufacturing, the same cannot be carried out with such limited quantity of chemicals as large-scale products are required for manufacturing processes. It is further submitted that as per the provisions of the Drugs & Cosmetics Act, Form-29 is a license for the purposes of manufacturing drugs for carrying out any examination or test or analysis. In the R&D establishment, research on the products development is carried out with a view to achieve the intended efficacy and performance. The Company refers to and relies upon Form-29 for all the products which have been referred to by your goodself, which will show that the necessary examination or tests / analysis have been carried out in respect of the said products and that no manufacturing activities have been carried out.

With reference to Para 5 of the show-cause notice, it is reiterated that at the R&D facility, no manufacturing of bulk or finished formulations medicines for commercial purposes are being carried out by the Company. The manufacturing activities for bulk medicines has been carried out by the Company at its Ambernath Plant.

BHARAT SERUMS & VACCINES LIMITED

Corporate Office

3rd Floor, Liberty Tower,
Airoli, Navi Mumbai - 400708,
Maharashtra, India
Tel : +91 22 4504 3456
Fax : +91 22 4504 3200

Registered Office

17th Floor, Hoechst House,
Nariman Point, Mumbai - 400021,
Maharashtra, India
CIN : U24230MH1971PLC015134

R & D Centre

3rd Floor, Liberty Tower,
Airoli, Navi Mumbai - 400708,
Maharashtra, India
Tel : +91 22 4504 3000
Fax : +91 22 4504 3200

Ambernath Factory

Plot No. K-27, Anand Nagar,
Additional M.I.D.C., Ambernath East - 421501,
Maharashtra, India
Tel : +91 251 262 7000
Fax : +91 251 262 7008



As regards Para 6 of your letter, the reference has been made to the 63 Scientists and Associates who are employed at the R&D establishment. It is submitted that the said Scientist and Associates have been carrying out jobs relating to examination or test or research on the products so as to improve their efficacy and performance.

With reference to Para 7 of the show-cause notice, it is reiterated that no manufacturing activities is being carried out in the R&D establishment which falls within the ambit of the definition of a 'factory' as defined under Section 2(m)(i) of the Factories Act.

With reference to Para 8 of the show-cause notice, the list of machines / equipment's referred to are not used for manufacturing process. The equipment / instruments viz. list of 225 for Equine, 224 for Biotech and 142 for NDDS are in respect of equipment's / instruments used for R&D process and not for manufacturing process.

With reference to Para 9 of the show-cause notice, it is submitted that since the activities carried out at the R&D establishment do not fall within the ambit of the definition of 'factory' as defined under the Factories Act, the Company is not required to obtain a license under Rule 6 of the Maharashtra Factories Rules, 1963 from the Chief Inspector of Factories, as per clause 4 of Rule 4 of the Maharashtra Factories Rules, 1963. The Company is therefore not required to obtain a factory license. Your goodself will therefore appreciate that the Company has not contravened the provisions of Clause 4 of Rule 4 of the Maharashtra Factories Rules, 1963.

With reference to Para 10 of the show-cause notice, it is submitted that since the activities at the R&D establishment do not fall within the ambit of the definition of 'manufacturing process', the Company is not required to obtain site plan on which the factory is situated or any building or extension used for the purpose of manufacturing process or any layout of the plant and machinery including the storages for raw materials and finish products. The Company therefore submits that it has not contravened the provisions of clause 1(a), (b) & (c) of Rule 4 of the Maharashtra Factories Rules, 1963 and confirm that the said R&D Centre is an 'Establishment' under the S&E Law.

With reference to Paras 12, 13 & 14 of the show-cause notice, it is reiterated that the activities carried out at the R&D Centre do not fall within the definition of a 'manufacturing process' as defined under the Factories Act.

BHARAT SERUMS & VACCINES LIMITED

Corporate Office

3rd Floor, Liberty Tower,
Airoli, Navi Mumbai - 400708,
Maharashtra, India
Tel : +91 22 4504 3456
Fax : +91 22 4504 3200

Registered Office

17th Floor, Hoechst House,
Nariman Point, Mumbai - 400021,
Maharashtra, India
CIN : U24230MH1971PLC015134

R & D Centre

3rd Floor, Liberty Tower,
Airoli, Navi Mumbai - 400708,
Maharashtra, India
Tel : +91 22 4504 3000
Fax : +91 22 4504 3200

Ambarnath Factory

Plot No. K-27, Anand Nagar,
Additional M.I.D.C., Ambarnath East - 421501,
Maharashtra, India
Tel : +91 251 262 7000
Fax : +91 251 262 7008



It is therefore requested that your goodself be pleased to take steps to withdraw the said show-cause notice dated 15.12.2022 and not take any steps furtherance thereto.

For **Bharat Serums and Vaccines Limited**

Authorized Signatory

BHARAT SERUMS & VACCINES LIMITED

Corporate Office

3rd Floor, Liberty Tower,
Airoli, Navi Mumbai - 400708,
Maharashtra, India
Tel : +91 22 4504 3456
Fax : +91 22 4504 3200

Registered Office

17th Floor, Hoechst House,
Nariman Point, Mumbai - 400021,
Maharashtra, India
CIN : U24230MH1971PLC015134

R & D Centre

3rd Floor, Liberty Tower,
Airoli, Navi Mumbai - 400708,
Maharashtra, India
Tel : +91 22 4504 3000
Fax : +91 22 4504 3200

Ambarnath Factory

Plot No. K-27, Anand Nagar,
Additional M.I.D.C., Ambarnath East - 421501,
Maharashtra, India
Tel : +91 251 262 7000
Fax : +91 251 262 7008

Workflow of Rabies Antiserums - Equine Department (R&D)

Raw material (Horse Plasma) is received from third party for Formulation and Analysis purposes on an R&D Scale. The raw material is enzymatically digested using Pepsin and the material is precipitated using Octanoic acid. The material is further filtered, dialyzed and loaded onto a column and the Flowthrough is collected and dialyzed with buffer containing cresol. The sample is further concentrated, analysed and charged into stability. Extensive experimentation is carried out on all above steps to study robustness. Analytical methods are also developed for characterization of the material.

Workflow of Snake Venom Antiserum - Equine Department (R&D)

Raw material (Horse Plasma) is received from third party for Formulation and Analysis purposes on an R&D Scale. The raw material is enzymatically digested using Pepsin and the material is precipitated using Octanoic acid. The material is further filtered, dialyzed and loaded onto a column and the Flowthrough is collected and dialyzed with buffer containing cresol. The sample is further concentrated, analysed and charged into stability. Extensive experimentation is carried out on all above steps to study robustness. Analytical methods are also developed for characterization of the material.

Workflow of Anti-T Lymphocyte Immunoglobulin - Equine Department (R&D)

Raw material (Horse Plasma) is received from third party for Formulation and Analysis purposes on an R&D Scale. The raw material is precipitated using Caprylic acid. The material is further filtered, dialyzed and loaded onto a column and the Flowthrough is collected and dialyzed with buffer. The sample is further concentrated, analysed and charged into stability. Extensive experimentation is carried out on all above steps to study robustness. Analytical methods are also developed for characterization of the material.

Workflow Diagram of Biotech Department (R&D)

The development work is initiated after the receipt of raw materials, consumables, reference standards for the development of upstream & downstream & formulation process. Analytical methods are developed & qualified. Once the process development work is completed, the process consistency & product stability is established at research & development center, Liberty Tower, Airoli, Navi Mumbai.

Process Flow for Recombinant Anti Rho-D Immunoglobulin

Upstream cell culture experiment starts with the revival of recombinant CHO cells, followed by seed expansion in shake flasks to generate sufficient cell mass for the inoculation of the bioreactor. The R&D scale Bioreactor is operated in fed-batch mode with defined feeding strategy. Harvest clarification is performed through series of depth filter and 0.2-micron filter. A standard downstream process employed for mAb purification consists of series of chromatography steps, low pH incubation and nanofiltration steps, UF/DF for concentration and buffer exchange, 0.2-micron filtration steps to control bioburden & stored at defined temperature.

The drug substance is processed further to prepare drug product for development work. The formulation buffer is prepared separately. The required volume of drug substance & formulation buffer is mixed together to prepare the targeted strength for research & development work.

Process flow for Recombinant Human Chorionic Gonadotropin

Upstream cell culture experiment starts with the revival of recombinant CHO cells, followed by seed expansion in shake flasks to generate sufficient cell mass for the inoculation of the bioreactor. The R&D scale Bioreactor is operated in fed-batch mode with defined feeding strategy. Harvest clarification is performed through series of depth filter and 0.2-micron filter. A downstream process employed for purification consists of series of chromatography steps, multiple UF/DF for concentration and buffer exchange, nanofiltration step, 0.2-micron filtration steps to control bioburden. The drug substance is stored at defined temperature.

The drug substance is processed further to prepare drug product for development work. The formulation buffer is prepared separately. The required volume of drug substance & formulation buffer is mixed together along with excipients to prepare the targeted strength for research & development work.

Process flow for Recombinant Human Follicle Stimulating Hormone

Upstream cell culture experiment starts with the revival of recombinant CHO cells, followed by seed expansion in shake flasks to generate sufficient cell mass for the inoculation of the bioreactor. The R&D scale Bioreactor is operated in batch mode. Harvest clarification is performed through series of depth filter and 0.2-micron filter. A downstream process employed for purification consists of series

of chromatography steps, multiple UF/DF for concentration and buffer exchange, nanofiltration step, 0.2-micron filtration steps to control bioburden. The drug substance is stored at defined temperature. The drug substance is processed further to prepare drug product for development work. The formulation buffer is prepared separately. The required volume of drug substance & formulation buffer is mixed together along with excipients to prepare the targeted strength for research & development work.

Workflow Diagram of NDDS Department (R&D)

The development work in department is initiated after the receipt of raw materials, consumables, reference standards, literature search of molecules, reference innovator product understanding followed by formulation development. Analytical specifications and controls are well defined, with validated analytical methods to ensure the quality and stability of the developed formulations. Once the compounding development work is completed, compatibility study & formulation stability is established at research & development center, Liberty Tower, Airoli, Navi Mumbai.

Process Flow for Liposomal Amphotericin B Injection

The development of liposomal preparations has meant that doses of amphotericin B can be safely escalated. Experiment start with Amphotericin B, lipids and dl-alpha tocopherol are combined to form Amphotericin B lipid powder which is then hydrated to obtain the liposomal dispersion and then homogenised to get the required particle size and distribution. The homogenised liposomal dispersion is filtered, filled and lyophilized to obtain the final formulation. Stability study for development batches is studied as per ICH guidelines thereby completing the development activity.

Process flow for Leuprolide Acetate Injection 3.75 mg

Leuprolide 3.75mg formulation is based on microsphere technology which has been specifically designed as a stable parenteral formulation for the continuous controlled release of the Leuprolide over the period. The experiment of Leuprolide acetate Microsphere 3.75 mg involves several processing variables like mixing of drug polymer organic internal solution to aqueous phase, homogenization, recovery of microspheres, washing & Lyophilization that is adjusted to achieve the objective of drug load, free drug and particle size of formulation. Stability study for development batches is studied as per ICH guidelines thereby completing the development activity.

Process flow for Ceftaroline powder for concentrate for solution for infusion

Ceftaroline powder for concentrate is being developed at R&D after patent and literature review of the innovator product whereby the readily available source of Ceftaroline fosamil + L-Arginine are evaluated for its suitability to be filled and evaluated for admixture and stability studies as per ICH guidelines thereby completing the development activity.

Process flow for Ceftazidime Avibactam powder for concentrate for solution for infusion

Ceftazidime Avibactam powder for concentrate is being developed at R&D after patent and literature review of the innovator product whereby the readily available source of Ceftazidime with sodium bicarbonate + Avibactam are evaluated for its suitability to be filled and evaluated for admixture and stability studies as per ICH guidelines thereby completing the development activity.

Process flow for Dydrogesterone tablets

Tablet is defined as a compressed solid dosage form containing medicaments with or without excipients. According to the Indian Pharmacopoeia Pharmaceutical tablets are solid, flat or biconvex dishes, unit dosage form, prepared by compressing a drug or a mixture of drugs, with or without diluents. It is the most popular dosage form and 70% of the total medicines are dispensed in the form of Tablet. Dydrogesterone Tablet is a simple film-coated tablet where the experiment involves granulating the drug with excipients, shifting of dried granules followed by blending with extra granular excipients and Compression to obtain round shaped tablets. To avoid direct exposure of Dydrogesterone tablets from surrounding atmosphere, film coating is performed on compressed tablets and are kept in HDPE bottles for stability studies as per ICH guidelines thereby completing the development activity.



himanshu pabreja <himanshupabreja07@gmail.com>

Fwd: Affidavit in Rejoinder - Bharat Serums and Vaccines Ltd.

1 message

bhashm <bhashm@gmail.com>
To: himanshu pabreja <himanshupabreja07@gmail.com>

Tue, Aug 1, 2023 at 7:37 PM

----- Forwarded message -----

From: **bhashm** <bhashm@gmail.com>
Date: Tue, 1 Aug 2023 at 19:35
Subject: Affidavit in Rejoinder - Bharat Serums and Vaccines Ltd.
To: Asim Suhas Sarode <asim.human@gmail.com>, <rothane@mpcb.gov.in>, <mpcbthane@mpcb.gov.in>, <apccfcentral-ngp-mef@gov.in>, <dirdish.mum-mh@gov.in>, <ceo@midcindia.org>, <setic.thanewrd@maharashtra.gov.in>, <bksharma.cpcb@nic.in>, <ccb.cpcb@nic.in>, Sanjay Jadhav <sjadhav82@gmail.com>
Cc: <ngt-pune@gov.in>

Dear Sir/Madam,

I am Advocate Bhash H. Mankad representing the Respondent No. 1 i.e. M/s. Bharat Serums and Vaccines Ltd. in Original Application no. 31 of 2023 filed by Mr. Prasad Mulye before the NGT Western ZOne Bench at Pune.

Please find attached the scanned copy of the Affidavit in Rejoinder on behalf of the Respondent No. 1 M/s. Bharat Serums and Vaccines Ltd. in the captioned matter for your kind reference.

An acknowledgement of receipt will be highly appreciated.

--

Regards

Bhash Mankad (Advocate)
17,Sumeru Bungalows
Bodakdev
Ahmedabad - 380054

--

Regards

Bhash Mankad (Advocate)
17,Sumeru Bungalows
Bodakdev
Ahmedabad - 380054



Affidavit in Rejoinder - Original Application No. 31 of 2023.pdf

1436K