

**MINUTES OF TECHNICAL EVALUATION COMMITTEE MEETING OF TENDER NO. BMSIC/DRUGS/18-12 (RATE CONTRACT AND SUPPLY OF DRUGS FOR DIFFERENT HEALTHCARE FACILITIES OF STATE OF BIHAR).**

**Date: 20<sup>th</sup> June 2019**

**Venue: BMSICL Conference Hall.**

The **Technical Evaluation Committee Meeting of Tender No. BMSIC/DRUGS/18-12** was held on 20<sup>th</sup> June 2019 under the Chairmanship of Dr. R. D. Ranjan, Director in Chief, Department of Health, GoB. The other committee members present in the meeting were:

1. Sh. Anil Kumar, Joint Secretary, Department of Health, GoB.
2. Sh. Khalid Arshad, AO, State Health Society, GoB.
3. Sh. Rajani Kant, CGM (Supply Chain), BMSICL.
4. Dr. N. K. Mishra, Additional Director, Health Dept., GoB.
5. Sh. Sunil Kumar Singh, GM (Logistics), BMSICL.
6. Dr. Biswaprakash Pradhan, DGM (Drugs), BMSICL.

**2. The Details of the invited tender are as follows:**

1. Tender Reference No. BMSIC/ DRUGS/18-12.
2. Tender floated date- 06/12/2018.
3. Last date of submission of Online bids-10/01/2019.
4. Tender Opening date- 11/01/2019.

**3. Tender has been floated for 30 drugs. It was found in online opening that total 22 (Twenty-Two) following bidders had participated in the tender:**

1. Aculife Healthcare Pvt. Ltd.
2. Alpa Laboratories Limited.
3. Ang Life Sciences India Ltd.
4. Bochem Healthcare Pvt. Ltd.
5. Eurolife Healthcare Pvt. Ltd.
6. Haseeb Pharmaceuticals Pvt. Ltd.
7. La- Chemico Pvt. Ltd.
8. Medicef Pharma.
9. Medopharm Pvt. Ltd.
10. Modern Laboratories
11. Ornate Labs Pvt. Ltd.
12. Otsuka Pharmaceutical India Pvt. Ltd.
13. Pharma Impex Laboratories Pvt. Ltd.
14. Scott-Edil Advance Research Laboratories & Education Ltd.
15. Shamshree Lifesciences Ltd.
16. Supermax Laboratories
17. Theon Pharmaceuticals Ltd.
18. Unicure India Ltd.



19. VADSP Pharmaceuticals
20. Venus Remedies Ltd.
21. Vivek Pharmachem (India) Ltd.
22. Wings Biotech

4. **The summary of Bid received status were as follows:**

1. No Bids received for 6 Drugs.
2. Single Bids received for 2 Drugs.
3. Multiple Bids received for 22 Drugs.

5. It was unanimously decided in tender opening committee meeting dated 11.01.19 to proceed further for preliminary technical evaluation of all the bids for **those 22 drugs** (NIT SN- 1,2,4,5,6,7,8,9,12,13, 14,15,16,17, 18,20, 21,22,23,24,27, and 28) for which multiple bids were received, by the team of Drug Inspectors deputed at BMSICL and retender for 8 drugs for which zero bid (NIT SN- 10,19,25,26,29 and 30) and single bids (NIT SN-3 and 11) were received.

6. The Preliminary Evaluation of technical bids of the above mentioned bidding firms was done by the team of Drug Inspectors deputed at BMSICL. Evaluation sheets were published on the website of BMSICL and Claims/Objections/Clarification were invited vide notice no.5040 dated 21.01.2019.

7. After comparison of the clarification received from the bidders in the light of that notice and close examination of the documents submitted by the bidding firms, the drug wise technical evaluation findings were recorded by the TEC in its meeting dated 11.02.2019 as follows:

S. N	NIT S. N	Name of the Drugs	Participating Firms	Qualified/Di squalified	Remarks
1.	1.	Lignocaine Hydrochloride Injection 2 % w/v 30 ml Vial	Modern Laboratories	Qualified	OK
			Vivek Pharmachem (India) Limited	Qualified	OK
			Aculife Healthcare Pvt. Ltd.	<b>Disqualified</b>	<b>Specification/ Strength for the approved product is not matching with NIT Specification.</b>
			Alpa Laboratories Ltd.	Qualified	OK
2.	2.	Tramadol Hydrochloride Injection 50 mg/ml 2ml Amp.	Modern Laboratories	Qualified	OK
			Alpa Laboratories Ltd.	Qualified	OK
3	4.	Albendazole Oral Suspension 200 mg/5 ml 10 ml Bottle	Modern Laboratories	Qualified	OK
			Vivek Pharmachem (India) Limited	Qualified	OK
			Wings Biotech	Qualified	OK

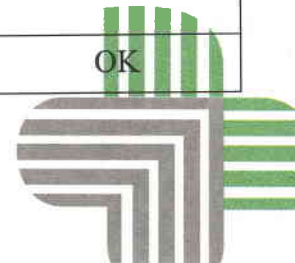
			La-Chemico Pvt. Ltd.	Qualified	OK
			Ornate Labs Pvt. Ltd.	Qualified	OK
			Unicure India Ltd.	Qualified	OK
4.	5.	Ampicillin and Cloxacillin Injection Each vial contains: Ampicillin-250 mg & Cloxacilin-250 mg	Modern Laboratories	Qualified	OK
			Ang Lifesciences India Limited.	Qualified	OK
			VADSP Pharmaceuticals	Qualified	OK
5.	6.	Cefotaxime Sodium Injection 500 mg Vial	Modern Laboratories	Qualified	OK
			Vivek Pharmachem (India) Limited	Qualified	OK
			Alpa Laboratories Ltd.	Qualified	OK
			Ang Lifesciences India Limited.	Qualified	OK
			Pharma Impex Laboratories Pvt. Ltd	Qualified	OK
			Shamshree Lifesciences Limited	Qualified	OK
			Theon Pharmaceuticals Limited	Qualified	OK
			VADSP Pharmaceuticals	Qualified	OK
6.	7.	Amoxycillin and Potassium Clavulanate Tablets Amoxycillin 500mg+ Clavulanic acid 125 mg 10 x 10	Medicef Pharma	Qualified	OK
			Medopharm Private Limited	Qualified	OK
			Scott- Edil Advance Research Laboratories and Education Limited	<b>Decision pending</b>	<b>NCC, WHO GMP/GMP and MPCC needs to be verified during factory inspection</b>
			Supermax Laboratories	Qualified	<b>The shortage Stamp duty of Rs. 90/- needs to be paid by the bidder, hence Stamp paper of that amount is required to be submitted.</b>
			Theon Pharmaceuticals Limited	Qualified	OK
7.	8.	Meropenem Injection	Modern Laboratories	Qualified	OK



		1000 mg	Vivek Pharmachem (India) Limited	Qualified	OK
			Alpa Laboratories Ltd.	Qualified	OK
			Ang Lifesciences India Limited.	Qualified	OK
			Pharma Impex Laboratories Pvt. Ltd	Qualified	OK
			Scott- Edil Advance Research Laboratories and Education Limited	<b>Decision pending</b>	<b>NCC, WHO GMP/GMP and MPCC needs to be verified during factory inspection</b>
			Shamshree Lifesciences Limited	Qualified	OK
			VADSP Pharmaceuticals	Qualified	OK
			Venus Remedies Limited	Qualified	OK
8.	9.	Chloroquine Phosphate Syrup 50 mg/5 ml 60 ml Bottle	Modern Laboratories	Qualified	OK
			Vivek Pharmachem (India) Limited	Qualified	OK
9.	12.	Ranitidine Tablets 150 mg 10 x 10	Modern Laboratories	Qualified	OK
			Vivek Pharmachem (India) Limited	Qualified	OK
			Bochem Healthcare Pvt. Ltd.	Qualified	OK
			Unicure India Ltd.	Qualified	OK
10.	13.	Dextrose Injection (Form, Fill & Seal process) 5% w/v 500 ml	Aculife Healthcare Pvt. Ltd.	Qualified	OK
			Eurolife Healthcare Pvt. Ltd.	<b>Decision pending</b>	<b>First approval date needs to be verified during factory inspection</b>
			Haseeb Pharmaceuticals Pvt. Ltd.	<b>Decision Pending</b>	<b>First approval date needs to be verified during factory inspection.</b>
			Otsuka Pharmaceutical India Private Limited	Qualified	OK
11.	14.	Dextrose Injection (Form, Fill & Seal	Aculife Healthcare Pvt. Ltd.	Qualified	OK



		process) Infusion 10% w/v 500 ml	Eurolife Healthcare Pvt. Ltd.	<b>Decision pending</b>	<b>First approval date needs to be verified during factory inspection</b>
			Haseeb Pharmaceuticals Pvt. Ltd.	<b>Decision Pending</b>	<b>First approval date needs to be verified during factory inspection.</b>
			Otsuka Pharmaceutical India Private Limited	Qualified	OK
12.	15.	Mannitol Injection (Form, Fill & Seal process) 20 % w/v 100 ml Bottle	Aculife Healthcare Pvt. Ltd.	Qualified	OK
			Eurolife Healthcare Pvt. Ltd.	<b>Decision pending</b>	<b>First approval date needs to be verified during factory inspection</b>
			Otsuka Pharmaceutical India Private Limited	Qualified	OK
13.	16.	Metronidazole Injection (Form, Fill & Seal process) Infusion 5 mg/ml 100 ml	Aculife Healthcare Pvt. Ltd.	Qualified	OK
			Eurolife Healthcare Pvt. Ltd.	Qualified	OK
			Haseeb Pharmaceuticals Pvt. Ltd.	<b>Decision Pending</b>	<b>First approval date needs to be verified during factory inspection.</b>
			Otsuka Pharmaceutical India Private Limited	Qualified	OK
14.	17.	Ciprofloxacin Injection (Form, Fill & Seal process) 2mg/ ml 100 ml	Aculife Healthcare Pvt. Ltd.	Qualified	OK
			Eurolife Healthcare Pvt. Ltd.	<b>Decision pending</b>	<b>First approval date needs to be verified during factory inspection</b>
			Haseeb Pharmaceuticals Pvt. Ltd.	<b>Decision Pending</b>	<b>First approval date needs to be verified during factory inspection.</b>
			Otsuka Pharmaceutical India Private Limited	Qualified	OK
15.	18.	Antacid Tablets	Modern Laboratories	Qualified	OK



		(Tablet Containing: Dried Aluminium Hydroxide Gel- 250 mg, Magnesium Hydroxide- 250mg, Activated Dimethicon 50mg) 10 x 10	Vivek Pharmachem (India) Limited	Qualified	OK
			La-Chemico Pvt. Ltd.	Qualified	OK
			Unicare India Ltd.	Qualified	OK
16.	20.	Prednisolone Tablets 5mg 10 x 10	Wings Biotech	Qualified	OK
			Ornate Labs Pvt. Ltd.	Qualified	OK
			Unicare India Ltd.	Qualified	OK
17.	21.	Prednisolone Tablets 10 x 10	Wings Biotech	Qualified	OK
			Ornate Labs Pvt. Ltd.	Qualified	OK
			Unicare India Ltd.	Qualified	OK
18.	22.	Calcium Tablets (Each tablet Contains: Calcium Carbonate equivalent to 500mg elemental calcium and Vitamin D3-250 I.U) 10 x 10	Modern Laboratories	Qualified	OK
			Wings Biotech	Qualified	OK
			Bochem Healthcare Pvt. Ltd.	Qualified	OK
			Ornate Labs Pvt. Ltd.	Qualified	OK
			Unicare India Ltd.	Qualified	OK
19.	23.	Atropine Injection 600µg/ml Ampoule	Modern Laboratories	Qualified	OK
			Alpa Laboratories Ltd.	Qualified	OK
20.	24.	Hydrocortisone Sodium Succinate Injection 100mg 20 ml Vial	Vivek Pharmachem (India) Limited	Qualified	OK
			Alpa Laboratories Ltd.	Qualified	OK
			Ang Lifesciences India Limited.	Qualified	OK
			VADSP Pharmaceuticals	Qualified	OK
21.	27	Vancomycin Intravenous Infusion 1000 mg Vial	Vivek Pharmachem (India) Limited	Qualified	OK
			Ang Lifesciences India Limited.	Qualified	OK
			Venus Remedies Limited	Qualified	OK
22.	28	Vancomycin Intravenous Infusion 500 mg Vial	Vivek Pharmachem (India) Limited	Qualified	OK
			Ang Lifesciences India Limited.	Qualified	OK
			Venus Remedies Limited	Qualified	OK



Regarding Blacklisting of the firm Aculife Healthcare Pvt. Ltd. by OSMCL, the Honorable Orissa High Court Order no. WP(C) 15723/2018 dated 03.09.2018 requires clarification. Hence the TEC in its last meeting dated 11.02.19 recommended for seeking legal opinion before taking the final decision on the issue of technical qualification otherwise the firm was found technically qualified for all quoted products except NIT SI no.1.

It was also recommended in that TEC meeting to carry out the factory inspection of those above mentioned firms which are technically qualified as well as of those whose technical qualification status depended upon factory inspection.

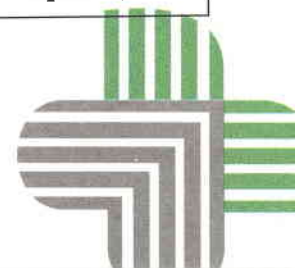
8. In accordance with the decision taken by the committee in its last meeting dated 11.02.2019, the factory inspection was conducted by the team of Drug Inspectors deputed for this purpose except the firms those have already been inspected during last one year.

Accordingly, the factory inspection reports and the legal opinion regarding Blacklisting of the firm Aculife Healthcare Pvt. Ltd. by OSMCL and the Honorable Orissa High Court Order no. WP(C) 15723/2018 dated 03.09.2018 that, “there is no legal bar nor the company is blacklisted in view of the order dt. 03.09.2018 passed by the Honorable High Court of Orissa” were placed before the committee in today’s meeting. After perusal of which, the drug wise technical evaluation finding in the TEC meeting dated 26.03.19 were recorded as follows:

S.N	NIT S. N	Name of the Drugs with Specification	Participating Firms	Recommendation of the TEC before Factory Inspection	Recommendation of TEC after factory inspection (Qualified/ Disqualified)
1.	1.	Lignocaine Hydrochloride Injection 2 % w/v 30 ml Vial	Modern Laboratories	Qualified	Qualified
			Vivek Pharmachem (India) Limited	Qualified	Qualified
			Alpa Laboratories Ltd.	Qualified	Qualified
2.	2.	Tramadol Hydrochloride Injection 50 mg/ml 2ml Amp.	Modern Laboratories	Qualified	Qualified
			Alpa Laboratories Ltd.	Qualified	Qualified
3	4.	Albendazole Oral Suspension 200 mg/5 ml 10 ml Bottle	Modern Laboratories	Qualified	Qualified
			Vivek Pharmachem (India) Limited	Qualified	Qualified
			Wings Biotech	Qualified	Qualified
			La-Chemico Pvt. Ltd.	Qualified	Qualified
			Ornate Labs Pvt. limited	Qualified	Qualified



			Unicare India Ltd.	Qualified	Qualified
4.	5.	Ampicillin and Cloxacillin Injection Each vial contains: Ampicillin-250 mg & Cloxacillin-250 mg	Modern Laboratories	Qualified	Qualified
			Ang Lifesciences India Limited.	Qualified	Qualified
			VADSP Pharmaceuticals	Qualified	Qualified
5.	6.	Cefotaxime Sodium Injection 500 mg Vial	Modern Laboratories	Qualified	Qualified
			Vivek Pharmachem (India) Limited	Qualified	Qualified
			Alpa Laboratories Ltd.	Qualified	Qualified
			Ang Lifesciences India Limited.	Qualified	Qualified
			Pharma Impex Laboratories Pvt. Ltd	Qualified	Decision pending (Clarification regarding valid pollution clearance certificate is required)
			Shamshree Lifesciences Limited	Qualified	Decision pending (Clarification regarding valid pollution clearance certificate is required)
			Theon Pharmaceuticals Limited	Qualified	Qualified
VADSP Pharmaceuticals	Qualified	Qualified			
6.	7.	Amoxicillin and Potassium Clavulanate Tablets Amoxicillin 500mg+ Clavulanic acid 125 mg 10 x 10	Medicef Pharma	Qualified	Qualified
			Medopharm Private Limited	Qualified	Qualified
			Scott Edil Advance Research Laboratories and Education Limited	Decision pending as NCC, WHO GMP/GMP and MPCC needs to be verified during factory inspection	Decision pending (Clarification regarding valid pollution clearance certificate is required)





			Supermax Laboratories	Qualified (The shortage Stamp duty of Rs. 90/- needs to be paid by the bidder, hence Stamp paper of that amount is required to be submitted)	Qualified (Required stamp duty is submitted)
			Theon Pharmaceuticals Limited	Qualified	Qualified
7.	8.	Meropenem Injection 1000 mg	Modern Laboratories	Qualified	Qualified
			Vivek Pharmachem (India) Limited	Qualified	Qualified
			Alpa Laboratories Ltd.	Qualified	Qualified
			Ang Lifesciences India Limited.	Qualified	Qualified
			Pharma Impex Laboratories Pvt. Ltd	Qualified	Decision pending (Clarification regarding valid pollution clearance certificate is required)
			Scott Edil Advance Research Laboratories and Education Limited	Decision pending as NCC, WHO GMP/GMP and MPCC needs to be verified during factory inspection	Decision pending (Clarification regarding valid pollution clearance certificate is required)
			Shamshree Lifesciences Limited	Qualified	Decision pending (Clarification regarding valid pollution clearance certificate is required)
			VADSP Pharmaceuticals	Qualified	Qualified
			Venus Remedies Limited	Qualified	Qualified



8.	9.	Chloroquine Phosphate Syrup 50 mg/5 ml 60 ml Bottle	Modern Laboratories	Qualified	Qualified
			Vivek Pharmachem (India) Limited	Qualified	Qualified
9.	12.	Ranitidine Tablets 150 mg 10 x 10	Modern Laboratories	Qualified	Qualified
			Vivek Pharmachem (India) Limited	Qualified	Qualified
			Bochem Healthcare Pvt. Ltd.	Qualified	Qualified
			Unicare India Ltd.	Qualified	Qualified
10.	13.	Dextrose Injection (Form, Fill & Seal process) 5% w/v 500 ml	Aculife Healthcare Pvt. Ltd.	Qualified	Qualified
			Eurolife Healthcare Pvt. Ltd.	Decision pending as First approval date needs to be verified during factory inspection	Qualified (The first approval date of the product 31.12.2013)
			Haseeb Pharmaceuticals Pvt. Ltd.	Decision Pending as First approval date needs to be verified during factory inspection	<b>Decision pending (Clarification regarding valid pollution clearance certificate &amp; validity of manufacturing license is required)</b>
			Otsuka Pharmaceutical India Private Limited	Qualified	Qualified
11.	14.	Dextrose Injection (Form, Fill & Seal process) Infusion 10% w/v 500 ml	Aculife Healthcare Pvt. Ltd.	Qualified	Qualified
			Eurolife Healthcare Pvt. Ltd.	Decision pending as First approval date needs to be verified during factory inspection	Qualified (The first approval date of the product 31.12.2013)
			Haseeb Pharmaceuticals Pvt. Ltd.	Decision Pending as First approval date needs to be	<b>Decision pending (Clarification regarding valid</b>



				verified during factory inspection.	<b>pollution clearance certificate &amp; validity of manufacturing license is required)</b>
			Otsuka Pharmaceutical India Private Limited	Qualified	Qualified
12.	15.	Mannitol Injection (Form, Fill & Seal process) 20 % w/v 100 ml Bottle	Aculife Healthcare Pvt. Ltd.	Qualified	Qualified
			Eurolife Healthcare Pvt. Ltd.	Decision pending as First approval date needs to be verified during factory inspection	Qualified (The first approval date of the product 10.11.2008)
			Otsuka Pharmaceutical India Private Limited	Qualified	Qualified
13.	16.	Metronidazole Injection (Form, Fill & Seal process) Infusion 5 mg/ml 100 ml	Aculife Healthcare Pvt. Ltd.	Qualified	Qualified
			Eurolife Healthcare Pvt. Ltd.	Qualified	Qualified
			Haseeb Pharmaceuticals Pvt. Ltd.	Decision Pending as First approval date needs to be verified during factory inspection.	<b>Decision pending (Clarification regarding valid pollution clearance certificate &amp; validity of manufacturing license is required)</b>
			Otsuka Pharmaceutical India Private Limited	Qualified	Qualified
14.	17.	Ciprofloxacin Injection (Form, Fill & Seal process) 2mg/ ml 100 ml	Aculife Healthcare Pvt. Ltd.	Qualified	Qualified
			Eurolife Healthcare Pvt. Ltd.	Decision pending as First approval date needs to be	Qualified (The first approval date of the product

				verified during factory inspection	10.11.2008)
			Haseeb Pharmaceuticals Pvt. Ltd.	Decision Pending as First approval date needs to be verified during factory inspection.	<b>Decision pending (Clarification regarding valid pollution clearance certificate &amp; validity of manufacturing license is required).</b>
			Otsuka Pharmaceutical India Private Limited	Qualified	Qualified
15.	18.	Antacid Tablets (Tablet Containing: Dried Aluminium Hydroxide Gel-250 mg, Magnesium Hydroxide-250mg, Activated Dimethicon 50mg) 10 x 10	Modern Laboratories	Qualified	Qualified
			Vivek Pharmachem (India) Limited	Qualified	Qualified
			La-Chemico Pvt. Ltd.	Qualified	Qualified
			Unicare India Ltd.	Qualified	Qualified
16.	20.	Prednisolone Tablets 5mg 10 x 10	Wings Biotech	Qualified	Qualified
			Ornate Labs Pvt. Ltd.	Qualified	Qualified
			Unicare India Ltd.	Qualified	Qualified
17.	21.	Prednisolone Tablets 10mg 10 x 10	Wings Biotech	Qualified	Qualified
			Ornate Labs Pvt. Ltd.	Qualified	Qualified
			Unicare India Ltd.	Qualified	Qualified
18.	22.	Calcium Tablets (Each tablet Contains: Calcium Carbonate equivalent to 500mg elemental calcium and Vitamin D3-250 I.U) 10 x 10	Modern Laboratories	Qualified	Qualified
			Wings Biotech	Qualified	Qualified
			Bochem Healthcare Pvt. Ltd.	Qualified	Qualified
			Ornate Labs Pvt. Ltd.	Qualified	Qualified
			Unicare India Ltd.	Qualified	Qualified
		Atrorpine Injection 600mcg/ml	Modern Laboratories Limited	Qualified	Qualified



		Ampoule	Alpa Laboratories Ltd.	Qualified	Qualified
20.	24.	Hydrocortisone Sodium Succinate Injection 100mg 20 ml Vial	Vivek Pharmachem (India) Limited	Qualified	Qualified
			Alpa Laboratories Ltd.	Qualified	Qualified
			Ang Lifesciences India Limited.	Qualified	Qualified
			VADSP Pharmaceuticals	Qualified	Qualified
21.	27	Vancomycin Intravenous Infusion 1000 mg Vial	Vivek Pharmachem (India) Limited	Qualified	Qualified
			Ang Lifesciences India Limited.	Qualified	Qualified
			Venus Remedies Limited	Qualified	Qualified
22.	28	Vancomycin Intravenous Infusion 500 mg Vial	Vivek Pharmachem (India) Limited,	Qualified	Qualified
			Ang Lifesciences India Limited.	Qualified	Qualified
			Venus Remedies Limited	Qualified	Qualified

9. As per the factory inspection reports submitted by the team of Drug inspectors, valid pollution clearance certificate was not available with M/s Shamshree Lifesciences Limited, M/s Haseeb Pharmaceuticals Pvt. Ltd., Pharma Impex Laboratories Pvt. Ltd & M/s Scott Edil Advance Research Laboratories and Education Limited. Hence the TEC recommended to ask for the clarification from the above said bidders and if the satisfactory reply is not received by BMSICL from the concerned bidders within 10 days of issue of this official communication, then the final decision will be taken in accordance with the report submitted by the team of Drug Inspectors.

10. As per the factory inspection report of M/s Haseeb Pharmaceuticals Pvt. Ltd., it has been observed that the license was issued by the concerned licensing authority on 13<sup>th</sup> April 1999 and was valid upto 31<sup>st</sup> December 2017, then the firm has submitted the retention fee in December 2017 but FDA Maharashtra issued a valid certificate from 31.07.2018 to 30.07.2023. Hence there is a gap between 01.01.2018 to 30.07.2018 for a period of seven months. Hence by considering the remarks of the inspection team the TEC in its meeting dated 26.03.2019 recommended to ask for the clarification from the bidder M/s Haseeb Pharmaceuticals Pvt. Ltd. regarding the continuity of the validity of manufacturing license of the firm and if the satisfactory reply is not received by BMSICL from the bidder within 10 days of issue of this official communication, then the final decision will be taken in accordance with the report submitted by the team of Drug Inspectors.



11. Accordingly, clarification was asked from the concerned firms. After comparison of the objection raised by the team of drug inspectors during factory inspection and clarification given by the respective firms, the concerned bidder wise technical evaluation findings of TEC in its meeting dated 17.05.19 were recorded in Table 1.

**Table 1**

S. N	Name of the firm	Objection raised by the Team of Drug Inspectors during factory inspection	Clarification given by the firm	Remarks of the TEC
1	M/s Haseeb Pharmaceuticals Pvt. Ltd	1)license was issued by the concerned licensing authority on 13 <sup>th</sup> April 1999 and was valid upto 31 <sup>st</sup> December 2017 then firm has submitted the retention fee in December 2017 but FDA Maharashtra issued a valid certificate from 31.07.2018 to 30.07.2023, hence there is a gap between 01.01.18 to 30.07.18.	1)Regarding renewal of licenses, I would like to inform you that M/s Haseeb pharmaceuticals since its inception till date has been following Drug & Cosmetic Act 1940 under the rule 1945 verbaton. The application for renewal has been duly submitted the competent authority before the date of expiry (Context: Retention Fee vide serial no 7087480. Dated 12.12.2017). The same has been confirmed by the Joint Inspector of Nagpur. This is known that after deposition of Retention Fees, the license is renewed automatically for the next 5 Years after Expiry Date. Due to typing error, a different date has been published on my renewal application which shall be rectified and sent to BMSICL at the earliest. Respected Sir, Kindly look into and examine my application personally. My M.L. No. and emergent dates are same on my application as on my original Manufacturing License. Kindly Acknowledge that in case of Non-Renewal, the license is automatically cancelled. If this happens, a new license has to be procured who's No. and Emergent dates are different and it further complicates the conditions for product approval. However, in my rental form, the same manufacturing No ND/44 and emergent date 13.04.1999 are marked which justifies my stand that a different date is the result of a mere typing error for which	The TEC recommended: 1) To invite the technical opinion from State Drug Controller regarding the continuity of its Manufacturing License for the said period i.e., 01.01.18 to 30.07.18 before taking the final decision in this regard.



			<p>punishing M/s Haseeb pharmaceuticals Pvt ltd by disqualifying will not be reasonable.</p> <p>Please note we have been actively participating and getting tenders across the country and have recently been awarded tenders in Odisha and Tamil Nadu corporation amongst others as well.</p>	
		2) Valid Pollution Control Clearance certificate was valid upto 30.09.2018.	2) Pollution certificate was made available on spot which had validity till 30/09/2018 and was issued by Maharashtra Pollution Control Board. Please find the pollution attached upto 30-09-2022. Please allow me to emphasise on the matter that as per Article-20 of the Indian Constitution any eligibility must not be squashed on the basis of criteria which as not been prescribed earlier. Rejection in this regard would not be just. Therefore, I would humbly like to request you not to deny my candidacy on the basis of pollution certificate.	2) Valid Pollution Control Clearance certificate issued by Maharashtra Pollution Control Board submitted (Consent No. MPCB/UAN No.54823/1811000 732 dated 16.11.2018 having validity upto 30.09.2022).
2	Pharma Impex Laboratories Pvt. Ltd	Pollution control clearance certificate was valid upto 31.12.18.	Renewal of Pollution control clearance certificate is submitted have been validity upto 08.05.2020.	Valid Pollution Control Clearance certificate issued by West Bengal pollution Control Board submitted (Consent No. 00106520 dated 08.05.2019 having validity 08.05.2019 to 08.05.2020).
3	Scott Edil Advance Research Laboratories and Education	Pollution control clearance certificate was valid upto 31.03.15 and fee for renewal is submitted.	We have been successfully granted with the all the Pollution clearances vide license no. MB/09/829 which was has been duly renewed within stipulated date can be verified with the authorities concerned, copy of the renewal filed with the authorities duly enclosed for your	The TEC recommended: To invite the legal opinion regarding the validity of pollution control clearance certificate before

	Limited		<p>kind perusal. Further submitted that we are successfully serving the to institutions since many decades without any fail and we rightly possess all the permission required for manufacturing of indent products. A fair reference could be drawn from the very fact that if we don't possess any pollution clearances, the manufacturing premises wouldn't be operative till today. Pertinent to mention out here that it is highly impractical and vague to ask for any pollution permission/certificates since it was never any requisite/ condition as per NIT document. Therefore, we request you to drop the same and treat our tender application very much legitimate &amp; complete. We wish to plead further that the same has been wrongly reported by the Drug Inspector owing to some illegitimate expectations which were not entertained by us, hence this victimization.</p>	<p>taking the final decision in this regard.</p>
4	Shamshree Lifesciences Limited	<p>Pollution control clearance certificate was valid upto 31.03.2018.</p>	<p>We have already deposited application for renewal of Pollution Control Certificate along with requisite fee of Rs. 3 lacs. Copy of acknowledgement and receipt of payment of fee are attached. We shall submit final certificate as soon as we receive the same.</p>	<p>The TEC recommended: To invite the legal opinion regarding the validity of pollution control clearance certificate before taking the final decision in this regard.</p>





12. After uploading the minutes of the TEC meeting dated 26.03.19 on the website of BMSICL a mail communication was received from Akhilesh Shahu, Executive- Institutional Business, Otsuka Pharmaceutical India Pvt. Ltd. regarding the technical qualification status of M/s. Aculife Healthcare Pvt. Ltd. The **Claim/ Objection disposal status was recorded by TEC in its meeting dated 17.05.19 in Table 2.**

**Table 2**

S.N.	Name of the Claimant/ Objector	Date and time of receipt of Claim/ Objection	Details of the Claim/ Objection	Supporting documents if any by the claimant	Disposal of the Claim/ Objection
1	Akhilesh Shahu- Executive-Institutional Business (Received vide mail from the mail ID: Akhilesh.shahu@otsukapharma.in	10 <sup>th</sup> May 2019 at 2:31 PM	M/s Aculife Healthcare Pvt. Ltd. is rejected by Kerala Medical Services Corporation Ltd. as the firm is debarred by Odisha State Medical Corporation Ltd.	Yes (75 pages)	The firm is technically qualified based upon the received legal opinion. The raised Claim/ Objection is found not tenable hence disposed.

13. The TEC in its meeting dated 17.05.2019 recommended to invite the legal opinion regarding the validity of pollution control clearance certificate for the firm M/s Scott Edil Advance Research Laboratories and Education Limited & M/s Shamsree Lifesciences Limited before taking the final decision in this regard.

Accordingly, the legal opinion has been sought and in accordance with the legal advice, the TEC in its meeting dated 13.06.2019 was unanimously recommended to technically disqualify both the above said firms i.e., M/s Scott Edil Advance Research Laboratories and Education Limited & M/s Shamsree Lifesciences Limited for their all quoted products.

14. The TEC in its meeting dated 17.05.2019 recommended to invite the technical opinion from State Drug Controller regarding the continuity of the Manufacturing License of M/s Haseeb Pharmaceuticals Pvt. Ltd for the period i.e., 01.01.2018 to 30.07.2018, vide letter no. 1094 dated 06.06.2019 before taking the final decision in this regard but the reply from the office of State Drug Controller is still awaited. The onus of continuity of manufacturing license lies with the bidder.



Hence the TEC in its last meeting dated 13.06.2019 was unanimously recommended to provide the last opportunity to M/s Haseeb Pharmaceuticals Pvt. Ltd. to justify the continuity of the validity of its manufacturing license for the said period i.e., 01.01.2018 to 30.07.2018 by providing the approval letter issued from their concerned licensing authority only and if the satisfactory reply is not received by BMSICL from the bidder within 7 days of issue of the official communication then the firm will be technically disqualified for all quoted items.

15. Accordingly, a letter has been sent to M/s Haseeb Pharmaceuticals Pvt. Ltd vide letter no.1231 dated 13.06.19 against which the firm has submitted the following clarification through its mail (from mail Id: Haseeb\_p@rediffmail.com) dated 17.06.19:

“As regards to discrepancies in validity period of drug manufacturing license bearing no. ND/44, we have already requested our licensing authority to correct the validity period on our retention license certificate. But being an I.V Fluids unit we are being jointly inspected by CDSCO and our local authority and hence any matter pertaining to our license is also being referred to CDSCO by our local licensing authority. As result, our application for correction in validity period of our license is pending with both the authorities as mentioned above and hence its status is still pending for which any time frame for obtaining the necessary correction cannot be obtained. Under the circumstances we can only request you to proceed as per your time lines and consider our matter accordingly.”

As the firm M/s Haseeb Pharmaceuticals Pvt, Ltd. is unable to justify the continuity of the validity of its manufacturing license for the said period i.e., 01.01.2018 to 30.07.2018 by providing the approval letter issued from their concerned licensing authority, the TEC is unanimously recommended to disqualify the said firm i.e., **M/s Haseeb Pharmaceuticals Pvt. Ltd.**

16. After consideration of all the above facts, the drug wise technical evaluation status is as follows:

S.N	NIT S. N	Name of the Drugs with Specification	Participating Firms	Technical Evaluation Status (Qualified/ Disqualified)
1.	1.	Lignocaine Hydrochloride Injection 2 % w/v 30 ml Vial	Modern Laboratories	Qualified
			Vivek Pharmachem (India) Limited	Qualified
			Alpa Laboratories Ltd.	Qualified
2.	2.	Tramadol Hydrochloride Injection 50 mg/ml 2ml Amp.	Modern Laboratories	Qualified
			Alpa Laboratories Ltd.	Qualified
3	4.	Albendazole Oral Suspension 200 mg/5 ml 10 ml Bottle	Modern Laboratories	Qualified
			Vivek Pharmachem (India) Limited	Qualified
			Wings Biotech	Qualified



			La-Chemico Pvt. Ltd.	Qualified
			Ornate Labs Pvt. Ltd.	Qualified
			Unicare India Ltd.	Qualified
4.	5.	Ampicillin and Cloxacillin Injection Each vial contains: Ampicillin-250 mg & Cloxacillin-250 mg	Modern Laboratories	Qualified
			Ang Lifesciences India Limited.	Qualified
			VADSP Pharmaceuticals	Qualified
5.	6.	Cefotaxime Sodium Injection 500 mg Vial	Modern Laboratories	Qualified
			Vivek Pharmachem (India) Limited	Qualified
			Alpa Laboratories Ltd.	Qualified
			Ang Lifesciences India Limited.	Qualified
			Pharma Impex Laboratories Pvt. Ltd	Qualified
			Shamshree Lifesciences Limited	<b>Disqualified</b>
			Theon Pharmaceuticals Limited	Qualified
VADSP Pharmaceuticals	Qualified			
6.	7.	Amoxicillin and Potassium Clavulanate Tablets Amoxicillin 500mg+ Clavulanic acid 125 mg 10 x 10	Medicef Pharma	Qualified
			Medopharm Private Limited	Qualified
			Scott Edil Advance Research Laboratories and Education Limited	<b>Disqualified</b>
			Supermax Laboratories	Qualified
			Theon Pharmaceuticals Limited	Qualified
7.	8.	Meropenem Injection 1000 mg	Modern Laboratories	Qualified
			Vivek Pharmachem (India) Limited	Qualified
			Alpa Laboratories Ltd.	Qualified
			Ang Lifesciences India Limited.	Qualified
			Pharma Impex Laboratories Pvt. Ltd	Qualified
			Scott Edil Advance Research Laboratories and Education Limited	<b>Disqualified</b>



			Shamshree Lifesciences Limited	<b>Disqualified</b>
			VADSP Pharmaceuticals	Qualified
			Venus Remedies Limited	Qualified
8.	9.	Chloroquine Phosphate Syrup 50 mg/5 ml 60 ml Bottle	Modern Laboratories	Qualified
			Vivek Pharmachem (India) Limited	Qualified
9.	12.	Ranitidine Tablets 150 mg 10 x 10	Modern Laboratories	Qualified
			Vivek Pharmachem (India) Limited	Qualified
			Bochem Healthcare Pvt. Ltd.	Qualified
			Unicare India Ltd.	Qualified
10.	13.	Dextrose Injection (Form, Fill & Seal process) 5% w/v 500 ml	Aculife Healthcare Pvt. Ltd.	Qualified
			Eurolife Healthcare Pvt. Ltd.	Qualified
			Haseeb Pharmaceuticals Pvt. Ltd.	<b>Disqualified</b>
			Otsuka Pharmaceutical India Private Limited	Qualified
11.	14.	Dextrose Injection (Form, Fill & Seal process) Infusion 10% w/v 500 ml	Aculife Healthcare Pvt. Ltd.	Qualified
			Eurolife Healthcare Pvt. Ltd.	Qualified
			Haseeb Pharmaceuticals Pvt. Ltd.	<b>Disqualified</b>
			Otsuka Pharmaceutical India Private Limited	Qualified
12.	15.	Mannitol Injection (Form, Fill & Seal process) 20 % w/v 100 ml Bottle	Aculife Healthcare Pvt. Ltd.	Qualified
			Eurolife Healthcare Pvt. Ltd.	Qualified
			Otsuka Pharmaceutical India Private Limited	Qualified
13.	16.	Metronidazole Injection (Form, Fill & Seal process) Infusion 5 mg/ml 100 ml	Aculife Healthcare Pvt. Ltd.	Qualified
			Eurolife Healthcare Pvt. Ltd.	Qualified
			Haseeb Pharmaceuticals Pvt. Ltd.	<b>Disqualified</b>



			Otsuka Pharmaceutical India Private Limited	Qualified
14.	17.	Ciprofloxacin Injection (Form, Fill & Seal process) 2mg/ ml 100 ml	Aculife Healthcare Pvt. Ltd.	Qualified
			Eurolife Healthcare Pvt. Ltd.	Qualified
			Haseeb Pharmaceuticals Pvt. Ltd.	<b>Disqualified</b>
			Otsuka Pharmaceutical India Private Limited	Qualified
15.	18.	Antacid Tablets (Tablet Containing: Dried Aluminium Hydroxide Gel- 250 mg, Magnesium Hydroxide- 250mg, Activated Dimethicon 50mg) 10 x 10	Modern Laboratories	Qualified
			Vivek Pharmachem (India) Limited	Qualified
			La-Chemico Pvt. Ltd.	Qualified
			Unicare India Ltd.	Qualified
16.	20.	Prednisolone Tablets 5mg 10 x 10	Wings Biotech	Qualified
			Ornate Labs Pvt. Ltd.	Qualified
			Unicare India Ltd.	Qualified
17.	21.	Prednisolone Tablets 10mg 10 x 10	Wings Biotech	Qualified
			Ornate Labs Pvt. Ltd.	Qualified
			Unicare India Ltd.	Qualified
18.	22.	Calcium Tablets (Each tablet Contains: Calcium Carbonate equivalent to 500mg elemental calcium and Vitamin D3-250 I.U) 10 x 10	Modern Laboratories	Qualified
			Wings Biotech	Qualified
			Bochem Healthcare Pvt. Ltd.	Qualified
			Ornate Labs Pvt. Ltd.	Qualified
			Unicare India Ltd.	Qualified
19.	23.	Atropine Injection 600µg/ml Ampoule	Modern Laboratories	Qualified
			Alpa Laboratories Ltd.	Qualified
20.	24.	Hydrocortisone Sodium Succinate Injection 100mg 20 ml Vial	Vivek Pharmachem (India) Limited	Qualified
			Alpa Laboratories Ltd.	Qualified
			Ang Lifesciences India Limited.	Qualified
			VADSP Pharmaceuticals	Qualified
21.	27	Vancomycin Intravenous Infusion 1000 mg Vial	Vivek Pharmachem (India) Limited	Qualified
			Ang Lifesciences India Limited.	Qualified



			Venus Remedies Limited	Qualified
22.	28	Vancomycin Intravenous Infusion 500 mg Vial	Vivek Pharmachem (India) Limited	Qualified
			Ang Lifesciences India Limited.	Qualified
			Venus Remedies Limited	Qualified

17. It was therefore unanimously decided to recommend for opening of the financial bids of the above mentioned technically qualified firms for the above mentioned drugs.

18. The meeting was thus concluded with a vote of thanks.

Sd/-  
**(Dr. Biswaprakash Pradhan)**  
DGM (Drugs), BMSICL, Patna

Sd/-  
**(Sunil Kumar Singh)**  
GM (logistics), BMSICL, Patna

Sd/-  
**(Dr. N. K. Mishra)**  
Additional Director, Health  
Dept., Govt. of Bihar

Sd/-  
**(Khalid Arshad)**  
Administrative Officer, SHSB.

Sd/-  
**(Rajani Kant)**  
CGM (Supply Chain), BMSICL,  
Patna.

Sd/-  
**(Anil Kumar)**  
Joint Secretary, Department  
Health, GoB

Sd/-  
**(Dr. R.D. Ranjan)**  
Director in Chief, Health Dept.  
Govt. of Bihar.

