Review of Oxytocin Injection Manufacturers in India

Empower School of Health (ESH)

Empower School of Health's vision is to promote access to quality-assured global health commodities. We work with health professionals from more than 30 countries to strengthen institutional capacity of global health programs. We also conduct assessments, research and provide advice to donors, governments and UN agencies on sourcing, logistics, pricing, quality, drug regulations, catalyzing local production and technology transfer. Empower is actively involved with several African Drug Regulatory Authorities in helping to build their capacity.

http://www.empower.net.in/webimages/ABOUT_EMPOWER.pdf

Background

Oxytocin Injection is widely used for the treatment of Post-partum haemorrhage and is on the WHO's List of Essential Medicines for Reproductive health. If quality-assured uterotonic medicines, including oxytocin, were available to all women giving birth over a ten-year period (2006-2016), it is projected that 41 million postpartum hemorrhage cases could be prevented and 1.4 million lives saved (where oxytocin is the first-line intervention for facility-based deliveries).[1]

The objective of this research was to identify manufacturers of Oxytocin Injection in India and help them become global market suppliers. In collaboration with QuRHM Programme of Concept Foundation, the manufacturers shall be facilitated to achieve WHOprequalification status.

Methodology

The methodology included the following steps:

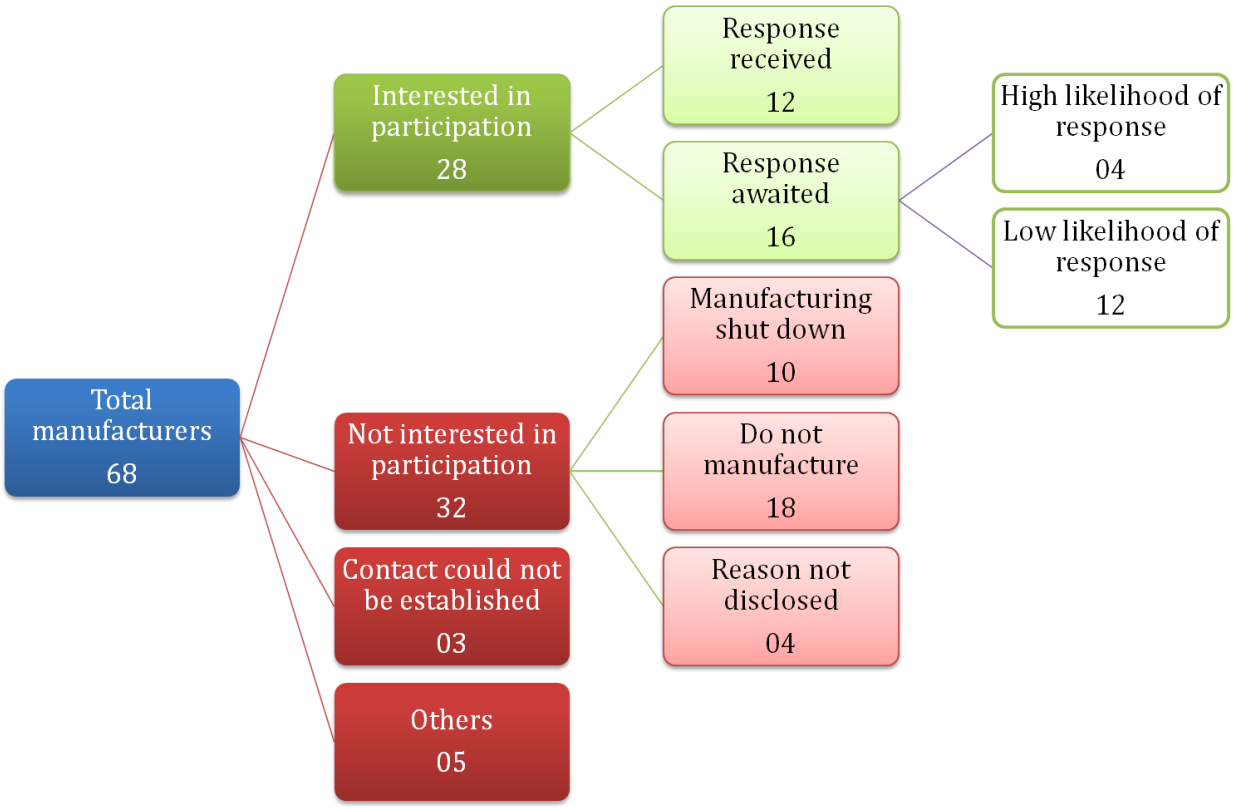
- Database creation- An exhaustive list of oxytocin injection manufacturers in India was created into a database. The source of information used were various Indian pharmaceutical directories along with extensive internet research.
- Questionnaire development and pretesting- Concept Foundation provided the draft questionnnaire, which included information pertaining to the company's corporate, manufacturing site and product information; this was made specific for the Indian and Oxytocin context and then converted into a 20 minute online survey, pretested and finalized. (Refer Appendix 2)
- Establishing contacts- All the manufacturers enlisted in the database were contacted via phone calls and emails for their participation in the survey
- Data collection- The link to the finalized online questionnaire was sent out to the manufacturers willing to participate. Regular follow ups (4-5 times/manufcaturer) were done to track the progress and if any assistance was needed to fill up the survey.
- Summary and analysis of findings- All the inputs were consolidated, organized and analyzed

Summary of findings

After extensive research using internet and other sources of information, an exhaustive database of manufacturers on Oxytocin Injection in India was created. The database comprised of 68 manufacturers spread majorly across the states of Maharashtra, Andhra Pradesh, Gujarat and Punjab. Rigorous attempts were made to reach out to all the manufacturers via calls and emails and Empower succeeded in establishing contacts with 65 of them. On discussion with each of the manufacturers, it was observed that not all were willing to be a part of this assessment process and also many had shut down their manufacturing sites dedicated for oxytocin injection. Number of manufacturers interested in WHO-PQP turned out to be 28, of which 12 of them completed the responses and another 4 are likely to submit their responses shortly. The balance list of 32 manufacturers who were not interested in participating in this project are listed in Appendix 1.

[1] http://www.everywomaneverychild.org/component/content/article/1-about/302-oxytocin--product-profile-

The responses received were categorized as following:



The summary tables of the manufacturers interested in WHO-PQP are shown below (Table 1, Table 2). The detailed response to the survey as received from 12 manufacturers has been compiled in Appendix 3.

Table 1: Summary table of list of manufacturers interested in WHO-PQP, response received

S.No	Name of manufacturer	Product	Product strength	Contact person	Contact details	Status of Product COA
1	TTK Healthcare Ltd., Chennai	Foetocin	5 IU	Mr. Venkatesh	venkatesh@ttkhealthcare.com 9940194960, 044-24633333	Received
2	Ind-Swift Limited, Chandigarh	Indox	5 IU	Dr. Munjal	gmunjal@indswift.com drmunjalg@gmail.com	Received
3	Mercury Laboratories Ltd., Vadodra	Meritocin	5 IU	Ms. Arpita Dave	raoff@baroda.mercurylabs.com	Received
4	Tribhawan Injectables, Delhi	Tricinon	5 IU, 10 IU	Mr. Bhatia	tribhawan_injectables@msn.com 09212705565	Received
5	Dev Life Corporation, Mumbai	Oxytocin Injection	10 IU	Mr. Devendra	dlc@devlifecorporation.co.in 09821529576	Received
6	Global Pharmatech Ltd., Hosur	Oxytocin Injection BP	5 IU, 10 IU	Mr. Deepak Keshav	Deepak@globalpharmatech.com info@globalpharmatech.com	Awaited
7	Quzer Pharma, Surat	Oxytocin Injection	5 IU, 10 IU	Mr. Jogani	quzerpharma@gmail.com 09904744577	Received
8	S.G.S. Pharmaceuticals (P) Ltd., Roorkee	Oxytocin Injection	5 IU	Mr. Nimish gupta	nimish.gupta@sgspharma.com 09810024943	Received
9	Gland Pharma, Hyderabad	Otoxin	10 IU	Mr. Shankar	shankar.r@glandpharma.com 9390879135	Received
10	Pharma Cure Laboratories, Jalandhar	Oxytocin Injection	5 IU	Mr. Singh	pharmacurelabs@yahoo.com 08586976213	Received
11	Taj Pharmaceuticals Ltd., Mumbai	Oxytocin Injection	5 IU, 10 IU	Mr. Amit Kumar	tajpharmaceuticals@gmail.com 2226374593	Awaited
12	Umedica Laboratories Pvt Ltd., Mumbai	Oxytocin Injection	75 mg/ml	Mr. Rajesh Gupta	exports@umedicalabs.com 02222085041	Received

Table 2: Summary table of list of manufacturers interested in WHO-PQP, response awaited

S.No.	Name of manufacturer	Product	Product strength	Contact Person	Contact Details	Likelihood of response
1	Neon Laboratories Ltd., Mumbai	Evatocin	5 IU	Ms. Naina	nayana@neongroup.com 02230077000	Low
2	Laborate Pharmaceuticals India Ltd., Panipat	Labtocin	5 IU	Mr. Krishan Kaushik	admin@laborate.com 01804092200	Low
3	Harson Laboratories, Vadodra	Oxyson	5 IU, 10 IU	Mr. Divyesh Vora Mr. Brahm Bhat	info@harsonlab.com factory@harsonlab.com 02652335481	Low
4	Inga Laboratories Pvt. Ltd., Mumbai	Oxyton 5	5 IU	Ms. Rashmi	sales@ingalabs.com 02228202932	Low
5	Pfizer, Thane	Pitocin	10 IU	Mr. Manish Paliwal	Manish.Paliwal@pfizer.com 02266932204	Low
6	Zota Healthcare Ltd (Sayona), Surat	Saytocin	5 IU	Mr. Himanshu Zota	info@zotahealthcare.com 261 2331601	Low
7	Zee Lab, Delhi	Zetocin	5 IU	Mr. Dinesh	dinesh@zeelab.co.in 9896113232	Low
8	Nitin Lifesciences Pvt. Ltd., Paonta Sahib	Nitocin	5 IU	Mr. Rahul Wadhwa	rw@nitinlifesciences.com info@nitinlifesciences.com 9992990073	Low
9	AstraZeneca, Bangalore	Partocin	5 IU	Mr. Saikat	09880668907 sentsentsaikat.chaudhury@ astrazeneca.com	Low
10	Ancalima Lifesciences Ltd., Sonipat	Oxytocin Inj ection	10 IU	Mr. Sandeep	rajeev@ancalima.com 8816088786	High
11	Korten Pharmaceuticals Pvt. Ltd., Mumbai	Oxytocine	5 IU, 10 IU	Ms. Sarita	sarita@neongroup.com 022-2678 3546	Low
12	Jackson Labs Pvt. Ltd. , Amritsar	Tocin	5 IU, 10 IU	Mr. Raj	rajjackson@ymail.com 09872891817	High
13	Bharat Parentarels Ltd., Vadodra	Oxytocin Injection	5 IU	Mr. Pankaj Shah	pankajshah@bplindia.in 0265 3935233	Low
14	Wockhardt	Not available	Not available	Mr. Sagar Joshi	Sagarj@wockhardt.com 9820198984	High
15	Brawn Laboratories Ltd., Delhi	Oxytocin Injection	5 IU	Mr. Arun	legal@brawnpharma.com solution@brawnpharma.co m 011- 32911528	High
16	Torque Pharma, Chandigarh	Oxymac	5 IU	Mr. Sajan Sahni	sajansahni@torquepharma.c om 0172-4991500	Low

Concluding remarks

On analysis of the manufacturers who have completed the questionnaire, it was observed:

- Out of the 12, two of them (TTK Healthcare Ltd., Ind-Swift Ltd.) ranked in the list of top 100 Indian pharmceutical manufacturers. This indirectly means that significant handholding in terms of technical assistance may be required to raise the product quality standards
- Also, Gland Pharma, Hyderabad is the only manufacturer (amongst the 12 participating manufacturers) to have GMP certifications from EU, US-FDA and TGA
- None of the manufacturers have any pharmaceutical product prequalified by WHO
- The manufacturers which have oxytocin injection registrations in other countries include:
    - Mercury Laboratories Ltd.- Egypt, Myanmar
    - Dev Life Corporation- Bhutan
    - Gland Pharma Ltd.- Nigeria, Kenya, Iraq, Mali, Madagascar Burkina Faso, Benin, Mali, Zimbabwe
    - Taj Pharma- Chile, Nigeria, Cuba, Peru, DR, Philippines, Ghana, Sri Lanka, InvimaColombia, Turkmenistan, Iraq, Uganda, Kenya, Vietnam, Kyrgystan, WHO-GMP, Nepal, Zambia
    - Umedica Laboratories Ltd.- Kenya, Mauritius, Gabon,Cameroon, Nepal, Malawi, Madagascar, Zimbabwe

The manufacturers showed keen interest in this initiative of WHO and see this as a platform to build their export network not only for oxytocin but for other products as well. However, there was general concern regarding the cost to reach WHO PQ status.

In order to address the matter of low interest of the manufacturers in the WHO-PQP, the ESH team made an effort to interview the manufacturers telephonically and enquire about the bottlenecks.

- Highly regulated Indian market for the sale of oxytocin injection: It was found out that despite being considered as an essential drug in medical practice for certain conditions in human and veterinary field, the alleged abundant availability and use of the drug ina clandestine way is a matter of great concern for public health in India. To monitor the illegal sale of this product, the Ministry of Health and Family welfare (MoHFW) issued an order to regulate the sale of oxytocin injection in Indiaunder Schedule H of the Drugs and cosmetic rules, 1945, which thus requires the drug to be dispensed only on prescription of a registered medical practioner. Further to avoid its bulk sale, oxytocin injection is required to be packed in single unit blister pack only [2]
- Low product cost (roughly US$0.26/unit)
- High investment involved in setting up of a sterile manufacturing site
- Oxytocin is temperature sensitive and loses effectiveness after three months of being stored at temperatures higher than 30 degrees Celsius[3]. Thus in turn calls for adequate cold storage conditions to be maintained in supply chain

[2] http://pharmabiz.com/NewsDetails.aspx?aid=79996&sid=1

[3] http://pharmabiz.com/NewsDetails.aspx?aid=79996&sid=1

Appendix 1

Summary table of list of manufacturers <u>not interested</u> in WHO-PQP

S.No.	Name of manufacturer	Product	Product strength	Status		
				Manufacturing shut down	Do not manufacture	Not interested
1	Intas Laboratories Pvt Ltd, Matoda Village Ahmedabad	Genox Injection	5IU			
2	Svizera Healthcare (Maneesh Pharmaceuticals Pvt Ltd.), Mumbai	Gynotocin	5IU			
3	Jpee Drugs, Haridwar	Oxitocin	5 IU			
4	Systacare Remedies, Amritsar	Oxycare	5 IU			
5	Cadila Pharmaceuticals Ltd. (Genstar), Ahmedabad	Oxystar	5 IU			
6	Pfiscar India Ltd., Sonepat	Pfiscocin	10 IU	Co-owned by Ancalima		
7	Indus Pharma Pvt. Ltd., Delhi	Prestocin -5	5 IU			
8	Novartis India, Mumbai	Syntocinon	5 IU	Innovator Product		
9	Valiant Healthcare Ltd., Chandigarh/ Delhi	Utocin	5 IU	Contact could not be established		
10	Prem Pharmaceuticals Pvt Ltd., Indore	Oxytocin Injection	5 IU	Contact could not be established		
11	Vinca Life Sciences	Tociv Injection	5 IU, 10 IU			
12	Ranbaxy laboratories Ltd., Delhi	Zygon	5 IU			
13	Alchemist Lifesciences Ltd., Solan	Utocin	5 IU			
14	Unique	Oxytzone	5 IU			
15	Anoco Pharmaceuticals (India) Pvt.Ltd., Muzzafarpur	Oxytocin IP	5 IU			
16	Wander Ltd (Now Wanbury Ltd.), Mumbai	Buctocin	Not available			
17	Parke Davis	Pitocin 1Ml Injection	Not available	Acquired by Pfizer		
18	Sri Pharmacare, Mumbai	Oxytocin Injection	5 IU, 10 IU			
19	Medexim India, Nagpur	Oxytocin	5 IU			

20	Jaiwik Biotech, Jaipur	Neoxy Injection	5 IU			
21	Bullford World Limited, Jaipur	Oxytocin Injection	5 IU			
22	Apoorv Nutra-Pharm Private Limited, Thane	Oxitin Injection BP	5 IU			
23	Polypeptide Laboratories Pvt. Ltd., Ambernath	Oxytocin	Not available			
24	Shreeji Pharma International, Vadodara	Oxytocin	Not available			
25	Axelia , Mumbai	Oxytocin	Not available			
26	Grewal Homeo Remedies, Mohali	Oxytocin	Not available			
27	Alembic	Gynotocin Injection	5 IU			
28	Eli lilly, Gurgaon	Oxytocin Injection	Not available			
29	Mekla (Alkem Laboratories Ltd.), Mumbai	Pitocin inj	Not available			
30	Cipla, Mumbai	Syntocinon Injection Syntomet inj (Oxytocin, ergometrine)	10 IU	No response		
31	Neiss Labs Ltd., Mumbai	Utocin Injection	Not available			
32	Biochem (India) Ltd., Mumbai	Zetocin Injection	5 IU	Contact could not be established		
33	Oriental Chemical Works Pvt. Ltd., Indore	Obcin	10 IU			
34	Sanofi India Ltd. , Mumbai	Orasthin, Orastina	5 IU			
35	Ferring Pharmaceuticals Pvt Ltd., Mumbai	Pabal / Duratocin / Lonactene / Duratobal	1 UT/ml			
36	Strides Arcolab Ltd., Bangalore	Erciton	10 IU			
37	Hindustan Pharmaceuticals, Vadodra/Amritsar	Not available	Not available			
38	Kon Test Chemicals, Kolkata	Not available	Not available			
39	M M Labs, Mumbai	Emtocin	5 IU			
40	Win Medicare Pvt Ltd., Delhi	Oxytocin Injection	5 IU			

Appendix 2

Online questionnaire developed by ESH for the survey

https://docs.google.com/forms/d/13QKS0ESCbxfN_f9m2Z0abYl0qfj_LKal-n2ydnWCzA4/viewform

Questionnaire for Oxytocin Manufacturers in India

The objective of this questionnaire is to identify Oxytocin Injection manufacturers in India and eventually help them increase their global exports to global health programmes. Empower and Concept Foundation aim to achieve this by facilitating the necessary technical assistance for achieving WHO Prequalification status.

The questionnaire is divided into 4 sections:
Part 1: Corporate information
Part 2: Manufacturing site information
Part 3: Product information
Part 4: WHO Prequalification Programme (WHO-PQP)

This questionnaire should not take more than 20 minutes to complete and requests for 'accurate' information.

PART 1: Corporate information

1.1 General information

1.1.a) Name of manufacturer

1.1.b) Physical address
(Complete address with city, pin code)

1.1.c) Postal address
(If same as physical address, mention "same")

1.1.d) Name of contact person
(Please mention the designation)

1.1.e) Telephone number
(Please mention STD code)

1.1.f) Mobile number

1.1.g) Fax number

1.1.h) Current manufacturing status?
(Please tick whatever is applicable)

- ☐ Domestic market
- ☐ Export market
- ☐ Both domestic and export market
- ☐ Engaged in contract manufacturing for other companies

1.1.i) Total number of staff
(including corporate headquarters and all manufacturing sites)

- ○ <10
- ○ 10-25
- ○ 25-50
- ○ 50-100
- ○ 100-200
- ○ >200

PART 2: Manufacturing site/s

2.1 Information on manufacturing site of Oxytocin Injection

2.1.a) Site name or identifier

2.1.b) Site physical address (Complete address with city, pin code)

2.1.c) Postal address (If same as physical address, mention "same")

2.1.d) Name of site contact person
(Please mention the designation)

2.1.e) Telephone number
(Please mention STD code)

2.1.f) Fax number

2.1.g) Name of site manager

2.1.h) Total number of staff at this site

- <50
- 50-100
- 100-200
- >200

2.1.i) Is the manufacturing site cGMP certified?

- Yes
- No

2.1.j) What is the annual production volume of the manufacturing site?
(as per single shift)

2.1.k) What is the annual production capacity of the manufacturing site?
(Mention in terms of injection ampoules/year)

2.1.l) Do you manufacture any other reproductive health medicines?

- Yes
- No

Please comment

2.1.m) Do you have other manufacturing sites for Oxytocin Injection?

- Yes
- No

2.2 Other manufacturing site/s

2.2.a) Site name or identifier

2.2.b) Site physical address
(Complete address with city, pin code)

2.2.c) Postal address
(If same as physical address, mention "same")

2.2.d) Site contact person
(Please mention the designation)

2.2.e) Telephone number
(Please mention STD code)

2.2.f) Fax number

2.2.g) Name of site manager

2.2.h) Total number of staff at this site

2.2.i) Is the manufacturing site cGMP certified?

- Yes
- No

2.2.j) What is the annual production volume of the manufacturing site?
(as per single shift)

2.2.k) What is the annual production capacity of the manufacturing site?
(Mention in terms of injection ampoules/year)

2.3 Other manufacturing site/s

2.3.a) Site name or identifier

2.3.b) Site physical address
(Complete address with city, pin code)

2.3.c) Postal address
(If same as physical address, mention "same")

2.3.d) Site contact person
(Please mention the designation)

2.3.e) Telephone number
(Please mention STD code)

2.3.f) Fax number

2.3.g) Name of site manager

2.3.h) Total number of staff at this site

2.3.i) Is the manufacturing site cGMP certified?

- Yes
- No

2.3.j) What is the annual production volume of the manufacturing site?
(as per single shift)

2.3.k) What is the annual production capacity of the manufacturing site?
(Mention in terms of injection ampoules/year)

PART 3: Product Information

3.a) Product brand name

3.b) Product generic name

3.c) Formulation type

- Injection
- Nasal solution
- Other:

3.d) What product strengths do you manufacture?

- 5 IU/mL
- 10 IU/mL

3.e) Does the formulation contain a buffer?

- Yes
- No

Please mention the buffer

3.f) What are the storage conditions included in the product information and packaging?
(Please input exact language from pack insert)

3.g) Do you have stability data to support the above claims?

- Yes
- No

3.h) Is the product constitution same for domestic and export markets?

- Yes
- No

Comments

3.i) Are the product specifications in compliance with compendia monographs (USP, BP, IP etc.)

- Yes
- No

Please mention the compendia

3.j) Does the product show pharmaceutical and/or therapeutic equivalence to the originator product?

- Yes
- No

3.k) Comparator product used for BE

(Mention product name and its manufacturer)

3.l) When were bioequivalence studies conducted?

3.m) Contract research organization(s) involved in generating bioequivalence data

3.n). Biowaiver applied for or granted:

Biowaiver: An exemption, granted to a biopharmaceutical company, to show bioequivalence to a product

- Yes
- No

3.o). Is the product approved by the CDSCO or any of the State Licensing Authorities in India?

(CDSCO- Central Drugs Standards Control Organization)

- Yes
- No

3.p). Are the labels and leaflets approved by the CDSCO or any of the State Licensing Authorities in India?

- Yes
- No

3.q). Is the product approved by the following Regulatory Authorities?

- European Medicines Agency

Mention the Registration number

Mention the expiry date

- US Food and Drug Administration

Mention the Registration number

Mention the expiry date

- Other Stringent Regulatory Agency (SRA)

Mention the regulatory agency

Mention the Registration number

Mention the expiry date

3.r) Please list registrations held in other countries

3.s) Active pharmaceutical ingredient (API) source

(Mention the company name)

3.t) Is there a complete Drug Master File (DMF) for the API?

(site of manufacture, route of synthesis, stability testing)

- Yes
- No

3.u). Please mail us a copy of COA for each product (COA: Certificate of Analysis)
Confirm if mail sent (Email id: prabhleen.arora@empower.net.in)

- Yes
- No

PART 4: WHO Prequalification Programme

4.a) Are you aware of the WHO Prequalification Programme?

- Yes
- No

4.b) Would you be interested in your product being approved by WHO Prequalification Programme?
(If yes, Empower/Concept Foundation would provide you the necessary technical assistance)

- Yes
- No

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Appendix 3

Response to questionnaires as received from the participating manufacturers

1. TTK HEALTHCARE LTD.

The objective of this questionnaire is to identify Oxytocin Injection manufacturers in India and eventually help them increase their global exports to global health programmes. Empower and Concept Foundation aim to achieve this by facilitating the necessary technical assistance for achieving WHO Prequalification status.

The questionnaire is divided into 4 sections:

Part 1: Corporate information
Part 2: Manufacturing site information
Part 3: Product information
Part 4: WHO Prequalification Programme (WHO-PQP)

This questionnaire should not take more than 20 minutes to complete and requests for 'accurate' information.

1.1 General information

1.1.a) Name of manufacturer
M/s TTK HEALTHCARE LTD

PART 1: Corporate information

1.1. b) Physical address
(Complete address with city, pin code)
No.6,

Cathedral Road,

Gopalapuram,

Chennai 600 086

1.1. c) Postal address
(If same as physical address, mention "same")
Same

1.1. d) Name of contact person
(Please mention the designation)

1.1. e) Telephone number
(Please mention STD code)

1.1. f) Mobile number

1.1. g) Fax number

1.1. h) Current manufacturing status?
(Please tick whatever is applicable)

- [x] Domestic market
- [ ] Export market
- [ ] Both domestic and export market
- [ ] Engaged in contract manufacturing for other companies

1.1. i) Total number of staff
(Including corporate headquarters and all manufacturing sites)

- ( ) <10
- ( ) 10-25
- ( ) 25-50
- ( ) 50-100
- ( ) 100-200
- (•) >200

PART 2: Manufacturing site/s

2.1 Information on manufacturing site of Oxytocin Injection

2.1.a) Site name or identifier
M/s Akums Drugs & Pharmaceuticals Ltd

2.1.b) Site physical address
(Complete address with city, pin code)
2,3,4&5 Sector-6B,

IIE, SIDCUL,

Haridwar - 249 403

India

2.1.c) Postal address
(If same as physical address, mention "same")
Same

2.1.d) Name of site contact person
(Please mention the designation)
Mr. Deepak

2.1.e) Telephone number
(Please mention STD code)

9368001262

2.1.f) Fax number

2.1.g) Name of site manager
Mr.Sathyaprakash

2.1.h) Total number of staff at this site

- ( ) <50
- ( ) 50-100
- ( ) 100-200
- (•) >200

2.1.i) Is the manufacturing site cGMP certified?

- (•) Yes
- ( ) No

2.1.j) What is the annual production volume of the manufacturing site?
(As per single shift)

2.1.k) What is the annual production capacity of the manufacturing site?
(Mention in terms of injection ampoules/year)

2.1.l) Do you manufacture any other reproductive health medicines?

- (•) Yes
- ( ) No

Please comment

2.1.m) Do you have other manufacturing sites for Oxytocin Injection?

- ( ) Yes
- (•) No

PART 3: Product Information

3.a) Product brand name
Foetocin

3.b) Product generic name
Oxytocin Injection IP

3.c) Formulation type

- [x] Injection
- [ ] Nasal solution
- [ ] Other:

3.d) What product strengths do you manufacture?

- [x] 5 IU/mL
- [ ] 10 IU/mL

3.e) Does the formulation contain a buffer?

- ( ) Yes
- (•) No

Please mention the buffer

3.f) What are the storage conditions included in the product information and packaging?
(Please input exact language from pack insert)

Store in a cold place, should not be allowed to Freeze

3.g) Do you have stability data to support the above claims?

- (•) Yes
- ( ) No

3.h) Is the product constitution same for domestic and export markets?

- (•) Yes
- ( ) No

Comments

3.i) Are the product specifications in compliance with compendia monographs (USP, BP, IP etc.)

- (•) Yes
- ( ) No

Please mention the compendia

3.j) Does the product show pharmaceutical and/or therapeutic equivalence to the originator product?

- ( ) Yes
- ( ) No

3.k) Comparator product used for BE
(Mention product name and its manufacturer)

3.l) When were bioequivalence studies conducted?

3.m) Contract research organization(s) involved in generating bioequivalence data

3.n). Biowaiver applied for or granted:
Biowaiver: An exemption, granted to a biopharmaceutical company, to show bioequivalence to a product

- ○ Yes
- ○ No

3.o). Is the product approved by the CDSCO or any of the State Licensing Authorities in India?
(CDSCO- Central Drugs Standards Control Organization)

- ◉ Yes
- ○ No

3.p). Are the labels and leaflets approved by the CDSCO or any of the State Licensing Authorities in India?

- ○ Yes
- ○ No

3.q). Is the product approved by the following Regulatory Authorities?

- ☐ European Medicines Agency

Mention the Registration number

Mention the expiry date

- ☐ US Food and Drug Administration

Mention the Registration number

Mention the expiry date

- ☐ Other Stringent Regulatory Agency (SRA)

Mention the regulatory agency

Mention the Registration number

Mention the expiry date

3.r) Please list registrations held in other countries

3.s) Active pharmaceutical ingredient (API) source
(Mention the company name)

3.t) Is there a complete Drug Master File (DMF) for the API?
(site of manufacture, route of synthesis, stability testing)

- ○ Yes
- ◉ No

3.u). Please mail us a copy of COA for each product (COA: Certificate of Analysis)
Confirm if mail sent (Email id: prabhleen.arora@empower.net.in)

- ◉ Yes
- ○ No

PART 4: WHO Prequalification Programme

4.a) Are you aware of the WHO Prequalification Programme?

- ◉ Yes
- ○ No

4.b) Would you be interested in your product being approved by WHO Prequalification Programme?
(If yes, Empower/Concept Foundation would provide you the necessary technical assistance)

- ◉ Yes
- ○ No

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2. IND SWIFT LTD.

The objective of this questionnaire is to identify Oxytocin Injection manufacturers in India and eventually help them increase their global exports to global health programmes. Empower and Concept Foundation aim to achieve this by facilitating the necessary technical assistance for achieving WHO Prequalification status.

The questionnaire is divided into 4 sections:

Part 1: Corporate information
Part 2: Manufacturing site information
Part 3: Product information
Part 4: WHO Prequalification Programme (WHO-PQP)

This questionnaire should not take more than 20 minutes to complete and requests for 'accurate' information.

1.1 General information

1.1.a) Name of manufacturer

Ind-Swift Limited

PART 1: Corporate information

1.1. b) Physical address
(Complete address with city, pin code)

Plot No. 781,
Industrial Area,
Phase-II, Chandigarh - 160002

1.1. c) Postal address
(If same as physical address, mention "same")

Same

1.1. d) Name of contact person
(Please mention the designation)

Dr. G Munjal

1.1. e) Telephone number
(Please mention STD code)

0172-4680800

1.1. f) Mobile number

1.1. g) Fax number
0172-2652242

1.1. h) Current manufacturing status?
(Please tick whatever is applicable)

- [ ] Domestic market
- [ ] Export market
- [x] Both domestic and export market
- [x] Engaged in contract manufacturing for other companies

1.1. i) Total number of staff
(Including corporate headquarters and all manufacturing sites)

- ( ) <10
- ( ) 10-25
- ( ) 25-50
- ( ) 50-100
- ( ) 100-200
- (•) >200

PART 2: Manufacturing site/s

2.1 Information on manufacturing site of Oxytocin Injection

2.1.a) Site name or identifier
Ind-Swift Limited

2.1.b) Site physical address
(Complete address with city, pin code)
Unit-III, Village :Malkumajra,

P.O. Bhud, Tehsil :Nalagarh,

Baddi, Distt. : Solan,

Himachal Pradesh - 173205

2.1.c) Postal address
(If same as physical address, mention "same")
Same

2.1.d) Name of site contact person
(Please mention the designation)
Dr. K.N.Singh

2.1.e) Telephone number
(Please mention STD code)
01765-662800

2.1.f) Fax number
01765-246831

2.1.g) Name of site manager
Mr. K.K.Borkar

2.1.h) Total number of staff at this site

- ( ) <50
- ( ) 50-100
- ( ) 100-200
- (•) >200

2.1.i) Is the manufacturing site cGMP certified?

- (•) Yes
- ( ) No

2.1.j) What is the annual production volume of the manufacturing site?
(As per single shift)
296 lacs/annum

2.1.k) What is the annual production capacity of the manufacturing site?
(Mention in terms of injection ampoules/year)
42,000,000/year (single shift basis)

2.1.l) Do you manufacture any other reproductive health medicines?

- (•) Yes
- ( ) No

Please comment
1. Suprox-SR

2. Anin

3. Voranin

2.1.m) Do you have other manufacturing sites for Oxytocin Injection?

- ( ) Yes
- (•) No

PART 3: Product Information

3.a) Product brand name
Indox

3.b) Product generic name
Oxytocin Injection IP

3.c) Formulation type

- [x] Injection
- [ ] Nasal solution
- [ ] Other: _____

3.d) What product strengths do you manufacture?

- [x] 5 IU/mL
- [ ] 10 IU/mL

3.e) Does the formulation contain a buffer?

- (•) Yes
- ( ) No

Please mention the buffer

Acetate Buffer

3.f) What are the storage conditions included in the product information and packaging?
(Please input exact language from pack insert)

Store at a temperature not exceeding 25 degree centigrade. Protect from light.

3.g) Do you have stability data to support the above claims?

- (•) Yes
- ( ) No

3.h) Is the product constitution same for domestic and export markets?

- (•) Yes
- ( ) No

Comments

3.i) Are the product specifications in compliance with compendia monographs (USP, BP, IP etc.)

- (•) Yes
- ( ) No

Please mention the compendia

3.j) Does the product show pharmaceutical and/or therapeutic equivalence to the originator product?

- ( ) Yes
- (•) No

3.k) Comparator product used for BE
(Mention product name and its manufacturer)

NA

3.l) When were bioequivalence studies conducted?

3.m) Contract research organization(s) involved in generating bioequivalence data

NA

3.n). Biowaiver applied for or granted:
Biowaiver: An exemption, granted to a biopharmaceutical company, to show bioequivalence to a product

Yes

No

3.o). Is the product approved by the CDSCO or any of the State Licensing Authorities in India?
(CDSCO- Central Drugs Standards Control Organization)

Yes

No

3.p). Are the labels and leaflets approved by the CDSCO or any of the State Licensing Authorities in India?

Yes

No

3.q). Is the product approved by the following Regulatory Authorities?

European Medicines Agency

Mention the Registration number

Mention the expiry date

US Food and Drug Administration

Mention the Registration number

Mention the expiry date

Other Stringent Regulatory Agency (SRA)

Mention the regulatory agency

Mention the Registration number

Mention the expiry date

3.r) Please list registrations held in other countries
NA

3.s) Active pharmaceutical ingredient (API) source
(Mention the company name)
Hemmo Pharmaceuticals Pvt. Ltd.

C-43, MIDC, TTC,

Ind. Area, TurbheOff Thane, Bilaspur Road, Thane - 400 613

3.t) Is there a complete Drug Master File (DMF) for the API?
(site of manufacture, route of synthesis, stability testing)

Yes

No

3.u). Please mail us a copy of COA for each product (COA: Certificate of Analysis)
Confirm if mail sent (Email id: prabhleen.arora@empower.net.in)

Yes

No

PART 4: WHO Prequalification Programme

4.a) Are you aware of the WHO Prequalification Programme?

Yes

No

4.b) Would you be interested in your product being approved by WHO Prequalification Programme?
(If yes, Empower/Concept Foundation would provide you the necessary technical assistance)

Yes

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3. MERCURY LABORATORIES LTD.

The objective of this questionnaire is to identify Oxytocin Injection manufacturers in India and eventually help them increase their global exports to global health programmes. Empower and Concept Foundation aim to achieve this by facilitating the necessary technical assistance for achieving WHO Prequalification status.

The questionnaire is divided into 4 sections:

Part 1: Corporate information
Part 2: Manufacturing site information
Part 3: Product information
Part 4: WHO Prequalification Programme (WHO-PQP)

This questionnaire should not take more than 20 minutes to complete and requests for 'accurate' information.

1.1 General information

1.1.a) Name of manufacturer
Mercury Laboratories Ltd.

PART 1: Corporate information

1.1. b) Physical address
(Complete address with city, pin code)
Unit No 1, 2/13-14,

Gorwa Industrial Estate,

Gorwa, Vadodra - 390 016

Gujarat

1.1. c) Postal address
(If same as physical address, mention "same")
Same

1.1. d) Name of contact person
(Please mention the designation)
Mr. R.R. Shah Managing Director

1.1. e) Telephone number
(Please mention STD code)
0265 2280180/181

1.1. f) Mobile number

0091 9825045055

1.1. g) Fax number
+ 91 265 2280027

1.1. h) Current manufacturing status?
(Please tick whatever is applicable)

- [ ] Domestic market
- [ ] Export market
- [x] Both domestic and export market
- [x] Engaged in contract manufacturing for other companies

1.1. i) Total number of staff
(Including corporate headquarters and all manufacturing sites)

- ( ) <10
- ( ) 10-25
- ( ) 25-50
- ( ) 50-100
- (•) 100-200
- ( ) >200

PART 2: Manufacturing site/s

2.1 Information on manufacturing site of Oxytocin Injection

2.1.a) Site name or identifier
Mercury Laboratories Limited

2.1.b) Site physical address
(Complete address with city, pin code)
Unit No 1, 2/13-14,

Gorwa Industrial Estate,

Gorwa, Vadodra - 390 016

Gujarat

2.1.c) Postal address
(If same as physical address, mention "same")
Same

2.1.d) Name of site contact person
(Please mention the designation)
Mr. R.R. Shah; Managing Director

2.1.e) Telephone number
(Please mention STD code)
0265 2280180/181

2.1.f) Fax number
+ 91 265 2280027

2.1.g) Name of site manager
Mr. R.R.Shah

2.1.h) Total number of staff at this site

- ( ) <50
- (•) 50-100
- ( ) 100-200
- ( ) >200

2.1.i) Is the manufacturing site cGMP certified?

- (•) Yes
- ( ) No

2.1.j) What is the annual production volume of the manufacturing site?
(As per single shift)
66,300,000 ampoules

2.1.k) What is the annual production of the manufacturing site?
(Mention in terms of injection ampoules/year)
132,600,000 Ampoules

2.1.l) Do you manufacture any other reproductive health medicines?

- (•) Yes
- ( ) No

Please comment

2.1.m) Do you have other manufacturing sites for Oxytocin Injection?

- ( ) Yes
- (•) No

PART 3: Product Information

3.a) Product brand name
Xyntoc

3.b) Product generic name
Oxytocin Injection BP

3.c) Formulation type

- [x] Injection
- [ ] Nasal solution

☐ Other:

3.d) What product strengths do you manufacture?

☑ 5 IU/mL

☑ 10 IU/mL

3.e) Does the formulation contain a buffer?

◉ Yes

○ No

Please mention the buffer

Glacial Acetic acid

3.f) What are the storage conditions included in the product information and packaging?
(Please input exact language from pack insert)

Store at temperature 2-8 degrees centigrade. Refrigerate. Do not freeze. Protect from light.

3.g) Do you have stability data to support the above claims?

◉ Yes

○ No

3.h) Is the product constitution same for domestic and export markets?

◉ Yes

○ No

Comments

3.i) Are the product specifications in compliance with compendia monographs (USP, BP, IP etc.)

◉ Yes

○ No

Please mention the compendia

BP

3.j) Does the product show pharmaceutical and/or therapeutic equivalence to the originator product?

○ Yes

◉ No

3.k) Comparator product used for BE
(Mention product name and its manufacturer)

3.l) When were bioequivalence studies conducted?

3.m) Contract research organization(s) involved in generating bioequivalence data

3.n). Biowaiver applied for or granted:
Biowaiver: An exemption, granted to a biopharmaceutical company, to show bioequivalence to a product

○ Yes
○ No

3.o). Is the product approved by the CDSCO or any of the State Licensing Authorities in India?
(CDSCO- Central Drugs Standards Control Organization)

◉ Yes
○ No

3.p). Are the labels and leaflets approved by the CDSCO or any of the State Licensing Authorities in India?

○ Yes
◉ No

3.q). Is the product approved by the following Regulatory Authorities?

☐ European Medicines Agency

Mention the Registration number

Mention the expiry date

☐ US Food and Drug Administration

Mention the Registration number

Mention the expiry date

☑ Other Stringent Regulatory Agency (SRA)

Mention the regulatory agency

Mention the Registration number
DR-XY40307

Mention the expiry date

17-11-2013

3.r) Please list registrations held in other countries
Egypt, Myanmar

3.s) Active pharmaceutical ingredient (API) source
(Mention the company name)
Hammo Pharmaceuticals

3.t) Is there a complete Drug Master File (DMF) for the API?
(Site of manufacture, route of synthesis, stability testing)

○ Yes
◉ No

3.u). Please mail us a copy of COA for each product (COA: Certificate of Analysis)
Confirm if mail sent (Email id: prabhleen.arora@empower.net.in)

- (•) Yes
- ( ) No

PART 4: WHO Prequalification Programme

4.a) Are you aware of the WHO Prequalification Programme?

- ( ) Yes
- (•) No

4.b) Would you be interested in your product being approved by WHO Prequalification Programme?
(If yes, Empower/Concept Foundation would provide you the necessary technical assistance)

- (•) Yes
- ( ) No

4. TRIBHAWAN INJECTABLES

The objective of this questionnaire is to identify Oxytocin Injection manufacturers in India and eventually help them increase their global exports to global health programmes. Empower and Concept Foundation aim to achieve this by facilitating the necessary technical assistance for achieving WHO Prequalification status.

The questionnaire is divided into 4 sections:

Part 1: Corporate information
Part 2: Manufacturing site information
Part 3: Product information
Part 4: WHO Prequalification Programme (WHO-PQP)

This questionnaire should not take more than 20 minutes to complete and requests for 'accurate' information.

1.1 General information

1.1.a) Name of manufacturer
Tribhawan Injectables

PART 1: Corporate information

1.1.b) Physical address
(Complete address with city, pin code)
14,Najafgarh Road,

Industrial Area,

New DelhiI-110015

1.1.c) Postal address
(If same as physical address, mention "same")
14,Najafgarh Road,

Industrial Area,

New DelhiI-110015

1.1.d) Name of contact person
(Please mention the designation)
Anju Mehta

1.1.e) Telephone number

(Please mention STD code)
1141428568

1.1.f) Mobile number
9811030340

1.1.g) Fax number
1141428568

1.1.h) Current manufacturing status?
(Please tick whatever is applicable)

- [x] Domestic market
- [ ] Export market
- [ ] Both domestic and export market
- [ ] Engaged in contract manufacturing for other companies

1.1.i) Total number of staff
(including corporate headquarters and all manufacturing sites)

- ( ) <10
- (•) 10-25
- ( ) 25-50
- ( ) 50-100
- ( ) 100-200
- ( ) >200

PART 2: Manufacturing site/s

2.1 Information on manufacturing site of Oxytocin Injection

2.1.a) Site name or identifier
Supermax Drugs & Pharmaceuticals PvtLtd..

2.1.b) Site physical address
(Complete address with city, pin code)
H-1231,

DSIIDC,Industrial Complex,

Narela,

Delhi-110040

2.1.c) Postal address
(If same as physical address, mention "same")
Same

2.1.d) Name of site contact person
(Please mention the designation)

K.K. Singh

2.1.e) Telephone number
(Please mention STD code)
9811139489

2.1.f) Fax number

2.1.g) Name of site manager
Dinesh Varshney

2.1.h) Total number of staff at this site
- (•) <50
- ( ) 50-100
- ( ) 100-200
- ( ) >200

2.1.i) Is the manufacturing site cGMP certified?
- (•) Yes
- ( ) No

2.1.j) What is the annual production volume of the manufacturing site?
(as per single shift)
6,000,000 Unit

2.1.k) What is the annual production of the manufacturing site?
(Mention in terms of injection ampoules/year)
12,000,000 Unit

2.1.l) Do you manufacture any other reproductive health medicines?
- (•) Yes
- ( ) No

Please comment

2.1.m) Do you have other manufacturing sites for Oxytocin Injection?
- ( ) Yes
- (•) No

PART 3: Product Information

3.a) Product brand name
Tricinon

3.b) Product generic name
Oxytocin Injection I.P

3.c) Formulation type
- [x] Injection

☐ Nasal solution
☐ Other:

3.d) What product strengths do you manufacture?

☑ 5 IU/mL
☑ 10 IU/mL

3.e) Does the formulation contain a buffer?

◉ Yes
○ No

Please mention the buffer

3.f) What are the storage conditions included in the product information and packaging?
(Please input exact language from pack insert)

STORE IN A COLD PLACE.

DO NOT ALLOW TO FREEZE

3.g) Do you have stability data to support the above claims?

○ Yes
◉ No

3.h) Is the product constitution same for domestic and export markets?

◉ Yes
○ No

Comments

3.i) Are the product specifications in compliance with compendia monographs (USP, BP, IP etc.)

◉ Yes
○ No

Please mention the compendia

3.j) Does the product show pharmaceutical and/or therapeutic equivalence to the originator product?

◉ Yes
○ No

3.k) Comparator product used for BE
(Mention product name and its manufacturer)

NA

3.l) When were bioequivalence studies conducted?

3.m) Contract research organization(s) involved in generating bioequivalence data
NA

3.n). Biowaiver applied for or granted:
Biowaiver: An exemption, granted to a biopharmaceutical company, to show bioequivalence to a product

- ○ Yes
- ◉ No

3.o). Is the product approved by the CDSCO or any of the State Licensing Authorities in India?
(CDSCO- Central Drugs Standards Control Organization)

- ◉ Yes
- ○ No

3.p). Are the labels and leaflets approved by the CDSCO or any of the State Licensing Authorities in India?

- ◉ Yes
- ○ No

3.q). Is the product approved by the following Regulatory Authorities?

☐ European Medicines Agency

Mention the Registration number

Mention the expiry date

☐ US Food and Drug Administration

Mention the Registration number

Mention the expiry date

☐ Other Stringent Regulatory Agency (SRA)

Mention the regulatory agency

Mention the Registration number

Mention the expiry date

3.r) Please list registrations held in other countries
NA

3.s) Active pharmaceutical ingredient (API) source
(Mention the company name)
HEMMO PHARMA

3.t) Is there a complete Drug Master File (DMF) for the API?

(site of manufacture, route of synthesis, stability testing)

- Yes
- No

3.u). Please mail us a copy of COA for each product (COA: Certificate of Analysis)
Confirm if mail sent (Email id: prabhleen.arora@empower.net.in)

- Yes
- No

PART 4: WHO Prequalification Programme

4.a) Are you aware of the WHO Prequalification Programme?

- Yes
- No

4.b) Would you be interested in your product being approved by WHO Prequalification Programme?
(If yes, Empower/Concept Foundation would provide you the necessary technical assistance)

- Yes
- No

5. DEV LIFE CORPORATION

The objective of this questionnaire is to identify Oxytocin Injection manufacturers in India and eventually help them increase their global exports to global health programmes. Empower and Concept Foundation aim to achieve this by facilitating the necessary technical assistance for achieving WHO Prequalification status.

The questionnaire is divided into 4 sections:

Part 1: Corporate information
Part 2: Manufacturing site information
Part 3: Product information
Part 4: WHO Prequalification Programme (WHO-PQP)

This questionnaire should not take more than 20 minutes to complete and requests for 'accurate' information.

1.1 General information

1.1.a) Name of manufacturer
Dev Life Corporation

PART 1: Corporate information

1.1.b) Physical address
(Complete address with city, pin code)
Property No. 3/80, N H No: 8,

Sabar Dairy Road, Piplodi,

Himatnagar 383 001

1.1.c) Postal address
(If same as physical address, mention "same")
3F 31, Kalpataru Aura,

LBS Marg, Ghatkopar (W),

Mumbai: 400086

1.1.d) Name of contact person
(Please mention the designation)
VaishaliAnjaria

1.1.e) Telephone number
(Please mention STD code)
00 91 22 651020

1.1.f) Mobile number
00 982152957

1.1.g) Fax number
00 9122251760

1.1.h) Current manufacturing status?
(Please tick whatever is applicable)

- [ ] Domestic market
- [x] Export market
- [ ] Both domestic and export market
- [x] Engaged in contract manufacturing for other companies

1.1.i) Total number of staff
(including corporate headquarters and all manufacturing sites)

- ( ) <10
- ( ) 10-25
- (•) 25-50
- ( ) 50-100
- ( ) 100-200
- ( ) >200

PART 2: Manufacturing site/s

2.1 Information on manufacturing site of Oxytocin Injection

2.1.a) Site name or identifier
Dev Life Corporation

2.1.b) Site physical address
(Complete address with city, pin code)
Property No: 3/80, N.H No: 8

Sabar Dairy Road, Piplodi,

Himatnagar 383 001

2.1.c) Postal address
(If same as physical address, mention "same")
3F 31, Kalpataru Aura,

LBS Marg, Ghatkopar (W),

Mumbai: 400086

2.1.d) Name of site contact person
(Please mention the designation)
DevendraGehlot

2.1.e) Telephone number
(Please mention STD code)
00 91 996913737

2.1.f) Fax number
00 91 22 251760

2.1.g) Name of site manager
Kalpesh Patel

2.1.h) Total number of staff at this site

- (●) <50
- ( ) 50-100
- ( ) 100-200
- ( ) >200

2.1.i) Is the manufacturing site cGMP certified?

- (●) Yes
- ( ) No

2.1.j) What is the annual production volume of the manufacturing site?
(as per single shift)
50,000

2.1.k) What is the annual production capacity of the manufacturing site?
(Mention in terms of injection ampoules/year)
15,000,000

2.1.l) Do you manufacture any other reproductive health medicines?

- (●) Yes
- ( ) No

2.1.m) Do you have other manufacturing sites for Oxytocin Injection?

- ( ) Yes
- (●) No

PART 3: Product Information

3.a) Product brand name
Devoxy

3.b) Product generic name
Oxytocin Injection

3.c) Formulation type

☑ Injection
☐ Nasal solution
☐ Other:

3.d) What product strengths do you manufacture?

☑ 5 IU/mL
☐ 10 IU/mL

3.e) Does the formulation contain a buffer?

○ Yes
◉ No

Please mention the buffer

3.f) What are the storage conditions included in the product information and packaging?
(Please input exact language from pack insert)

Store at a temperature between 2 to 8C

3.g) Do you have stability data to support the above claims?

◉ Yes
○ No

3.h) Is the product constitution same for domestic and export markets?

○ Yes
◉ No

Comments

3.i) Are the product specifications in compliance with compendia monographs (USP, BP, IP etc.)

◉ Yes
○ No

Please mention the compendia

3.j) Does the product show pharmaceutical and/or therapeutic equivalence to the originator product?

○ Yes
◉ No

3.k) Comparator product used for BE
(Mention product name and its manufacturer)

NA

3.l) When were bioequivalence studies conducted?

3.m) Contract research organization(s) involved in generating bioequivalence data

3.n). Biowaiver applied for or granted:

Biowaiver: An exemption, granted to a biopharmaceutical company, to show bioequivalence to a product

- ○ Yes
- ◉ No

3.o). Is the product approved by the CDSCO or any of the State Licensing Authorities in India?

(CDSCO- Central Drugs Standards Control Organization)

- ◉ Yes
- ○ No

3.p). Are the labels and leaflets approved by the CDSCO or any of the State Licensing Authorities in India?

- ○ Yes
- ◉ No

3.q). Is the product approved by the following Regulatory Authorities?

☐ European Medicines Agency

Mention the Registration number

Mention the expiry date

☐ US Food and Drug Administration

Mention the Registration number

Mention the expiry date

☐ Other Stringent Regulatory Agency (SRA)

Mention the regulatory agency

Mention the Registration number

Mention the expiry date

3.r) Please list registrations held in other countries
Bhutan

3.s) Active pharmaceutical ingredient (API) source
(Mention the company name)
Hemmo Pharmaceuticals Pvt Ltd

3.t) Is there a complete Drug Master File (DMF) for the API?
(site of manufacture, route of synthesis, stability testing)

- (•) Yes
- ( ) No

3.u). Please mail us a copy of COA for each product (COA: Certificate of Analysis)
Confirm if mail sent (Email id: prabhleen.arora@empower.net.in)

- ( ) Yes
- (•) No

PART 4: WHO Prequalification Programme

4.a) Are you aware of the WHO Prequalification Programme?

- (•) Yes
- ( ) No

4.b) Would you be interested in your product being approved by WHO Prequalification Programme?
(If yes, Empower/Concept Foundation would provide you the necessary technical assistance)

- (•) Yes
- ( ) No

6. GLOBAL PHARMATECH LTD.

The objective of this questionnaire is to identify Oxytocin Injection manufacturers in India and eventually help them increase their global exports to global health programmes. Empower and Concept Foundation aim to achieve this by facilitating the necessary technical assistance for achieving WHO Prequalification status.

The questionnaire is divided into 4 sections:

Part 1: Corporate information
Part 2: Manufacturing site information
Part 3: Product information
Part 4: WHO Prequalification Programme (WHO-PQP)

This questionnaire should not take more than 20 minutes to complete and requests for 'accurate' information.

1.1 General information

1.1.a) Name of manufacturer
Global PhamatechPvt Ltd

PART 1: Corporate information

1.1.b) Physical address
(Complete address with city, pin code)
Global Pharmatech Pvt. Ltd.

No. 32, Sipcot Industrial Complex, Phase-I, Hosur- 635126,

Tamil Nadu State, INDIA

1.1.c) Postal address
(If same as physical address, mention "same")
Same

1.1.d) Name of contact person
(Please mention the designation)
Deepak Vagale

1.1.e) Telephone number
(Please mention STD code)
+91-4344 406105

1.1.f) Mobile number
91 8971937888

1.1.g) Fax number
91-4344 406107

1.1.h) Current manufacturing status?
(Please tick whatever is applicable)

- [ ] Domestic market
- [ ] Export market
- [x] Both domestic and export market
- [x] Engaged in contract manufacturing for other companies

1.1.i) Total number of staff
(including corporate headquarters and all manufacturing sites)

- ( ) <10
- ( ) 10-25
- (•) 25-50
- ( ) 50-100
- ( ) 100-200
- ( ) >200

PART 2: Manufacturing site/s

2.1 Information on manufacturing site of Oxytocin Injection

2.1.a) Site name or identifier
Global PharmatechPvt Ltd

2.1.b) Site physical address
(Complete address with city, pin code)
Global Pharmatech Pvt. Ltd.

No. 32, Sipcot Industrial Complex, Phase-I,

Hosur- 635126,

Tamil Nadu State,

India

2.1.c) Postal address
(If same as physical address, mention "same")
Global Pharmatech Pvt. Ltd.

No. 32, Sipcot Industrial Complex, Phase-I,

Hosur- 635126,

Tamil Nadu State,

India

2.1.d) Name of site contact person
(Please mention the designation)
Deepak Vagale

2.1.e) Telephone number
(Please mention STD code)
+91-4344 406105

2.1.f) Fax number
91-4344 406107

2.1.g) Name of site manager
Chezian

2.1.h) Total number of staff at this site

- (•) <50
- ( ) 50-100
- ( ) 100-200
- ( ) >200

2.1.i) Is the manufacturing site cGMP certified?

- (•) Yes
- ( ) No

2.1.j) What is the annual production volume of the manufacturing site?
(as per single shift)
36,000,000

2.1.k) What is the annual production of the manufacturing site?
(Mention in terms of injection ampoules/year)
50,000,000

2.1.l) Do you manufacture any other reproductive health medicines?

- ( ) Yes
- (•) No

2.1.m) Do you have other manufacturing sites for Oxytocin Injection?

- ( ) Yes
- (•) No

PART 3: Product Information

3.a) Product brand name

3.b) Product generic name
Oxytocin Injection

3.c) Formulation type

- [x] Injection
- [ ] Nasal solution
- [ ] Other:

3.d) What product strengths do you manufacture?

- [x] 5 IU/mL
- [x] 10 IU/mL

3.e) Does the formulation contain a buffer?

- ( ) Yes
- (•) No

Please mention the buffer

3.f) What are the storage conditions included in the product information and packaging?
(Please input exact language from pack insert)
2 to 8 degree celicius

3.g) Do you have stability data to support the above claims?

- ( ) Yes
- (•) No

3.h) Is the product constitution same for domestic and export markets?

- (•) Yes
- ( ) No

Comments

3.i) Are the product specifications in compliance with compendia monographs (USP, BP, IP etc.)

- (•) Yes
- ( ) No

Please mention the compendia

3.j) Does the product show pharmaceutical and/or therapeutic equivalence to the originator product?

- ( ) Yes
- (•) No

3.k) Comparator product used for BE
(Mention product name and its manufacturer)

3.l) When were bioequivalence studies conducted?

3.m) Contract research organization(s) involved in generating bioequivalence data

3.n). Biowaiver applied for or granted:

Biowaiver: An exemption, granted to a biopharmaceutical company, to show bioequivalence to a product

- Yes
- No

3.o). Is the product approved by the CDSCO or any of the State Licensing Authorities in India?

(CDSCO- Central Drugs Standards Control Organization)

- Yes
- No

3.p). Are the labels and leaflets approved by the CDSCO or any of the State Licensing Authorities in India?

- Yes
- No

3.q). Is the product approved by the following Regulatory Authorities?

- European Medicines Agency

Mention the Registration number

Mention the expiry date

- US Food and Drug Administration

Mention the Registration number

Mention the expiry date

- Other Stringent Regulatory Agency (SRA)

Mention the regulatory agency

Mention the Registration number

Mention the expiry date

3.r) Please list registrations held in other countries

3.s) Active pharmaceutical ingredient (API) source
(Mention the company name)
HEMMO

3.t) Is there a complete Drug Master File (DMF) for the API?
(site of manufacture, route of synthesis, stability testing)

- (●) Yes
- ( ) No

3.u). Please mail us a copy of COA for each product (COA: Certificate of Analysis)
Confirm if mail sent (Email id: prabhleen.arora@empower.net.in)

- ( ) Yes
- (●) No

PART 4: WHO Prequalification Programme

4.a) Are you aware of the WHO Prequalification Programme?

- (●) Yes
- ( ) No

4.b) Would you be interested in your product being approved by WHO Prequalification Programme?
(If yes, Empower/Concept Foundation would provide you the necessary technical assistance)

- (●) Yes
- ( ) No

7. QUZER PHARMA

The objective of this questionnaire is to identify Oxytocin Injection manufacturers in India and eventually help them increase their global exports to global health programmes. Empower and Concept Foundation aim to achieve this by facilitating the necessary technical assistance for achieving WHO Prequalification status.

The questionnaire is divided into 4 sections:

Part 1: Corporate information
Part 2: Manufacturing site information
Part 3: Product information
Part 4: WHO Prequalification Programme (WHO-PQP)

This questionnaire should not take more than 20 minutes to complete and requests for 'accurate' information.

1.1 General information

1.1.a) Name of manufacturer
Quzer Pharma

PART 1: Corporate information

1.1.b) Physical address
(Complete address with city, pin code)
B/215,

Yash Plaza,

OppDanamilRoad,

Varachha,Surat,

Gujarat,India-395006

1.1.c) Postal address
(If same as physical address, mention "same")
B/215,

Yash Plaza,

OppDanamil Road,

Varachha,Surat,

Gujarat,India-395006

1.1.d) Name of contact person
(Please mention the designation)
Sagar Jogani

1.1.e) Telephone number
(Please mention STD code)

1.1.f) Mobile number
+91 9904744577

1.1.g) Fax number

1.1.h) Current manufacturing status?
(Please tick whatever is applicable)

- [ ] Domestic market
- [ ] Export market
- [x] Both domestic and export market
- [ ] Engaged in contract manufacturing for other companies

1.1.i) Total number of staff
(including corporate headquarters and all manufacturing sites)

- (•) <10
- ( ) 10-25
- ( ) 25-50
- ( ) 50-100
- ( ) 100-200
- ( ) >200

PART 2: Manufacturing site/s

2.1 Information on manufacturing site of Oxytocin Injection

2.1.a) Site name or identifier
www.quzerpharma.com

2.1.b) Site physical address
(Complete address with city, pin code)
B/215, Yash Plaza,

OppDanamilroad,Varachha,

Surat,Gujarat,India-395006

2.1.c) Postal address
(If same as physical address, mention "same")
B/215,Yash Plaza,

OppDanamilRoad,Varachha,

Surat,Gujarat,india-395006

2.1.d) Name of site contact person
(Please mention the designation)
Savaj Pratik

2.1.e) Telephone number
(Please mention STD code)
+919712646353

2.1.f) Fax number

2.1.g) Name of site manager
HardikVadaliya

2.1.h) Total number of staff at this site

- (•) <50
- ( ) 50-100
- ( ) 100-200
- ( ) >200

2.1.i) Is the manufacturing site cGMP certified?

- (•) Yes
- ( ) No

2.1.j) What is the annual production volume of the manufacturing site?
(as per single shift)
More

2.1.k) What is the annual production capacity of the manufacturing site?
(Mention in terms of injection ampoules/year)
More

2.1.l) Do you manufacture any other reproductive health medicines?

- (•) Yes
- ( ) No

Please comment

2.1.m) Do you have other manufacturing sites for Oxytocin Injection?

- (•) Yes
- ( ) No

PART 3: Product Information

3.a) Product brand name
As you require (Third Party/Contract manufacturer)

3.b) Product generic name
As you require (Third Party/Contract Manufacturer)

3.c) Formulation type

- [x] Injection
- [x] Nasal solution
- [x] Other: Tablets, Capsules, Injections, Nasal solution

3.d) What product strengths do you manufacture?

- [x] 5 IU/mL
- [x] 10 IU/mL

3.e) Does the formulation contain a buffer?

- ( ) Yes
- (•) No

Please mention the buffer

3.f) What are the storage conditions included in the product information and packaging?
(Please input exact language from pack insert)
Good and well storage as required products

3.g) Do you have stability data to support the above claims?

- ( ) Yes
- (•) No

3.h) Is the product constitution same for domestic and export markets?

- (•) Yes
- ( ) No

Comments

3.i) Are the product specifications in compliance with compendia monographs (USP, BP, IP etc.)

- (•) Yes
- ( ) No

Please mention the compendia

3.j) Does the product show pharmaceutical and/or therapeutic equivalence to the originator product?

Yes

No

3.k) Comparator product used for BE

(Mention product name and its manufacturer)

3.l) When were bioequivalence studies conducted?

3.m) Contract research organization(s) involved in generating bioequivalence data

3.n). Biowaiver applied for or granted:

Biowaiver: An exemption, granted to a biopharmaceutical company, to show bioequivalence to a product

Yes

No

3.o). Is the product approved by the CDSCO or any of the State Licensing Authorities in India?

(CDSCO- Central Drugs Standards Control Organization)

Yes

No

3.p). Are the labels and leaflets approved by the CDSCO or any of the State Licensing Authorities in India?

Yes

No

3.q). Is the product approved by the following Regulatory Authorities?

European Medicines Agency

Mention the Registration number

Mention the expiry date

US Food and Drug Administration

Mention the Registration number

Mention the expiry date

☐ Other Stringent Regulatory Agency (SRA)

Mention the regulatory agency

Mention the Registration number

Mention the expiry date

3.r) Please list registrations held in other countries

3.s) Active pharmaceutical ingredient (API) source
(Mention the company name)

3.t) Is there a complete Drug Master File (DMF) for the API?
(site of manufacture, route of synthesis, stability testing)

○ Yes
○ No

3.u). Please mail us a copy of COA for each product (COA: Certificate of Analysis)
Confirm if mail sent (Email id: prabhleen.arora@empower.net.in)

◉ Yes
○ No

PART 4: WHO Prequalification Programme

4.a) Are you aware of the WHO Prequalification Programme?

◉ Yes
○ No

4.b) Would you be interested in your product being approved by WHO Prequalification Programme?
(If yes, Empower/Concept Foundation would provide you the necessary technical assistance)

◉ Yes
○ No

8. S.G.S PHARMACEUTICALS PVT. LTD.

The objective of this questionnaire is to identify Oxytocin Injection manufacturers in India and eventually help them increase their global exports to global health programmes. Empower and Concept Foundation aim to achieve this by facilitating the necessary technical assistance for achieving WHO Prequalification status.

The questionnaire is divided into 4 sections:

Part 1: Corporate information
Part 2: Manufacturing site information
Part 3: Product information
Part 4: WHO Prequalification Programme (WHO-PQP)

This questionnaire should not take more than 20 minutes to complete and requests for 'accurate' information.

1.1 General information

1.1.a) Name of manufacturer
SGS Pharmaceuticals Pvt. Ltd.

PART 1: Corporate information

1.1. b) Physical address
(Complete address with city, pin code)
E-13/1 Kavi Nagar Industrial Area Sector -17

Ghaziabad

(Uttar Pradesh) 201002

1.1. c) Postal address
(If same as physical address, mention "same")
Same

1.1. d) Name of contact person
(Please mention the designation)
Nimish Gupta

1.1. e) Telephone number
(Please mention STD code)
0120 6512840

1.1. f) Mobile number
+919810024943

1.1. g) Fax number
0120 4559510

1.1. h) Current manufacturing status?
(Please tick whatever is applicable)

- [ ] Domestic market
- [ ] Export market
- [ ] Both domestic and export market
- [x] Engaged in contract manufacturing for other companies

1.1. i) Total number of staff
(Including corporate headquarters and all manufacturing sites)

- ( ) <10
- ( ) 10-25
- (•) 25-50
- ( ) 50-100
- ( ) 100-200
- ( ) >200

PART 2: Manufacturing site/s

2.1 Information on manufacturing site of Oxytocin Injection

2.1.a) Site name or identifier
SGS Pharmaceuticals Pvt. Ltd.

2.1.b) Site physical address
(Complete address with city, pin code)
162/1 PuhanaIqbalpur Road,

Nanhera

Roorkee district

Haridwar

(Uttarakhand) 247667.

2.1.c) Postal address
(If same as physical address, mention "same")
Same

2.1.d) Name of site contact person
(Please mention the designation)
Pramod Kumar

2.1.e) Telephone number
(Please mention STD code)
01332 234016

2.1.f) Fax number
01332 234016

2.1.g) Name of site manager
+91 7500122388

2.1.h) Total number of staff at this site

- ( ) <50
- (•) 50-100
- ( ) 100-200
- ( ) >200

2.1.i) Is the manufacturing site cGMP certified?

- (•) Yes
- ( ) No

2.1.j) What is the annual production volume of the manufacturing site?
(as per single shift)
12,000,000

2.1.k) What is the annual production capacity of the manufacturing site?
(Mention in terms of injection ampoules/year)
36,000,000

2.1.l) Do you manufacture any other reproductive health medicines?

- ( ) Yes
- (•) No

Please comment
Only Oxytocin injection manufacture as reproductive health medicine.

2.1.m) Do you have other manufacturing sites for Oxytocin Injection?

- ( ) Yes
- (•) No

PART 3: Product Information

3.a) Product brand name
Oxytomed injection 5IU/ml

3.b) Product generic name
Oxytocin injection IP

3.c) Formulation type

- [x] Injection
- [ ] Nasal solution
- [ ] Other:

3.d) What product strengths do you manufacture?

- [x] 5 IU/mL

☐ 10 IU/mL

3.e) Does the formulation contain a buffer?

◉ Yes

○ No

Please mention the buffer

Sodium acetate buffer

3.f) What are the storage conditions included in the product information and packaging?
(Please input exact language from pack insert)

Store : At the temperature 2□C - 8□C

3.g) Do you have stability data to support the above claims?

◉ Yes

○ No

3.h) Is the product constitution same for domestic and export markets?

◉ Yes

○ No

Comments

3.i) Are the product specifications in compliance with compendia monographs (USP, BP, IP etc.)

◉ Yes

○ No

Please mention the compendia

3.j) Does the product show pharmaceutical and/or therapeutic equivalence to the originator product?

○ Yes

◉ No

3.k) Comparator product used for BE
(Mention product name and its manufacturer)

3.l) When were bioequivalence studies conducted?

3.m) Contract research organization(s) involved in generating bioequivalence data

3.n). Biowaiver applied for or granted:
Biowaiver: An exemption, granted to a biopharmaceutical company, to show bioequivalence to a product

○ Yes

◉ No

3.o). Is the product approved by the CDSCO or any of the State Licensing Authorities in India?
(CDSCO- Central Drugs Standards Control Organization)

◉ Yes
○ No

3.p). Are the labels and leaflets approved by the CDSCO or any of the State Licensing Authorities in India?

◉ Yes
○ No

3.q). Is the product approved by the following Regulatory Authorities?

☐ European Medicines Agency

Mention the Registration number

Mention the expiry date

☐ US Food and Drug Administration

Mention the Registration number

Mention the expiry date

☐ Other Stringent Regulatory Agency (SRA)

Mention the regulatory agency

Mention the Registration number

Mention the expiry date

3.r) Please list registrations held in other countries

3.s) Active pharmaceutical ingredient (API) source
(Mention the company name)
Hemmo Pharmaceuticals Mumbai

3.t) Is there a complete Drug Master File (DMF) for the API?
(site of manufacture, route of synthesis, stability testing)

◉ Yes
○ No

3.u). Please mail us a copy of COA for each product (COA: Certificate of Analysis)
Confirm if mail sent (Email id: prabhleen.arora@empower.net.in)

◉ Yes

No

PART 4: WHO Prequalification Programme

4.a) Are you aware of the WHO Prequalification Programme?

Yes

No

4.b) Would you be interested in your product being approved by WHO Prequalification Programme?
(If yes, Empower/Concept Foundation would provide you the necessary technical assistance)

Yes

No

9. GLAND PHARMA LTD.

The objective of this questionnaire is to identify Oxytocin Injection manufacturers in India and eventually help them increase their global exports to global health programmes. Empower and Concept Foundation aim to achieve this by facilitating the necessary technical assistance for achieving WHO Prequalification status.

The questionnaire is divided into 4 sections:

Part 1: Corporate information
Part 2: Manufacturing site information
Part 3: Product information
Part 4: WHO Prequalification Programme (WHO-PQP)

This questionnaire should not take more than 20 minutes to complete and requests for 'accurate' information.

1.1 General information

1.1.a) Name of manufacturer
Gland Pharma limited

PART 1: Corporate information

1.1. b) Physical address
(Complete address with city, pin code)
Survey No. 143-148, 150 & 151,
Near Gandimaisamma Cross Roads
D.P.Pally, Quthbullapur Mandal,
R.R. District,
Hyderabad – 500 043.
Andhra Pradesh, INDIA.

1.1. c) Postal address
(If same as physical address, mention "same")
Same

1.1. d) Name of contact person
(Please mention the designation)
Mr. Raghuram.K

1.1. e) Telephone number
(Please mention STD code)
+91-40-3051 0999
Ext: 234

1.1. f) Mobile number

1.1. g) Fax number
+91-40-3051 0810

1.1. h) Current manufacturing status?
(Please tick whatever is applicable)

- ☐ Domestic market
- ☐ Export market
- ☑ Both domestic and export market
- ☐ Engaged in contract manufacturing for other companies

1.1. i) Total number of staff
(including corporate headquarters and all manufacturing sites)

- ○ <10
- ○ 10-25
- ○ 25-50
- ○ 50-100
- ○ 100-200
- ◉ >200

PART 2: Manufacturing site/s

2.1 Information on manufacturing site of Oxytocin Injection

2.1.a) Site name or identifier
Gland Pharma limited

2.1.b) Site physical address
(Complete address with city, pin code)
Survey No. 143-148, 150 & 151,
Near Gandimaisamma Cross Roads
D.P.Pally, Quthbullapur Mandal,
R.R. District,
Hyderabad – 500 043.
Andhra Pradesh, INDIA

2.1.c) Postal address
(If same as physical address, mention "same")
Same

2.1.d) Name of site contact person
(Please mention the designation)
Mr. Raghuram K

2.1.e) Telephone number

(Please mention STD code)
+91-40-3051 0999
Ext: 234

2.1.f) Fax number
+91-40-3051 0810

2.1.g) Name of site manager
Mr. Ravichandra

2.1.h) Total number of staff at this sites

○ No

2.1.j) What is the annual production volume of the manufacturing site?
(as per single shift)
200, 000 Units/day

2.1.k) What is the annual production capacity of the manufacturing site?
(Mention in terms of injection ampoules/year)
150,000,000 Units/year

2.1.l) Do you manufacture any other reproductive health medicines?

○ Yes
◉ No

2.1.m) Do you have other manufacturing sites for Oxytocin Injection?

○ Yes
◉ No

PART 3: Product Information

3.a) Product brand name

3.b) Product generic name
Oxytocin injection BP

3.c) Formulation type

☑ Injection
☐ Nasal solution
☐ Other:

3.d) What product strengths do you manufacture?

☐ 5 IU/mL
☑ 10 IU/mL

3.e) Does the formulation contain a buffer?

- ( ) Yes
- (•) No

Please mention the buffer

3.f) What are the storage conditions included in the product information and packaging?
(Please input exact language from pack insert)

Store between 2 – 8ºC

3.g) Do you have stability data to support the above claims?

- (•) Yes
- ( ) No

3.h) Is the product constitution same for domestic and export markets?

- (•) Yes
- ( ) No

Comments

3.i) Are the product specifications in compliance with compendia monographs (USP, BP, IP etc.)

- (•) Yes
- ( ) No

Please mention the compendia

British pharmacopoeia

3.j) Does the product show pharmaceutical and/or therapeutic equivalence to the originator product?

- (•) Yes
- ( ) No

3.k) Comparator product used for BE
(Mention product name and its manufacturer)

Not Applicable for Parental products

3.l) When were bioequivalence studies conducted?

Not Applicable

3.m) Contract research organization(s) involved in generating bioequivalence data
Not Applicable

3.n). Biowaiver applied for or granted:
Biowaiver: An exemption, granted to a biopharmaceutical company, to show bioequivalence to a product

- ( ) Yes

(•) No

3.o). Is the product approved by the CDSCO or any of the State Licensing Authorities in India?
(CDSCO- Central Drugs Standards Control Organization)

(•) Yes
( ) No

3.p). Are the labels and leaflets approved by the CDSCO or any of the State Licensing Authorities in India?

(•) Yes
( ) No

3.q). Is the product approved by the following Regulatory Authorities?

[ ] European Medicines Agency

Mention the Registration number

Mention the expiry date

[ ] US Food and Drug Administration

Mention the Registration number

Mention the expiry date

[ ] Other Stringent Regulatory Agency (SRA)

Mention the regulatory agency

Mention the Registration number

Mention the expiry date

3.r) Please list registrations held in other countries
Nigeria, Kenya, Iraq, Mali, Madagascar Burkina Faso, Benin, Mali, Zimbabwe

3.s) Active pharmaceutical ingredient (API) source
(Mention the company name)

Hemmo pharmaceutical limited

3.t) Is there a complete Drug Master File (DMF) for the API?
(site of manufacture, route of synthesis, stability testing)

(•) Yes

No

3.u). Please mail us a copy of COA for each product (COA: Certificate of Analysis)
Confirm if mail sent (Email id: prabhleen.arora@empower.net.in)

Yes

No

PART 4: WHO Prequalification Programme

4.a) Are you aware of the WHO Prequalification Programme?

Yes

No

4.b) Would you be interested in your product being approved by WHO Prequalification Programme?
(If yes, Empower/Concept Foundation would provide you the necessary technical assistance)

Yes

No

10. PHARMA CURE LABORATORIES

The objective of this questionnaire is to identify Oxytocin Injection manufacturers in India and eventually help them increase their global exports to global health programmes. Empower and Concept Foundation aim to achieve this by facilitating the necessary technical assistance for achieving WHO Prequalification status.

The questionnaire is divided into 4 sections:

Part 1: Corporate information
Part 2: Manufacturing site information
Part 3: Product information
Part 4: WHO Prequalification Programme (WHO-PQP)

This questionnaire should not take more than 20 minutes to complete and requests for 'accurate' information.

1.1 General information

1.1.a) Name of manufacturer
Pharma Cure Laboratories

PART 1: Corporate information

1.1. b) Physical address
(Complete address with city, pin code)
Pharma Cure Laboratories

Near Govt. High School,

Garha,

Jalandhar (Punjab) 144 022

1.1. c) Postal address
(If same as physical address, mention "same")
Same

1.1. d) Name of contact person
(Please mention the designation)
Amarinder Singh

1.1. e) Telephone number
(Please mention STD code)
0181-4614402

1.1. f) Mobile number

1.1. g) Fax number

1.1. h) Current manufacturing status?
(Please tick whatever is applicable)

- [x] Domestic market
- [ ] Export market
- [ ] Both domestic and export market
- [ ] Engaged in contract manufacturing for other companies

1.1. i) Total number of staff
(Including corporate headquarters and all manufacturing sites)

- ( ) <10
- (•) 10-25
- ( ) 25-50
- ( ) 50-100
- ( ) 100-200
- ( ) >200

PART 2: Manufacturing site/s

2.1 Information on manufacturing site of Oxytocin Injection

2.1.a) Site name or identifier
Pharma Cure Laboratories

2.1.b) Site physical address
(Complete address with city, pin code)
Pharma Cure Laboratories

Near Govt. High School,

Garha,

Jalandhar (Punjab) 144 022

2.1.c) Postal address
(If same as physical address, mention "same")
Same

2.1.d) Name of site contact person
(Please mention the designation)
Amarinder Singh (Administartor)

2.1.e) Telephone number
(Please mention STD code)
0181-4614402

2.1.f) Fax number

2.1.g) Name of site manager
Amarinder Singh

2.1.h) Total number of staff at this site

- (●) <50
- ( ) 50-100
- ( ) 100-200
- ( ) >200

2.1.i) Is the manufacturing site cGMP certified?

- ( ) Yes
- (●) No

2.1.j) What is the annual production volume of the manufacturing site?
(As per single shift)

2.1.k) What is the annual production of the manufacturing site?
(Mention in terms of injection ampoules/year)
15,000,000 ampoules/year (approx.)

2.1.l) Do you manufacture any other reproductive health medicines?

- ( ) Yes
- (●) No

2.1.m) Do you have other manufacturing sites for Oxytocin Injection?

- ( ) Yes
- (●) No

PART 3: Product Information

3.a) Product brand name
Curocin

3.b) Product generic name
Oxytocin Injection IP

3.c) Formulation type

- [x] Injection
- [ ] Nasal solution
- [ ] Other: ____

3.d) What product strengths do you manufacture?

- [x] 5 IU/mL

☐ 10 IU/mL

3.e) Does the formulation contain a buffer?

○ Yes

○ No

Please mention the buffer

3.f) What are the storage conditions included in the product information and packaging?
(Please input exact language from pack insert)

Can be stored upto 30 degrees C

3.g) Do you have stability data to support the above claims?

○ Yes

◉ No

3.h) Is the product constitution same for domestic and export markets?

○ Yes

○ No

Comments

3.i) Are the product specifications in compliance with compendia monographs (USP, BP, IP etc.)

◉ Yes

○ No

Please mention the compendia

3.j) Does the product show pharmaceutical and/or therapeutic equivalence to the originator product?

◉ Yes

○ No

3.k) Comparator product used for BE
(Mention product name and its manufacturer)

3.l) When were bioequivalence studies conducted?

3.m) Contract research organization(s) involved in generating bioequivalence data

3.n). Biowaiver applied for or granted:
Biowaiver: An exemption, granted to a biopharmaceutical company, to show bioequivalence to a product

Yes

No

3.o). Is the product approved by the CDSCO or any of the State Licensing Authorities in India?
(CDSCO- Central Drugs Standards Control Organization)

Yes

No

3.p). Are the labels and leaflets approved by the CDSCO or any of the State Licensing Authorities in India?

Yes

No

3.q). Is the product approved by the following Regulatory Authorities?

European Medicines Agency

Mention the Registration number

Mention the expiry date

US Food and Drug Administration

Mention the Registration number

Mention the expiry date

Other Stringent Regulatory Agency (SRA)

Mention the regulatory agency

Mention the Registration number

Mention the expiry date

3.r) Please list registrations held in other countries

3.s) Active pharmaceutical ingredient (API) source
(Mention the company name)
Hemmo Pharma, Mumbai

3.t) Is there a complete Drug Master File (DMF) for the API?
(site of manufacture, route of synthesis, stability testing)

Yes

- [x] No

3.u). Please mail us a copy of COA for each product (COA: Certificate of Analysis)
Confirm if mail sent (Email id: prabhleen.arora@empower.net.in)

- [ ] Yes
- [ ] No

PART 4: WHO Prequalification Programme

4.a) Are you aware of the WHO Prequalification Programme?

- [ ] Yes
- [x] No

4.b) Would you be interested in your product being approved by WHO Prequalification Programme?
(If yes, Empower/Concept Foundation would provide you the necessary technical assistance)

- [x] Yes
- [ ] No

11. TAJ PHARMA

The objective of this questionnaire is to identify Oxytocin Injection manufacturers in India and eventually help them increase their global exports to global health programmes. Empower and Concept Foundation aim to achieve this by facilitating the necessary technical assistance for achieving WHO Prequalification status.

The questionnaire is divided into 4 sections:

Part 1: Corporate information
Part 2: Manufacturing site information
Part 3: Product information
Part 4: WHO Prequalification Programme (WHO-PQP)

This questionnaire should not take more than 20 minutes to complete and requests for 'accurate' information.

1.1 General information

1.1.a) Name of manufacturer
Taj Pharma

PART 1: Corporate information

1.1. b) Physical address
(Complete address with city, pin code)
Taj Group of Companies

Taj Pharmaceuticals Ltd.

B/134, Oshiwara Industrial Centre,

Oshiwara Bus Depot,

Link Road, Goregaon (West),

Mumbai – 400104.

Phone : General EPA BX :

91 - (0)22 - 26374592 (IST)

91 - (0)22 - 26374593

Fax : 91-(0)22-26341274

E-mail :tajgroup@tajpharma.com

tajpharmaceuticals@gmail.com

1.1. c) Postal address
(If same as physical address, mention "same")
Taj Group of Companies

Taj Pharmaceuticals Ltd.

B/134, Oshiwara Industrial Centre,

Oshiwara Bus Depot,

Link Road, Goregaon (West),

Mumbai – 400104.

Phone : General EPA BX :

91 - (0)22 - 26374592 (IST)

91 - (0)22 - 26374593

Fax : 91-(0)22-26341274

E-mail :tajgroup@tajpharma.com

tajpharmaceuticals@gmail.com

1.1. d) Name of contact person
(Please mention the designation)
Mr.Amit Kumar

1.1. e) Telephone number
(Please mention STD code)
91 - (0)22 - 26374592

1.1. f) Mobile number

1.1. g) Fax number
91-(0)22-26341274

1.1. h) Current manufacturing status?
(Please tick whatever is applicable)

- ☐ Domestic market
- ☐ Export market
- ☑ Both domestic and export market
- ☑ Engaged in contract manufacturing for other companies

1.1. i) Total number of staff
(Including corporate headquarters and all manufacturing sites)

- ○ <10
- ○ 10-25
- ○ 25-50
- ○ 50-100
- ○ 100-200

- (•) >200

PART 2: Manufacturing site/s

2.1 Information on manufacturing site of Oxytocin Injection

2.1.a) Site name or identifier
Taj Pharma Sarigam

2.1.b) Site physical address
(Complete address with city, pin code)
Plot No. - 1019, Vill. - Sarigam,

G.I.D.C., Road No. 10,

Dist. - Valsad,

Gujarat.

Pin Code - 396142

2.1.c) Postal address
(If same as physical address, mention "same")
Same

2.1.d) Name of site contact person
(Please mention the designation)
Dr.Amir Michael

2.1.e) Telephone number
(Please mention STD code)
0091 02192 - 278323

2.1.f) Fax number
0091 02192 - 278324

2.1.g) Name of site manager
Dr. Amir Michael

2.1.h) Total number of staff at this site

- ( ) <50
- (•) 50-100
- ( ) 100-200
- ( ) >200

2.1.i) Is the manufacturing site cGMP certified?

- (•) Yes
- ( ) No

2.1.j) What is the annual production volume of the manufacturing site?
(As per single shift)
250,000 boxes (10x10)

2.1.k) What is the annual production capacity of the manufacturing site?
(Mention in terms of injection ampoules/year)
550,000 boxes (10x10)

2.1.l) Do you manufacture any other reproductive health medicines?

- (•) Yes
- ( ) No

Please comment
We offer an extensive range of dosage forms and delivery systems including oral solids, controlled-release, steriles, injectables, topicals, liquids, transdermals, semi-solids and high-potency products.

2.1.m) Do you have other manufacturing sites for Oxytocin Injection?

- ( ) Yes
- (•) No

PART 3: Product Information

3.a) Product brand name
Litocin

3.b) Product generic name
Oxytocin Injection USP

3.c) Formulation type

- [x] Injection
- [ ] Nasal solution
- [ ] Other:

3.d) What product strengths do you manufacture?

- [x] 5 IU/mL
- [x] 10 IU/mL

3.e) Does the formulation contain a buffer?

- ( ) Yes
- (•) No

Please mention the buffer

3.f) What are the storage conditions included in the product information and packaging?
(Please input exact language from pack insert)
Store at 2 - 8 degree C.

HowSupplied :

Litocin (Oxytocin Injection,USP) Synthetic is available as follows:

Packages of ten 1-mL ampoules, each containing 10 units of oxytocin.

Packages of twenty-five oversized 1-mL Steri-Vials, each containing 10 units of oxytocin.

Intravenous or intramuscular Adult: 1. Induction of labour: Initial dose: 0.5- 1 milliunits /minute as IV infusion and if needed rate can be gradually increased by 1 - 2 milliunits/minute until sufficient response is obtained. 2. Augmentation of labour: Initial dose: 2milliunits/minute as intravenous infusion and then gradually increase the dose maximum up to 20milliunits/minute 3. Reduction of postpartum bleeding after expulsion of placenta: 20 - 40 milliunits/minute as intravenous infusion after delivery of placenta. 4. Induce abortion: 10 - 100 milliunits/minutes 5. Oxytocin challenge test to assess fetal distress in high risk pregnancies greater than 31 weeks` gestation: Initial dose: 0.5milliunits/minute followed by gradual increase in infusion rate every 15 minutes up to 20milliunits/minute. When 3 moderate uterine contractions occur in a 10 minute interval then stop the use of medicament.

3.g) Do you have stability data to support the above claims?

(•) Yes

( ) No

3.h) Is the product constitution same for domestic and export markets?

( ) Yes

(•) No

Comments

3.i) Are the product specifications in compliance with compendia monographs (USP, BP, IP etc.)

(•) Yes

( ) No

Please mention the compendia

USP, BP, IP, EP

3.j) Does the product show pharmaceutical and/or therapeutic equivalence to the originator product?

(•) Yes

( ) No

3.k) Comparator product used for BE

(Mention product name and its manufacturer)

3.l) When were bioequivalence studies conducted?

16-11-2010

3.m) Contract research organization(s) involved in generating bioequivalence data

Ritz Regulatorry

3.n). Biowaiver applied for or granted:

Biowaiver: An exemption, granted to a biopharmaceutical company, to show bioequivalence to a product

( ) Yes

(•) No

3.o). Is the product approved by the CDSCO or any of the State Licensing Authorities in India?

(CDSCO- Central Drugs Standards Control Organization)

Yes

No

3.p). Are the labels and leaflets approved by the CDSCO or any of the State Licensing Authorities in India?

Yes

No

3.q). Is the product approved by the following Regulatory Authorities?

European Medicines Agency

Mention the Registration number

Mention the expiry date

US Food and Drug Administration

Mention the Registration number

Mention the expiry date

Other Stringent Regulatory Agency (SRA)

Mention the regulatory agency

Mention the Registration number

Mention the expiry date

3.r) Please list registrations held in other countries

Chile, Nigeria, Cuba, Peru, DR, Philippines, Ghana, Sri Lanka, InvimaColombia, Turkmenistan, Iraq, Uganda, Kenya, Vietnam, Kyrgystan, WHO-GMP, Nepal, Zambia

3.s) Active pharmaceutical ingredient (API) source

(Mention the company name)

Taj Active Pharmaceuticals Ingredients

3.t) Is there a complete Drug Master File (DMF) for the API?

(site of manufacture, route of synthesis, stability testing)

Yes

No

3.u). Please mail us a copy of COA for each product (COA: Certificate of Analysis)

Confirm if mail sent (Email id: prabhleen.arora@empower.net.in)

Yes

No

PART 4: WHO Prequalification Programme

4.a) Are you aware of the WHO Prequalification Programme?

- (●) Yes
- ( ) No

4.b) Would you be interested in your product being approved by WHO Prequalification Programme?
(If yes, Empower/Concept Foundation would provide you the necessary technical assistance)

- ( ) Yes
- (●) No

12. UMEDICA LABORATORIES PVT. LTD.

The objective of this questionnaire is to identify Oxytocin Injection manufacturers in India and eventually help them increase their global exports to global health programmes. Empower and Concept Foundation aim to achieve this by facilitating the necessary technical assistance for achieving WHO Prequalification status.

The questionnaire is divided into 4 sections:

Part 1: Corporate information
Part 2: Manufacturing site information
Part 3: Product information
Part 4: WHO Prequalification Programme (WHO-PQP)

This questionnaire should not take more than 20 minutes to complete and requests for 'accurate' information.

1.1 General information

1.1.a) Name of manufacturer
Umedica Laboratories Pvt. Ltd

PART 1: Corporate information

1.1. b) Physical address
(Complete address with city, pin code)
105/108,

Rewa Chamber,

31, New Marine Lines,

Mumbai 400 020, India

1.1. c) Postal address
(If same as physical address, mention "same")
Same

1.1. d) Name of contact person
(Please mention the designation)
Rajesh Gupta

1.1. e) Telephone number
(Please mention STD code)
91 22 22085041

1.1. f) Mobile number
+91 9967872681

1.1. g) Fax number
91 22 2206 6518

1.1. h) Current manufacturing status?
(Please tick whatever is applicable)

- [ ] Domestic market
- [x] Export market
- [ ] Both domestic and export market
- [x] Engaged in contract manufacturing for other companies

1.1. i) Total number of staff
(Including corporate headquarters and all manufacturing sites)

- ( ) <10
- ( ) 10-25
- ( ) 25-50
- ( ) 50-100
- ( ) 100-200
- (•) >200

PART 2: Manufacturing site/s

2.1 Information on manufacturing site of Oxytocin Injection

2.1.a) Site name or identifier
Umedica Laboratories Pvt. Ltd.

2.1.b) Site physical address
(Complete address with city, pin code)
Umedica Laboratories Pvt. Ltd.,

Plot No. 221, G.I.D.C.,

Vapi-396 195,

Gujarat, India

2.1.c) Postal address
(If same as physical address, mention "same")
Same

2.1.d) Name of site contact person
(Please mention the designation)
Mr. Narendra Hegde- General Manager QA

2.1.e) Telephone number
(Please mention STD code)
91 260 2400193

2.1.f) Fax number
91 260 2431945

2.1.g) Name of site manager
Mr. N. M. Desai

2.1.h) Total number of staff at this site

- ○ <50
- ○ 50-100
- ○ 100-200
- ◉ >200

2.1.i) Is the manufacturing site cGMP certified?

- ◉ Yes
- ○ No

2.1.j) What is the annual production volume of the manufacturing site?
(As per single shift)
500 Ltrs

2.1.k) What is the annual production capacity of the manufacturing site?
(Mention in terms of injection ampoules/year)
30,000,000 injection amp/year

2.1.l) Do you manufacture any other reproductive health medicines?

- ○ Yes
- ◉ No

2.1.m) Do you have other manufacturing sites for Oxytocin Injection?

- ○ Yes
- ◉ No

PART 3: Product Information

3.a) Product brand name
Ucin

3.b) Product generic name
Oxytocin BP

3.c) Formulation type

- ☑ Injection
- ☐ Nasal solution
- ☐ Other:

3.d) What product strengths do you manufacture?

- ☑ 5 IU/mL
- ☑ 10 IU/mL

3.e) Does the formulation contain a buffer?

- ○ Yes

(•) No

Please mention the buffer

3.f) What are the storage conditions included in the product information and packaging?
(Please input exact language from pack insert)
Store at temperature not exceeding 30 degree centigrade

3.g) Do you have stability data to support the above claims?
(•) Yes
( ) No

3.h) Is the product constitution same for domestic and export markets?
(•) Yes
( ) No

Comments

3.i) Are the product specifications in compliance with compendia monographs (USP, BP, IP etc.)
(•) Yes
( ) No

Please mention the compendia
BP

3.j) Does the product show pharmaceutical and/or therapeutic equivalence to the originator product?
( ) Yes
(•) No

3.k) Comparator product used for BE
(Mention product name and its manufacturer)
Be not applicable

3.l) When were bioequivalence studies conducted?

3.m) Contract research organization(s) involved in generating bioequivalence data
Not Applicable

3.n). Biowaiver applied for or granted:
Biowaiver: An exemption, granted to a biopharmaceutical company, to show bioequivalence to a product
( ) Yes
(•) No

3.o). Is the product approved by the CDSCO or any of the State Licensing Authorities in India?
(CDSCO- Central Drugs Standards Control Organization)

(•) Yes
( ) No

3.p). Are the labels and leaflets approved by the CDSCO or any of the State Licensing Authorities in India?

(•) Yes
( ) No

3.q). Is the product approved by the following Regulatory Authorities?

[ ] European Medicines Agency

No

Mention the Registration number

Mention the expiry date

[ ] US Food and Drug Administration

No

Mention the Registration number

Mention the expiry date

[ ] Other Stringent Regulatory Agency (SRA)

Mention the regulatory agency

Mention the Registration number

Mention the expiry date

3.r) Please list registrations held in other countries
Kenya, Mauritius, Gabon,Cameroon, Nepal, Malawi, Madagascar, Zimbabwe etc.

3.s) Active pharmaceutical ingredient (API) source
(Mention the company name)
Hemo Pharma Oxytocin

3.t) Is there a complete Drug Master File (DMF) for the API?
(Site of manufacture, route of synthesis, stability testing)

(•) Yes
( ) No

3.u). Please mail us a copy of COA for each product (COA: Certificate of Analysis)
Confirm if mail sent (Email id: prabhleen.arora@empower.net.in)

- (●) Yes
- ( ) No

PART 4: WHO Prequalification Programme

4.a) Are you aware of the WHO Prequalification Programme?

- (●) Yes
- ( ) No

4.b) Would you be interested in your product being approved by WHO Prequalification Programme?
(If yes, Empower/Concept Foundation would provide you the necessary technical assistance)

- (●) Yes
- ( ) No