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WHO Prequalification Unit – Inspection Services
WHO INSPECTION REPORT
(WHOPIR)
Desk Assessment of Finished Product Manufacturer

Part 1	**General information**	
Company information		
Name of Manufacturer	**Steril-Gene Life Sciences (P) Ltd**	
Corporate address of manufacturer	No.15, Gopalakrishnan Road T-Nagar Chennai India 600017 Tel: +91 442345 2030-34 Fax: +91 442345 2036	
Contact person	Mr Chanpreet Singh (24h contact person) Tel: +91 7373 133333, +91 413 2661103 Email: ppm@steril-gene.com	
Inspected site		
Name & address of manufacturing site	M/S Steril-Gene Life Sciences (P) Ltd No. 45 Mangalam Main Road Mangalam Village Villianur commune Puducherry 605110 India Tel: +91 413 2661103, +91 7373244777, +91 737 3288777, +91 893 9909663 Fax: +91 413 2661102 GPS Co-ordinates: 11.892668° Latitude, 79.737183° Longitude	
Production Block/Unit	Block C	
Manufacturing license number	Licence number DDC/U.II/WHO-GMP/2019-20/07(R)-04 was issued by the Government of Puducherry, Department of Drug Control, India, on 9 December 2022, with an expiry date of 30 October 2025.	
Desk assessment details		
Start and end dates of review	29 – 31 January 2024	
Inspection record number	INSP-FPP-2023-0029	
Products covered by this desk assessment	RH083 (Oxytocin Solution for injection 10IU/ml) – WHO prequalified in 2019	
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments**	
FDA, USA	Dates of inspection:	17 – 25 November 2022
	Type of inspection:	Pre-Approval and General GMP

	Block/Unit:	Block C Block B Block D (General OSD QC and Micro laboratory
	Type of products/Dosage forms covered:	Injections - SVP: Sterile filed, Lyophilized, terminally sterilized. Tablets Soft gelatine capsules
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	The last WHO inspection was performed by the PQT Inspection Services team from 13 to 17 June 2022. This was the 1st WHO on-site inspection conducted at the site. The inspection concluded that the site is considered to be compliant with WHO GMP guidelines after the submission and implementation of CAPAs in response to the identified GMP deficiencies.	
Summary of manufacturing activities	The site is involved with the production, quality control, and distribution of tablets, capsules (hard and soft gelatin), injectables (including lyophilized), hormones, and high-potency products. The site manufactures both human and veterinary medicines. It has 6 independent manufacturing blocks. Potent antibiotics, hormones, and sterile products are manufactured on-site. Penicillin group products and cytotoxic products were not manufactured on-site. • Block C is engaged with liquid and injection manufacturing. It is not dedicated to the production of Oxytocin sterile injection products. Both aseptic and terminal sterilization products share the facility and production lines. • Block D covers General OSD production (ground floor) with potent products manufactured on the 2nd floor. In addition, it houses the QC and micro laboratories. • Block A: Solid orals. • Block J: Prefilled syringes, ophthalmic formulations, and additional QC laboratory area.	
General information about the company and manufacturing site	Steril-Gene Life Sciences (P) Ltd. is a joint venture (50:50) between "The Madras Pharmaceuticals-Chennai, India" and "Lloyd Laboratories Inc, Philippines". The Steril-Gene manufacturing site is situated in Mangalam Village of Puducherry, which is accessible from Chennai, a 3-hour journey by road, and a 32-minute drive from Puducherry airport. According to company information, the corporate office handles Regulatory Affairs dossier submission, Marketing, and export-related activities.	
Focus of the last WHO inspection	The inspection focused on the sterile manufacturing of *Oxytocin sterile injection.*	
Areas inspected	• Quality management system • Injectable Production Block C: Rota filling line • Quality Control laboratories: Physical, chemical and microbiology labs • Utilities: Water and Nitrogen system • Warehouses	
Out of scope and restrictions (last WHO inspection)	All other products and production facilities on the site were outside the inspection scope and were not visited.	
WHO products	RH083 Oxytocin Solution for Injection 10 IU/ml	

covered by the last WHO inspection	
Additional products to be covered by this desk assessment:	No additional products.

Abbreviations	**Meaning**
AHU	Air handling unit
API	Active pharmaceutical ingredient
BMR	Batch manufacturing record
BPR	Batch production record
CAPA	Corrective and preventive action
CC	Change control
FPP	Finished pharmaceutical product
GMP	Good manufacturing practices
NC	Non-conformity
NRA	National regulatory agency
PQR	Product quality review
PQS	Pharmaceutical quality system
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
SMF	Site master file
SOP	Standard operating procedure

Part 4	**Summary of the assessment of supporting documentation**

a) List of all regulatory inspections performed in the last 5 years and their outcomes:

	NRA	**Ref number**	**Type of audit**	**Outcome/validity**
1.	USFDA	FEI number: 3014319211 17 – 25 November 2022	Injections, hormones, potent	NAI
2	ANVISA, Brazil	Oct 27, 2021	Injections	GMP certificate extended until 03/11/2025
3.	ANVISA, Brazil	1175363/4551183/22-9	Non-sterile, OSD, Desk Assessment	04/12/2024
4.	National Institute of Pharmacy and Nutrition, EU	OGYEI/52010-13/2018	Hormone, G-OSD, potent	GMP certificate extended until Dec 2024
5.	National Institute of Pharmacy and Nutrition, EU	OGYEI/6343-6/2018	Sterile injections	GMP certificate extended until Dec 2024

	NRA	Ref number	Type of audit	Outcome/validity
6.	Health Canada	HC6-61-13-24	Hormone	GMP compliant
7.	Ministry of Trade and Industry of the Russian Federation	GMP/EAEU/RU/01058-2023	Block A Block C	2 Nov 2026

b) Manufacturing authorization granted by national authorities:
A GMP certificate, DDC/U.II/WHO-GMP/2019-20/07(R)-04 was issued on 9 December 2022, with an expiry date of 30 October 2025 by the Government of Puducherry, Department of Drug Control, India, following an inspection on 11 and 13 October 2022, to allow for the manufacturing of tablets, capsules, and injectables.

c) Site master file:
A site master file, QA/SMF/01-16, dated 4 January 2024 with a review date indicated as 3 January 2026, was submitted. It included layouts of water treatment and air-handling systems and pipeline and instrumentation drawings.

d) List of all the products and dosage forms manufactured on-site:
The list was provided and reviewed as part of the desk assessment.

e) Most recent product quality review(s) (PQR)(s) of the concerned WHO product(s):
The PQR was reviewed for the period January – December 2022 for the active ingredient Oxytocin, indicating the following information:

Batches	**Oxytocin injection BP 10 IU/ml**
Manufacturing area	Block C: injections
Manufactured	40 batches manufactured
Approved	40 batches approved
Rejected	0 #
Deviation	20 # CAPA introduced. All deviations closed
Analytical incidents	0 #
OOS	1 # CAPA introduced. Closed
OOT	0 #
Reprocessing	0 #
Change Control	26 # of which 25 Closed
Complaints	0 #
Returns	0 #
Recalls	0 #

From the data presented, it was concluded that the manufacturing process was robust, and the acceptance criteria were met, with no findings detected in the documentation reviewed.

f) Batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of relevant product(s):
Completed Batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of Oxytocin Injection BP 10 IU/ml, were submitted. No objections to the submitted documentation were identified.

g) Master batch manufacturing and packaging record(s) of the product(s) of interest:

Master batch manufacturing and master packaging records for Oxytocin injection BP 10 IU/ml were submitted and found acceptable.

h) If any of the products are sterile, the completed batch records for the most recent media fill validation that is relevant to the product(s) of interest and report on its outcome:
The media fill validation as per the respective protocol for the sterile product, Oxytocin ampoules, 1 ml, confirmed that the entire environment conditions, aseptic processing equipment, practices/techniques followed during aseptic processing, and the process were found adequate. It was concluded on 19/08/2023 that the periodic media fill simulation on the Rota line with 1 ml ampoule was valid.

i) Recalls in the past three years related to products with quality defects:
A confirmation was received from Head: Quality Assurance that no recalls had been executed in the past 3 years.

j) Confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the product(s) has been performed and all matters dealt with:
A confirmation was received from the Vice-President: Quality Assurance.

k) Copy of any warning letter, or equivalent regulatory action, issued by any authority to which the site provides or has applied to provide the product:
A declaration was received from the Head of Quality Assurance that no warning letter or any regulatory action had been received from any NRA to whom the site supplies any products.

l) Out-of-stock situations:
No declaration was received.

m) Additional documents submitted:
None

Part 5	Conclusion – Desk assessment outcome

Based on the previous WHO inspections and on the GMP evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site ***Steril-Gene Life Sciences Pvt Ltd***, located at ***No. 45, Mangalam Main Road, Mangalam Village, Villianur commune, Puducherry, 605110, India*** is considered to be operating at an acceptable level of compliance with WHO GMP guidelines.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted by this period is positive.

Part 6	List of guidelines referenced in this inspection report

1. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eight Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2.
Short name: WHO TRS No. 986, Annex 2
https://www.who.int/publications/m/item/trs986-annex2

2. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2.
   Short name: WHO TRS No. 957, Annex 2
   https://www.who.int/publications/m/item/annex-2-trs-957

3. WHO guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report. Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 9.
   Short name: WHO TRS 1010, Annex 9
   https://www.who.int/publications/m/item/trs1010-annex9

4. WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 3.
   Short name: WHO TRS No. 1033, Annex 3
   https://www.who.int/publications/m/item/annex-3-trs-1033

5. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4.
   Short name: WHO TRS No. 929, Annex 4
   https://www.who.int/publications/m/item/annex-4-trs-929

6. WHO good practices for pharmaceutical quality control laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1.
   Short name: WHO TRS No. 957, Annex 1
   https://www.who.int/publications/m/item/trs957-annex1

7. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 3.
   Short name: WHO TRS No. 957, Annex 3
   https://www.who.int/publications/m/item/trs957-annex3

8. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty Second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8.
   Short name: WHO TRS No. 1010, Annex 8
   https://www.who.int/publications/m/item/Annex-8-trs-1010

9. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Third Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1019), Annex 2.
   Short name: WHO TRS No. 1019, Annex 2
   https://www.who.int/publications/m/item/trs1019-annex2

10. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
Short name: WHO TRS No. 1044, Annex 4
https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/production/trs1044-annex4-technology-transfer-in-pharmaceutical-manufacturing.pdf

11. WHO good manufacturing practices for sterile pharmaceutical products. Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
Short name: WHO TRS No. 1044, Annex 2
https://www.who.int/publications/m/item/trs1044-annex2

12. General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-First Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3. ***Short name: WHO TRS No. 943, Annex 3***
https://www.who.int/publications/m/item/trs943-annex3

13. WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2.
Short name: WHO TRS No. 961, Annex 2
https://www.who.int/publications/m/item/trs961-annex2

14. WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2.
Short name: WHO TRS No. 981, Annex 2
https://www.who.int/publications/m/item/trs981-annex2

15. WHO guidelines on variation to a prequalified product. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 3.
Short name: WHO TRS No. 981, Annex 3
https://www.who.int/publications/m/item/annex-3-trs-981

16. WHO guidelines for drafting a site master file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14.
Short name: WHO TRS No. 961, Annex 14
https://www.who.int/publications/m/item/tr961-annex14

17. Good Manufacturing Practices: Guidelines on validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Third Report Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 3.
Short name: WHO TRS No. 1019, Annex 3
https://www.who.int/publications/m/item/trs1019-annex3

18. WHO General guidance on hold-time studies WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4.
Short name: WHO TRS No. 992, Annex 4
https://www.who.int/publications/m/item/trs992-annex4

19. Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9.
***Short name: WHO TRS No. 961, Annex* 9**
https://www.who.int/publications/m/item/trs961-annex9-modelguidanceforstoragetransport

20. WHO Technical supplements to Model Guidance for storage and transport of time – and temperature – sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5.
Short name: WHO TRS No. 992, Annex 5
https://www.who.int/publications/m/item/trs992-annex5

21. WHO Recommendations for quality requirements when plant – derived artemisinin is used as a starting material in the production of antimalarial active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 6.
Short name: WHO TRS No. 992, Annex 6
https://www.who.int/publications/m/item/trs-992-annex-6

22. Guideline on data integrity. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 4.
Short name: WHO TRS No. 1033, Annex 4
https://www.who.int/publications/m/item/annex-4-trs-1033

23. WHO general guidance on variations to multisource pharmaceutical products. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 10.
Short name: WHO TRS No. 996, Annex 10
https://www.who.int/publications/m/item/trs966-annex10

24. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 10. ***Short name: WHO TRS No. 1010, Annex 10***
https://www.who.int/publications/m/item/trs1010-annex10

25. Points to consider when including Health-Based Exposure Limits in cleaning validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 2.
Short name: WHO TRS No. 1033, Annex 2
https://www.who.int/publications/m/item/annex-2-trs-1033

26. Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance. WHO Expert Committee on Specifications for Pharmaceutical

Preparations. Fifty-Fourth Report Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 6.
Short name: WHO TRS No. 1025, Annex 6
https://www.who.int/publications/m/item/trs-1025-annex-6

27. Production of water for injection by means other than distillation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 3.
Short name: WHO TRS No. 1025, Annex 3
https://www.who.int/publications/m/item/trs-1025-annex-3-water-for-injection

27. Good chromatography practice. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 4.
Short name: WHO TRS No. 1025, Annex 4
https://www.who.int/publications/m/item/trs1025-annex4