20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Prequalification Unit Inspection services
WHO PUBLIC INSPECTION REPORT

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 600 017 +91 73731333, +91-413-2661103		
Inspected site			
Name & address of manufacturing site	Steril-Gene Life Sciences (P) Ltd. 45, Mangalam Main Road, Mangalam Village, Villianur Commune, Puducherry, 605 110, India		
Production Block/Unit	Block C (liquid injectables)		
Desk assessment details			
Start and end dates of review	30 November and 01- 03 December 2020		
Products covered by this desk assessment	**PQ number**	**Product name**	**Status**
	RH083	Oxytocin Solution for injection 10IU/mL	Prequalified
	PQ-FPP-2020-0033	Carbetocin Solution for injection 100 mcg/ml	Under screening
List of documents submitted	1. SMF and attachments 2. List of regulatory inspections 3. US FDA EIR cover letter, dated 21 April 2020 4. US FDA EIR, dates of inspection 2 – 10 December 2019 5. US FDA form 483, dates of inspection 2 – 10 December 2019 6. Responses and CAPAs to US FDA form 483, dates of inspection 2 – 10 December 2019 7. National Institute of Pharmacy and Nutrition (OGYEI) Hungary inspection report, dates of inspection 26-30 2018 and OGYEI GMP certificate. Note: not reviewed as WHO previous desk assessment is based on OGYEI inspection report 8. GMP certificate No DDC/U-II/WHO-GMP/2019-20/07, issued by Government of Puducherry Department of Drugs Control 9. List of products manufactured at Liquid injections block C 10. PQRs a. Oxytocin injection BP 10 IU/ml Jan 2019 – Dec 2019, annual summary report for environmental monitoring: trend analysis of Block C – liquid injectable 2019 and graphical trends – stability b. Carbetocin Solution for injection 100 mcg/ml Jan 2018 – Dec 2018, annual summary report for environmental monitoring: trend analysis of Block C – liquid injectable 2018 and graphical trends, stability report 2018 11. BMR/BPR and analytical raw data Oxytocin Injection BP 10 IU/mL, batch XX 12. Master BMR/BPRs Oxytocin injection BP 10 IU/ml and Carbetocin Solution for injection 100 mcg/ml 13. Aseptic process simulation study protocol		

	14. BMR Block C aseptic media fill – 1 ml ampoule, batch XX, batch size YY ampoules, May 2020 15. Summary report for septic process simulation 1ml ampoules 16. Statement: product recalls 17. Statement: self-inspection 18. Statement: warning letter, or equivalent regulatory action 19. Statement: upcoming inspections 20. Statement: products covered by SRA inspection	
Any documents missing?	No	
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments**	
US FDA, USA	Dates of inspection:	2 – 10 December 2019
	Type of inspection:	Pre-approval inspection (first inspection) of Animal Sterile Drug manufacturing block
	Block/Unit:	Block C (liquid injectables)
	Type of products/Dosage forms covered:	Enrofloxacin Injectable Solution 2.27%, terminally sterilized Products under WHO PQ was not specifically covered. Note: products under WHO PQ are manufactured by sterile filtration
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	On-site inspection was not performed by the WHO. Desk assessment inspection was performed in 2019. Outcome of desk assessment: Based 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 Lifesciences (P) 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 compliance status shall be valid until 20 September 2020 or when another inspection is conducted by WHO or by a stringent regulatory authority. WHO may, at its discretion, perform an onsite inspection or desk assessment at an earlier date	
Summary of manufacturing activities	According to the Site Master File: The site manufactures both human and veterinary medicines. There are potent, antibiotics, hormones and sterile products manufactured on site but no penicillins and no cytotoxics. The site declared manufacturing hormones using a dedicated facility along with appropriate measures to avoid cross contamination. Block C which is used for the PQ Product manufactures both human and veterinary sterile products.	
General information about the company and manufacturing	According to the Site Master File, The site is divided in the following blocks: • Block A: Administrative, QA on 1st floor. • Block B: Hormones on ground floor and 1st floor. • Block C: Liquid injectables	

site	• Block D: General OSD (Ground floor), QC and MB (First Floor), Potent (Second floor) • Block E: Utility • Block F: ETP • Block G: AH and Time office • Glock H General canteen • Block I: Security office • Block J: R and D • Block K: General warehouse
Focus of the last WHO inspection	RH083 Oxytocin solution for injection 10IU/mL
WHO products covered by the last WHO inspection	RH083 Oxytocin solution for injection 10IU/mL
Abbreviations	**Meaning**
ADA	Adverse drug reaction
AHU	Air handling unit
BMR	Batch manufacturing record
BPR	Batch production record
CAPA	Corrective and preventive action
CC	Change control
EIR	Establishment inspection report
FPP	Finished pharmaceutical product
GMP	Good manufacturing practices
PQR	Product quality review
SMF	Site master file
WFI	Water for injection

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

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

No	Authority	Date of inspection	Inspected facilities	Outcome
1	USFDA, USA	02/12/2019 to 10/12/2019	Injection block C	Approved
2	National institute of Pharmacy and Nutrition, (Hungary)	26/03/2018 to 30/03/2018	Injection block C	Approved
3	Ukraine	19/03/2018 to 23/03/2018	Injection block C	Approved
4	Republic of Yemen	12/02/2018 to 15/02/2018	Entire Facility	Approved
5	Medicines Control Authority of Zimbabwe	18/06/2018 to 19/06/2018	Injection block C	Approved
6	Direction of inspection and certification DIGEMID (PERU)	04/12/2017 to 08/12/2017	Oral solid dosage facility of GOSD, Hormone & Injection block C	Approved
7	Iran MOH	07 Aug 2014	Entire facility	Approved
8	Ministry of health Kingdom of Cambodia	May 2016	Entire Facility	Approved
9	Ministry of health	23/07/2018 to 24/07/2018	Entire Facility	Approved

	Pharmacy and poisons Board-Kenya			
10	Food medicine and health care administration and control authority of Ethiopia (FMHACA)	30/07/2019 to 01/08/2019	Injection block C	Approved

NOTE: The above list covers the audit related to the Injection facility.

b) Manufacturing authorization granted by national authorities:
Manufacturing & distribution license, form 25 No 08132289, valid up to 18/02/2024
Manufacturing & distribution license, form 28 No 08222288, valid up to 18/02/2024
Manufacturing & distribution license, form 28B No 17244242, valid up to 08/03/2022
Manufacturing & distribution license, form 28D No 17264238, valid up to 29/01/2022
GMP certificate No DDC/U-II/WHO-GMP/2019-20/07, issued by Government of Puducherry Department of Drugs Control

c) Site master file:
SMF submitted and reviewed. SMF written according to the WHO TRS No. 961, Annex 14

d) List of products and dosage forms manufactured on-site:
Liquid sterile injectables in ampoules, vials and sterile lyophilised powders in vials.

- Antivirals – Influenza and Herpes Simplex
- Anesthetics
- Vitamins
- Diuretics
- Non-steroidal anti-inflammatory drugs
- Antiarrhythmic Agents
- Proton pump inhibitors
- Anti-Emetics
- Analgesics
- Antibacterials
- Diluent
- Sympathomimetics
- 5-HT_3 receptor antagonists
- Hormones
- Barbiturates
- Antihistamines
- H2 blockers
- Anti-fibrinolytic
- Antifungals
- Hypercalcemia
- Nonsteroidal anti-inflammatory drugs
- Neuromuscular reversal drug
- Alkalinizing Agents
- Calcium channel blockers
- Multiple Myeloma

e) Most recent product quality reviews (PQR)s of the concerned WHO products:
Submitted and reviewed:
1. Oxytocin injection BP 10 IU/ml Jan 2019 – Dec 2019, annual summary report for environmental monitoring: trend analysis of Block C – liquid injectable 2019 and graphical trends - stability.
2. Carbetocin Solution for injection 100 mcg/ml Jan 2018 – Dec 2018, annual summary report for environmental monitoring: trend analysis of Block C – liquid injectable 2018 and graphical trends, stability report 2018.

f) Batch manufacturing and packaging records, including the analytical part, for the most recently released batch of relevant products:
Submitted and reviewed: BMR/BPR and analytical raw data Oxytocin Injection BP 10 IU/mL, batch XX

g) Master batch manufacturing and packaging records of the products of interest:
Submitted and checked
- Oxytocin injection BP 10 IU/ml
- Carbetocin Solution for injection 100 mcg/ml

h) If any of the products are sterile, the completed batch records for the most recent media fill validation that is relevant to the products of interest and report on its outcome:
Submitted and reviewed:
1. Aseptic process simulation study protocol
2. BMR Block C aseptic media fill – 1 ml ampoule, batch No XX, batch size YY ampoules, May 2020.
3. Summary report for septic process simulation 1ml ampoules

i) Recalls in the past three years related to products with quality defects:
Statement submitted: no recalls in past 3 years

j) Confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the products has been performed and all matters dealt with:
Statement submitted: a full self-inspection or external audit dedicated to the products has been performed and all matters dealt with

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:
Statement submitted: no warning letter, or equivalent regulatory action, issued by any authority

l) Out-of-stock situations:
Statement submitted: no out-of-stock situations

m) Additional documents submitted:
N/A

Part 5	Conclusion – Desk assessment outcome

Based on the previous WHO desk assessment 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 Lifesciences (P) Ltd manufacturing block C***, 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 during 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-eighth Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. ***Short name: WHO TRS No. 986, Annex 2***
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

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***
   http://www.who.int/medicines/publications/44threport/en/

3. WHO good manufacturing practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-sixth Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2.
   Short name: WHO TRS No. 970, Annex 2
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/

4. 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
   http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

5. 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**
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1010/en/

6. Supplementary guidelines on good manufacturing practices: validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4.
   Short name: WHO TRS No. 937, Annex 4
   http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

7. 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
   http://www.who.int/medicines/publications/44threport/en/

8. 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
   http://www.who.int/medicines/publications/44threport/en/

9. WHO good manufacturing practices for sterile 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 6.
Short name: WHO TRS No. 961, Annex 6
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

10. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7.
Short name: WHO TRS No. 961, Annex 7
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

11. 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**
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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***
http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

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
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

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***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

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***
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

17. WHO Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 3. ***Short name: WHO TRS No. 992, Annex 3***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

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***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

19. 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***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

20. Guidance on good data and record management practices. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 5.
Short name: WHO GDRMP guidance or ***WHO TRS No. 996, Annex 5***
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf

21. WHO general guidance on variations to multisource pharmaceutical products. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 10.
Short name: WHO Multisource guidance or ***WHO TRS No. 996, Annex 10***
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

22. 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
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

23. 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-detail/978-92-4-000182-4

24. 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-detail/978-92-4-000182-4

25. 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-detail/978-92-4-000182-4

26. 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/medicines/areas/quality_safety/quality_assurance/TRS1010annex9.pdf?ua=1