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Prequalification Unit Inspection Services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)

Desk Assessment of Active Pharmaceutical Ingredient (API) Manufacturer

Part 1	**General information**
Company information	
Name of Manufacturer	Aurore Pharmaceuticals Private Limited- Unit I
Corporate address of manufacturer	Plot # 68,69, 2nd Floor, Jubilee Heights, Beside Shilparamam, Madhapur, Hyderabad, Telangana. Pin Code: 500081 India Telephone +91-40-68303211 Fax: +91-40-23110044
Contact person	Mr. Dr. G. Sampath Kumar Reddy (Head – Quality & Regulatory) Phone: +91-40-68150349 Mobile: +91-8185804214 Email: drsampath@aurorels.com Mr. N. Shanmugavelu (Vice President Operation) Phone: +91-40-68150309 Mobile: +91-9063239680 Email: Velu.NS@aurorels.com
Inspected site	
Name & address of manufacturing site	Aurore Pharmaceuticals Private Limited- Unit I Plot No. 35, 36, 38 to 40, 49 to 51, Phase IV, IDA, Jeedimetla, Quthbullapur (M) Medchal-Malkajigiri District, Hyderabad, Telangana State Pin: 500055, India Phone: +91-40-68150333, 23097777 Fax: +91-40-23098572 DUNS: 91-656-8827 Latitude N: 17° 31.842 Longitude E: 78° 26.184 FEI NUMBER 3003937580
Synthetic Unit/Block/Workshop	Unit 1

Manufacturing license number	License no. 99/RR/AP/B/CC	
Desk assessment details		
Start and end dates of review	4 – 6 March 2025	
Inspection record number	INSP-API-2022-0040	
APIs covered by this desk assessment	WHOAPI-435 Dolutegravir Sodium APIMF461 Nirmatrelvir	
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments**	
United States Food and Drug Administration (USFDA).	Dates of inspection:	27 – 31 May 2024
	Type of inspection:	Surveillance and Pre-Approval inspection
	Block/Unit/Workshop:	Aurore Pharmaceuticals Private Limited (Unit I)
	APIs covered:	The commercial APIs covered during the surveillance portion of the inspection were: • Clozapine (ZCL) - DMF 036645 • Valganciclovir (VGN) - DMF 034600 • Telmisartan III (TST) - contract manufactured product for Mylan laboratories. • Armodafinil (RMF) - contract manufactured product for Mylan laboratories. • Candesartan Cilexetil (CDC) • Levothyroxine Sodium (LTS): nonsterile API for injectable products - DMF034044 • Benazepril HCl (BHAF) - contract manufactured product for Aurobindo Pharma Limited • Oxcarbazepine (OCZF) - DMF 034484 • Itraconazole (ITCF) Pre-approval coverage during the inspection was provided to the following APIs: • Verapamil HCl (VPH) - DMF 034043 • Acyclovir (ALV) - DMF 034516
	Physical areas inspected:	Surveillance portion of the inspection included coverage for Quality, Facilities and

		Equipment, Materials, and Laboratory Controls systems. The inspection covered manufacturing blocks I, II, and IV.
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	The last onsite audit of this site was performed from 13 to 16th March 2018. The site changed name from Mylan Unit III to Aurore Pharmaceuticals Private Limited in August 2018.	
Additional products to be covered by this desk assessment:	None	
Abbreviations	**Meaning**	
BMR	Batch manufacturing record	
BPR	Batch production record	
CAPA	Corrective and preventive action	
CC	Change control	
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	
SOP	Standard operating procedure	

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

a) Manufacturing authorization and GMP certificate granted by the local authority:
Drug Control Administration, Government of Telangana had issued manufacturing license No. 99/RR/AP/B/CC, which was valid until 28 October 2028. Dolutegravir and Nirmatrelvir were among the list of products approved to be manufactured in the letter associated with the of the manufacturing license.

The company had Good Manufacturing Certificate No. 168476/TS/2025 dated 25 February 2025 and valid until 24 February 2026, issued by Drug Control Administration Government of Telangana.

b) Site master file (SMF):
A detailed SMF (APLU1/SMF/001/10) effective 16 January 2025 was submitted and found acceptable.

c) List of all the APIs or other products (intermediates, dosage forms) manufactured on-site:
A list of all the APIs and intermediates manufactured on-site was provided and reviewed. No issues of concerns were found with respect to the provided list.

d) List of all regulatory inspections performed in the last 3 years and their outcomes:

Authority	Date	Outcome
MFDS – Republic of Korea	19-21 November 2024	Approved
US - FDA	27-31 May 2024	Approved (VAI)
ANVISA - Brazil	27 November – 1 December 2023	Approved
CDSCO/ DCA - India	22-23 May 2023	Approved
CDSCO/ DCA - India	17-19 January 2022	Approved

e) Most recent product quality review(s) (PQR)(s) of the concerned WHO API(s):
The Product Quality Review for Dolutegravir Sodium (DGS) covering the period from January 2024 to December 2024 and Product Quality Review for Nirmatrelvir (LCC) covering the period from January 2024 to December 2024 were reviewed.

Generally, the PQRs were acceptable.

f) Batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of relevant API(s):
Batch manufacturing and packaging record(s), including the analytical part of the last commercial batches of Dolutegravir Sodium and Nirmatrelvir were submitted. These were generally found acceptable.

g) Master batch manufacturing and packaging record(s) of the API(s) of interest:
Master batch manufacturing and packaging records of Dolutegravir Sodium and Nirmatrelvir were submitted and reviewed.
The documents were generally found acceptable.

h) Recalls in the past three years related to APIs with quality defects:
The company provided a statement confirming that no recalls had taken place prior to submission of the application for the desk assessment.

i) Confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the API(s) has been performed and all matters dealt with:
The company had in place a system for intra audits. The intra audit report and its CAPA response were submitted and the same were reviewed. The documents were generally found acceptable.

j) Copy of any warning letter, or equivalent regulatory action, issued by any authority for their market, to which the site provides or has applied to provide the API(s):
The company submitted a statement confirming that no warning letters had been issued by any regulatory authorities against the site until the application for desk assessment was submitted.

k) Out-of-stock situations:
The company submitted a statement confirming that no out-of-stock situation was foreseen for WHO PQ products.

l) Additional documents submitted:
The company submitted upcoming inspection declaration letter to confirm that there was no notification from competent national regulatory authorities and no regulatory audits were planned for the next 6 months.

Part 5	Conclusion – Desk assessment outcome

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 **Aurore Pharmaceuticals Private Limited-Unit I** located at **Plot No. 35, 36, 38 to 40, 49 to 51, Phase IV, IDA, Jeedimetla, Medchal-Malkajigiri District, Hyderabad, 500055, 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
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. Fifty-seventh Report. Geneva, World Health Organization, 2024 (WHO Technical Report Series, No. 1052), Annex 4.
   Short name: WHO TRS No. 1052, Annex 4
   https://www.who.int/publications/i/item/9789240091030

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. Fiftieth 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

28. Good trade and distribution practices for pharmaceutical starting materials. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 6.
Short name: WHO TRS No. 996, Annex 6
https://www.who.int/publications/m/item/annex-6-trs-996

29. WHO guidelines for preparing a laboratory information file. *WHO Expert Committee on Specifications for Pharmaceutical Preparations.* Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 13.
Short name: WHO TRS No. 961, Annex 13
https://www.who.int/publications/m/item/trs961-annex13

30. WHO good manufacturing practices for excipients used in pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-seventh Report. Geneva, World Health Organization, 2024 (WHO Technical Report Series, No. 1052), Annex 1.
Short name: WHO TRS No. 1052, Annex 1
https://www.who.int/publications/i/item/9789240091030