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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	SYMED LABS LIMITED (Unit-II)
Corporate address of manufacturer	Plot No.290, Srivalli's Corporate, Road No.6, Kakatiya Hills, Madhapur, Hyderabad - 50008 1, Telangana, INDIA. Tel: +9 1 -40 23635000 Fax: +9 1 -40-23549428
Inspected site	
Name & address of manufacturing site	SYMED LABS LIMITED UNIT-II, Plot No. 25/B, Phase-III, IDA, Jeedimetla (Village), Quthbullapur (Mandal), Medchal-Malkajgiri (Dist.) - 500 055 Telangana, INDIA. Tel: +9 1-40-23 191 337 Fax No: +9 1 -40-23 549428
Synthetic Unit/Block/Workshop	Unit -II
Manufacturing license number	FORM 25 NO: 26/RR/AP/2003/B/R
Desk assessment details	
Start and end dates of review	24 – 27 November 2025
Inspection record numbe	INSP-API-2019-0056
APIs covered by this desk assessment	WHOAPI-332 Linezolid (pre-qualified)
List of documents submitted	a. list of all regulatory inspections performed in the last 3 years and their outcomes. b. The full inspection reports, including deficiency letters, for inspections performed by a competent stringent regulatory authority in the past three years with a certified translated copy where this is not in English. c. Proof of CAPA implementation and final decision by the competent stringent regulatory authority. d. A copy of the manufacturing authorization and GMP certificate granted by the local national authority. e. The list of all the products including API manufactured onsite.

	f. The most recent product quality review (PQR) of the concerned products. g. The list of any recalls in the past three years related to any product manufactured on site with quality defects. h. A confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the product has been performed and all matters dealt with. i. Master batch manufacturing and packaging records of the WHO product of interest. j. 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. k. Description of any recent or foreseen out-of-stock situations. l. A list of notifications of upcoming inspections by competent national regulatory authorities in the next 6 months. m. Table to specify which parts of the manufacturing process for the concerned product were covered by the inspection of the competent SRA authorities performed in the last 3 years.	
Any documents missing?	Not applicable	
Part 2	**Summary of SRA/WLA inspection evidence considered**	
National Centre for Public Health and Pharmacy (NCPHP), Hungary.	Dates of inspection:	19 – 24 May 2025
	Type of inspection:	The inspection was carried out on the behalf of the EU to check the compliance of APIs with EU GMP standards.
	Block/Unit/Workshop:	Unit II
	APIs covered:	Amisulpride - Agomelatine (Form-I & Form-II) Brimonidine Tartrate Carvedilol R0-CEP Cynitapride Hydrogen Tartrate Dapoxetine HCl Eszopiclone Hydroxyzine HCl Itopride HCl Ketorolac Tromethamine Lanthanum Carbonate Levocetirizine Dihydrochloride **Linezolid (Form-III)** Meclozine HCl Racecadotril

		Iron Sucrose Thalidomide
	Physical areas inspected:	Full inspection according to Eudralex Vol. 4, including QMS, Personnel, Facilities and Equipment, Documentation, Production, Quality Control, Outsourced Manufacturing, Complaints and Recall, and Self-Inspection.
United States Food and Drug Administration (USFDA), US.	Dates of inspection:	21 – 25 April 2025
	Type of inspection:	Voluntary action indicated (VAI)
	Block/Unit/Workshop:	(Unit II)
	APIs covered:	Non-sterile API by chemical synthesis manufactured at Unit II, including **Linezolid** and Hydroxyzine Pamoate.
	Physical areas inspected:	Quality, Production, Packaging and Labeling, and Laboratory Systems.
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	The site was not subject to an onsite inspection by WHO in the last 5 years.	

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:
License issued from Drug Control Administration, Government of Telangana, Number of license FORM 25 NO: 2/RP/AP/2003/B/R. Issued on 28/05/2023 and Valid up to 26/05/2028.

Certificate of GMP from Drug Control Administration, Government of Telangana No:186852/TS/2025, valid up to 14/10/2026.

b) Site Master File (SMF):
A detailed SMF was submitted and found acceptable.

c) List of all the APIs or other products (intermediates, dosage forms) manufactured on-site:
32 Products are manufactured on site II and these were reviewed, no issues of concerns were found.

d) List of all regulatory inspections performed in the last 3 years and their outcomes:
Symed Labs Limited **(Unit-II)** Regulatory Inspection Details

No.	Authority	Date	Outcome
1	Anvisa-Brazil	31 /07 /2023 - 04/08/2023	Accepted
2	USFDA	21/04/2025 - 25/04/2025	Accepted
3	NIP-Hungary	19/05/2025 - 24/05/2025	Accepted
4	Anvisa-Brazil (Desk Review)	18/09/2025 - 22/09/2025	Accepted
5	CDS CO	25/06/2025 - 26/06/2025	Accepted

e) Most recent product quality review(s) (PQR)(s) of the concerned WHO API(s):
Product Quality Review for Linezolid covered the whole year of 2024. Generally, the PQR was 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 Linezolid was 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 record(s), of Linezolid was submitted. These 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 have taken place at Unit II for the last three years.

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:
A letter was submitted stating that self-inspections and also external inspections were conducted and CAPAs were implemented to ensure the status of compliance is maintained for all quality systems.

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 confirmed that no warning letters have been issued by any regulatory authorities against the site (Unit II) until the application for desk assessment was submitted.

k) Out-of-stock situations:
The company declared that no out-of-stock situation is foreseen for WHO PQ products

l) Additional documents submitted:
Not applicable

Part 5	Conclusion – Desk assessment outcome

Based on the previous ***National Centre for Public Health and Pharmacy (NCPHP), Hungary*** **and The** ***United States Food and Drug Administration (USFDA),*** 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 **SYMED LABS LIMITED, UNIT-II** located at **Plot No. 25/B, Phase-III, IDA, Jeedimetla (Village), Quthbullapur (Mandal), Medchal-Malkajgiri (Dist.) - 500 055 Telangana, 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