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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	Neuland Laboratories Limited
Corporate address of manufacturer	11th Floor (5th Office Level), Phoenix IVY Building, Plot No. 573A-III, Road No. 82, Jubilee Hills, Hyderabad - 500033, Telangana, India
Inspected site	
Name & address of manufacturing site	Neuland Laboratories Limited Unit-I, Sy. No.: 291, 346P, 347, 348P, 473, 474, 490/2, Veerabhadraswamy Temple Road, Domadugu Village, Bonthapally Village, Gummadidala Mandal, Sangareddy District, 502 313 Telangana State, India.
Synthetic Unit/Block/ Workshop	Unit-1, Block 1 (Line II) is approved to manufacture the levofloxacin API (the site also contains the following manufacturing blocks: Block-II, Block-III, Block-IV, Block-V, Block-H, Block-KL, Block-S)
Desk assessment details	
Date of review	8 June 2026
APIs covered by this desk assessment	Levofloxacin Hemihydrate
List of documents submitted	→ List of all regulatory inspections performed in the last 3 years, including outcomes; → US FDA Establishment Inspection Report (EIR), including deficiencies; → EDQM inspection report, including deficiencies; → Manufacturing authorization and GMP certificate issued by the local authority; → Current Site Master File (SMF), including water and HVAC system descriptions; → Full list of all products manufactured on-site, including INNs and product types; → Annual Product Quality Review (PQR) for Levofloxacin; → Completed batch manufacturing and packaging records for the most recent Levofloxacin batch, including analytical data; → List of product recalls in the last 3 years;

	→ Declaration confirming completion of self-inspection or external audit for Levofloxacin; → Master batch manufacturing and packaging records for Levofloxacin; → Declaration confirming absence of warning letters or regulatory enforcement actions; → Declaration on past or anticipated out-of-stock situations; → Declaration of any planned regulatory inspections within the next 6 months; → Completed table specifying: • manufacturing facilities/rooms • equipment • packaging lines • shared vs dedicated status • coverage by SRA inspections. • confirmation that the last released batch was indeed manufactured in 2024 (BMR, BPR and analytical report provided). • Information regarding shared product-contact equipment that is used for levofloxacin and other APIs, as well as the cleaning validation approach.	
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments**	
USFDA	Dates of inspection:	18–22 March 2024
	Type of inspection:	GMP inspection (pre-announced)
	Block/Unit/Workshop:	All
	Type of APIs covered:	Multiple APIs including Levofloxacin Hemihydrate
EDQM/ ANSM	Dates of inspection:	7-9 June 2023
	Type of inspection:	GMP inspection (specific type not specified)
	Block/Unit/Workshop:	Not specified
	Type of APIs covered:	Enalapril maleate (CEP)
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	Neuland Unit 1 had been inspected by the WHO PQT Inspection Services Team on 6-9 February 2018 and was found to be GMP compliant for the manufacture of levofloxacin hemihydrate API. It was desk-assessed in 2022 with a conclusion that the site is GMP compliant for the manufacture of levofloxacin hemihydrate API.	
Brief summary of manufacturing activities	The site manufactures a broad portfolio of diverse active pharmaceutical ingredients and intermediates.	

General information about the company and manufacturing site	The firm operates from three manufacturing facilities – Unit-1 (Bonthapally), Unit-2, (Pashamylaram), Unit-3 (Gaddapotharam) and one R&D facility (Bonthapally). Unit 1 was established in 1984 for the manufacture of Active Pharmaceutical Ingredients (APIs) and intermediates. It is authorized by the local authority for the manufacture of non-beta lactam and non-penicillin APIs and intermediates only. Its area is approximately 16.2 acres and comprises eight production blocks dedicated to API and intermediate manufacturing. All production blocks are multipurpose, except for Block S, dedicated to peptides and specific products manufacturing. Block S also houses a process development laboratory for optimization and investigation activities. Additional infrastructures include QC laboratories, kilo lab, multiple warehouses, utility areas and administrative buildings. Warehouses are segregated by material type. There is a total of 453 employees at the site. The raw water supply is sourced from bore wells and undergoes pre-treatment including chlorination and filtration. Water systems include generation of raw, soft, and purified water using RO, EDI and ultrafiltration processes. Purified water is circulated through loops with UV disinfection, meeting pharmacopoeial standards (USP and EP). HVAC systems support cleanroom environments classified to ISO8, with HEPA filtration (0.3 µm) and controlled airflow parameters. Cleanroom environments are validated periodically, with monitoring of airflow, pressure differentials, particle counts, temperature and humidity.
Focus of the last WHO inspection	Not applicable
Areas inspected	Not applicable
Out of scope and restrictions (last WHO inspection)	Not applicable
WHO APIs covered by the last WHO inspection	The last desk assessment covered the same API, levofloxacin hemihydrate.
Additional products to be covered by this desk assessment:	There are no additional products to be covered.
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:
The Drugs Manufacturing License dated: 01/01/2022, valid up to: 31/12/2026 was provided.

b) Site master file (SMF):

The current SMF was submitted. While the facility, utilities, and general QMS framework are well described, the SMF did not contain significant detail to support extensive multipurpose manufacturing. Overall, the SMF is acceptable but does not include detailed, risk-based GMP documentation. Nevertheless, the USFDA inspection report clearly covered the levofloxacin API, as well as cleaning validation and cross-contamination controls, therefore these areas are considered to meet GMP requirements overall.

c) List of all the APIs or other products (intermediates, dosage forms) manufactured on-site:

The site manufactures 34 different APIs in total. The list includes many high potency and pharmacologically diverse APIs (highly active CNS products, hormone-like products (eg. Elagolix sodium), antifungals, fluoroquinolone antibiotics, APIs active at very low doses, such as paliperidone palmitate). Therefore the cross-contamination control strategy and risk-based cleaning limits are considered essential. There should be justification for shared facilities vs dedicated areas. This is considered to have been covered by the inspections performed by EDQM/ANSM and USFDA and therefore is considered to meet GMP requirements overall. Furthermore, the manufacturer was requested, on 27 May 2026 to provide the list of APIs that are manufactured on the same equipment as for levofloxacin hemihydrate and the risk-based justification for the cleaning that is used in between product change overs, if applicable. The manufacturer responded stated that the levofloxacin hemihydrate equipment train was shared with mirtazapine, rabeprazole sodium, escitalopram oxalate

and provided information on the applied limits and controls that is considered acceptable in view of the coverage of these aspects by the authorities who inspected the site.

d) List of all regulatory inspections performed in the last 3 years and their outcomes:
The site declared having been inspected only by the EDQM (June 7 to June 9, 2023) and by the USFDA (March 18 to March 22, 2024) in the last 3 years.

e) Most recent product quality review(s) (PQR)(s) of the concerned WHO API(s):
One PQR was submitted, covering the period of January 2025 to December 2025. A significant number of batches was manufactured and released. Information on OOSs was provided with identification of root cause. No rejected batches, recalls or complains/returns were reported for this API. Only one significant (major) deviation was reported.

The manufacturing process is considered robust and capable based on statistical indicators (Cpk above 1.0 for all key quality attributes).

The validation status review stated that no new process of cleaning validation was performed. The existing validation was considered adequate by the company. It is noted that no revalidation activity was reported by the company (ie., limited details on validation lifecycle management are limited).

Laboratory incidents and change controls were described. No reprocessing or rework was done.

f) Batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of relevant API(s):
The executed records and analytical records were submitted for the last batch manufactured and tested by the manufacturer. No issues were noted during the review of these documents.

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

The master batch records were submitted. No issues were noted.

h) Recalls in the past three years related to APIs with quality defects:
The list of recalls in the last 3 years was provided. There have been no recalls for levofloxacin hemihydrate API.

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 signed declaration was submitted, that a full self-inspection has been completed.

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):
A signed statement was provided, confirming that no regulatory actions (Warning letter or equivalent) were taken by any regulatory authority in the last three years.

k) Out-of-stock situations:
A signed declaration was submitted, confirming that there are no foreseeable out of stock situations and that such situations have not occurred recently either.

l) Additional documents submitted:

-A signed statement was submitted, dated 13 March 2026, that no inspections have been accounted by any competent authorities for the next six months.

-A signed document, entitled "Areas and products covered by the SRA authorities" was submitted. In the dossier, it is stated that Unit-1, Block 1 (Line II) is used to manufacture the levofloxacin hemihydrate API.

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 ***Neuland Laboratories Limited,*** *Unit-I* located at *Sy. No.: 291, 346P, 347, 348P, 473, 474, 490/2, Veerabhadraswamy Temple Road, Domadugu Village, Bonthapally Village, Gummadidala Mandal, Sangareddy District, Pin code 502 313, Telangana State, India*, is considered to be operating at an acceptable level of compliance with WHO GMP guidelines for APIs.

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-eight Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. ***Short name: WHO TRS No. 986, Annex 2***
   https://digicollections.net/medicinedocs/documents/s21467en/s21467en.pdf

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***
   untitled (digicollections.net)

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://digicollections.net/medicinedocs/documents/s23457en/s23457en.pdf

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
   https://www.who.int/publications/m/item/trs-1025-annex-4

5. 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 1019, Annex 3
   https://www.who.int/publications/m/item/trs1019-annex3

6. 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

7. 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

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
   https://www.who.int/publications/m/item/trs957-annex3

9. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Sixth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 2.
   Short name: WHO TRS No. 1044, Annex 2
   TRS 1044 - 56th report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations

10. WHO guidelines on transfer of technology in pharmaceutical manufacturing. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Sixth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
    Short name: WHO TRS No. 1044, Annex 4
    TRS 1044 - 56th report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations

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
https://cdn.who.int/media/docs/default-source/medicines/norms-and standards/guidelines/distribution/trs961-annex9-modelguidanceforstoragetransport.pdf?sfvrsn=b80e925f_5

12. 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

13. 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

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/docs/default-source/medicines/norms-and-standards/guidelines/production/trs981-annex2-who-quality-risk-management.pdf

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://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs981-annex3-who-variations-prequalified-product.pdf?sfvrsn=809e81b_2

16. 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://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/distribution/trs992-annex4.pdf?sfvrsn=2a1980f0_2

17. 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://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/distribution/trs992-annex5.pdf?sfvrsn=99aedfbe_2

18. 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 Multisource guidance or **WHO TRS No. 996, Annex 10**
https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/regulatory-standards/trs966-annex10.pdf?sfvrsn=5d94f486_2

19. 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/docs/default-source/medicines/norms-and-standards/guidelines/production/trs1010-annex8-who-gmp-heating-ventilation-airconditioning.pdf?sfvrsn=c77698e2_0

20. 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://extranet.who.int/pqweb/sites/default/files/documents/TRS1010_Annex10.pdf

21. Production of water for injection by means other than distillation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Forth 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

22. Good chromatography practice. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Forth 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

23. 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-Forth 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

24. Points to consider when including Health-Based Exposure Limits (HBELs) 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 1033, Annex 2**
https://www.who.int/publications/m/item/annex-2-trs-1033

25. 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 1033, Annex 3
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

26. 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 1033, Annex 4
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations