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Prequalification Team Inspection Services
WHO PUBLIC INSPECTION REPORT

Desk Assessment of Finished Product Manufacturer

Part 1	**General information**
Company information	
Name of Manufacturer	Cipla Ltd
Corporate address of manufacturer	Cipla House Peninsula Business Park Ganpatrao Kadam Marg Lower Parel, Mumbai-400 013 India
Inspected site	
Name & address of manufacturing site	Cipla Ltd. Unit VII Plot No. S-103 to S-105, S-107 to S-112, L-147, L-147/1 to L-147/3, L-138 and L-147/A; Verna Industrial Estate, Verna, Salcette, Goa. Pin: 403 722, India
Production Block/Unit	Unit VII
Desk assessment details	
Start and end dates of review	5 –8 May 2025
Products covered by this desk assessment	1. CV021 – Molnupiravir Capsules, hard 200mg (Not commercialized) 2. IN001 – Oseltamivir (phosphate) Capsules, hard 75mg (Not commercialized) 3. HA702 – Dolutegravir (sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg (Not commercialized) 4. HA060 – Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg 5. HA500 – Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/200mg/300mg 6. HA439 – Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 200mg/300mg 7. TB205 – Levofloxacin Tablet, Film-coated 250mg 8. TB227 – Levofloxacin Tablet, Film-coated 500mg
List of documents submitted	a. Regulatory Inspections List (Past 3 years) b. Current full inspection report (Past 3 years) c. Proof of CAPA implementation-Latest inspection report d. Manufacturing Authorization and GMP certificate e. Site Master File f. List of all the products and dosage forms manufactured on-site g. Product Quality Reviews h. Completed BMR and BPR including the analytical part

	i. List of Recalls (Past 3 years) j. A confirmation by SQA -Self-inspection or external audit k. Master BMR and BPR-WHO product(s) l. Copy of any warning letter, or equivalent regulatory action m. Description of recent or foreseen out-of-stock situations n. A list of upcoming inspections (Next 6 months) o. Manufacturing Process for the concerned products covered by the inspection of the competent SRA authorities performed (Past 3 years)
Any documents missing?	None.
Part 2	**Summary of SRA/NRA inspection evidence considered and comments**

US FDA, USA	Dates of inspection:	10 to 21 June 2024
	Type of inspection:	Un-announced for-cause GMP inspection
	Block/Unit:	Unit I, Unit III, Unit IV, Unit V, Unit VII, Unit VIII and Unit X.
	Type of products/Dosage forms covered:	Sterile and non-sterile drug products for the US market including oral solid dosage, topical gel/cream, sterile inhalation products and sterile injectable products.
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	18-20 and 22-23 March 2019 GMP compliant after CAPAs.	
Brief summary of manufacturing activities	Unit VII: Production and quality control of solid dosage forms: uncoated, coated tablets, hard gelatin capsules.	
General information about the company and manufacturing site	Cipla Ltd. is a public limited company established in 1935. It manufactures a wide range of pharmaceutical formulations, Active Pharmaceutical Ingredients & Medical device products. The site at Goa including 9 Units (in operation) are engaged in manufacturing of pharmaceutical formulations. Each manufacturing unit has independent water system, warehouse, technical floor for HVAC systems and Analytical Laboratory.	
Focus of the last WHO inspection	The focus of the inspection included storage, production and quality control areas where WHO Prequalification products were manufactured.	
Areas inspected	**Document reviewed including but not limited** • Organization Chart	

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- Job descriptions for key personnel
- Product Quality Review
- Quality Risk Management
- Management Review
- Responsibilities of the quality units and production
- Complaints and Recalls
- Deviation control and change control
- OOS and investigation
- CAPA procedure
- Material release
- Validation and qualification
- Equipment calibration
- Data integrity
- Sampling and testing of materials
- Batch processing records
- Materials management system
- Purified water system

Sites visited

Unit VII - stores, production and packing, and quality control
</td></tr>
<tr><td>Out of scope and restrictions (last WHO inspection)</td><td>Products not submitted to WHO for Prequalification was out of inspection scope.</td></tr>
<tr><td>WHO products covered by the last WHO inspection</td><td>
<table>
<tr><th></th><th>WHO No.</th><th>Product Name</th><th>Manufacturing Unit</th></tr>
<tr><td colspan="4">List of products commercially supplied since last WHO inspection in June 2016</td></tr>
<tr><td>1.</td><td>HA039</td><td>Nevirapine Tablet 200mg</td><td>III & (IV, VII)</td></tr>
<tr><td>2.</td><td>HA060</td><td>Lamivudine/Zidovudine 150/300mg tablets</td><td>III & VII (IV)</td></tr>
<tr><td>3.</td><td>HA365</td><td>Lamivudine/ Nevirapine/ Zidovudine 150/200/300mg tablets</td><td>III & VII (IV)</td></tr>
<tr><td>4.</td><td>HA352</td><td>Efavirenz Tablet, Film coated 600mg</td><td>IV & VII</td></tr>
<tr><td>5.</td><td>HA439</td><td>Emtricitabine/ Tenofovir disoproxil fumarate 200/300mg fil coated tablet</td><td>VII & (III, IV)</td></tr>
<tr><td>6.</td><td>HA500</td><td>Efavirenz/ Emtricitabine/ Tenofovir disoproxil fumarate 600/200/300 film coated tablet</td><td>VII & (III, IV)</td></tr>
<tr><td>7.</td><td>HA401</td><td>Tenofovir disoproxil fumarate 300mg film coated tablet</td><td>VII & (III, IV)</td></tr>
<tr><td>8.</td><td>HA593</td><td>Efavirenz/ Lamivudine/ Tenofovir 600/300/300mg tablets</td><td>VII & VII PDII</td></tr>
<tr><td>9.</td><td>RH039</td><td>Misoprostol tablet 200mcg</td><td>VIII</td></tr>
<tr><td>10.</td><td>RH040</td><td>Levonorgestrel Tablet 750mcg</td><td>VIII</td></tr>
<tr><td>11.</td><td>RH046</td><td>Levonorgestrel Tablet 1.5mg</td><td>VIII</td></tr>
<tr><td>12.</td><td>HA353</td><td>Lamivudine Tablet 150mg</td><td>III, IV & VII</td></tr>
<tr><td>13.</td><td>MA064</td><td>Artemether/ Lumefantrine tablets</td><td>III, IV & VII</td></tr>
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			20/120mg	
	14.	TB205	Levofloxacin Tablet Film coated 250mg	III, IV & VII
	15.	TB227	Levofloxacin Tablet Film coated 500mg	III, IV & VII
	16.	HA352	Efavirenz Tablet Film coated 600mg	III
	17.	TB228	Cycloserine Capsules 250mg	IV & VII
	18.	HA518	Abacavir and Lamivudine 60/30mg	VII
	19.	IN013	Oseltamivir PO4 Capsules hard 45mg	VII
	20.	IN012	Oseltamivir PO4 Capsules hard 30mg	VII
	21.	IN001	Oseltamivir PO4 Capsules hard 75mg	VII
	22.	RH030	Ethinylestradiol/ Levonorgestrel + Placebo Ethinylestradiol/ Levonorgestrel Tablet + Placebo tablet 0.03mg/0.150mg+0mg	VIII
	Dossier under assessment			
	HA702		Dolutegravir/ Lamivudine/ Tenofovir disoproxil fumarate 50 mg/ 300 mg/ 300 mg Tablets	VII & VII PD II
Additional products to be covered by this desk assessment:	None.			

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	Nonconformity
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 3 years and their outcomes:

Sr. No	Dates of Inspection	Regulatory Authority	Outcome
1.	20 – 22 August 2024	ZAMRA, Zambia	Final Inspection Report Awaited
2.	10-21 June 2024	US FDA	VAI
3.	26-27 March 2024	MCAZ, Zimbabwe	Approved
4.	7-9 August 2023	MOH Libya	Approved
5.	3-4 July 2023	MOH Yemen	Company Re-registration. Certificate awaited
6.	20 – 24 March 2023	INVIMA, Colombia	Approved
7.	02 – 03 February 2023	PPB, Kenya	Approved
8.	14-15 November 2022	TMDA Tanzania	Approved
9.	16-26 August 2022	US FDA	OAI
10.	25-26 April 2022	CDSCO and DFDA, Goa Joint Inspection	Approved
11.	Desk assessment	TGA, Australia	Approved
12.	8-9 February 2022, Desktop assessment	RFDA, Rwanda	Approved

b) Manufacturing authorization and GMP certificate granted by the local authority:

1. The copy of following manufacturing licenses issued by Food &Drugs Administration (FDA), Goa, India was provided.

Name of the license holder and Address	License no.	Valid up to
M/s Cipla Limited, Plot No. S-103 to S-105, S-107 to S-112, L-138, L-147, L-147/1 to L-147/3, L-147-A, Verna Industrial Estate, Verna, Salcete-Goa - 403 722.	611 in Form 28	18/03/2028
	616 in Form 25	19/05/2028

2. The copy of GMP certificate No. 789/MFG/WHO-GMP/DFDA/2022/886 issued by Food &Drugs Administration, Government of Goa, India on 22/06/2022 was provided, which is valid until 13th June 2025.

c) Site master file:

The copy of Site Master File: SMF/CIP/GOA/F Version No.: 18, effective on 26 September 2024, copy of P & ID of Water System and copy of P & ID of Air Handling Unit were provided and reviewed with no objectional findings.

According to the SMF, 3270 people was employed on the Goa site, which included 1669 in Production, 407 in QA and 917 in QC Department, 159 in Storage and distribution and 118 in Engineering Department. No activity other than manufacturing of pharmaceutical formulations is carried out at the site. Site does not manufacture sensitizing materials like Beta-lactams (Penicillin) or Cephalosporin or biological preparations e.g., live organisms. Types of products currently manufactured on-site were documented in the SMF. The site has 9 different units and Unit IX was shut down. Types of products currently manufactured on-site were documented in the SMF.

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

e) Most recent product quality reviews (PQRs) of the concerned WHO products:
The manufacturing status of products in the desk assessment scope was provided by the company. The following APQRs provided were reviewed with no objectional findings.

Sr. No	PQ No.	FPP	APQR Review Period
1.	CV021	Molnupiravir Capsules, hard 200mg	APQR/1009/24-24
2.	IN001	Oseltamivir (phosphate) Capsules, hard 75mg	APQR/1009/23-24
3.	HA702	Dolutegravir (sodium)/ Lamivudine/ Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/ 300mg/ 300mg	APQR/1009/24-24
4.	HA060	Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg	APQR/1009/24-24
5.	HA500	Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/ 200mg/ 300mg	APQR/1009/24-24
6.	HA439	Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 200mg/300mg	APQR/1009/24-24

f) Batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of relevant product(s):
The company provided the BMRs/BPRs of following products. They were reviewed with no objectional findings.

Sr. No.	Product Name
1.	Molnupiravir Capsules, hard 200mg (CV021)
2.	Oseltamivir (phosphate) Capsules, hard 75mg (IN001)
3.	Dolutegravir (sodium)/ Lamivudine/ Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/ 300mg/300mg (HA702)
4.	Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg (HA060)
5.	Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/ 200mg/ 300mg (HA500)
6.	Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 200mg/300mg (HA439)

g) Master batch manufacturing and packaging record(s) of the product(s) of interest:
Master BMRs/BPRs for CV02, IN001, HA060, HA500, HA702 and HA439 were provided, and reviewed with no objectional findings.

h) Recalls in the past three years related to products with quality defects:
The company declared that, there were no recalls in the past 3 years.

I) 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:
The company confirmed that, as per Internal Audits SOP, the internal audits program is being carried out at a defined frequency for Goa site. The internal audits were conducted at., Unit III, IV, VII, VII PD II and VIII at Goa site of Cipla Ltd. and each reported observation was satisfactorily complied.

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:

The company declared that, currently, no warning letter, or equivalent regulatory action, is in force by any authority to Cipla Ltd. Unit VII, Plot No. S-103 to S-105, S-107 to S-112, L-147, L-147/1 to L-147/3, L-138 and L-147/A; Verna Industrial Estate, Verna, Salcette, Goa. Pin: 403 722, India.

k) Out-of-stock situations:

The company declared that, the products which were commercialized were found/observed with no out of stock situation.

l) Additional documents submitted:

No upcoming Inspection notification is received to Cipla Ltd. Unit VII, Plot No. S-103 to S-105, S-107 to S-112, L-147, L-147/1 to L-147/3, L-138 and L-147/A, Verna Industrial Estate, Verna, Salcette, Goa. Pin: 403 722, India.

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 **Cipla Ltd., Unit VII** located at **Plot No. S-103 to S-105, S-107 to S-112, L-147, L-147/1 to L-147/3, L-138 and L-147/A; Verna Industrial Estate, Verna, Salcette, Goa, 403722, 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 GMP or TRS No. 986, Annex 2***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

2. 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

4. 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/

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

6. 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/

7. 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, 2019 (WHO Technical Report Series, No. 1019), Annex 2. **Short name: WHO TRS No. 1019, Annex 2**
https://apps.who.int/iris/bitstream/handle/10665/312316/9789241210287-eng.pdf?ua=1

8. 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://apps.who.int/iris/bitstream/handle/10665/312316/9789241210287-eng.pdf?ua=1

8. 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. 961, 957), Annex 1
http://www.who.int/medicines/publications/44threport/en/

9. 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 2.
Short name: WHO TRS No. 957, Annex 2
http://www.who.int/medicines/publications/44threport/en/

10. 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

11. 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

12. 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

13. 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

14. 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

15. 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/

16. 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/

17. 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

18. 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

19. 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

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

21. 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 TRS No. 996, Annex 5
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf

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