World Health Organization

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Prequalification Unit Inspection Services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Desk Assessment of Finished Product Manufacturer

Part 1	**General information**
Company information	
Name of Manufacturer	Cipla Ltd, Patalganga Unit II, Formulation (FPP)
Corporate address of manufacturer	Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400 013, India. Telephone: + 91 22 24826000 Website: www.cipla.com
Contact person	Mr. P. Gnanamoorthy Tel: +91 2192 660900 (Unit - I) / 660400 (Unit - II) Email: p.gnanamoorthy@cipla.com
Name & address of manufacturing site	Cipla Ltd. Plot No.: A-42 (Unit-II) MIDC, Patalganga, District Raigad, Maharashtra 410 220 India. Telephone: +91 2192 660400 (Unit - II) FEI NUMBER 3002806710 D-U-N-S 916940208
Production Block/Unit	Unit II, Formulations, Plot No. A-42
Manufacturing license number	License No 25-KD-620 and 28-KD-453 issued on18.08.2021.
Desk assessment details	
Start and end dates of review	05/02/2025 to 08/02/2025
Inspection record number	INSP-FPP-2020-0159
Products covered by this desk assessment	1. MA102 Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg 2. MA103 Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg 3. MA104 Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg 4. HA662 Abacavir (sulfate)/Lamivudine Tablet, Dispersible 120mg/60mg 5. HA639 Isoniazid/Pyridoxine hydrochloride/ Sulfamethoxazole/ Trimethoprim Tablet 300mg/25mg/800mg/160mg 6. MA079 Artesunate/Mefloquine (hydrochloride) Tablet, Film-coated 100mg/200mg 7. MA078 Artesunate/Mefloquine (hydrochloride) Tablet, Film-coated 25mg/50mg

	8. MA064 Artemether/Lumefantrine Tablet 20mg/120mg 9. ANDA 203759 USFDA Ritonavir Tablet 100mg 10. HA741 Ritonavir Tablet, Film-coated 25mg 11. HA743 Abacavir (sulfate)/Lamivudine Tablet, Film-coated 600mg/300mg- 12. HA770 Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 400mg/300mg/300mg 13. HA778 Ritonavir Tablet, Film-coated 100 mg 14. CV016 Nirmatrelvir Tablet, Film-coated + Ritonavir Tablet, Film-coated. 150mg + 100mg (DA applied to Ritonavir Tablet only) 15. CV016 Nirmatrelvir Tablet, Film-coated + Ritonavir Tablet, Film-coated. 150mg + 100mg (DA applied to Ritonavir Tablet only) 16. CV016 Nirmatrelvir Tablet, Film-coated + Ritonavir Tablet, Film-coated. 150mg + 100mg (PQ status: under assessment) 17. CV028 Nirmatrelvir Tablet, Film-coated + Ritonavir Tablet, Film-coated. 150mg + 100mg (DA applied to Ritonavir Tablet only) 18. HA797 Dolutegravir (sodium)/Lamivudine/Tenofovir alafenamide Tablet, Film-coated 50mg/300mg/25mg (PQ status: under assessment) 19. HA666 Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated300mg/300mg	
Any documents missing?	Nil	
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments**	
United States Food and Drug Administration (USFDA), US	Dates of inspection:	28 Match 2024 – 04 April 2024
	Type of inspection:	NA
	Block/Unit:	Units I (API) and II (API and Formulation).
	Type of products/Dosage forms covered:	The inspection report indicated that the firm produces and distributes API's and oral solid dosage forms for several markets, including the US. The report was included several exhibits including a list of finished drug products and for APIs that the firm has manufactured and distributed to all countries since the last inspection. As well as lists of the firm's products and APIs shipped to the US market.
	Physical areas inspected:	This inspection focused on the firm's QMS, Quality, Production, Facilities and Equipment, Packaging and Labelling, and Laboratory Systems that serve as the foundation for production at the Patalganga site. The inspection included physical inspection of the firm's facilities and equipment, observation of manufacturing, review of records, and interviews with employees.

Part 3	Summary of the last WHO inspection
Date and conclusion of most recent WHO inspection	The site was not inspected onsite by WHO in the last 5 years. The last WHO inspection was made through desk assessment in 2020 and the site was concluded as compliant with WHO GMP guidelines.

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	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
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:

Authority	Date	Inspection type	Outcome
United States Food and Drug Administration (USFDA), US	28/03/2024 - 04/04/2024	onsite	EIR received
Zazibona Countries Inspection Team	14/03/2024 - 16/03/2024	cGMP compliance	Approved
State of Libya Ministry of Health (Pharmacy Department), Libya	05/10/2023	onsite	Approved
Ministry of Health and population, supreme Board of Drugs and Medical Appliances, Republic of Yemen	24/07/2024	onsite	Approved
WHO-GMP, Central Drugs Standard Control Organization (COSCO) Unit-II	18/07/2022 - 19/07/2022	onsite	Approved

b) Manufacturing authorization granted by national authorities:
License issued from Food & Drugs Administration (Maharashtra State). Number of license 25-KD-620 and 28-KD-453 issued on 18.08.2021 and valid up to: 17/08/2026.

c) Site master file:
A detailed SMF (SMF/CIP/PTG/F) dated 14/01/2025 was submitted and found acceptable.

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 reviewed, and no issues of concerns were found.

e) Most recent product quality review(s) (PQR)(s) of the concerned WHO product(s):
The APQR of the following products were submitted and were generally acceptable.

- MA102, MA103, and MA104 Amodiaquine (hydrochloride)/Artesunate Tablet (67.5mg/25mg), (135mg/50mg) and (270mg/100mg)
- HA662 Abacavir (sulfate)/Lamivudine Tablet, Dispersible 120mg/60mg
- HA639 Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim Tablet300mg/25mg/800mg/160mg
- MA079 and MA078 Artesunate/Mefloquine (hydrochloride) Tablet, Film-coated (25mg/50mg) and (100mg/200mg)
- MA064 Artemether and Lumefantrine Tablets 20mq/120mg
- HA770 Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated400mg/300mg/300mg
- CV028 Nirmatrelvir Tablet, Film-coated + Ritonavir Tablet, Filmcoated 150mg + 100mg.
- HA797 Dolutegravir (sodium)/Lamivudine/Tenofovir alafenamide Tablet, Film-coated50mg/300mg/25mg

f) Batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of relevant product(s):
These batch manufacturing and packaging records were included, these were revised and found acceptable. The BMR / BPR for some products ware not submitted as these were not WHO commercialized.

g) Master batch manufacturing and packaging record(s) of the product(s) of interest:
MBMR and MBPR were submitted and generally were acceptable.

h) If any of the products are sterile, the completed batch records for the most recent media fill validation that is relevant to the product(s) of interest and report on its outcome:
Nil

i) Recalls in the past three years related to products with quality defects:
The company provided a statement confirming that no recalls have taken place until the application for desk assessment was submitted.

j) 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:

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

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:

The company confirmed that no warning letters have been issued by any regulatory authorities against the site until the application for desk assessment was submitted.

l) Out-of-stock situations:

No out-of-stock situation is foreseen for WHO PQ products.

m) Additional documents submitted:

Nil

Part 5	**Conclusion – Desk assessment outcome**

Based on the previous **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 **Cipla Ltd, Patalganga Unit II, Formulation (FPP)** located at **Cipla Ltd. Plot No.: A-42 Formulation (Unit-II), MIDC Patalganga, District Raigad, Maharashtra 410 220, 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://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 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
9789240020900-eng.pdf (who.int)

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://digicollections.net/medicinedocs/documents/s21440en/s21440en.pdf

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**
https://digicollections.net/medicinedocs/documents/s23455en/s23455en.pdf

7. 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
https://digicollections.net/medicinedocs/documents/s20108en/s20108en.pdf

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
https://digicollections.net/medicinedocs/documents/s18681en/s18681en.pdf

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 3.
Short name: WHO TRS No. 957, Annex 3
https://digicollections.net/medicinedocs/documents/s22358en/s22358en.pdf

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
https://digicollections.net/medicinedocs/documents/s19959en/s19959en.pdf

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
https://digicollections.net/medicinedocs/documents/s18677en/s18677en.pdf

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***
https://digicollections.net/medicinedocs/documents/s18683en/s18683en.pdf

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***
https://digicollections.net/medicinedocs/#d/s21438en

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
https://digicollections.net/medicinedocs/documents/s18682en/s18682en.pdf

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
https://digicollections.net/medicinedocs/#d/s20177en/

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
https://digicollections.net/medicinedocs/#d/s20175en/

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. 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://digicollections.net/medicinedocs/documents/s23697en/s23697en.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***
Essential Medicines and Health Products Information Portal (digicollections.net)

21. 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***
9789240020900-eng.pdf (who.int)

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

23. 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

24. WHO good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (part 2): interpretation of guidelines. 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://digicollections.net/medicinedocs/documents/s23699en/s23699en.pdf

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**
9789240020900-eng.pdf (who.int)

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**
9789240001824-eng.pdf (who.int)

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-detail/978-92-4-000182-4

28. 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