

**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	Cipla Ltd, Patalganga Unit I (API)	
Corporate address of manufacturer	Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400 013 India. Telephone + 91 22 24826000 Web site www.cipla.com	
Contact person	P Gnanamoorthy Tel: +91 2192 660900 (Unit - I) Email: p.gnanamoorthy@cipla.com	
Inspected site		
Name & address of manufacturing site	Cipla Ltd. Plot No.: A-33, A-2 & A-37/2/2 (Unit-I) API MIDC Patalganga, 410 220, District Raigad, Maharashtra, India. FEI NUMBER 3002806710 Telephone +91 2192 660900 (Unit - I) D-U-N-S 916940208	
Synthetic Unit/Block/Workshop	Plot No.: A-33, A-2 & A-37/2/2 (Unit-I)	
Manufacturing license number	License no. 25- 845 and 28- 707 valid up to 31/12/2027.	
Desk assessment details		
Start and end dates of review	9 – 11 February 2025	
Inspection record number	INSP-API-2020-0157	
APIs covered by this desk assessment	APIMF004 Artesunate APIMF328 Daclatasvir dihydrochloride	
Any documents missing?	Not applicable	
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:	28 March - 4 April 2024
	Type of inspection:	Not available
	Block/Unit/Workshop:	Units I (API) and II (API and Formulation).
	APIs 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

Cipla Ltd, Patalganga Unit I (API), Patalganga, India

9 – 11 February 2025

This inspection report is the property of the WHO

Contact: prequalinspection@who.int

		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 subject to an onsite inspection 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	
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 Food & Drugs Administration (Maharashtra State). Number of license no. 25- 845 and 28- 707 issued on 01.01.2023 and valid up to: 31.12.2027.

Certificate of GMP from office of the commissioner, Food and Drug Administration M. S. Bandra, Mumbai No: NEW-WHO-GMP/CER/KD/143185/2025/11/53767 valid up to 10.02.2028.

b) Site master file (SMF):

A detailed SMF (SMF/CIP/PTG/A) dated 13/01/2025 was submitted and found acceptable.

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

A list of APIs produced at the site was submitted and the same was reviewed. No issues of concerns were found.

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

Authority	Inspection type	Date	Outcome
United States Food and Drug Administration (USFDA)	GMP onsite inspection	28 Mar – 04 Apr 2024	EIR issued with VAI classification
WHO-GMP, Central Drugs Standard Control Organisation (CDSCO) Unit-I	GMP onsite inspection	28 – 29 Nov 2024	Approved
Pharmaceuticals and Medical Devices agency (PMDA), Japan	Desk assessment	08 Mar 2024	Approved
Therapeutic Goods Administrations TGA. Australia	Desk assessment	13 Dec 2022	Approved
ANVISA, Brazil	GMP onsite inspection	10 – 14 Jul 2023	Approved

e) Most recent product quality review(s) (PQR)(s) of the concerned WHO API(s):

Product Quality Review for Artesunate covering the period from September 2023 to August 2024 was submitted and the same was reviewed..

Product Quality Review for Daclatasvir dihydrochloride covering period from March 2023 to February 2024 was submitted and the same was reviewed.

Generally, the PQRs were found 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 Artesunate and Daclatasvir dihydrochloride 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 record(s), of Artesunate and Daclatasvir dihydrochloride were 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 until the application for desk assessment was submitted.

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 are conducted and CAPAs are 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 until the application for desk assessment was submitted.

k) Out-of-stock situations:

A statement was provided by the manufacturer which indicated 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 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** located at **Plot No.: A-33, A-2 & A-37/2/2 (Unit-I, API), MIDC Patalganga, 410 220, District Raigad, Maharashtra, 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>