

**Prequalification Unit Inspection services  
WHO PUBLIC INSPECTION REPORT  
(WHOPIR)**

**Desk Assessment of Active Pharmaceutical Ingredient (API) Manufacturer**

<b>Part 1</b>	<b>General information</b>	
<b>Company information</b>		
Name of Manufacturer	Sun Pharmaceutical Industries Limited	
Corporate address of manufacturer	SPARC, Tandalja, Vadodara – 390012 Gujarat, India 24 Hrs. Contact No: (+91) 7069010539, (+91) 7069010540	
Contact Person	Contact Person: Mr. Bhojusing Girase Telephone No: (+91)-2641-280000 Email: <a href="mailto:Bhojusing.Girase@sunpharma.com">Bhojusing.Girase@sunpharma.com</a>	
<b>Inspected site</b>		
Name & address of manufacturing site	Plot No. Z-15, Dahej SEZ-1 Industrial Area, Dahej-392130, Taluka-Vagra, District-Bharuch, Gujarat, India. Geographical location: - Latitude (N): 21°42'16.11" N - Longitude (E): 72°37'42.84" E FEI Number: 3010027135 DUNS Number: 860038081	
Synthetic Unit/Block/Workshop	Not applicable	
Manufacturing license number	Form 25 No: G/25/2044 granted on 11 April 2014. It was valid up to 10 April 2029.	
<b>Desk assessment details</b>		
Start and end date of review	7 and 10 March 2025	
Inspection record number	INSP-API-2022-0016	
APIs covered by this desk assessment	WHOAPI-354 Dolutegravir Sodium WHOAPI-436 Dolutegravir Sodium	
<b>Part 2</b>	<b>Summary of SRA/NRA inspection evidence considered (from most recent to last)</b>	
<i>Pharmaceutical and Medical Devices Agency (PMDA), Japan</i>	Dates of inspection:	4 – 7 April 2023
	Type of inspection:	GMP compliance inspection before approval of partial changes in approved information related to the addition of a manufacturing site of the API, "Fluvastatin Sodium".
	Block/Unit/Workshop:	Pilot Plant A402A, A402B, A401
	Type of APIs covered:	Fluvastatin Sodium

	Physical areas inspected:	Buildings and facilities of the manufacturing site as well as the manufacturing and quality controls of “Fluvastatin Sodium,” the active pharmaceutical ingredient (API) of the product under inspection, included: <ul style="list-style-type: none"> <li>• Manufacturing area: Pilot Plant A402A, A402B, A401</li> <li>• Testing area: Physicochemical Laboratory, Microbiological Laboratory</li> <li>• Storage area: Product warehouse, raw material warehouse, low-temperature raw material warehouse, primary packaging material warehouse, secondary packaging material warehouse</li> <li>• Others: Utilities</li> </ul>
<b>Part 3</b>	<b>Summary of the last WHO inspection</b>	
Date and conclusion of most recent WHO inspection	No previous onsite inspection had been conducted by WHO of this site. The last WHO inspection of this site was conducted through desk assessment in 2021 and the site was concluded as compliant with WHO GMP guidelines.	
Additional products covered by this desk assessment:	N/A	
<b>Abbreviations</b>	<b>Meaning</b>	
BMR	Batch manufacturing record	
BPR	Batch production record	
CAPA	Corrective and preventive action	
CC	Change control	
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	
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 license to manufacture for sale in Form 25 No: G/25/2044 granted on 11 April 2014 was valid through 10 April 2029. The list of products manufactured on site according to the license included Dolutegravir Sodium.

GMP Certificate No. 24095254 was issued by the Food and Drugs Control Administration Gujarat State, India based on the inspection carried out on 18-19 April 2024 and 6 September 2024. Dolutegravir Sodium was included in the list of products (APIs) approved for grant of COPP as per the national guidelines which was based on WHO GMP Guidelines valid from 12 September 2024 to 11 September 2027.

**b) Site master file (SMF):**

Site Master File No. SMF000019 version 5.0 dated 25 January 2024 was submitted. Overall, the information on the SMF was in accordance with the WHO TRS No. 961, Annex 14.

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

Based on the Annexure of the SMF, there were a total of 13 products manufactured on site, including Dolutegravir Sodium.

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

No	Date of Audit	Name of Authority	Status
1.	4-7 April 2023	Pharmaceutical and Medical Devices Agency, Japan	Complies
2.	6-10 March 2023	National Health Surveillance Agency (ANVISA), Brazil	Complies

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

The Product Quality Review of Dolutegravir Sodium (DOT) and Dolutegravir Sodium (DOL) for January 2023 to December 2023 were submitted. Both documents were 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) of the last commercial batches of Dolutegravir Sodium manufactured using the Process 1 and Process 2 methods were submitted. These were generally found acceptable.

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

The company submitted the master documents for manufacturing of Dolutegravir Sodium using the Process 1 and Process 2 methods. These were generally found acceptable.

**h) Recalls in the past three years related to APIs with quality defects:**

The company confirmed that there was no product recall including quality defects in the past three years from the date of signature.

**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:**

The company submitted a statement confirming that they had system and programme for conducting self-inspections. The self-inspections were performed annually covering all internal functions.

**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 submitted a statement confirming that there was no warning letter or any equivalent regulatory action by any regulatory authority where the API Dolutegravir Sodium was manufactured.

**k) Out-of-stock situations:**

The company submitted a statement confirming that there was no out-of-stock situation considering the API Dolutegravir Sodium.

**l) Additional documents submitted:**

N/A

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 **Sun Pharmaceutical Industries Limited** located at **plot no. z-15, Dahej Sez-1 Industrial area, Dahej-392130, Taluka-Vagra, District-Bharuch, Gujarat, 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 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 GMP for APIs or TRS No. 957, Annex 2**  
<http://apps.who.int/medicinedocs/documents/s20119en/s20119en.pdf>
2. 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 Guidelines or WHO TRS No. 986, Annex 2**  
[http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/expert\\_committee/trs\\_986/en/](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/)

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/medicines/areas/quality\\_safety/quality\\_assurance/TRS1010annex9.pdf?ua=1](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/](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](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/](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1010/en/)
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**  
[http://whqlibdoc.who.int/trs/WHO\\_TRS\\_937\\_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_937_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](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](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](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](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](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/](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/](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](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](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](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](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](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](http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf)

23. WHO Recommendations for quality requirements when plant – derived artemisin is used as a starting material in the prosecution 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**

[http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/expert\\_committee/WHO\\_TRS\\_992\\_web.pdf](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf)

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**

[http://www.who.int/medicines/publications/pharmprep/WHO\\_TRS\\_996\\_annex10.pdf](http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf)