

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

Part 1	General information
Company information	
Name of Manufacturer	RV Lifesciences Limited
Corporate address of manufacturer	401-405, Hubtown Viva, Western Express Highway, Shankarwadi, Jogeshwari (East), Mumbai-400060, Maharashtra, India. Phone: 0091 22 68170901 Email: info@rvlifesciences.com
Inspected site	
Name & address of manufacturing site	Plot No. H-19, MIDC, Waluj, Chhatrapati Sambhajnagar- 431133 Maharashtra State – India Phone: 0091 240 6649300 Email: contact@rvlifsciesnces.com GPS Coordinates: 19.85663, 7522193 D-U-N-S: 65-030-3245
Production Block/Unit	Solid dosage form (coated) Tablets.
Manufacturing license number	Manufacturing license No. AD/011 (frm-25: Non-Biological products) valid up to 31/12/2027
Desk assessment details	
Start and end dates of review	8 – 10 April 2026
Inspection record number	INSP-FPP-2025-0015
Products covered by this desk assessment	HP035 Entecavir tablets film coated 0.5 mg. HP036 Entecavir tablets, film coated 1 mg
List of documents submitted	<ol style="list-style-type: none"> a) A list of all regulatory inspections performed in the last 5 years and their outcomes. b) The full inspection reports, including deficiency letters, for inspections performed by a competent stringent regulatory authority in the past five years with a certified translated copy where this is not in English. c) Proof of CAPA implementation and final decision by the competent stringent regulatory authority. d) A copy of the manufacturing authorization and GMP certificate granted by the local national authority. e) A site master file whose approval date was not more than one year ago. f) The list of all the products including API and FPPs manufactured onsite.

	<p>g) The most recent product quality review (PQR) of the concerned products.</p> <p>h) The completed process validation protocol and report, batch manufacturing and packaging records.</p> <p>i) The list of any recalls in the past three years related to any product manufactured on site with quality defects.</p> <p>j) A confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the product has been performed and all matters dealt with.</p> <p>k) Master batch manufacturing and packaging records of the WHO product of interest.</p> <p>l) 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.</p> <p>m) Description of any recent or foreseen out-of-stock situations.</p> <p>n) A list of notifications of upcoming inspections by competent national regulatory authorities in the next 6 months.</p> <p>o) Table to specify which parts of the manufacturing process for the concerned product were covered by the inspection of the competent SRA authorities performed in the last 3 years.</p>	
Missing documents?	Not applicable	
Part 2	Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments	
<i>European medicine agency (EU audit, INFARMED, Portugal)</i>	Dates of inspection:	24 – 28 February 2025
	Type of inspection:	Routine inspection
	Block/Unit:	<ul style="list-style-type: none"> ➤ Reception and warehouse for raw materials (GF-099), packaging and finished products (GF-093). ➤ Production rooms (Dispensing-II for excipients (GF-019), dispensing-I for active pharmaceutical ingredients (GF-015) and dispensed materials room (GF-018). GF-008 and GF-006 – Sampling rooms. ➤ Production rooms associated to products to be marketed in the European market: GF-115 and GF-049 – compression rooms 6 and 1; GF-037 – blending-II; GF-035 – Granulation-3; GF-056 – Coating-2; GF-067 and GF-063 – inspection-II and inspection I; GF-047 – capsule filling room; GF-039 and GF-065 - bulk storage room; GF-045 and GF-063 – Change part rooms; GF-071 – packaging-3.

		<ul style="list-style-type: none"> ➤ The quality control areas and stability room ➤ The purified water system; air treatment system, compressed air system.
	Type of products/Dosage forms covered:	<ul style="list-style-type: none"> ➤ Tablets, including coated, and uncoated unit ➤ Hard gelatin capsules unit The inspection scope included quality control testing operations namely (1) chemical / physical and (2) microbiological (non-sterility).
	Any sections of GMP not covered?	N/A
<i>European medicine agency (EU audit, INFARMED, Portugal)</i>	Dates of inspection:	18 – 22 April 2022
	Type of inspection:	Pre-Certification
	Block/Unit:	- Tablets, including coated, and uncoated unit - Hard gelatin capsules unit
	Type of products/Dosage forms covered:	Rivaroxaban Tablets 10/15/20 mg Deferiprone Capsules 500 mg
	Any sections of GMP not covered?	N/A
Part 3	Summary of the last WHO inspection	
Date and conclusion of most recent WHO inspection	The site has never been subject to WHO onsite inspection. Instead, and earlier desk assessment was performed in 2025.	
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
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a) List of all regulatory inspections performed in the last 5 years and their outcomes:

Authority	Inspection type	Date	Outcome
TMDA – Tanzania Medicines and Medical Devices Authority, Tanzania.	Pre-certification	20 - 21 Dec 2019	Approved (certificate issued)
State FDA Audit, Maharashtra	Routine renewal	31 Mar 2021	Approved (certificate issued)
Central Drugs Standard Control Organization (CDSCO) and State Licensing Authority, India.	Pre-certification	14 - 15 Sep 2021	Approved (certificate issued)
European Medicine Agency (EU Audit- INFARMED, Portugal)	Pre-certification	18 - 22 Apr 2022	Approved (certificate issued)
PICS NPRA – National Pharmaceutical Regulatory Agency, Malaysia.	Routine renewal	18 - 21 Jul 2022	PIC/S CAPA response was completed and handed over to MA Holder in Malaysia. However, it was eventually decided to pursue local distribution of the product with EU approval status instead of PIC/S.
FDA, Ministry of Health, Uzbekistan	Pre-certification	27 - 28 Jul 2022	Approved (certificate issued)
State FDA Audit, Maharashtra	Routine renewal	15 - 16 Feb 2023	Approved (certificate issued)
State FDA Audit, Maharashtra	Routine renewal	15 - 16 Mar 2024	Approved (certificate issued)
European Medicine Agency (EU Audit- INFARMED, Portugal)	Pre-certification	24 – 28 Feb 2025	Approved (certificate issued)

b) Manufacturing authorization granted by national authorities:

The manufacturing license and GMP compliance documentation were submitted. These were found to be valid until 31 Dec 2027.

c) Site Master File (SMF):

A detailed SMF was submitted and found acceptable.

d) List of all the products and dosage forms manufactured on-site:

The manufacturer provided two types of lists of products manufactured at the facility:

- 64 products manufactured for the company's own distribution.
- 33 products manufactured under contract manufacturing for other facilities.

A review of these lists confirmed that no beta-lactam antibiotics or other highly sensitizing products were included. No issues of concern were identified.

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

APQR (Annual product quality review) of Entecavir 0.5 mg tablets for the review period of October 2022 to September 2023 was submitted. Generally, the PQR was acceptable.

APQR (Annual product quality review) of Entecavir 1 mg tablets was submitted. Generally, the PQR was acceptable.

f) Batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of relevant product(s):

Batch manufacturing and packaging record(s), including the analytical part of the last commercial batches of Entecavir 0.5 mg and 1mg tablets were submitted. These were generally found acceptable.

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

The MBMR and MBPR of Entecavir 0.5 mg and 1 mg tablets were submitted. These were found generally acceptable.

i) Recalls in the past three years related to products with quality defects:

The manufacturer provided a statement signed on the 26th of September 2024 confirming that no recalls have taken place in the previous three years 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 by the manufacturer stating that self-inspections and external audits 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 manufacturer provided a statement confirming 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:

The manufacturer submitted a statement informing that no out-of-stock situation is foreseen for WHO PQ products.

D) Additional documents submitted:

Not applicable

Part 5	Conclusion – Desk assessment outcome
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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 **RV Lifesciences Limited**, located at **Plot No. H-19, MIDC, Waluj, Chhatrapati Sambhajnagar - 431133 Maharashtra State – 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
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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://digidocuments.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 (digidocuments.net)**
<https://digidocuments.net/medicinedocs/documents/s23457en/s23457en.pdf>
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://digidocuments.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 \(who.int\)](https://digidocuments.net/medicinedocs/documents/s23457en/s23457en.pdf)
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://digidocuments.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 \(digicollections.net\)](https://www.who.int/medicines/essential/essential_medicines_and_health_products_information_portal)
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 \(who.int\)](https://www.who.int/medicines/essential/essential_medicines_and_health_products_information_portal)

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. 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://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 \(who.int\)](http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf)
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 \(who.int\)](http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf)
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>