20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

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	Alivira Animal Health Limited
Corporate address of manufacturer	Alivira Animal Health Limited 301, 3rd Floor, Dosti Pinnacle, Plot No. E7, Road No.22 Wagle Industrial Estate, Thane (W), Mumbai – 400 604, India
Inspected site	
Name & address of manufacturing site	Plot No 104 to 109 & Part of 112 & 113, JNPC-SEZ Parawada Mandal Anakapalli District, Visakhapatnam, Andhra Pradesh, 531 019, India
Synthetic Unit/Block/Work shop	Production Building: PB-I Clean Room-101 Production Building: PB-I (Intermediate Area: Module-I & Module-II)
Desk assessment details	
Date of review	01-08 July 2025
APIs covered by this desk assessment	Praziquantel
List of documents submitted	1st Submission a) USFDA Inspections b) Establishment Inspection Report FDA 2023 c) USFDA CAPA Report d) Mfg License & GMP Certificate i. GMP & GLP ii. Form -28 Retention License iii. Retention License Form-25 e) SMF f) List of Products g) Praziquantel APQR h) Executed BMRs i) Sterile declaration j) Product Recall Declaration k) Internal audit declaration l) Master BMRs m) Declaration on regulatory actions n) Declaration on Out of stock o) Declaration on Upcoming Audits p) SRA Declaration

This inspection report is the property of the WHO
Contact: prequalinspection@who.int

	2nd submission 1. Manufacturing Facility Information 2. SMF Annexures 3. Process Flows 4. EIR & EIR Exhibits 5. US FDA 483 Form 6. USFDA EIR letter 7. Corporate Address Acknowledgment 8. Contact Details List	
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last)**	
US FDA	Dates of inspection:	18-22 September 2023
	Type of inspection:	Routine surveillance drug inspection
	Block/Unit/Workshop:	Production Block 1 Production Block 2
	Type of APIs covered:	8 products which are dispatched to the US market
Part 3	**Summary of the last WHO inspection**	

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

This inspection report is the property of the WHO
Contact: prequalinspection@who.int

Part 4	Summary of the assessment of supporting documentation

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

Drugs Manufacturing License issued by Government Of Andhra Pradesh Drugs Control Administration as per the provisions of Drugs and Cosmetics Act,1940 and Rules made there under.

- Form-25 bearing No. 24/VSP/AP/2014/B/R, Dated:19/07/2019 valid up to 18/07/2029
- Form-28 bearing No. 09/VSP/AP/2019/B/R, Dated:08/05/2019 valid up to 07/05/2029

License retention certificate issued by Government Of Andhra Pradesh Drugs Control Administration

b) Site master file (SMF):

Site Master File has been prepared in line with the format and guidance provided in WHO Technical Report Series No. 961, Annex 14.

It described the brief information of the firm, manufacturing activities performed, description of the quality system, regulatory compliance status, personnel, premises, equipment, sanitation, documentation, production, quality control, contract manufacturing, self-inspections, list of products., It also recorded the site's regulatory inspection history and licensing status. The document was scheduled for periodic review and update. The review of the submitted SMF revealed no non-conformities.

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

1. Albendazole
2. Butaphosphan
3. Carprofen
4 Clorsulon
5 Closantel Sodium
6 Febantel
7. Fenbendazole
8. Flunixin Meglumine
9. Firocoxib
10. Nitroscanate
11. Nitroxynil
12 Oxfendazole
13. Buparvaquone
14. Praziquantel
15. Triclabendazole
16 Toltrazuril
17. Ponazuril
18. Diclazuril
19. Robenacoxib
20. Ricobendazole
21. Deracoxib
22 Ractopamine HCl
23. Buparvaquone
24. Xylazine HCl
25. Decoquinate
26. Tulathromycin
27. Mavacoxib
28. Imidocarb dipropionate
29. Fluazuron
30. Zilpaterol HCI
31. Tildipirosin
32. Flubendazole
33. Levamisole Hydrochloride
34. Tetramisole Hydrochloride
35. Gamithromycin
36. Lufenuron
37. Afoxolaner
38. Fluralaner

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

Regulatory Authority	Year	Conclusion
US FDA	2023	Voluntary action Indicated (VAI)
CDSCO, India	2023	Approved
CDSCO, India	2024	Approved
CDSCO, India	2025	Approved

This inspection report is the property of the WHO
Contact: prequalinspection@who.int

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

The submitted Product Quality Review covered:

- Review on intermediates/APIs batches produced along with the dispatch details,
- Review on intermediates/APIs yield and quality trend of the batches with ±3 sigma,
- Review on intermediates/ APIs critical process parameter data and trend results,
- Review on intermediates/ APIs in-process control data and trend,
- Review on change controls (Product Related),
- Review on deviation reports filed and corrective action reports approved,
- Review on Lab Deviation reports filed,
- Review on number of customer complaints, returned goods and recalled goods,
- Review on number of reprocess and rework batches,
- Review on key starting material trend and rejections and check qualification state of vendors,
- Review on bioburden of product,
- Review on the stability data of intermediates/ APIs,
- Review on the retained samples,
- Review on Validation packages (Process, equipment, and test procedures),
- Review on drug master file and technical packages,
- Review on Regulatory Affairs,
- Review on out of specifications and brief description of out of specifications,
- Review on OOT,
- Review on product related specifications and Method of analysis
- Review on environmental monitoring.,
- Review of CAPA's

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

The batch manufacturing and packaging records demonstrated that the production was under validated and GMP-compliant conditions.

The provided manufacturing, packaging and testing records were in line with the master records (please refer to below item g) and confirmed that all quality control parameters met their respective specifications. The documentation was suitable to support GMP compliance under desk review.

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

The manufacturing of the APIs and their intermediates were based on formally approved and version-controlled Master Batch Manufacturing Records (MBMR).

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

The Company declared that there was no product recall during the past three years with any kind of quality defects for the products manufactured at the site.

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 declared that the full self-inspection dedicated to the products Praziquantel API has been performed as defined in internal audit procedure and all the CAPAs were dealt with.

This inspection report is the property of the WHO
Contact: prequalinspection@who.int

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 declared that no warning letter or equivalent regulatory action was issued by any authority.

k) Out-of-stock situations:
The Company declared that the Praziquantel API has no recent or foreseen out-of-stock situation.

l) Additional documents submitted:
None

Part 5	Conclusion – Desk assessment outcome

Based on the GMP evidence received and reviewed, the desk assessment is acceptable in lieu of a WHO onsite inspection. The site **Alivira Animal Health Limited,** located at **Plot No 104 to 109 & Part of 112 & 113, JNPC-SEZ Parawada Mandal, Anakapalli District, Visakhapatnam, Andhra Pradesh, 531 019, India** is considered to be operating at an acceptable level of compliance with WHO GMP guidelines for APIs.

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***
   untitled (digicollections.net)

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***
   https://digicollections.net/medicinedocs/documents/s21467en/s21467en.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://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

This inspection report is the property of the WHO
Contact: prequalinspection@who.int

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. 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

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

25. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation and air-conditionning 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

This inspection report is the property of the WHO
Contact: prequalinspection@who.int

26. 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)

27. 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)

This inspection report is the property of the WHO
Contact: prequalinspection@who.int