LICENSING AND ENFORCEMENT DIVISION

PUBLIC cGMP INSPECTION REPORT OF PHARMACEUTICAL MANUFACTURER:

Name of Company: Mistair Health & Hygiene (Pvt) Ltd

1.0 General information

1.1 Name of Inspected company	Mistair Health & Hygiene (Pvt) Ltd
1.2 Physical address	Mistair Health & Hygiene Pvt. Ltd. Plot No.3, MIDC, Shiroli, Kolhapur, 416122, India
1.3 Corporate address	5/8, Chandrashekhar Society, Vijaynagar Compound, Andheri East, Mumbai – 400069
1.4 Summary of the main activities performed	Manufacture of the following dosage forms for Human and Veterinary Use: i. Liquid Orals dosage forms – (Suspensions and Solutions) ii. Liquid and Semi-Solid dosage forms for external use - (Shampoos, Liquids, Cream, Ointments, and Aerosols) iii. Oral solid dosage forms – (Oral powders)
1.5 Scope of Inspection	Product based inspection to verify compliance to cGMP guidelines for the manufacture of Veterinary general: • Liquid Orals Dosage forms – (Suspensions) • Oral Solid Dosage Forms – (Oral Powders)
1.6 Purpose of Inspection	To ascertain cGMP compliance for the products which have been submitted for registration and those currently registered with the Medicines Control Authority of Zimbabwe (MCAZ)
1.7 Inspectors	Mr. Tendai Samkange – **Co-inspector** Mr. Clive S. Kamhoti – **Lead Inspector**
1.8 Date of Inspection	17th to 18th March, 2025

2.0 Abbreviations List

Abbreviation	Full Form / Meaning
cGMP	Current Good Manufacturing Practice(s)
GMP	Good Manufacturing Practice(s)
WHO	World Health Organization
MCAZ	Medicines Control Authority of Zimbabwe
PQR	Product Quality Review
CAPA	Corrective and Preventive Action
SOP	Standard Operating Procedure
BMR	Batch Manufacturing Record
BPR	Batch Packing Record
OOS	Out-of-Specification
QA	Quality Assurance
QC	Quality Control
AMV	Analytical Method Validation/Verification
PDE	Permissible Daily Exposure
HBEL	Health Based Exposure Limits
GRN	Goods Receipt Note / Goods Received Note
ERP	Enterprise Resource Planning

Abbreviation	Full Form / Meaning
MDMS	Manufacturing Document Management System
MRP	Maximum Retail Price (or possibly Manufacturing Record Page in this context)
API	Active Pharmaceutical Ingredient
HDPE	High-Density Polyethylene
HVAC	Heating, Ventilation, and Air Conditioning
AHU	Air Handling Unit
HEPA	High-Efficiency Particulate Air (filter)
TOC	Total Organic Carbon
USP	United States Pharmacopeia
IPQC	In-Process Quality Control
BP	British Pharmacopoeia
PH EUR / EUR	European Pharmacopoeia (Pharmacopoeia Europaea)
NF	National Formulary (often paired with USP as USP-NF)

Abbreviation	Full Form / Meaning
BPM	Bottles/Batches Per Minute
ACPH	Air Changes Per Hour
HMI	Human-Machine Interface
SCDA	Soybean Casein Digest Agar (a type of culture media)
EM	Environmental Monitoring
LIMS	Laboratory Information Management System
e-LIMS	Electronic Laboratory Information Management System

3.0 Summary

3.1 Brief summary about the facility

Mistair Health & Hygiene Pvt. Ltd. Plot No.3, MIDC, Shiroli, Kolhapur, 416122, India, was the site under the scope of the inspection, it was used for the manufacture of the following dosage forms for Human and Veterinary Use - Liquid Orals Dosage Forms (Suspensions and Solutions), Liquid and Semi-Solid Dosage Forms for External Use (Shampoos, Liquids, Cream, Ointments, and Aerosols), and Oral Solid Dosage Forms (Oral powders).
No sensitizing materials such as Beta-Lactams, or Penicillin were handled at the site.

The audit was conducted from the 17th to the 18th of March 2025. The company had been audited by other regulatory bodies as follows:

Country	Agency
Uganda	NDA Uganda
Nigeria	NAFDAC
Austrilia	APVMA

Zimbabwe	MCAZ
Ethiopia	VDFAC
South Africa	SAHPRA

3.2 General Information about the Company and the Site

This was a routine inspection of the site by the Medicines Control Authority of Zimbabwe (MCAZ) Inspectorate, to support the continuous registration of products registered in Zimbabwe. The inspection was product-based and focused on the products that were intended for the Zimbabwean market, as provided below:

Product	**Dosage Form**
Albendazole (Benvet) 10% Suspension, 200ml, 500ml, 1000ml & 5000ml bottles	Liquid oral dosage form (Suspension)

The inspection was conducted over two (2) days. The first day involved an introduction and company presentation meeting attended by senior members of the Mistair Health & Hygiene Pvt. Ltd, team and the MCAZ inspectorate.

The inspection was conducted with reference to and in accordance with the WHO Good Manufacturing Practices detailed in the Technical Report Series 986, Annex 2 of 2014, among other relevant current guidelines.

3.3 Areas inspected *(Not exhaustive)*

- **Quality Management**: Product Quality Review (PQR), Quality Risk Management, Deviation control, finished product and starting material batch release, Contract agreements and Supplier approval.
- **Materials Management**: Receipt, handling, quarantine, sampling, release, reject, temperature (and humidity) monitoring and dispensing.
- **Good Practices in Production**: Production areas, production equipment, documentation and instructions, sanitation cleaning and maintenance, batch records, calibration, contamination control, in process controls.
- **Quality Control**: Review of test procedures and specifications.
- **Utilities**: HVAC, Purified Water, Compressed Air system
- **Environmental Monitoring**: EM programme
- **Equipment qualification** and preventive maintenance

3.4 Utilities

a. Water Purification system
b. HVAC system
c. Compressed Air System

3.5 Documentation reviewed *(Not exhaustive)*

As stated in the final report

4.0 System Summaries

Walk through inspection

Warehouse Tour

A vertical inspection of the warehouse was done starting with the receiving, quarantine, under-test, approved materials areas. The receiving area was maintained in a good state of repair with a weather shield for product protection upon receipt. There was use of a receiving checklist for different materials received in the warehouse. Temperature was controlled and monitored in the different warehouse areas.

Batch Manufacturing Records

The batch manufacturing records of products in the scope of the inspection were reviewed and considered to be satisfactory. All the machine setup parameters were defined. Line clearance was being executed as per the requisite checklists. IPQC was being executed.

Annual Product Quality Review

The procedure for conducting product quality reviews was reviewed. The APQR reviewed the following aspects in line with the WHO TRS 986, Annex 2:

a. Review of starting/packaging materials
b. finished product results
c. Review of batches that failed to meet specifications, and investigations
d. Deviations, investigations & CAPA
e. Changes made to the processes or analytical methods
f. Dossier variations
g. Stability Monitoring program
h. Returns, complaints and recalls
i. Adequacy of Corrective actions
j. Post marketing commitments for new dossiers and variations to dossiers
k. Qualification status of equipment, utilities and area
l. Quality technical agreements

Preventative maintenance program

The site preventative maintenance program was reviewed. There was a generalized SOP for preventative maintenance as well as equipment-based SOPs for preventative maintenance. The frequency of preventative maintenance for production and other critical equipment was based on several factors such as frequency of breakdowns, criticality of equipment *et cetera*.

Vendor approval

The SOP for vendor approval for Raw and packaging materials was reviewed. The roles and responsibilities of the Head QA was clearly outlined in the procedure and included overseeing vendor audits. There was provision for annual vendor rating and disqualification.

Quality Control Tour

The Quality Control Laboratory was inspected and was found to be generally satisfactory. There was a system in place to account for samples for analysis from sampling intimation to sample receipt and analysis. There was a robust analyst qualification program in place.

Process Validation

The process validation protocols and reports of products in the scope of the inspection were reviewed. The acceptance criteria we well defined. Three batches were considered for validation validations triggered by major and critical changes.

Area Qualifications/HVAC qualification

Qualification of cleanrooms was in line with ISO 14644 guidelines.

Stability Monitoring

The procedure for stability monitoring of products was reviewed. There was a program in place for on-going stability monitoring.

Environmental Monitoring program

The Environmental Monitoring program SOP was reviewed. Active Air sampling was the main method of monitoring the clean rooms and was done once every month. Tryptic Soy Agar (TSA) was the main media in use as it accommodated the growth of bacteria and fungi.

Purified Water System (PW)

The pretreatment, generation and distribution line were inspected. The approach to sanitization of the water system was verified. The approach to preventative maintenance was verified. Critical parameters were being monitored online with provision of failure safe mechanisms. Sanitization records and critical parameters trend reports were submitted for review.

5.0 Observations

As stated in the final report

6.0 Conclusion

Based on the areas inspected, the people met, and the documents reviewed including the observations listed in the Inspection Report, **Mistair Health & Hygiene (Pvt) Ltd** located at, **Plot No.3, MIDC, Shiroli, Kolhapur, 416122, India** was considered to be operating at an acceptable level of compliance with cGMP guidelines for the manufacture of Veterinary Oral Solid Dosage Forms packaged as Powders and Veterinary Oral Liquid Dosage Forms.

All the non-compliances observed during the inspection listed in the full report were addressed by the manufacturer to a satisfactory level prior to the publication of the MCAZ PIR.

The site will be reinspected **2 years** from the date of the last inspection in line with the risk-based reinspection frequency determination.

7.0 References

1. WHO good manufacturing practices for pharmaceutical products: main principles. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Eight Report* Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2
   http://www.who.int/medicines/publications/pharmprep/en/index.html

2. WHO guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8, https://www.who.int/publications/m/item/Annex-8-trs-1010

3. Supplementary guidelines on good manufacturing practices: validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva,

World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 3 https://cdn.who.int/media/docs/default-source/medicines/norms-and standards/guidelines/production/trs1019-annex3-gmp-validation.pdf?sfvrsn=9440a5c_0&download=true

4. 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 http://www.who.int/medicines/publications/pharmprep/en/index.html

5. 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 http://www.who.int/medicines/publications/pharmprep/en/index.html

6. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. *WHO Expert Committee on specifications for pharmaceutical preparations*. *Forty-third report.* Geneva, World Health Organization, 2009. (WHO Technical Report Series, No. 953), Annex 2 http://www.who.int/medicines/publications/pharmprep/en/index.html

7. 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 http://www.who.int/medicines/publications/pharmprep/en/index.html

8. WHO Expert Committee on Specifications for Pharmaceutical Preparations. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty Ninth Report* Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 3 http://www.who.int/medicines/publications/pharmprep/en/index.html

9. WHO Expert Committee on Specifications for Pharmaceutical Preparations. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty Ninth Report* Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4 http://www.who.int/medicines/publications/pharmprep/en/index.html