INSPECTION METRICS REPORT – GMP INSPECTIONS FEBRUARY TO AUGUST 2025

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This report summarises inspection outcomes for public awareness and regulatory transparency in line with WHO Good Regulatory Practices.

LIST OF ABBREVIATIONS

APQR	–	Annual Product Quality Review
CAPA	–	Corrective Action and Preventive Action
cGMP	–	current Good Manufacturing Practice
GBT	–	Global Benchmarking Tool (WHO)
GMP	–	Good Manufacturing Practice
GPP	–	Good Practices in Production
HVAC	–	Heating, Ventilation and Air Conditioning
MCAZ	–	Medicines Control Authority of Zimbabwe
PQS	–	Pharmaceutical Quality System
PLC	–	Programmable Logic Controller
QC	–	Quality Control
RLAF	–	Reverse Laminar Airflow
SOP	–	Standard Operating Procedure
TOC	–	Total Organic Carbon
WHO	–	World Health Organization

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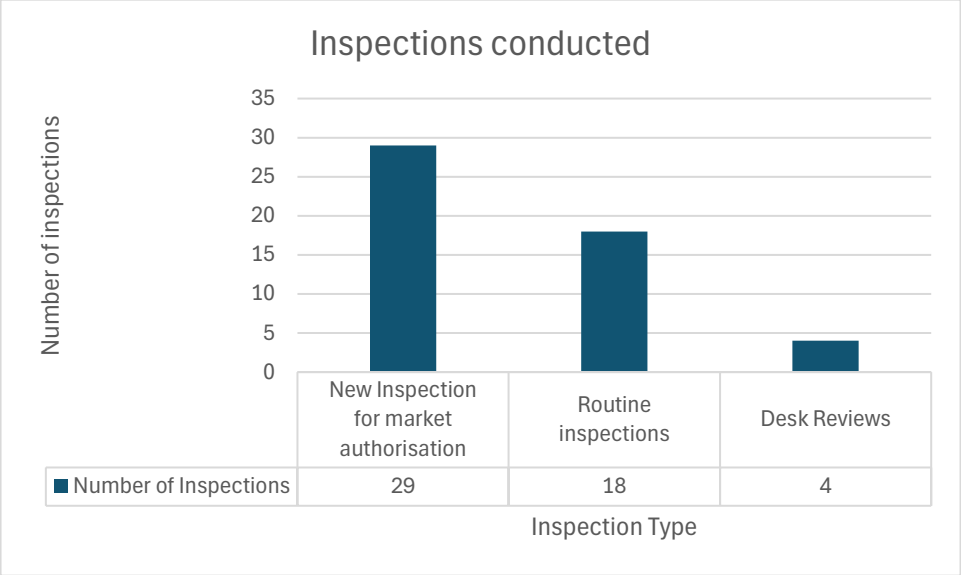
1.0 EXECUTIVE SUMMARY

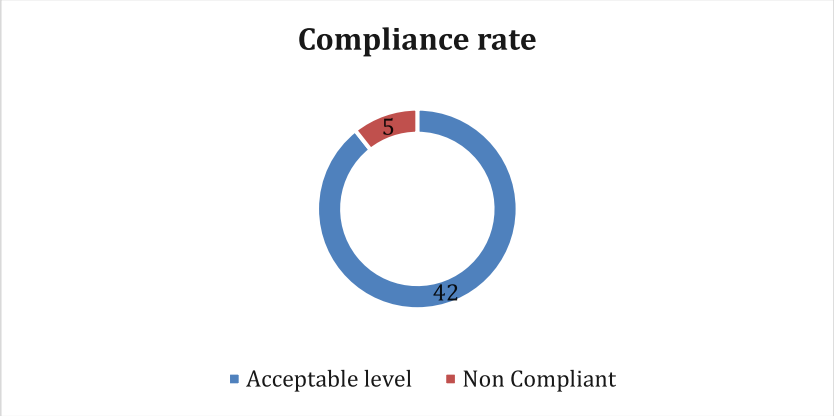
This report summarizes deficiencies identified across 47 GMP inspections, categorized by severity and inspection type. A total of 682 findings were recorded: 7 Critical, 496 Major, and 175 Minor. April 2025 showed the highest concentration of findings, while March 2025 also recorded a significant average (12 per inspection). Recurring deficiencies were most notable in Data Integrity, Visual Inspection/Defect Trending, and HVAC or Environmental Controls.

FIGURE 1: Number and type of inspections



MCAZ conducts inspections to support market authorization and in the period under review, a total of 29 companies were inspected before market authorization. A total of 18 companies were routinely inspected in line with the authority's risk-based scheduling and 4 desk reviews were conducted in line with the Authority's reliance policy. Of the 47 companies, 5 companies were operating below an acceptable level of compliance at the time of issuance of the final inspection report. All the desk reviews were acceptable. Of note, is that 47 represents the companies and not the individual facilities and dosage forms for each company.

FIGURE 2: Compliance Rate



From the 47 inspections conducted both locally and externally, a compliance rate of 89% was noted at the time of the final inspection report.

TABLE 1: Distribution of Findings by Severity

Category	Count	% of Total
Critical	7	1%
Major	496	73%
Minor	175	26%
Total	678*	100%

FIGURE 3: Distribution of Findings by Severity

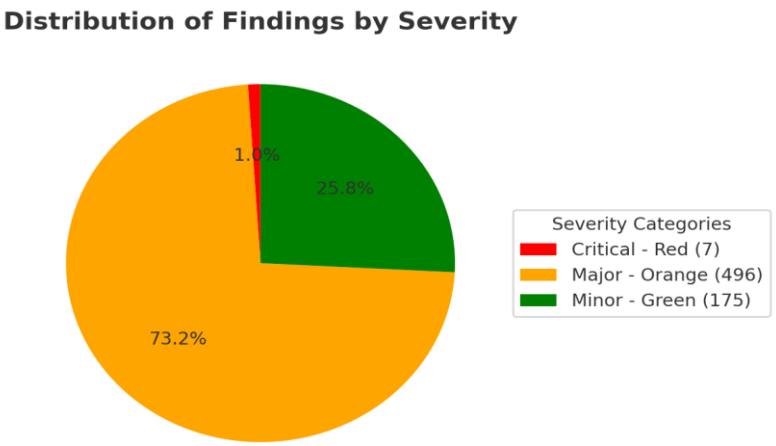
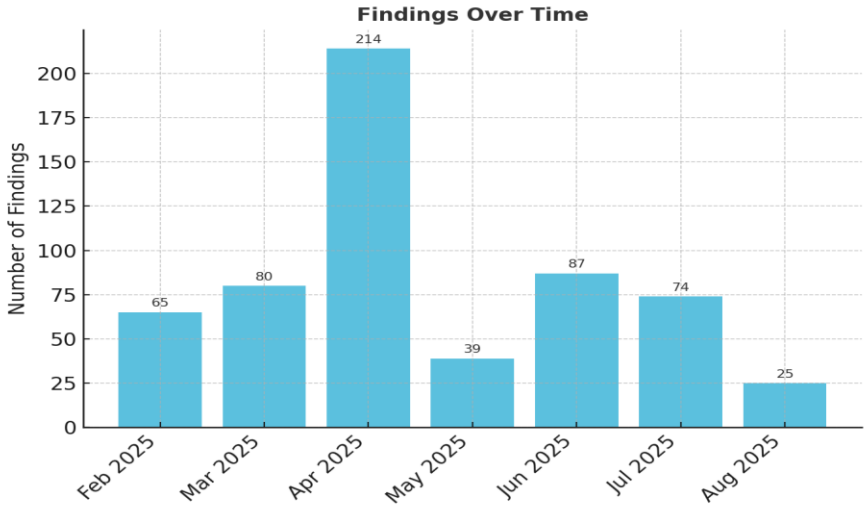


TABLE 2: Observations Over Time

Period	Reports	Findings	Avg / Report
Feb 2025	7	65	9.28
Mar 2025	7	80	11.43
Apr 2025	8	214	26.75
May 2025	5	39	7.8
Jun 2025	7	87	12.43
Jul 2025	8	74	9.25
Aug 2025	5	25	5

Highest deficiencies were observed in April 2025, averaging over 26 findings per inspection. March 2025 showed a combined total of 80 findings across six reports, averaging 12 per inspection. The lowest average finding rate occurred during August 2025 (5 observations per report). The inspections in April were mainly initial inspections to support market authorization and hence the number of observations. August inspections were mainly routine inspections of previously approved facilities.

FIGURE 4: Findings Over Time (with Values)



The observations noted were individual observations which would then be grouped according to the WHO seven (6) systems and data integrity being given as a standalone system. In April, the greatest number of observations were noted as new inspections to support market authorization were conducted.

2.0 SYSTEM-LEVEL SUMMARIES

2.1 Data Integrity & Documentation

Most prevalent deficiency, noted in 34 reports. Included multiple Critical findings.

2.2 Visual Inspection & Defect Trending

Cited in 19 reports. Deficiencies included lack of defect albums, inadequate trending, and poor AQL practices.

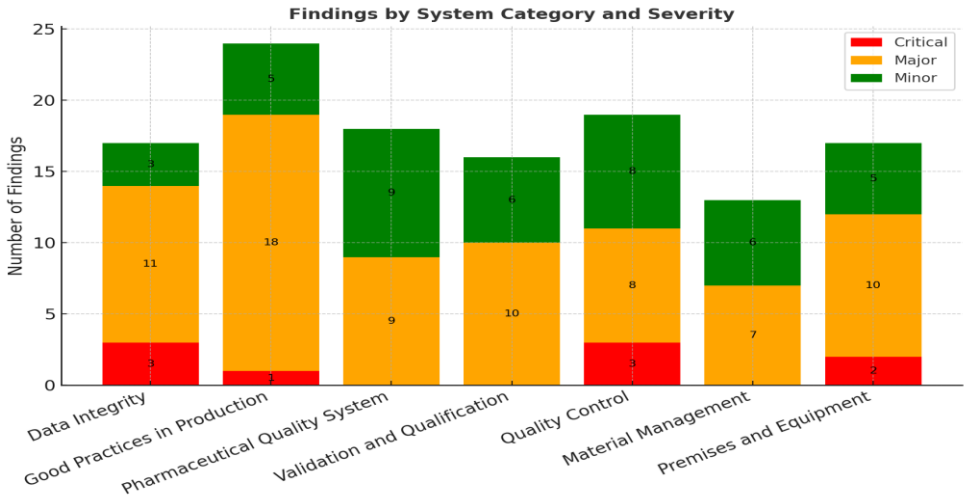
2.3 HVAC & Environmental Controls

Reported in 17 reports. Observations included absence of tamper-proof seals, non-continuous monitoring, leaking plenums and inadequate pressure controls.

TABLE 3: Quantification of Observations by System Category

System Category	Critical	Major	Minor	Total
Data Integrity	3	11	3	17
Good Practices in Production	1	18	5	24
Pharmaceutical Quality System	0	9	9	18
Validation and Qualification	0	10	6	16
Quality Control	3	8	8	19
Material Management	0	7	6	13
Premises and Equipment	2	10	5	17

FIGURE 5: Findings by System Category and Severity (with Values)



3.0 EXECUTIVE OVERVIEW OF THE NOTED GMP OBSERVATIONS

Across the reviewed facilities, systemic deficiencies were noted in critical utilities (HVAC, Water), premises/equipment integrity, production practices, laboratory controls, and PQS governance. Most findings related to monitoring gaps, poor documentation/data integrity, and inadequate preventive systems. These deficiencies represent risks of contamination, cross-contamination, and unreliable product quality assurance.

3.1 HVAC System

Key Risks: Environmental control failures, inadequate monitoring, poor maintenance.

Monitoring & Alarms

i. Absence of tamper-proof seals, missing operating/action limits.
ii. Lack of continuous pressure differential monitoring.

Filter Integrity

i. HEPA leaks and missing Poly Alpha Olefin documentation.
ii. Supply or return grills lacked identification.
iii. No SOPs for duct or plenum inspections.

Maintenance

i. Preventive checklists were vague and unsafe filter cleaning methods reported.

3.2 Premises & Equipment

Key Risks: Structural deterioration, hygiene gaps, inadequate segregation, equipment-related cross-contamination.

Premises

i. Old or damaged doors, non-flush fittings and cracked drains.
ii. Poor segregation of washing and production areas.

Equipment

i. Non-functional leak testers and poorly positioned machines.
ii. Shared RLAF in hormonal areas.
iii. Unsafe exhaust of hormone-contaminated air.

3.3 Good Practices in Production

Key Risks: Data integrity lapses, contamination risks, insufficient environmental monitoring.

Documentation

i. Retrospective Batch Manufacturing Record entries, missing parameters and manual dispensing slips.
ii. Weak SOP governance.

Contamination Control

i. Poor gowning and aseptic practices.
ii. Residues detected in common corridors.
iii. Scoops not verified at changeover.

Monitoring

i. No continuous Grade A monitoring during filling.
ii. No trending of visual defect reports.

3.4 Quality Control (QC)

Key Risks: Laboratory data reliability, stability oversight failures.

Data Integrity

i. Manual entries due to lack of printouts.
ii. Use of obsolete software.

Stability

i. Unacknowledged alarms in chambers.
ii. Incomplete stability monitoring at early time points.

Testing Practices

i. No environmental isolates libraries.
ii. Alert limit exceedances without investigations.

3.5 Raw Material Management

Key Risks: Warehouse control weaknesses, traceability failures, vendor oversight gaps.

Monitoring

i. Non-continuous temperature monitoring.
ii. Malfunctioning probes.

Traceability

i. Rejected material not identifiable electronically.

Cold Chain

i. Shipments without data loggers with no deviations raised.

Vendor Qualification

i. Critical suppliers not qualified or documented.

3.6 Pharmaceutical Quality System (PQS)

Key Risks: Weak APQRs, obsolete SOPs, inadequate validation/risk management.

3.7 Annual Product Quality Reviews (APQR)

i. Lack of utility performance review.
ii. Poor cross-referencing with stability and Environment Monitoring.
iii. Incomplete vendor/test coverage.

3.8 Documentation

i. Obsolete SOPs in critical areas.

3.9 Validation

i. Missing product-specific validation.
ii. Risk reports lacked detail.

3.10 Water System

Key Risks: Data integrity gaps, inadequate alarm/SOP systems, poor accessibility for maintenance.

Monitoring

i. Total Organic Carbon (TOC) performed offline.
ii. PLC lacked printing and alarms were not reviewed.

Maintenance/Design

i. Vent filter temperature not monitored.
ii. Inaccessible pipework.
iii. Incomplete schematics.
iv. No SOP for spare pump servicing.

4.0 CROSS-CUTTING THEMES

4.1 Data Integrity Failures – retrospective records, missing printouts, unacknowledged alarms.

4.2 Preventive Maintenance Weaknesses – HVAC, water, equipment, and stability chambers lack robust PM frameworks.

4.3 Inadequate SOP Control – obsolete or missing SOPs across Pharmaceutical Quality System, HVAC, and laboratories.

4.4 Environmental & Contamination Risks – poor gowning, segregation failures, and weak Environmental Monitoring trending.

5.0 CONCLUSION & RECOMMENDATIONS

Facilities with significant data integrity deficiencies were suspended from importation, and market authorization was placed on hold until satisfactory Corrective and Preventive Actions (CAPAs) were received. In some cases, these facilities supplied

essential medicines (e.g., oxytocin, bupivacaine) through the public sector. To mitigate risk, such products were subjected to pre-distribution and post-market surveillance testing, confirming no direct patient safety concerns. Furthermore, alternative suppliers were available, preventing drug shortages in the market.

The compliance risk and intrinsic risk of facilities were systematically used to determine re-inspection frequencies. Facilities cleared for cGMP and market authorization were scheduled for follow-up inspections accordingly.

From the trends observed, it is evident that onsite inspections in high-risk jurisdictions should be prioritized prior to granting market authorization, while reliance mechanisms may be strategically applied in low-risk jurisdictions.

5.1 TRAINING AND CAPACITY BUILDING

Training needs were highlighted, particularly in:

i. Data integrity oversight
ii. Good Practices in Production (GPP)

5.2 RECOMMENDATIONS

Continued capacity-building for inspectors in these areas is recommended to strengthen consistency, enhance inspection quality, and align with WHO GBT requirements.