MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

GMP

10th PAN-RUSSIAN GMP CONFERENCE

JFDA GMP Inspection Deficiency Data Trend

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Main Goal – Drug Control & Inspection Department

Applying GMP principles to ensure **quality, safety**, and **efficacy** of pharmaceutical products

Types of GMP Inspections

The inspection team preforms different types of GMP inspections to verify the compliance of pharmaceutical product manufacturers, using risk-based assessment for sites.

Announced GMP inspection

For manufacturing site authorization for;

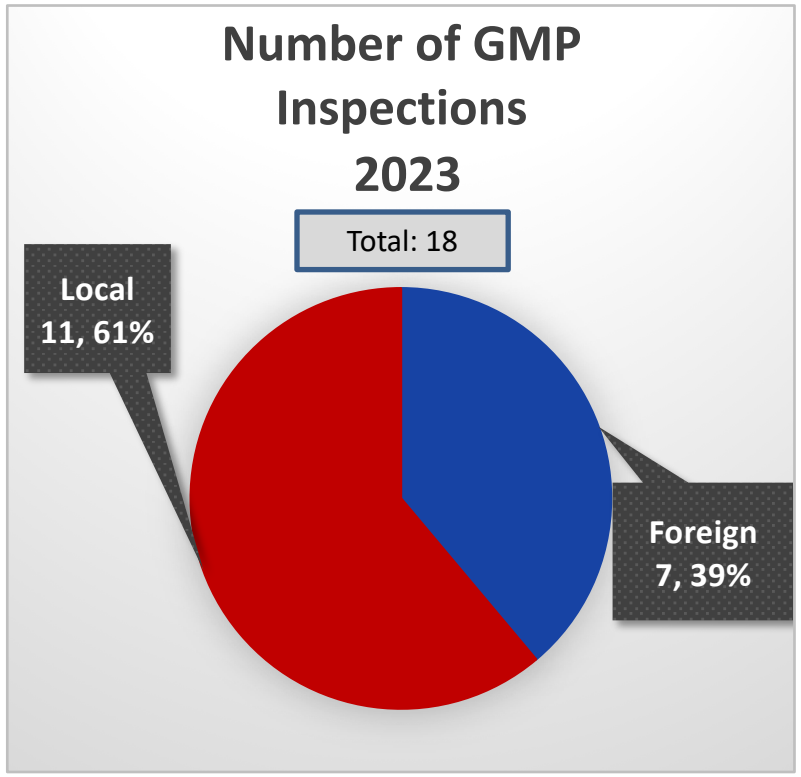
- GMP issuance
- GMP renewal,
- Follow-up inspection

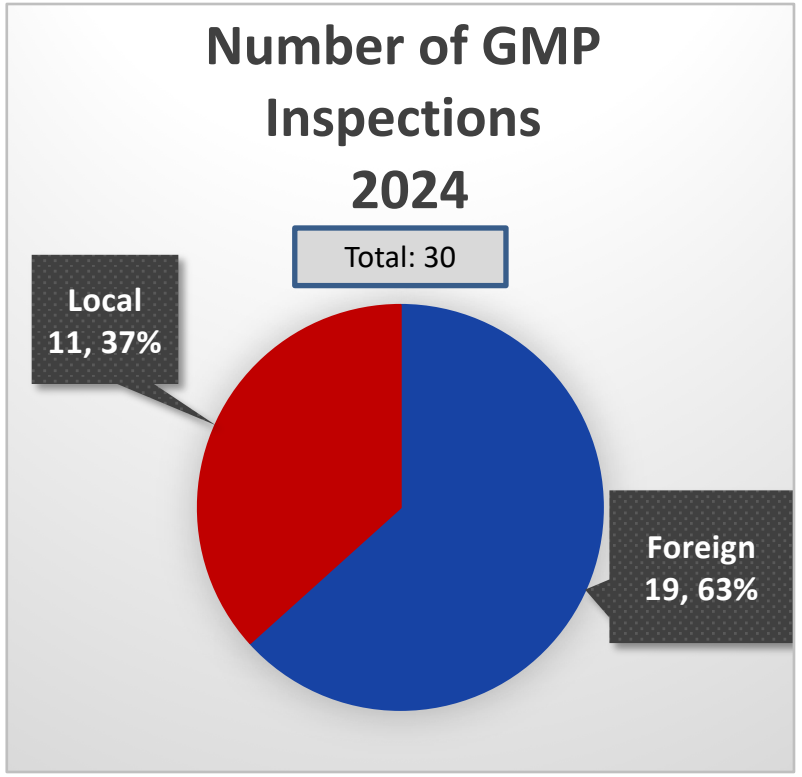
Unannounced GMP inspection

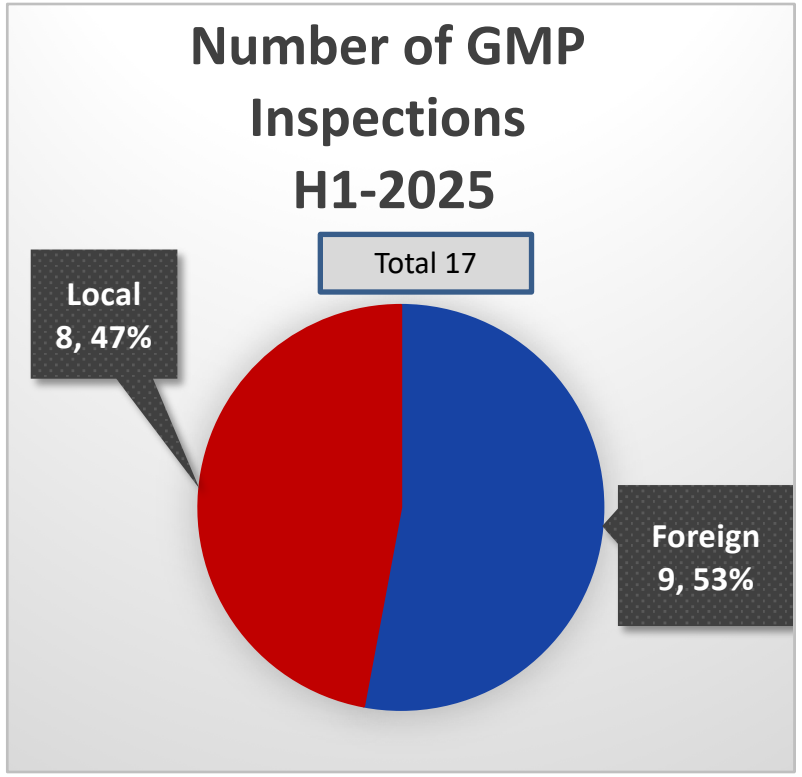
For investigation in case of

- complaint or recall

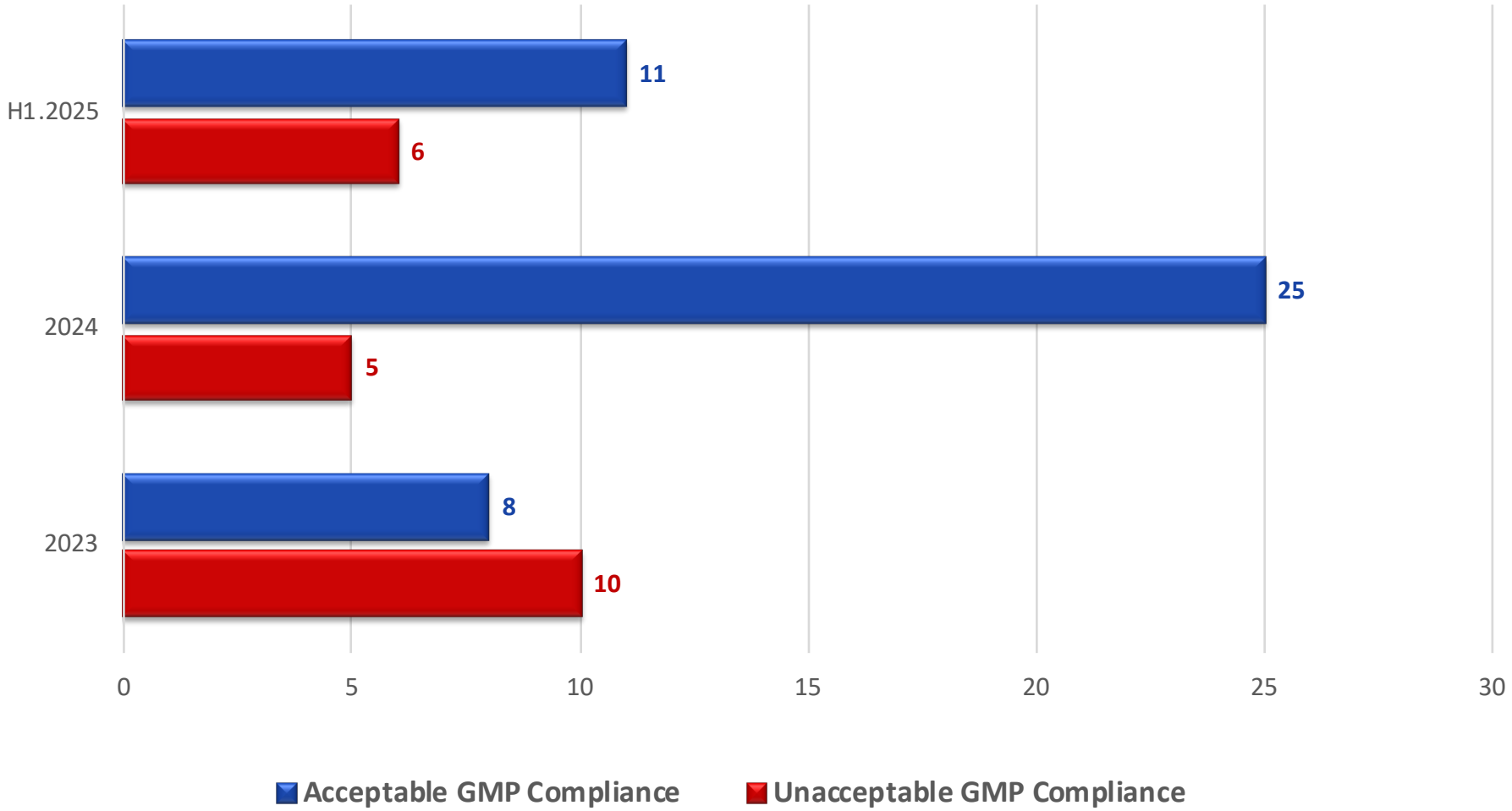
Number of Conducted GMP Inspections



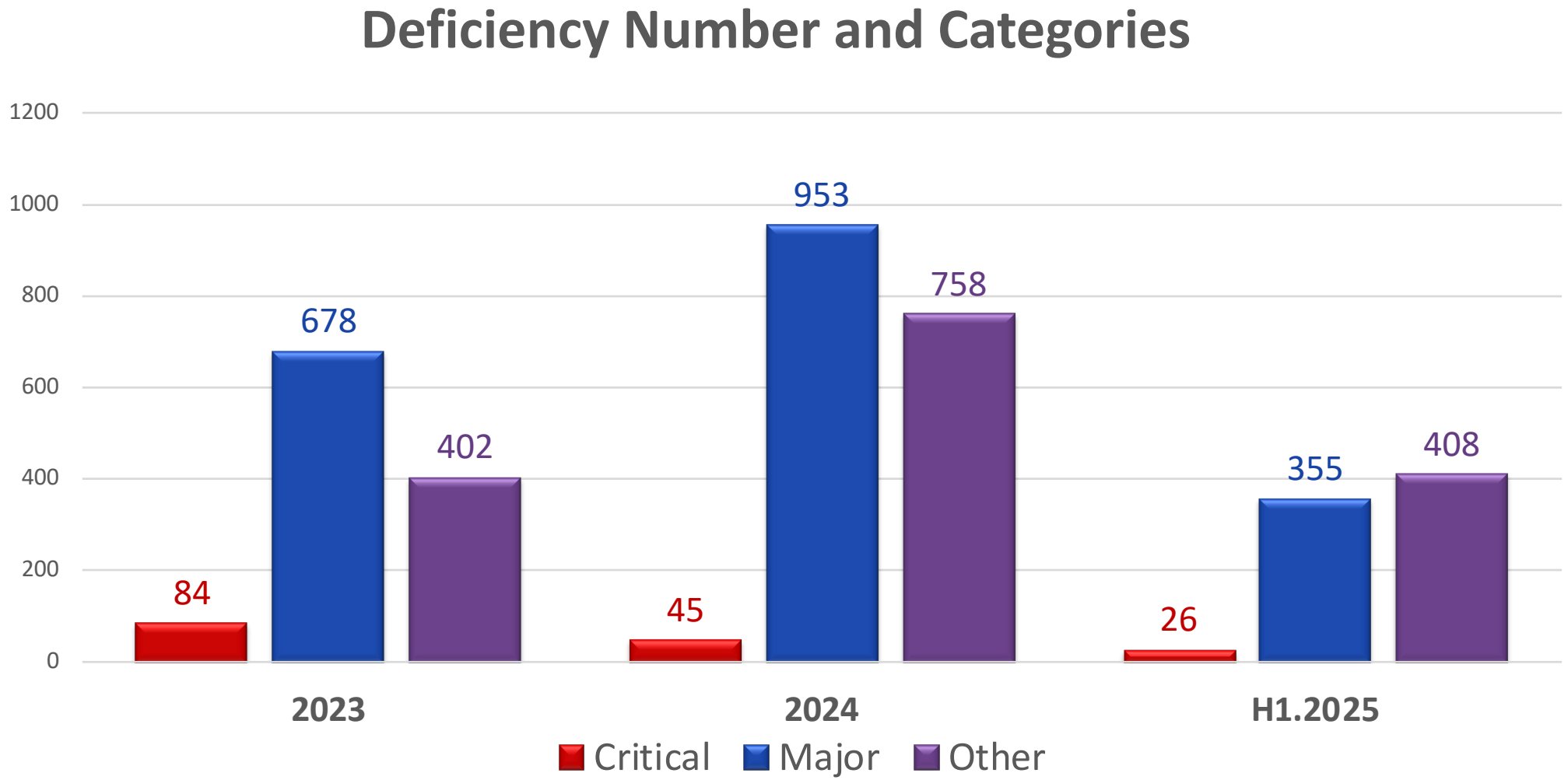




Data on GMP Inspection



Deficiencies



Examples of critical (or major) deficiencies

No	Paragraph or Chapter of GMP guidance	Example of critical (or major) deficiencies
1	Annex 16 – Certification by a Qualified Person and Batch Release	• No Technical manager was registered in Ministry of Health, and proper delegation for an experienced qualified QA person for batch release purposes.
2	Chapter 1 – Pharmaceutical Quality System Chapter 3 – Premises and Equipment Annex 15 – Qualification and Validation	• Performing major changes in production area and related utilities (water treatment unit, AHU) without notifying JFDA.
3	Chapter 3 – Premises and Equipment	• Using unlicensed warehouses for the storage of printed materials, released products or rejected products.
4	Annex 1 – Manufacture of Sterile Medicinal Products	• Compliance with updated Annex-1 including contamination control strategy.
5	Chapter 1 – Pharmaceutical Quality System Chapter 6 – Quality Control Chapter 8 – Complaints and Product Recall	• Many observations were noticed about handling OOS (Out of specification) especially stability OOS: ✓ No proper action / CAPAs were taken by the manufacturers (No recall for failed batches nor other affected batches). ✓ JFDA was not notified ✓ Investigations exceeded the timeline.
6	Chapter 3 – Premises and Equipment Chapter 6 – Quality Control	• No back up stability chambers/ No stability chambers
7	Chapter 3 – Premises and Equipment Annex 1 – Manufacture of Sterile Medicinal Products	• Conveyor between primary and secondary packaging material is not proper, no monitoring for differential pressure readings, no recording for differential pressure reading on batch line clearance.

Thank You!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JORDAN FOOD & DRUG
ADMINISTRATION
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