MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

GMP

10th PAN-RUSSIAN GMP CONFERENCE

GMP Inspection In Malaysia

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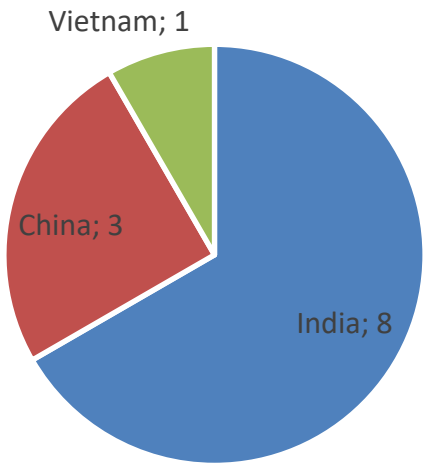
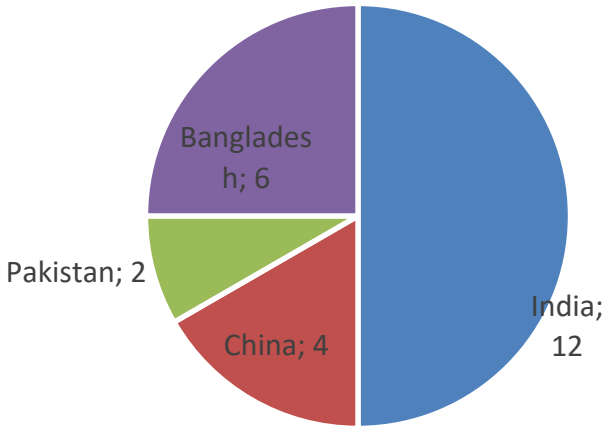
Number of conducted inspections

Types of Inspection	2023	2024	2025 (I-II quarter)
Foreign manufacturing	12	24	25
Local manufacturing	419	292	222
Acceptable GMP inspection results	413	306	241
Unacceptable GMP inspection results	18	10	6

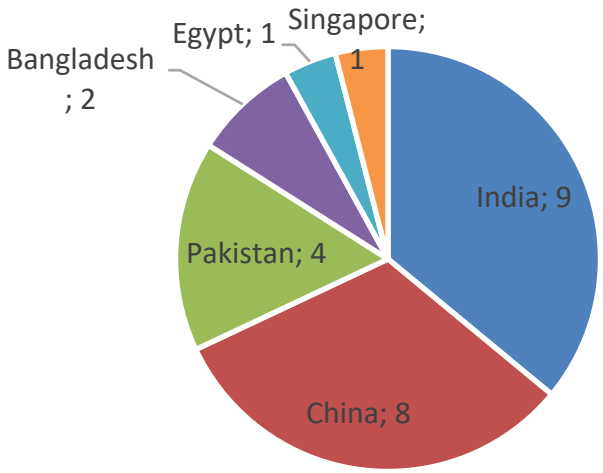
Number of GMP inspections 2023



Number of GMP inspections 2024



Number of GMP inspections 2025

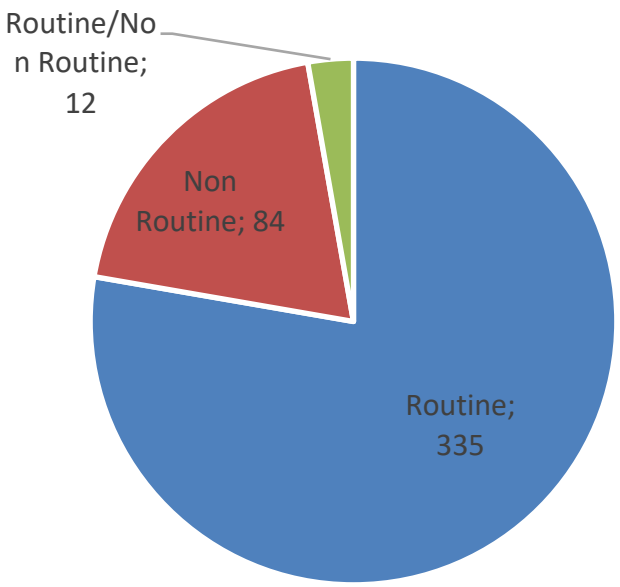


Data on GMP inspection

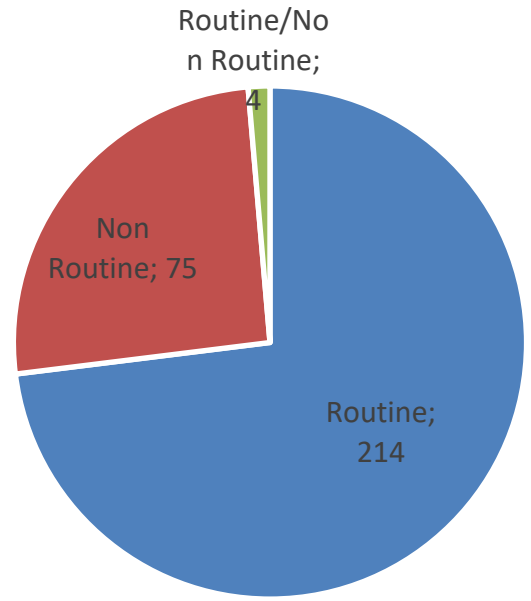
Data on GMP inspections

	2023	2024	2025
Total number of inspections held	431	316	247
Number of GMP certificates issued	666	482	403
Number of GMP certificates denied	18	10	6
Decision is yet to be made (CAPA)	0	0	6

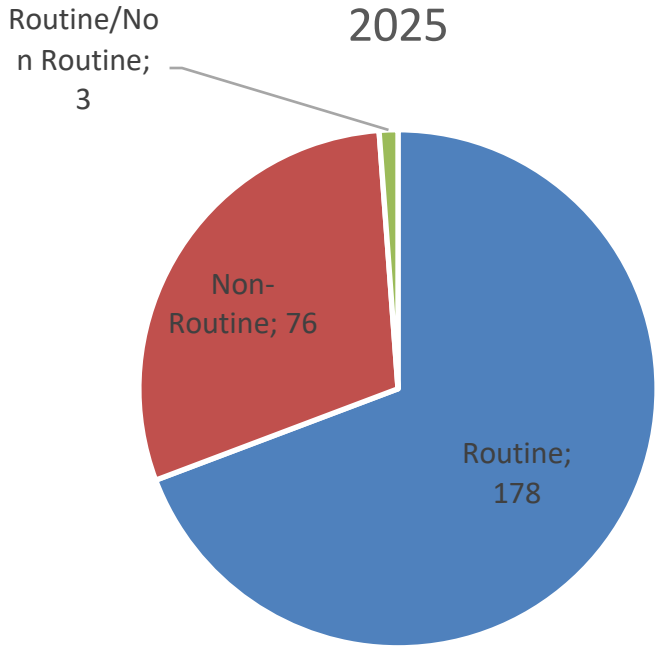
Number of GMP inspections 2023



Number of GMP inspections 2024

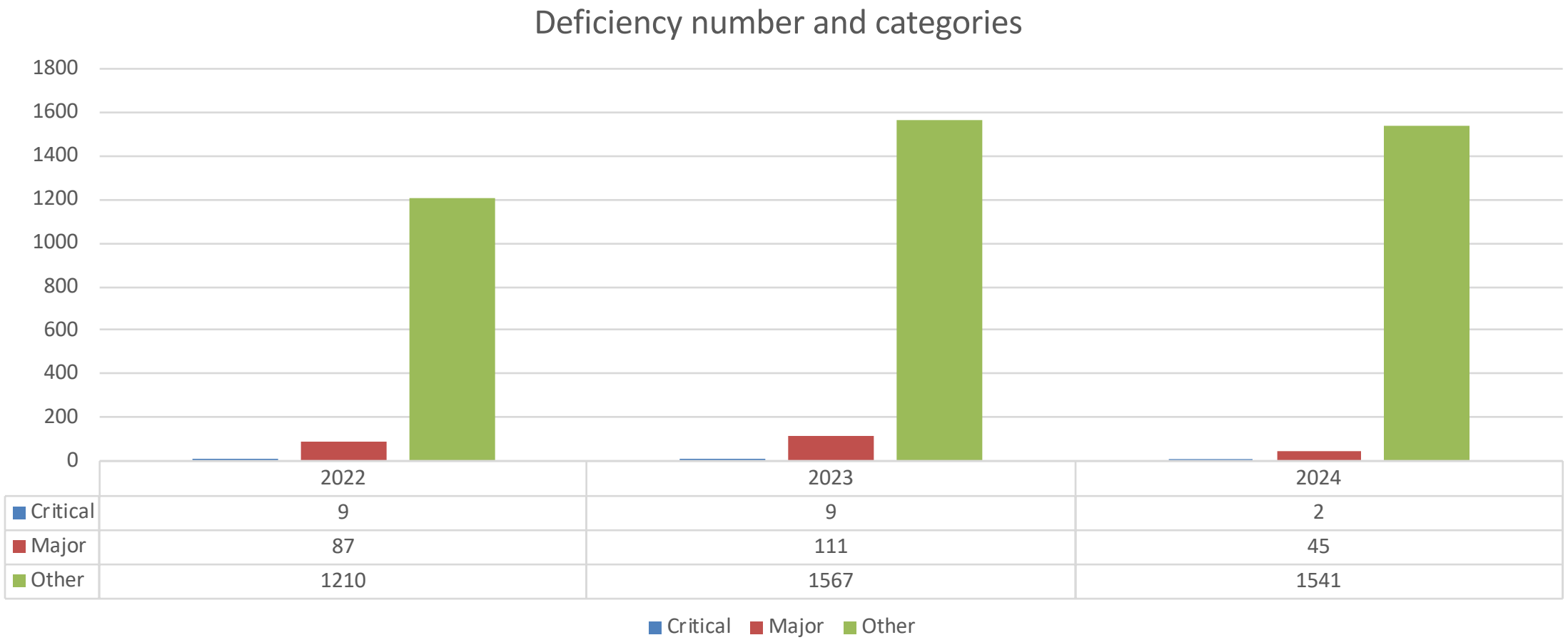


Number of GMP inspections 2025

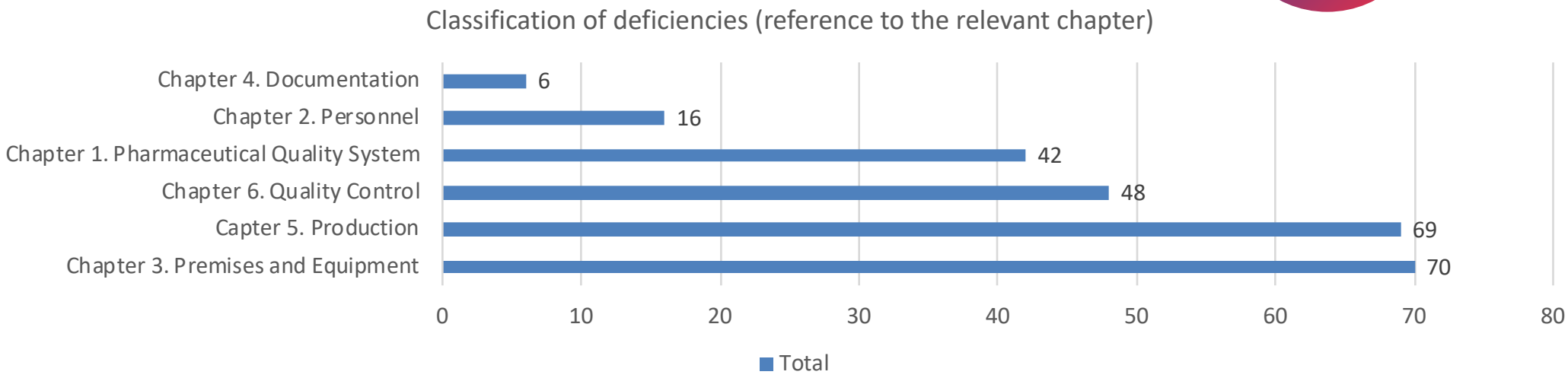


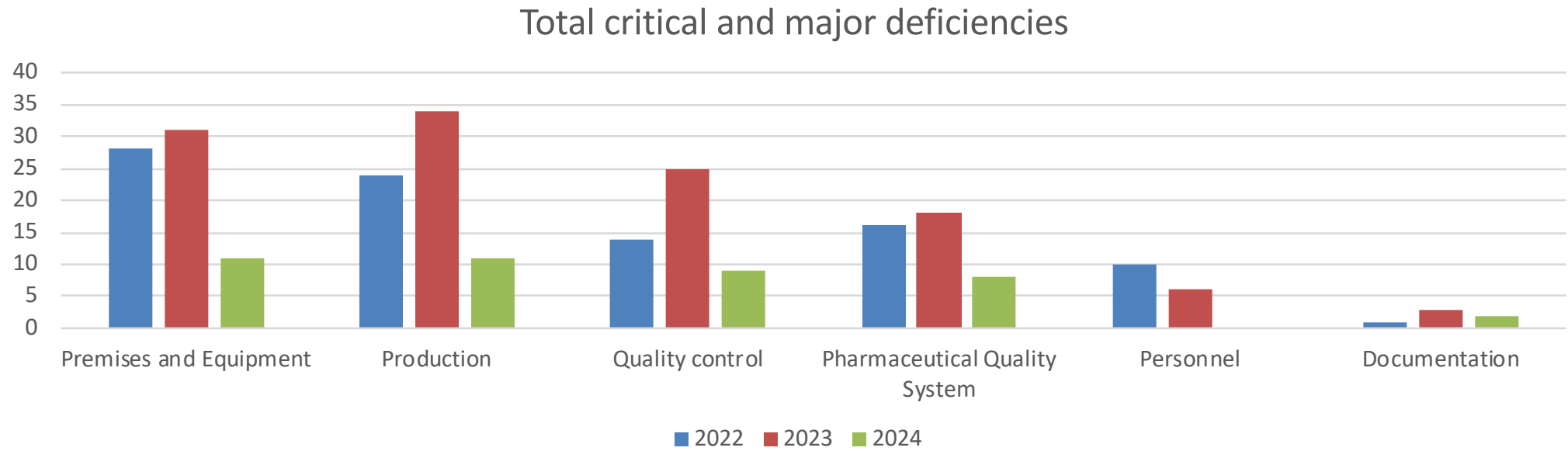
Deficiencies

	2022	2023	2024
Critical	9	9	2
Major	87	111	45
Other	1210	1567	1541



Classification of deficiencies





Examples of critical (or major) deficiencies

No	Paragraph or Chapter of GMP guidance	Example of critical (or major) deficiencies (no more than 10 examples)
1	Chapter 1	Unsatisfied PQS system to ensure safety and quality of product. Poor ventilation system maintenance. Unsatisfactory rework of sterile products. Sterility retest samples not per BP. Inadequate QC sampling of finished products
2	Chapter 2	Personnel not wearing gowns in production area. Insufficient supply of production gowns
3	Annex 15 Cleaning Validation	Cleaning Validation Planning Schedule (2023) not available. No justification for product selection (Elosten T Cream vs. Micosten H Cream). No summary report of validation outcomes. Batch numbers not stated in validation reports. Repeated finding from previous inspection.
4	Chapter 3 – Maintenance of equipment	Deficiencies in Premises & Equipment Maintenance - Uneven ceiling with cracks (External Staging Room, G37), Peeling paint on ceiling above Liquid Tank (NPP017, G45), Hot water pipe leakage (Washing Room, G38), Masking tape used on Liquid Tank cover (NPP017, G45), Dented/damaged doors & walls (G116, G115, G104)
5	Annex 15 – Process Validation	Routine manufacturing of *African Sea Coconut Brand Cough Mixture* was not adequately validated after replacement of TORQ Filling Machine (10 nozzles, ID: E-PD-76) in 2019. Machine qualified (26/08/2022) but process validation protocol only prepared in 2024.
6	Chapter 4 -Documentation	Same handwriting across different BMRs despite different personnel. Old analysis reports (2023) reused in 2024 BMRs. Temperature monitoring data entered manually; no raw data provided. 2023 internal audit report identical to 2022 (only date changed). Discrepancy in retention sample records (6 units vs. 20 units)
7	Chapter 5 – Temperature monitoring	No monitoring in Intermediate Room, Raw Material Store, Finished Product Store, and Retention Sample Store.Set specification (20–25°C, 50–70%) not suitable for certain materials (e.g. capsules require 15–25°C, 35–65%).No daily monitoring template (ST-06A-01) available.Sensors fixed with unsuitable adhesive tape, risk of dust contamination.RH in Finished Product Store fluctuated (72–80%), exceeding limit.
8	Chapter 5 - Traceability	Inadequate Labelling – Risk of Mix-up. Semi-finished product containers only labelled with processing date; no other label. Multiple batches produced in a day. Finished product cartons lacked batch number and product status. Outer packaging seal must be broken to identify batch, increasing mix-up risk.