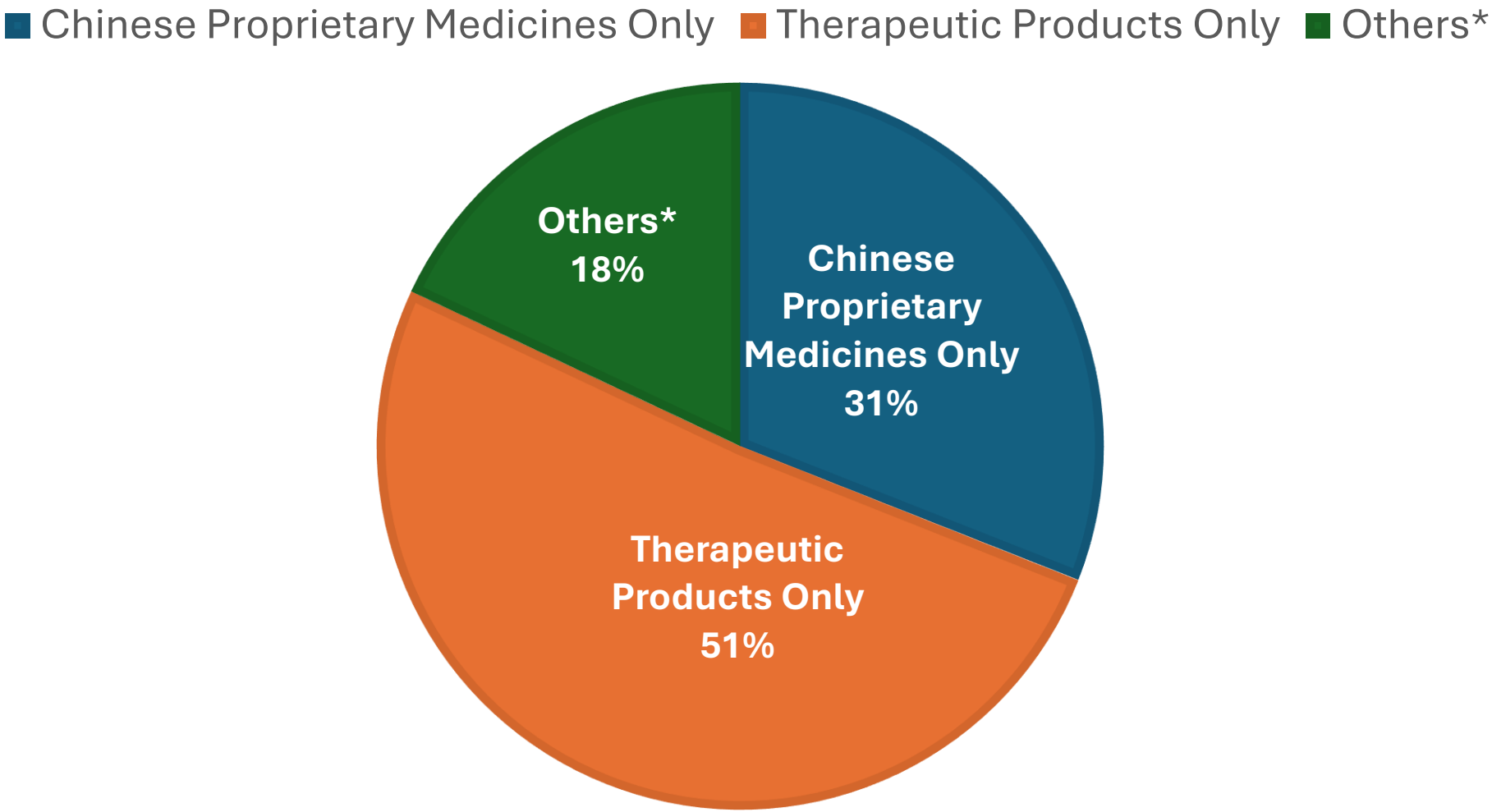
TRENDING OF GOOD DISTRIBUTION PRACTICE (GDP) DEFICIENCIES 2025

Compilation of GDP Inspections conducted in 2025

All Rights Reserved, Health Sciences Authority

Profile of Dealers Inspected in 2025

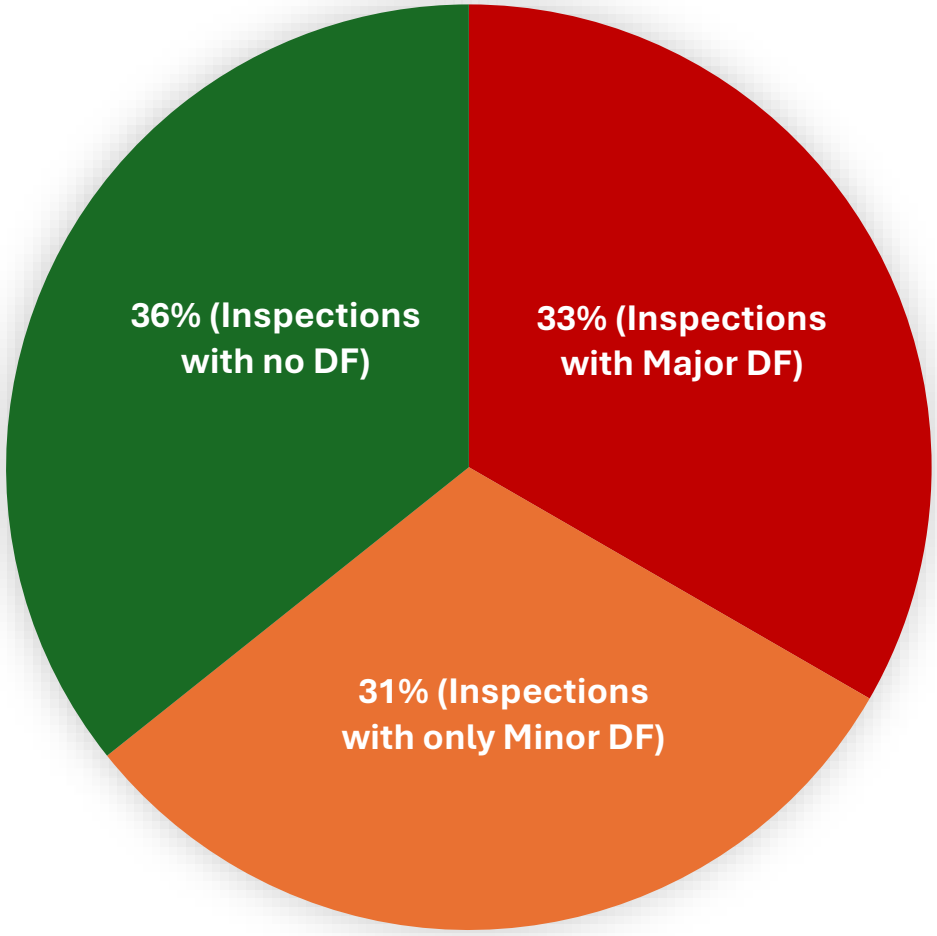


** Companies dealing in various product categories including Active Ingredients and Cell, Tissue & Gene Therapy Products*

All Rights Reserved, Health Sciences Authority

Overview of GDP inspections in 2025

- At least one Major deficiency (DF) was observed in 33 % of inspections.
- At least one Minor DF was observed in 31% of inspections
- No DF was observed in 36 % of inspections.



All Rights Reserved, Health Sciences Authority

Summary of GDP Deficiencies in 2025

5 most-commonly cited GDP deficiencies

5 most-commonly cited GDP deficiencies

All Inspections

#	GDP Chapters	Percentage
1	Premises & Equipment	31%
2	Documentation	26%
3	Cold Chain	10%
4&5	Personnel	6%
4&5	Stock Handling	6%

CPM* Dealer Inspections

#	GDP Chapters	Percentage
1	Premises & Equipment	32%
2	Documentation	30%
3	Personnel	11%
4	Stock Handling	7%
5	Self Inspection & Disposal of Products	4%

TP** Dealer Inspections

#	GDP Chapters	Percentage
1	Premises & Equipment	26%
2	Documentation	26%
3	Cold Chain	18%
4	Self Inspection	6%
5	Contract Agreement & Stock handling	5%

*CPM refer to Chinese Proprietary Medicines
**TP refer to Therapeutic Products

All Rights Reserved, Health Sciences Authority

Common GDP Deficiencies in 2025

S/N	GDP Chapters	Example of Deficiencies
1	Premises and Equipment	• Gaps were observed beneath entrance doors leading to storage areas which could lead to ingress of pests. • Thermo-hygrometers used for environmental monitoring were found to be past their calibration validity periods, with some instruments remaining uncalibrated for extended periods. • Staff personal belongings including beverages and food items were found in designated storage areas, which may attract pests and lead to contamination. • Products that required segregation were stored without proper identification or restricted access. Quarantined items found on open shelves accessible to all warehouse staff rather than authorised personnel only.
2	Documentation	• SOPs were revised without proper version control. Several procedures were not available during audit and there was no system to prevent inadvertent use of superseded versions. • Multiple procedures were not kept up-to-date and referenced outdated versions of guidance documents. • Alteration of information on cleaning records and temperature monitoring forms using correction tape which did not allow for reading of the original details.

All Rights Reserved, Health Sciences Authority

Common GDP Deficiencies in 2025

S/N	GDP Chapters	Example of Deficiencies
3	Annex 1 Cold Chain	• There shipper boxes used for transportation of cold chain products were not qualified or validated. There was no evidence to demonstrate that the current packing configurations used in the shipper could provide intended storage conditions during transportation for the defined durations. • Packing operations of cold chain products were not documented and no independent check was conducted to confirm compliance with established packing configurations of the products. • Temperature deviations were observed in the refrigerators but root cause investigation and product quality impact assessment were not performed. There was also no documentation of corrective actions taken. • Written procedures for regular preventive maintenance of cold room were not available. The last maintenance was carried out 5 years ago which did not provide adequate assurance on the correct/proper functioning of the temperature control system. • The temperature monitoring system lacked defined alert and action limits and there was no periodic alarm testing.

All Rights Reserved, Health Sciences Authority

Common GDP Deficiencies in 2025

S/N	GDP Chapters	Example of Deficiencies
4	Personnel	• Training procedure and training records were not available to demonstrate competency of warehouse personnel in cold chain operations. • The frequency for continuing GDP training of warehouse personnel was not defined in the procedures and there was no evidence that such training was conducted.
5	Stock Handling	• The containers used for product delivery were not adequately secured with locks which posed risks of tampering and pilferage during transportation of products. • There was no formal process established for managing and investigating stock discrepancies found during stock counts. • While the returned products procedure described criteria for accepting returns there was no documentation to prove that assessments of the returned products were done according to the established criteria. • Essential traceability information, such as the product's batch number and expiry date, was missing from records of product disposal.

All Rights Reserved, Health Sciences Authority