

2024 Good Manufacturing Practice (GMP) Deficiency Analysis

Inspections on Pharmaceutical, Traditional Medicines and Health Supplement
(TMHS), and Cosmetics Manufacturer by the National Pharmaceutical
Regulatory Agency (NPRA)

OVERVIEW OF INSPECTION ACTIVITY



70

Pharmaceutical



76

TMHS
(Traditional Medicines
& Health Supplements)



110

Cosmetics

2024 GMP INSPECTION OUTCOMES

National Pharmaceutical Regulatory Agency (NPRA)

Acceptable Unacceptable



Cosmetic

108

110

108

2



TMHS

74

76

74

2



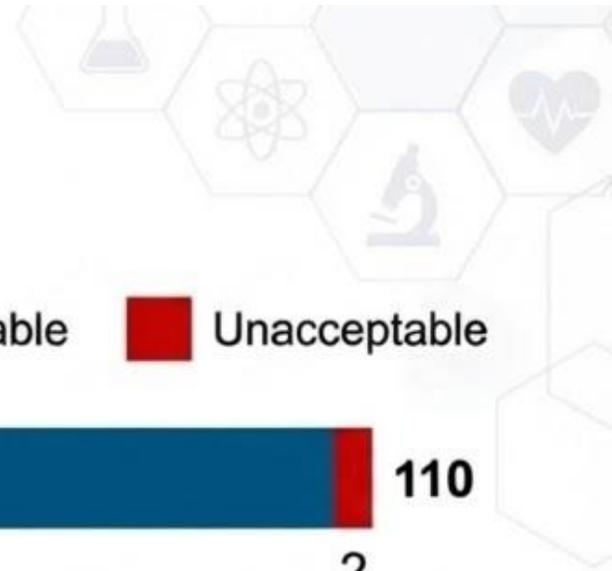
Pharmaceutical

64

70

64

6



TYPES OF INSPECTION

Breakdown of inspection types across Pharmaceutical, TMHS, and Cosmetic sectors (2024)



Pharmaceutical



Routine

45



Pre-Licensing Inspection

6



Pre-Certification Foreign Inspection

19



TMHS



Routine

63



Pre-Licensing Inspection

13



Cosmetic



Routine

87



Initial Inspection

23

PHARMACEUTICAL MANUFACTURER INSPECTIONS

Analysis of critical, major, and minor findings distributed across Chapters 1 to 9 of the PIC/S Guide to GMP, including Chapter 10 for issues related to Distribution and Shipment



Top Deficiencies by Chapter: Pharmaceuticals

Chapter	Critical Deficiency Clauses	Major Deficiency Clauses
Ch. 1 (Pharmaceutical Quality System)	1.1	1.4 & 1.8
Ch. 2 (Personnel)	—	2.10
Ch. 3 (Premises and Equipment)	3.9 & 3.36	3.2
Ch. 5 (Production)	—	5.18
Ch. 6 (Quality Control)	—	6.15

* Clauses aligned with PIC/S Guide to GMP (PE 009-17).

Comparative Analysis: Pharma (2022–2024)

Classification	2022 Data	2023 Data	2024 Data
Critical	1.1	1.8	1.1
	2.18	6.15	3.9
	5.29		3.36
Major	Annex 15	5.23	1.4
	1.8	6.15	1.8
	3.20	6.16	5.18
	5.25		6.15

TMHS MANUFACTURER INSPECTIONS

IClauses cited aligns with the Guidelines: Good Manufacturing Practice for TMHS, First Edition, 2008.



Top Deficiencies by Chapter: TMHS

Chapter	Critical Deficiency Clauses	Major Deficiency Clauses
Ch. 1 (Quality Management System)	1.2	1.2
Ch. 3 (Premises and Equipment)	3.1,3.2,3.13 & 3.14	3.16
Ch. 4 (Documentation)	-	4.2
Ch. 5 (Production)	5.17	5.18
Ch. 6 (Quality Control)	6.1	6.15

Comparative Analysis : TMHS (2022–2024)

Classification	2022 Data	2023 Data	2024 Data
Critical	1.2	1.2	1.2,
	1.3,	1.3	3.1
	3.41	3.41	3.2
			3.13
			3.14
			5.17
Major	1.2	1.2	6.1
	3.13	3.16	1.2
	5.12	3.51	3.16
			4.2

Key Persistence: Clause 1.2 has remained the most repeated critical and major finding for three consecutive years (2022–2024).

COSMETIC MANUFACTURER INSPECTIONS

Clauses aligned with the Guidelines for Control of Cosmetic Products in Malaysia-Second Edition Annex I, Part 11.



Top Deficiencies by Chapter: Cosmetics

Chapter	Critical Deficiency Clauses	Major Deficiency Clauses
Ch. 1 (Quality Management System)	1.2.3	1.2.1
Ch. 3 (Premises)	3	3.1
Ch. 4 (Equipment)	-	4.3
Ch. 5 (Sanitation and Hygiene)	-	5.3.1
Ch. 6 (Production)	6.1.1, 6.4.2 & 6.4.5	6.8.1

Comparative Analysis : Cosmetics (2023–2024)

Classification	2023 Data	2024 Data
Critical	1.2.1	1.2.3
	6.4.5	3
	8.3.2	6.1.1
		6.4.2
Major		6.4.5
	3.1	1.2.1
	7.1.2	3.1
	8.3.2	4.3
		5.3.1