



Zambia Medicines Regulatory Authority

GUIDELINES ON CLASSIFICATION OF GMP DEFICIENCIES

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1. INTRODUCTION

The Zambia Medicines Regulatory Authority (ZAMRA) is a statutory regulatory body established by the Medicines and Allied Substances Act, No. 3 of 2013 of the laws of Zambia. The Authority is mandated by sections 5 and 34 of the Act to inspect premises used for manufacturing, grant pharmaceutical licences, regulate and control the manufacture of medicines and allied substances.

Section 68 of the Act further mandates the Authority to make guidelines that are necessary for the better implementation of the Act. The Authority may amend any part of these guidelines from time to time.

These guidelines follow internationally recognised standards such as WHO GMP (Technical Report Series) and inspection frameworks. In an event of any conflict between these standards and national law, the Medicines and Allied Substances Act No. 3 of 2013 will take precedence.

2. PURPOSE

The objective of these guidelines is to standardise the classification of GMP deficiencies to facilitate harmonised reporting from inspections conducted by the Authority.

Standardisation will help ensure that there is a consistent view of what constitutes a “Critical”, “Major” or “Minor (Other)” deficiency. Risk management principles will be applied in the categorisation of these deficiencies dependent on the type of product manufactured or process.

This guidance is also intended to:

- a) provide actions to be taken by the Authority in response to the reporting of critical and major deficiencies;
- b) enhance communication, information sharing and scientific exchange to promote increased consistency and predictability in regulatory assessments and decisions and the rapid exchange of safety and quality information regarding manufacturers.

3. SCOPE

These guidelines apply to all GMP inspection deficiencies arising from inspections covering the full scope of manufacturing activities for human and veterinary medicines. An equivalent classification by severity of deficiencies for medical devices and other allied substances may be referenced to the current IMDRF, MDSAP or applicable ISO standards.



4. DEFINITIONS

In these guidelines, unless the context otherwise requires -

“Act” means the Medicines and Allied Substances Act (No. 3) of 2013;

“Allied Substances” include acaricides, cosmetics, disinfectants, food supplements, feed additives and supplements, medical and surgical sundries, medical devices and condoms;

“Authority” means the Zambia Medicines Regulatory Authority;

“Correction” means any action that is taken to eliminate a nonconformity. However, corrections do not address causes. When applied to products, corrections can include reworking products, reprocessing them, regrading them, assigning them to a different use, or simply destroying them.

“Corrective action” means steps that are taken to eliminate the causes of existing nonconformities in order to prevent recurrence. The corrective action process tries to make sure that existing deficiencies or nonconformities and potentially undesirable situations do not happen again. While corrective actions prevent recurrence, preventive actions prevent occurrence. Both types of actions are intended to prevent nonconformities.

“Deficiency” means a Non-fulfilment of a requirement. In this sense this term can be used interchangeably with “nonconformity”.

“Good Manufacturing Practice” means the part of quality management that ensures that a product is consistently produced and controlled according to the quality standards appropriate to its intended use and as required by the marketing authorisation; clinical trial authorisation or product specification.

“Inspection observation” means a finding or a statement of fact made during an inspection and substantiated by objective evidence. Such findings may be positive or negative. Positive observations should take the form of a description of the processes that the firm is carrying out particularly well and that may be considered examples of particularly good practice. Negative observations are findings of non-compliance with requirements;

“Manufacture” in relation to a medicine or allied substance, includes any process carried out in the course of making that medicine or allied substance, but does not include the process of dissolving or dispensing a product in, or diluting or mixing it with, some other substance for purposes of administering it; or the incorporation of a medicine in any animal feed;

“Manufacturer” means a company that carries out operations such as production, packaging, repackaging, labelling and relabeling of medicines or allied substances;

“Medicine” means human medicine, veterinary medicine, medicinal product, herbal medicine or any substance or mixture of substances for human or veterinary use intended to be used or manufactured for



use for its therapeutic efficacy or for its pharmacological purpose in the diagnosis, treatment, alleviation, modification or prevention of disease or abnormal physical or mental state or the symptoms of disease in a person or animal;

“Nonconformity” means a failure to comply with requirements. A requirement is a need, expectation or obligation. It can be stated or implied by an organisation, its customers or other interested parties. There are many types of requirements. These include legal requirements, quality requirements, customer requirements, management requirements, product requirements and process requirements. and. Whenever an organisation fails to meet one of these requirements, a nonconformity occurs.

“Preventive Action” means steps that are taken to remove the causes of potential nonconformities or potential situations that are undesirable.

5. ABBREVIATIONS

CAPA:	Corrective and Preventive Action
COA:	Certificate of Analysis
GMP:	Good Manufacturing Practice
GUD:	Guideline
IMDRF:	International Medical Device Regulators Forum
ISO:	International Organisation for Standardisation
MDSAP:	Medical Device Single Audit Program
OOS:	Out of Specification
SOP:	Standard Operating Procedures
WHO:	World Health Organisation
ZAMRA:	Zambia Medicines Regulatory Authority



6. DEFICIENCIES / NON-COMPLIANCE STATEMENTS

The non-compliance statement to be communicated to the manufacturer shall fulfill the following:

- 6.1 The non-compliance statement will include the requirement (R), evidence (E) and deficiency (D).

Example: (R) The relevant cleaning records and source data should be kept in cleaning validation reports; (E) the source of three samples taken for recovery testing during the process equipment validation was not traceable; (D) cleaning validation reports did not include sufficient data

- 6.2 Deficiencies/noncompliance statements should distinguish whether the defect lies in the system itself or in a failure to comply with the system. For instance, when cleaning is found to be suboptimal, it is important to know whether the standard operating procedures (SOPs) are inadequate or lacking, or whether adequate written procedures exist but are not followed by personnel. The failure may also be in both.

- 6.3 Where more than one deficiency relates to the same basic quality system failure, the deficiencies are grouped and listed as a single observation, under a heading that reflects the basic system failure.

- 6.4 Deficiencies are reported with a focus on risk to patient health and/or need for corrective and preventive action (CAPA).

7. CLASSIFICATION OF GMP DEFICIENCIES

Deficiencies are classified into categories “Critical”, “Major”, “Minor (Other)” and also in accordance with the functions related to product and personnel. The following are the definitions for the above classes:

- 7.1 A critical deficiency may be defined as an observation that has resulted, or may result in a significant risk of producing, a product that is harmful to the user.

- 7.2 A major deficiency may be defined as a non-critical observation that:

- 7.2.1 has produced or may produce a product that does not comply with its marketing authorisation
- 7.2.2 indicates a major deviation from the GMP guide;
- 7.2.3 indicates a failure to carry out satisfactory procedures for release of batches;
- 7.2.4 indicates a failure of the person responsible for quality assurance/ quality control to fulfil his or her duties;



- 7.2.5 consists of several minor or other deficiencies, none of which on its own may be major, but which together may represent a major deficiency.
- 7.3 A deficiency may be classified as minor (other) if it cannot be classified as either critical or major but indicates a departure from GMP. A deficiency may be minor either because it is judged as such or because there is insufficient information to classify it as major or critical.
- 7.4 Classification of a deficiency is based on the assessed risk level and may vary depending on the nature of the products manufactured.
- 7.5 A deficiency that was reported at a previous inspection and was not corrected may be reported with a higher classification.
- 7.6 One-off minor lapses or less significant issues may not usually be formally reported but are brought to the attention of the manufacturer during the inspection.

8. CONSIDERATIONS TO SUPPORT CONSISTENT AND OBJECTIVE CLASSIFICATION OF GMP DEFICIENCIES IN ACCORDANCE WITH RISK MANAGEMENT PRINCIPLES

- 8.1 When classifying a deficiency as “Critical”, determination shall be made if there is clear evidence by considering risk of harm as in the definition under 7.1.
- 8.2 When a deficiency is identified but its classification is not clear, the deficiency may be rated as “Major” or “Minor (Other)”. A determination regarding the classification is made for which the following guidance may be followed:
- 8.2.1 A detailed evaluation of the deficiency is made to determine an initial classification.
- 8.2.2 An evaluation of factors that would either increase or reduce the risk from the initial classification is performed; Then,
- 8.2.3 A decision is made as to whether the initial risk classification may be:
- a. maintained,
 - b. upgraded due to effects that increase the risk, i.e. risk-increasing effects, or
 - c. downgraded due to effects that reduce the risk, i.e. risk-reducing effects.

8.3 Possible Risk Increasing Factors

A deficiency may be upgraded to a higher classification when conditions exist to satisfy the intent of the definition for the upgraded risk classification. This may be achieved when defined risk increasing factors are present. Some risk-increasing factors may include:

8.3.1 Repeat or recurring deficiencies



These are issues previously identified during inspections that remain unresolved due to failure to implement appropriate corrective actions. Such deficiencies may increase risk classification, especially where there is evidence of deliberate or inadequate effort to resolve them.

8.3.2 Grouping or combination of deficiencies

Related issues identified during an inspection can be grouped into a single deficiency if they support the same core problem. Multiple “minor (other)” deficiencies, which may not individually qualify as “Major,” can collectively be considered a “Major” deficiency provided the criteria for the higher classification is met.

8.3.3 Product risk

- a. Risk increasing or reducing may be applied based on product risk. For high-risk products such as sterile formulations, deficiencies may be upgraded if they meet the criteria for higher classification. For low-risk products deficiencies may be downgraded unless the criteria for higher risk classification are clearly met.
- b. Manufacturer’s failure to identify and take prudent measures to reduce the patient risk to an acceptable level for a product distributed and future production from a deficient practice or process.

8.4 Possible Risk Reducing Factors

A deficiency may be downgraded to a lower classification if conditions exist to satisfy the intent of the definition for the downgraded risk classification. This may be achieved when defined risk-reducing factors are present. Risk reducing factors may include:

- a. Minimizing product risk
- b. Minimizing risk of patient harm
- c. Actions taken by the manufacturer such as CAPA plan to reduce the risk of the deficiency

8.5 Some possible deficiency classification examples are provided in Annex 1.



9. ACTION TO BE TAKEN IN RESPONSE TO THE REPORTING OF CRITICAL AND MAJOR DEFICIENCIES

- 9.1 Compliance and enforcement measures are dependent upon a number of factors, including significance of violations such as a “Critical” deficiency and a large number of “Major” deficiencies, history of the site, potential risks to products, and assessment of the manufacturer’s proposed corrective actions. Where appropriate, this may include assessment of interim risk mitigating actions while long term remediation continues.
- 9.2 The clinical impact of the deficiencies on human and animals as a result of the observed failures are considered and used to inform quality defect decisions and market actions such as recall. When assessing the clinical impact of observed deficiencies, expert advice such as medical and toxicological input may be sought.
- 9.3 If the findings are linked to patient safety, immediate action needs to be taken.
- 9.4 Additional factors that are considered include:
- a) the risk to health and safety;
 - b) compliance history of the manufacturer;
 - c) whether the manufacturer acted with indifference or premeditation;
 - d) the degree of co-operation offered;
 - e) the likelihood that the same problem will reoccur;
 - f) the likelihood of the enforcement action being effective.
- 9.5 Typically, the first steps could include a letter of warning/cautionary letter or a re-inspection for which failure to address risk with repeat deficiencies may result in a non-compliance or similar rating.
- 9.6 Depending upon the severity of the deficiency, the Authority will determine if appropriate regulatory actions are needed. The actions that can be taken may include but not limited to:
- a) compliance related communications which alert the manufacturer to the Authority’s concern, and possibility for future regulatory action if remedial action is not effective;
 - b) regulatory action against the site authorisation or GMP approval (refusal, suspension or amendment of an establishment licence);
 - c) market actions such as recall (voluntary or mandated by the Authority);
 - d) prohibition of supply / importation;
 - e) prosecution;



- f) communications to the public using public warning/public advisory or information updates;
- g) suspension or cancellation of Marketing Authorisation/Product Licence/GMP Clearance;
- h) health product label or packaging changes.

10. DETERMINATION OF COMPLIANCE WITH GMP BASED ON THE NUMBER AND NATURE OF DEFICIENCIES

10.1 When there are minor (other) deficiencies only:

- 10.1.1 The site is considered to be operating at an acceptable level of GMP compliance,
- 10.1.2 The manufacturer is expected to provide CAPAs,
- 10.1.3 CAPAs are evaluated and followed up during the next routine inspection.

10.2 When there are minor (other) and a few major deficiencies (e.g. < 6):

- 10.2.1 The site is compliant with GMP after assessing the CAPAs (CAPA must be satisfactory),
- 10.2.2 CAPAs for deficiencies to include actions implemented and/or planned, timelines and documented evidence of completion, as appropriate,
- 10.2.3 CAPAs are evaluated on paper and may or may not include an on-site, follow-up inspection.

10.3 When there are several major deficiencies (e.g. ≥ 6):

- 10.3.1 The site is considered to be operating at an unacceptable level of compliance with GMP guidelines,
- 10.3.2 Appropriate regulatory action(s) may be applied as provided for in 9.6 relative to the identified deficiencies

10.4 When there is a critical observation:

- 10.4.1 Appropriate regulatory actions are applied as provided for in 9.6
- 10.4.2 The site is considered to be operating at an unacceptable level of compliance with GMP guidelines.

11. MANUFACTURING SITE RISK RATING AND GMP COMPLIANCE VALIDITY

- 11.1 In determining a site's risk rating, the Authority applies a risk-based approach by focusing on past deficiencies, uninspected or weak areas, resource gaps, site changes, and quality signals such as recalls. These factors guide inspection scope and ensure attention is given to both known and potential risks, supported by professional judgement.



11.2 GMP deficiency classification determines compliance risk and contributes to GMP validity assignment, with critical and multiple major deficiencies indicating high risk and reduced regulatory confidence. This affects site rating, inspection frequency, and whether GMP status is maintained or compromised.

11.3 Intrinsic and compliance related risk is considered using the following key criteria:

11.3.1 Assessment of Intrinsic Risk associated with the site –

The following factors contribute to a sites intrinsic risk:

- Complexity of site (processes and products)
- Criticality of the products manufactured by the site, or the criticality of the analytical testing or other service offered provided by the site

An overall intrinsic risk rating associated with a site is determined as: Low / Medium / High

11.3.2 Site Compliance related Risk -

The site's compliance related risk is assessed based on the recent deficiency profile and assigned a rating as below:

- **Low Risk** (No Major or Critical Deficiencies observed in previous inspection)
- **Medium Risk** (1 to 5 Major Deficiencies observed on previous inspection)
- **High Risk** (1 or more Critical Deficiencies or more than 5 Major Deficiencies observed in previous inspection)

11.3.3 Site Overall Risk Rating

The site's combined risk score is determined using a combination of the intrinsic risk score and compliance -related risk score. The overall risk score/rating may fall into one of the following three categories:

A: Low Risk

B: Medium Risk

C: High Risk

11.3.4 Determination of Inspection Frequency

The inspection frequency / compliance validity is assigned based on the site's risk rating:

- A → Reduced frequency (3.5 to 4 yrs)



- B → Moderate frequency (2 to 3 Yrs)
- C → Increased frequency (≤ 2 yrs)

11.3.5 Determination of Scope of Next Inspection

Based on the site's risk rating, considerations will be made on the scope and aspects to be considered in the next inspection. These include but are not limited to:

- Previous deficiencies identified
- gaps or areas not assessed in previous inspection
- Major changes at the site
- Quality issues

NB: Annex 1 lists typical GMP deficiencies that inspectors may observe during an inspection. It is not intended to be an all-inclusive/ exhaustive list, and inspectors may identify other observations.

12. REFERENCES

- i. WHO TRS 996 Annex - WHO GMP inspection report writing
- ii. PI 040-1- PIC/S Guidance on classification of GMP deficiencies.



13. ANNEXURES

ANNEX 1: TABLE OF TYPICAL GMP DEFICIENCIES (NON-EXHAUSTIVE)

GMP SYSTEM	CRITICAL	MAJOR	MINOR (OTHER)
PREMISES	i. No air filtration system (WHO TRS 1010 Annex 8:4.6, 4.8)	i. Malfunctioning of the ventilation system that could result in possible localized or occasional cross-contamination. (WHO TRS 1010 Annex 8:7.1)	i. Manometric gauges used to monitor pressures in the rooms, not temperature sealed after calibration. (WHO TRS 1010 Annex 8:7.10)
	ii. Design of premises does not allow logical flow of material and personnel - cross contamination/mix up evident (WHO TRS 986 Annex 2:12.10)	ii. No separate area/Insufficient precautions to prevent contamination or cross-contamination during raw material sampling (WHO TRS 986 Annex 2:12.22)	i. Inadequate rest, change, wash-up and toilet facilities. (WHO TRS 986 Annex 2:12.12)
EQUIPMENT	i. Equipment used for complex manufacturing operations of critical products not qualified and with evidence of malfunctioning or lack of appropriate monitoring. (WHO TRS 1019 Annex 3:5.10-5.11, 10)	i. Equipment used during the critical steps of fabrication, packaging/labelling, and testing, including computerized systems, is not qualified. (WHO TRS 1019 Annex 3:5.10-5.11, 10) (WHO TRS 1019 Annex 3: 1.1 Appendix 5)	i. Minor equipment for non critical products not qualified (WHO TRS 1019 Annex 3:5.10-5.11)
	ii. Evidence of contamination of products by foreign materials such as grease, oil, rust and particles from the equipment. (WHO TRS 986 Annex 2:13.1, 13.9)	ii. Inappropriate equipment for production: surfaces porous/potentially reactive and non cleanable/material shed particles.	ii. Insufficient distance between equipment and walls to permit cleaning. (WHO TRS 986 Annex 2: 13.1, 13.3)



		(WHO TRS 986 Annex 2:13.9)	
PERSONNEL	i. Individual in charge of Quality Control (QC) or production for a fabricator of critical/high risk products does not hold a relevant qualification in a science related field to the work being conducted and does not have sufficient practical experience in their responsibility area. (WHO TRS 986 Annex 2:9.7)	i. Individual in charge of QC or Production for a manufacturer of a low-risk product does not hold a relevant qualification in a science related field to the work being conducted and does not have sufficient practical experience in their responsibility area. (WHO TRS 986 Annex 2:9.7) ii. Delegation of responsibilities for QC or Production to insufficiently qualified persons. (WHO TRS 986 Annex 2: 9.3, 9.15)	i. Inadequate records. ii. Insufficient written training program (WHO TRS 986 Annex 2: 10.1, 10.2)
SANITATION & HYGIENE	i. Evidence of widespread accumulation of residues/extraneous matter indicative of inadequate cleaning. (WHO TRS 986 Annex 2:3.1) ii. Evidence of gross infestation. (WHO TRS 986 Annex 2:12.9)	i. Sanitation program not in writing but premises in acceptable state of cleanliness. (WHO TRS 986 Annex 2:15.48) ii. Cleaning procedures for production equipment not validated (including analytical methods). (WHO TRS 1019 Annex 3:3.1 Appendix 3)	i. Incomplete sanitation procedure. ii. Incomplete implementation of the written sanitation program. (WHO TRS 986 Annex 2:15.48)



GOOD PRACTICE IN PRODUCTION	i. No written Master Formula. (WHO TRS 986 Annex 2: 15.22) ii. Evidence of falsification or misrepresentation of manufacturing and packaging orders. (WHO TRS 1033 Annex 3: 4.5)	i. Master Formula prepared/verified by unqualified personnel. (WHO TRS 986 Annex 2: 15.22) ii. Deviations from instructions during production not documented and not approved by QC. (WHO TRS 986 Annex 2: 2.1 f)	i. Incomplete SOPs for handling materials and products. (WHO TRS 986 Annex 2: 16.2) ii. Inadequate checks for incoming materials. (WHO TRS 986 Annex 2: 14.10)
	i. No person in charge of QC available on premises. (WHO TRS 986 Annex 2: 9.6) ii. Quality Control department is not a distinct and independent unit, lacking real decisional power, with evidence that QC decisions are often overruled by production department or management. (WHO TRS 986 Annex 2: 9.6, 9.7) iii. Evidence of falsification or misrepresentation of analytical results. (WHO TRS 1033 Annex 3: 4.5)	i. Inadequate facilities, personnel and testing equipment. (WHO TRS 986 Annex 2: 2.1c (i), (ii)) ii. Products made available for sale without approval of QC department (WHO TRS 986 Annex 2: 9.13, 9.14 (i)) iii. Raw material/packaging material used in production without prior approval of QC. (WHO TRS 986 Annex 2: 14.4) iv. Insufficient testing of raw material. (WHO TRS 986 Annex 2: 14.12, 14.14)	i. No agreement between the contract laboratory and the establishment covering the testing activities. (WHO TRS 986 Annex 2: 7.1) ii. Investigations of non-conformances not completed in timely manner. (WHO TRS 986 Annex 2: 1.10, 5.5, 5.87) iii. Lots identified for confirmatory testing used in production without QC approval. (WHO TRS 986 Annex 2: 14.15)



DOCUMENTATION	Evidence of falsification or misrepresentation of records (WHO TRS 1033 Annex 3: 4.5)	i. Lack of or incomplete Production Documents. (WHO TRS 986 Annex 2: 15.22, 15.23) ii. Unavailability of documentation from suppliers in a timely manner. (WHO TRS 986 Annex 2: 17.16)	i. Insufficient retention time for evidence and records to be maintained. (WHO TRS 1033 Annex 4: 11.17) ii. No organisation charts. (WHO TRS 986 Annex 2: 9.3)
STABILITY	i. No data available to establish the shelf-life of products. (WHO TRS 986 Annex 2: 17.23) ii. Evidence of falsification or misrepresentation of stability data/forgery of COA. (WHO TRS 1033 Annex 3: 4.5)	iii. Insufficient number of lots to establish shelf-life. (WHO TRS 1010 Annex 10 :2.2.3) (WHO TRS 986 Annex 2: 17.24c) iv. No action taken when data shows that the products do not meet their specifications prior to the expiry date. (WHO TRS 986 Annex 2: 1.5s, 16.36, 17.20)	i. Stability testing not performed at the time required by the written program. (WHO TRS 986 Annex 2: 17.24d)
STERILE PRODUCTS	i. Lack of or inadequate validation of critical sterilization cycles. (WHO TRS 1044 Annex 2: 8.35, 8.39) ii. No media fill performed to validate aseptic filling operations (WHO TRS 1044 Annex 2: 9.32) iii. No environmental controls/No monitoring for viable microorganisms during filling for aseptically filled products. (WHO TRS 1044 Annex 2: 9.1, 9.2, 9.24)	i. Aqueous-based products not subject to terminal steam sterilization without proper justification or approval through the marketing authorization. (WHO TRS 1044 Annex 2: 8.34) ii. Insufficient environmental controls/Insufficient monitoring for viable microorganisms during filling for aseptically filled products. (WHO TRS 1044 Annex 2: 9.1, 9.2, 9.24)	i. Inadequate control on the maximum number of personnel present in clean and aseptic areas. (WHO TRS 1044 Annex 2: 7.2)



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PHARMACEUTICAL QUALITY SYSTEM	i. Non existing pharmaceutical quality system, no SOPs or policies on OOS, deviations, change management, market complaints handling. (WHO TRS 986 Annex 2:1.1, 1.5)	i. Deviations, market complaints and OOS not recorded or adequately investigated. (WHO TRS 986 Annex 2:1.5(m), (n))	i. Lack of / inadequate periodic trending of deviations, incidents, OOS, complaints, changes, risk assessments. (WHO TRS 986 Annex 2:1.5(m), (p))



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