



Zambia Medicines Regulatory Authority

**GUIDELINES ON THE CATEGORIZATION OF GOOD STORAGE AND DISTRIBUTION
PRACTICES INSPECTION DEFICIENCIES**

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1. INTRODUCTION

The Zambia Medicines Regulatory Authority (ZAMRA) was established under the Medicines and Allied Substances Act No. 3 of 2013 of the Laws of Zambia to regulate and control the manufacture, importation, storage, distribution, supply, sale, and use of medicines and allied substances. Its principal objective is to ensure that all medicines and allied substances made available to the Zambian public consistently meet established standards of quality, safety, and efficacy.

Section 5 of the Medicines and Allied Substances Act No. 3 of 2013 of the Laws of Zambia requires that pharmaceutical outlets be inspected for the purpose of ensuring compliance with the law.

These guidelines relate to deficiencies for all inspections covering pharmaceutical wholesale outlets, retail and hospital pharmacies, health shops and agro-veterinary shops.

2. OBJECTIVE

The objective of these guidelines is to standardise the classification of deficiencies arising from inspections of pharmaceutical wholesale outlets, retail or hospital pharmacies, agro-veterinary shops, health shops or any other storage area of medicines and allied substances.

Standardisation will help ensure that there is a consistent view of what constitutes a “Critical”, “Major” or “Minor” deficiency. Risk management principles will be applied in the categorisation of these deficiencies depending on the type of inspection or premises.

3. SCOPE

These guidelines apply to all GSDP inspection deficiencies arising from inspections and provide actions to be taken by the Authority in response to the reporting of critical and major deficiencies.

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.



“Corrective action” means steps that are taken to eliminate the causes of existing nonconformities in order to prevent recurrence.

“Deficiency” means a non-fulfilment of a specified requirement.

“Good Manufacturing Practice (GMP)” 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.

“Good Storage and Distribution Practice (GSDP)” means the part of quality assurance that ensures that the quality of medicines and allied substances is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from , unapproved, illegally imported, stolen, substandard and falsified medicines and allied substances.

“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.

“ 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;

“Quality management system” means a documented system with a collection of business processes focused on consistently meeting customer requirement and enhancing their satisfaction. It is aligned with an organization’s purpose and strategic direction. It provides a proactive approach to identifying, evaluating and controlling potential risk to quality. It facilitates continual improvement process performance and maintenance of product quality.

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

“Standard operating procedure (SOP)” means a written set of step-by-step instructions that explains how to carry out a specific task or process consistently and correctly.

“Responsible person” includes a pharmacist, pharmacy technologist, veterinary surgeon, veterinary para-professional, or as the case may be, or such other person as the Authority may determine.



5. ABBREVIATIONS

APC:	Annual Practicing Certificate
CAPA:	Corrective and Preventive Action
GMP:	Good Manufacturing Practice
GSDP:	Good Storage and Distribution Practice
HPCZ:	Health Professions Council of Zambia
VAZ:	Veterinary Association of Zambia
WHO:	World Health Organisation
ZAMRA:	Zambia Medicines Regulatory Authority

6. CLASSIFICATION OF GSDP DEFICIENCIES

6.1 Deficiencies are classified as **Critical, Major**, or Others (**Minor**), and are further categorized according to the functions related to **premises, products, and personnel**. The definitions of these classifications are as follows:

6.2

- i. **Critical Deficiency** is defined as any departure from the principles of Good Storage and Distribution Practices (GSDP) that results in, or is likely to result in, premises in respect of which the application is made is inadequate in size, poses a significant risk to public or animal health. Examples of critical deficiencies include, but are not limited to, the following:
 - ii.
 - iii. . a) Storage of medicinal products requiring refrigeration at ambient temperature;
b) Procurement of medicinal products from, or supply of medicinal products to, unauthorized persons or entities; and
c) Identification of rejected or recalled products within saleable stock, among others.
- iv. **Major deficiency** is defined as a non-critical observation that:
 - a) Indicates a significant deviation from (GSDP) which may result in a medicinal product failing to comply with the conditions of its marketing authorisation, particularly with respect to storage and transportation requirements;
 - b) Indicates a failure of the Responsible Person to adequately fulfil his or her duties and responsibilities; and



- c) Consists of several other deficiencies which, individually, may not be classified as major, but which collectively represent a major deficiency and should therefore be explained and reported as such.
- v. **Other (Minor) deficiency** is defined as a deficiency that cannot be classified as either critical or major, but which nonetheless represents a departure from (GSDP) guidelines. Such a deficiency may be classified as minor where it is considered to have limited impact, or where insufficient information is available to justify classification as either a major or critical deficiency.
- 6.3 Classification of a deficiency shall be based on the level of risk assessed and may vary depending on the nature of the business. For example, in certain circumstances, a deficiency that would ordinarily be considered minor may be classified as major in a retail pharmacy or health shop, as applicable.
- 6.4 A deficiency identified during a previous inspection that has not been adequately corrected may be assigned a higher classification during a subsequent inspection.
- 6.5 One-off minor lapses or less significant issues may not usually be formally reported but are brought to the attention of the responsible person during the inspection.

The annexure below shows the typical GSDP non-conformances that inspectors may observe during an inspection. It is not intended to be an all-inclusive/ exhaustive list, and inspectors may identify other observation.

7. Annex I Criteria and guidance for classification of deficiencies (The table below classifies deficiencies where applicable)

GDP areas	Critical	Major	Minor/ Other
PREMISES (I)	i. No natural ventilation ii. No permanent structure for running the business iii. No artificial ventilation iv. No lighting system v. No main front/sales shop or showroom vi. Main/front shop with inadequate size vii. No dispensary viii. Dispensary with inadequate size. ix. Consultation room with inadequate size.	i. Inadequate artificial ventilation. ii. Inadequate natural ventilation (Windows and/or vents etc.). iii. Inadequate artificial lighting. iv. Inadequate natural lighting. v. Inadequate clean workspace and free from obstruction vi. Walls and paintwork that are not in a good state of repair. vii. Ceilings not in a good state of repair. viii. No burglar bars on doors and windows or inadequate security features.	i. Details of Location (Indicate information as applicable) ii. Premises not readily identifiable as retail pharmacy/wholesale/H ealth Shop/Agro-veterinary Shop iii. Signage inappropriate and not in good repair iv. No suitable area for medication counselling.



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GDP areas	Critical	Major	Minor/ Other
	x. Lack of a lockable recalled products room	ix. Lack of appropriate measures in place for security of the premises. (e. g guard(s) and/or alarm)	
	xi. Inadequate size of storeroom	x. Non-availability of floor that is smooth (made of concrete, terrazzo, tiles, wooden or earth nature).	
	xii. No bulk storeroom		
	xiii. Inadequate size of office	xi. Non-availability of adequate and appropriate firefighting facilities.	
	xiv. Bulk storeroom with inadequate size	xii. No receiving bay.	
	xv. Non-availability of the main warehouse	xiii. No dispatch bay.	
	xvi. No lockable expired products room/area/cupboard.	xiv. No quarantine area/room.	
		xv. No adequate pallets.	
		xvi. No adequate shelves.	
		xvii. Non-availability of transportation facilities.	



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GDP areas	Critical	Major	Minor/Other
	xvii. Lack of Controlled Substances Cupboard or separate storeroom xviii. No sufficient storage area for segregation of different stocks on the premises. xix. Non-availability of building of sound construction and of permanent nature	xviii. Facility has cracks, holes and/or signs of water damage xix. Dispensary not suitably located e.g. located near the area for cleaning equipment or toilet(s). xx. No lockable and labelled Cupboard or room for stocking Controlled substances	
EQUIPMENT AND ACCESSORIES (02)	i. Storage area not equipped with shelves and/or pallets with easy access to medicines	i. No measuring cylinders. ii. No weighing balance. iii. No mortar and pestle. iv. No counting trays.	i. No appropriate pallets for keeping medicines and allied substances



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GDP areas	Critical	Major	Minor/Other
		v. No refrigerator or cold room. vi. Non-availability of distilled water (or an electric kettle). vii. No self-adhesive labels. viii. No self-sealing plastic bags. ix. Non-availability of suitable thermometer for the refrigerator, front shop, dispensary, storeroom and bulk store. x. No suitable hands free or pedal waste bins for waste materials. xi. Non-availability of temperature charts for recording of room and cold-chain temperature xii. Equipment not calibrated.	



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GDP areas	Critical	Major	Minor/ Other
PERSONNEL (03)	i. Non-engagement of fully registered responsible person. ii. Engagement of responsible person without valid annual practicing certificate iii. Responsible person engaged is in full-time employment elsewhere	i. Inadequate personnel engaged as support staff. ii. No responsible person is available at time of inspection. iii. No evidence of initial or continued training in accordance with a written program iv. No employment contract signed by both parties and v. No job description for the employees	i. No safety procedure relating to relevant personnel
SANITATION & HYGIENE (04)	i. Premises not maintained in an orderly, clean and hygienic manner. ii. Lack of water closet (toilet) or access to a	i. Surroundings not clean and tidy. ii. No soap (preferably liquid soap). iii. Working surfaces uncleanable, cluttered and susceptible to dirt and moisture.	



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GDP areas	Critical	Major	Minor/ Other
	toilet(s) that is clean and hygienic. iii. Door of toilet opening directly to the medicines and allied substances storage areas	iv. Working surfaces not clean, rough and made of material that is not easy to maintain in a hygienic condition. v. Adequate personal hygiene and sanitation. vi. Lack of hand-washing facility. vii. No source of clean water.	
GOOD STORAGE AND DISTRIBUTION PRACTICE (05)		i. No system for monitoring expiry dates of products. ii. No system for monitoring substandard and falsified products iii. Not stocking products in compliance with a prescribed list as outlined by the regulation.	
DOCUMENTATION (06)	i. Non-availability of Certificate of Incorporation or Certificate of Business	i. Non-conspicuous display of Certificate of Incorporation or Certificate of Business Registration (PACRA), ZAMRA Certificate of	i. No computer(s) or any other system for record keeping of products.



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GDP areas	Critical	Major	Minor/ Other
	Registration (PACRA), Certificate of Payment (Business Levy) and Fire Certificate	Registration/Licence/Permit, Certificate of Payment (Business Levy), Fire Certificate, and HPCZ/VAZ full registration certificate and valid APC of the responsible person not conspicuously displayed on the premises. ii. No Receipt/issue books provided. iii. No Goods Received Note available. iv. No Dispatch Notes v. No Invoices/ Delivery notes vi. No requisition/order book(s) vii. No bin cards or electronic system to monitor stock at the premises. viii. No prescription files/books ix. No Expired Product Register x. No Dangerous Drug Register.	ii. No customised prescriptions pads/books/other. iii. No Inspectors' book in place. iv. Non-availability of the following recommended Recent Edition Reference Materials:

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GDP areas	Critical	Major	Minor/ Other
		xi. No Recalled Product Register xii. No Quarantined Product Register? xiii. No logbook for Part-time Pharmacist or Veterinary Surgeon? xiv. Non-availability of the following Mandatory Recent Edition Reference Materials: • Medicines & Allied Substances Act No. 3 of 2013 • Health Professions Act No. 17 of 2023 • Controlled Substances Act No.2 of 2023 • Narcotic Drugs & Psychotropic Substances Act No. 35 of 2021 • Animal Health Act No. 27) 2010. • Veterinary Professions and Para-Professions Act (No.45) of 2010.	



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GDP areas	Critical	Major	Minor/ Other
		• Zambia National Formulary (ZNF) • Standard Treatment Guidelines • Standards of Pharmaceutical Practices British National Formulary • British National Formulary Pediatrics • Martindale • Agro-veterinary Guidelines 2018 • Health Shop Guidelines • Good Storage and Distribution Practice Guidelines • Good Cold Chain Management Practices Guidelines	
		xv. Non-availability of recommended Standard of Operating Procedures (SOPs).	



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GDP areas	Critical	Major	Minor/Other
QUALITY MANAGEMENT SYSTEM (07)		Non availability of the following Standards operating procedure (SOPs), but not limited to the list: i. SOP on Complaint Handling. ii. SOP on handling Recalled products. iii. SOP on handling Expired products. iv. SOP on handling Quarantined Products. v. SOP on Storage and Distribution of products. vi. SOP on Cleaning Procedures. vii. SOP on Management of waste generated. viii. SOP on Maintenance of Equipment provided. ix. SOP on reporting of adverse drugs reactions/events. x. SOP on contingency in the event no pharmacist is present	i. SOP on CAPA handling



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8. Annex II: Compliance status determination Scenarios Pre-licensing

Scenario Number	Scenario Number	Inspection conclusion
Pre-licensing Scenarios		
1.	Other (minor) deficiencies and/or one (1) to five (5) major deficiencies not structural	CAPA to be evaluated and subject to an internal approval process.
2	Other (minor) deficiencies plus (+) six (6) or more major deficiencies or any other major deficiencies which are structural	Re-inspection
3	Critical deficiencies	Rejection
Post-licensing Scenarios		
No responsible person engaged	Issue notice of intent to suspend operation	
Conducting services outside the scope of the respective Permit, Certificate of Registration and Pharmaceutical Licence.	Issue notice of intent to suspend operation	
Non-compliance with the terms and conditions of the Certificate of Registration, Permit and Pharmaceutical Licence	Issue notice of intent to suspend operation	



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*Refer to above scenarios for other observations other than the ones specified under post-licensing specifics – shall result in
issuance of notice of intent to suspend operation.*