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RWANDA FDA Rwanda Food and Drugs Authority	**Title:** **SUSPECTED POOR QUALITYPRODUCT REPORTING FORM**	Revision Number : 2 Revision Date: : 05/08/2022 Effective Date : 12/08/2022 Review Due Date : 05/08/2025 Ref Doc. :FDISM/PVSM/GDL/003

I. PRODUCT CATEGORY (Tick as appropriate)

Medicinal product ☐Vaccine ☐ Other Biological Products ☐Herbal product ☐Other *(Please Specify):*

……

II. PRODUCT DETAILS

Brand name				Generic Name			
Batch/Lot Nº		Manufacturing Date		Expiry date		Date of receipt	
Name of manufacturer				Physical Address and Country of Origin			
Name of Distributor/Supplier				Distributor/ Supplier's Address			

III. PRODUCT FORMULATION

☐ Tablets /capsules
☐ Suspension/Syrup
☐ Injectable/Infusions
☐ Creams/Ointment/Liniment/Paste
☐ Pessaries
☐ Suppository
☐ Powder for reconstitution of oral suspension
☐ Powder for reconstitution of injection
☐ Ear/Eye drops
☐Diluents
☐Nebulizing solutions
☐Other *(Please Specify)* ……

IV. DESCRIPTION OF PRODUCT COMPLAINT

☐Color/odor change
☐Molding
☐Turbidity
☐Mislabelling
☐Poor Packaging/ lack of patient leaflet/ lack measuring devices
☐Therapeutic ineffectiveness
☐Particulate matter
☐Seal Integrity of packs and/ or Leakage
☐Caking
☐Separating
☐ Incomplete packs
☐Powdering/crumbling
☐ Suspected falsified/ Substandard
☐Others*Specify)* ……

Describe the Complaint in details:

……
……

V. PRODUCT STORAGE CONDITIONS

Does product require refrigeration? **YES☐NO☐**
Does product require protection from light? **YES☐NO☐**
Does product require protection from Moisture? **YES☐NO ☐**
Was it stored following manufacturer/Rwanda FDA guidelines?**YES☐ NO☐**

Other Storage details *(if necessary):*

VI. CIRCUMSTANCE AND TIME OF THE POOR-QUALITY DETECTION

When did you notice the poor-quality problem?
☐Before taking/administering the product
☐While taking/administering the product
☐After taking/administering the product
☐When the patient returned the product

☐After a complaint of the patient
☐After Visual inspection
☐After quality control
☐Other(specify)…….

VII. ACTION TAKEN

☐ Stop Taking/Administration of the product
☐Quarantining the product
☐ Returning the product to the supplier
☐Other (specify):…….

Have you experienced any adverse event after taking this medicine? **YES** ☐ **NO** ☐If **YES,** please complete the ADR/AEFI Reporting Form.

VIII. REPORTER INFORMATION

Name of reporter:		Qualification:		Phone number:	
Name of Health Facility		District:		Report Reference No:	
E-mail Address:		Contact/Tel No:		Date of report:	

All information is held in strict confidentiality and will not disclose reporter's identity in response to any public request. Information supplied will contribute to the improvement of safety and vigilance of Medical Products in Rwanda. Once this form is completed please send it to Rwanda FDA via the following email: ***pv_sm@rwandafda.gov.rw***