



**MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD
DEPARTMENT OF PHARMACOVIGILANCE
FORM FOR REPORTING POOR QUALITY MEDICINAL PRODUCTS**

IN CONFIDENCE

Name of Facility	District Name	Province Name
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Facility Address	Facility Telephone
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PRODUCT IDENTITY

Brand Name		Generic Name	
Batch/Lot Number	Date of Manufacture	Date of Expiry	Date of Receipt
Name of Manufacturer		Country of Origin	
Name of Distributor/Supplier	Distributor/Supplier's Address		

PRODUCT FORMULATION (Tick appropriate box)	COMPLAINT (Tick appropriate box/boxes)
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<input type="checkbox"/> Oral tablets / capsules <input type="checkbox"/> Oral suspension / syrup <input type="checkbox"/> Injection <input type="checkbox"/> Diluent <input type="checkbox"/> Powder for reconstitution of suspension <input type="checkbox"/> Powder for reconstitution of injection <input type="checkbox"/> Eye drops <input type="checkbox"/> Ear drops <input type="checkbox"/> Nebuliser solution <input type="checkbox"/> Cream / Ointment / Liniment / Paste <input type="checkbox"/> Other	<input type="checkbox"/> Colour change <input type="checkbox"/> Separating <input type="checkbox"/> Powdering / crumbling <input type="checkbox"/> Caking <input type="checkbox"/> Moulding <input type="checkbox"/> Change of odour <input type="checkbox"/> Mislabeling <input type="checkbox"/> Incomplete pack <input type="checkbox"/> Other
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Describe complaint in detail:

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Storage Conditions

Does the product require refrigeration?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<i>Other details (if necessary):</i>
Was product available at facility?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Was product dispensed and returned by client?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Was product stored according to manufacturer/MoH recommendations?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	

Comments (if any)

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Name of Reporter	Contact number
Cadre / Job Title	Signature

Once completed one copy of this form should be e-mailed or posted to:

Pharmacy and Poisons Board	Department of Pharmacovigilance	P. O. Box 27663-00506 NRB	Fax: 2713431	E-mail: pv@pharmacyboardkenya.org
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Your support in this Pharmacovigilance program is appreciated.

Submission of a complaint does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to an event. All information is held in strict confidence and programme staff is not expected to and will not disclose reporter's identity in response to any public request. Information supplied by you will contribute to the improvement of drug safety and therapy in Kenya. Once completed please send to:
The Pharmacy and Poisons Board on the above address