

UNITED REPUBLIC OF TANZANIA  
MINISTRY OF HEALTH



TANZANIA FOOD AND DRUGS AUTHORITY  
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**FACILITY PHYSICAL EXAMINATION RESULTS FORM (TFDAINS Form 003)**

**1. General Information**

Facility Type (circle)	Warehouse	Wholesale/ Retail	Retail Part I	DLDB (Part II)/ DLDM	Hospital	Health Centre	Dispensary
Name of Facility							

**2. Product Information**

Product Name:		
Batch #:	Date of Manufacture:	Date of Expiry:
Manufacturer:		
Country of Manufacturer:		
Product Form/Category (select one)	Tablets (go to Section 3A)	
	Capsules (go to Section 3B)	
	Liquids: solutions and syrups (go to Section 3C)	
	Liquids: suspensions (go to Section 3D)	
	Parenterals: solutions and suspensions (go to Section 3E)	

### 3. Test Results and Observations

<b>A) Tablets</b>				
	<b>Parameter</b>	<b>Specifications</b>	<b>Status</b>	
			<b>Pas s</b>	<b>Fai l</b>
1	Odour (immediately on opening the outer container)	No odour, except for flavoured tablets and those with active ingredients normally having characteristic odour		
2	Odour (after exposing the tablets according to recommended plan of exposure)	No odour, except for flavoured tablets and those with active ingredients normally having characteristic odour		
3	Uniformity of size, shape, colour, and coating (visual inspection)	Uniform in size and shape, uniformity of colour and coating		
4	Tablet core fully covered	Uniform coating with core fully covered		
5	Polishing	Uniformly polished and free of adhering fine powders		
6	Markings (scoring, letters, etc.)	Uniform and identical		
7	Breaks, cracks, splitting, capping, and cavitations	Free of breaks, cracks, splitting, capping, and cavitations		
8	Embedded surface spots, foreign particulate contamination	Free of embedded surface spots, foreign particulate contamination		
9	Other (specify)			
<b>B) Capsules</b>				
	<b>Parameter</b>	<b>Specifications</b>	<b>Status</b>	
			<b>Pas s</b>	<b>Fai l</b>
1	Odour (on immediately on opening the outer container)	No odour, except for those with active ingredients normally having characteristic odour		
2	Odour (after exposing the capsules according to recommended plan of exposure)	No odour, except for those with active ingredients normally having characteristic odour		
5	Presence of empty, broken, or separated capsules	Free of empty capsules, no broken capsules		
4	Pinholes in capsules	Free of pinholes in capsules		
5	Stickiness between capsules	Capsules are not sticky		
6	Container/bottle free of powder and/or extraneous material	Container/bottle free of powder and/or extraneous material		
7	Weak point in body of capsule	No weak point in body of capsule		
8	Other (specify)			

<b>C) Liquids: Solutions/Syrups</b>				
	<b>Parameter</b>	<b>Specifications</b>	<b>Status</b>	
			<b>Pass</b>	<b>Fail</b>
1	Particulate matter	Should be entirely free from foreign particles		
2	Clarity	Should be clear and free of turbidity		
3	State of primary container	Should not show any evidence of cracks, breaks, tears, or leakage		
4	Other (specify)			
<b>D) Suspensions</b>				
	<b>Parameter</b>	<b>Specifications</b>	<b>Status</b>	
			<b>Pass</b>	<b>Fail</b>
1	Dispersability	Easily dispersed to obtain a homogeneous suspension upon moderate shaking for 20 seconds and remain homogeneous for 3 minutes		
2	State of primary container	Should not show any evidence of cracks, breaks, tears, and leakage		
3	Other (specify)			
<b>E) Solutions/Suspensions</b>				
	<b>Parameter</b>	<b>Specifications</b>	<b>Status</b>	
			<b>Pass</b>	<b>Fail</b>
1	Clarity	Should be clear and free of turbidity		
2	Dispersability	Easily dispersed to obtain a homogeneous suspension upon moderate shaking for 20 seconds and remain homogenous for at least 3 minutes		
3	Flowability (aqueous)	Aqueous injectable suspensions should flow freely without binding when the contents of vial/ampoule are aspirated through a 22-gauge, 1-inch hypodermic needle, using a hypodermic syringe with a suitable volume		
4	Flowability (non-aqueous)	Non-aqueous injectable suspensions should flow freely without binding when the contents of the vial/ampoule are aspirated through an 18-gauge, 1.5-inch hypodermic needle, using a hypodermic syringe with a suitable volume		
5	State of primary container	Should not show any evidence of cracks, breaks, tears, or leakage		
6	Other (specify)			

#### 4. Conclusion/Decision

<b>STATUS: The sample as visually inspected</b> (tick as appropriate)		<i>Remarks (if any):</i>
<input type="checkbox"/>	<b>Pass</b>	
<input type="checkbox"/>	<b>Fail</b>	

#### 5. Is there any other batch for physical examination? Y / N (circle one)

If yes, return to Section 2, Product Information, and fill in the remainder of the form for the new batch. If no, go to #6.

#### 6. Names of Inspector:

#### Signature:

<b>(a)</b>		
<b>(b)</b>	<b>Date:</b>	

*Note:* SOP No. TFDAINS 002 requires the inspector to skip physical examination for suppositories, pessaries, creams/ointments, and solutions packaged in opaque containers (e.g., eyedrops).

<b>Prepared by:</b>	<b>Checked by:</b>	<b>Approved by:</b>
<b>Date:</b>	<b>Date:</b>	<b>Date:</b>