UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

TANZANIA FOOD AND DRUGS AUTHORITY
Tel: +255-22-2450512/2450751
FAX: +255-22-2450793
Web site: http//www.tfda.or.tz

PORT OF ENTRY (POE) PHYSICAL EXAMINATION RESULTS FORM (TFDAINS Form 002)

1. POE Name

POE (circle)	DIA	DRH	MSD	NAM	SIR	KIA	MWA	MWH
	TAN	HOR	HOL	KIG	TUN	KYE	MTU	MTW

Control Type (circle)	R	AWB	C21	C29	F89	
Control Type Number						

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

A) Tablets

	Parameter	Specifications	Status	
			Pass	Fail
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) Capsules				
	Parameter	**Specifications**	**Status**	
			Pass	**Fail**
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)			

C) Liquids: Solutions/Syrups				
	Parameter	**Specifications**	**Status**	
			Pass	**Fail**
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)			

D) Suspensions				
	Parameter	**Specifications**	**Status**	
			Pass	**Fail**
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)			

E) Solutions/Suspensions				
	Parameter	**Specifications**	**Status**	
			Pass	**Fail**
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

STATUS: The sample as visually inspected (tick as appropriate)		*Remarks (if any):*
	Pass	
	Fail	

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. Name of Inspector: Signature:

	Date:	

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).

Prepared by:	**Checked by:**	**Approved by:**
Date:	**Date:**	**Date:**