UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

TANZANIA FOOD AND DRUGS AUTHORITY
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PORT OF ENTRY (POE) CONSIGNMENT INSPECTION FORM
(TFDAINS Form 001)

(A rejoinder to SOP for Inspection of Pharmaceutical Consignments at Ports of Entry)

Particulars in this checklist must be filled in for every consignment imported into the country.

A) Consignment Information

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

2. Is consignee (importer) registered with the TFDA? (Y / N)

Name of Consignee……

3					**4**	**5**	**6**	
Control Type (circle)					**Control Type Number**	**Date of Inspection**	**Name of Manufacturer and Country of Origin**	
R	**AWB**	**C21**	**C29**	**F89**			Manufacturer	Country

7	**8**	**9**	
Is the consignment a donation? (Circle)	**Monetary Value of Consignment**	**Currency** (Circle)	
Y / N		U.S. Dollar ($) E.U. Euro (€) U.K. Pound (£) Kenyan Shilling (Ksh) S.A. Rand (R)	Swiss Franc (CHF) Egyptian Pound (£) Tanzanian Shilling (Tsh) Other: (please indicate) ……..

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

B) Documentation

Observations		Results/Decision (Circle Y for yes or N for no. Unless otherwise specified, if no, write "DETAINED"[1] in right column)			
1a.	Does the consignee have a Pro Forma Invoice (PI) with an original endorsement by the Tanzania Food and Drugs Authority (TFDA)? If yes, proceed to #1b.	**Y**	**N**		
1b.	If the consignment includes controlled drugs, does the consignee have an Import Certificate (IC) with an original endorsement by the authorised official of the TFDA? If yes, proceed to #1c.	**Y**	**N**	**N/A**	
1c.	Are the specified products imported from sources indicated in the PI/IC? If yes, proceed to #1d.	**Y**	**N**		
1d.	Is the consignment being imported through the declared POE? If yes, enter the PI[2] or IC number and date and proceed to #2.	**Y**	**N**		
		PI #:		**IC #:**	
		PI Issue Date:		**IC Issue Date:**	
2.	Is the Clean Report of Findings (CRF)/Final Classification and Valuation Report (FCVR)/Import Declaration Form (IDF) receipt date within the expiry date of the PI/IC? If yes, record the date of receipt and proceed to #3.	**Y**	**N**	**Date Consignment Received at POE:**	
3.	Are the exporter and importer named in the CRF/FCVR the same as those listed in the PI? If yes, proceed to item #4.	**Y**	**N**		
4a.	Does the free on board (FOB) value of the CRF/FCVR/IDF **match** the value indicated in the authorised PI? If yes, proceed to item #4b.	**Y**	**N**		
4b.	Do the item's description and the quantities for each of the products indicated in the CRF/ FCVR **match** the quantities authorised in the PI? If no, see #4c and #4d. If yes, proceed to item #5.	**Y**	**N**		

[1] "DETAINED" means: (a) stop the inspection; (b) complete a Rejection/Detention Form; (c) inform the TRA/C&E of the rejection/detention; (d) give a copy of the Rejection/Detention Form to the TRA. If detention issues are resolved by written instructions from the TFDA, proceed from where the inspection stopped.

[2] Pro Forma Invoice will be valid for six months from date of endorsement by the TFDA.

4c.	Are the item's description and quantities indicated in the CRF **greater than** those authorised in the PI? If no, see #4d. If yes, detain consignment.	**Y**	**N**		
4d.	Are the item's description and quantities indicated in the CRF **less than** those authorised in the PI? If yes, mark the quantities of short-landed items on the PI, write "partial shipment," and proceed to #5a.	**Y**	**N**		
5a.	Does the consignment require a Certificate of Analysis (COA)? If yes, go to #5b. If no, go to Section C (Physical Examination and Testing).	**Y**	**N**		
5b.	Is the COA present with the consignment?	**Y**	**N**		
5c.	Is there COA for each pharmaceutical batch?	**Y**	**N**		
5d.	If the consignment contains vaccines, is there a COA from the manufacturer and an approval from the regulatory authority of the country of origin?	**Y**	**N**	**NA**	
5e.	Is the COA signed and stamped by authorised person(s)?	**Y**	**N**		
5f.	Are the reported test results within specified limits?	**Y**	**N**		
5g.	For products with **more than** 24 months' shelf life, is 60% of their shelf life remaining?	**Y**	**N**	**NA**	
5h.	For the products with **less than** 24 months' shelf life, is 80% of their shelf life remaining?	**Y**	**N**	**NA**	
5i.	Do the batch numbers on the unit samples and the COAs match? If yes, proceed to #5j. If no, detain shipment.	**Y**	**N**		
5j.	Do the expiration dates on the unit samples and the COAs match? If yes, proceed to Section C (Physical Examination and Testing) for further verification of the consignment. If no, detain shipment.	**Y**	**N**		

(C) Physical Examination and Testing

1.	Indicate the categories of products:			
		Human Medicines		
		Pharmaceutical Raw Materials		
		Veterinary Medicines		
		Medical Supplies		
		Medical Equipment		
		Vaccines		
2.	Total number of products in the consignment	Enter #		
3.	Number of pharmaceutical products	Enter #		
4.	Number of pharmaceutical batches	Enter #		
5.	Does the label show any evidence of tampering? If no, proceed to #6. If yes, proceed to Section D (Conclusion) and reject.	**Y**	**N**	
6.	Is the language written on the label and package insert Swahili and/or English? If yes, proceed to #7. If no, proceed to Section D (Conclusion) and reject.	**Y**	**N**	
7.	Do unit samples collected from each batch have tamperproof seals? Are the seals intact? If both are yes, proceed to #8. If either are no, go to Section D (Conclusion) and reject.	**Y**	**N**	
8.	Does the consignment contain expired units? If no, go to #9. If yes, go to Section D (Conclusion) and reject.	**Y**	**N**	
9.	Conduct physical examination for all batches according to SOP No. TFDAINS 002 and using the POE Physical Examination Results Form (TFDAINS Form 002). Do samples pass physical examination? If yes, proceed to #10. If no, go to Section D (Conclusion).	**Y**	**N**	
10.	Does the consignment include products in the surveillance programmes? If yes, go to #11. If no, go to Section D (Conclusion).	**Y**	**N**	
11.	Total number of products in this consignment included in a surveillance programme			
12.	Total number of batches in this consignment included in a surveillance programme			
13.	Take samples for GPHF Minilab screening according to the Drug Quality Surveillance Programme's SOPs: SPD 02-01, SPD 03-01, and SPD 05-01			

(D) Conclusion

The consignment as inspected and tested as required is hereby:	*Remarks (if any):*
Released	
Rejected	*Reasons for rejection must be clearly indicated:*
Detained	*Reasons for detainment must be clearly indicated:*

Name(s) of Inspector(s)	**Signature and Date**