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

PART I DRUG DISPENSING OUTLET INSPECTION FORM (RETAIL PHARMACIES AND WHOLESALERS) (TFDAINS Form 004)

1. General

1.1	Region where the facility is situated (circle one on the list below)			
Arusha	Kagera	Manyara	Mwanza	Singida
Dar es Salaam	Kigoma	Mara Mbeya	Pwani Rukwa	Tabora
Dodoma	Kilimanjaro	Morogoro	Ruvuma	Tanga
Iringa	Lindi	Mtwara	Shinyanga	

1.2	Name of Outlet:			
1.3	Type: (circle)			
	Warehouse	Wholesale	Wholesale/Retail (Part I)	Retail Part I

1.4 Mailing Address:	1.5 Physical Address/Location:
…………….………………………………......	Street/Ward…………………………………….....................
…………….……………………………….…......	District……………………………………………....................

1.6	Telephone Number:	1.7	Fax Number:		
1.8	E-mail Address:				
1.9	Premises Licence Number:	1.10	Is the licence valid? Y / N	1.11	Is the original licence displayed? Y / N
1.12	Name of Pharmacist in Charge:	1.13	Pharmacist Registration Number:	1.14	Is the Certificate of Registration displayed? Y / N
1.15	Date of Inspection:	1.16	Date of Last Inspection:		
1.17	Ownership/Name of Proprietor(s):				
1.18	If the owner is not a pharmacist, does he/she have a valid contract with a registered pharmacist? Y/ N/ NA				

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

2. Personnel

2.1 Responsible Staff (other than the pharmacist in charge)

2.1.1	Name:	
2.1.2	Qualification:	
2.1.3	Position/Title:	

2.2 Sales Person(s)

2.2.1	Name	2.2.2	Qualifications
1.			
2.			
3.			

3. Type of Inspection

3.1. Circle one: Announced/Unannounced	3.2 Circle one: Routine, Concise, Follow-up, Special, Investigative	3.3 Postmarketing surveillance done? Y / N If yes, go to #10. If no, go to #4.

4. General Condition of Premises

4.1	Is the premises appropriate for the intended purpose in respect to: (please indicate Y for yes [pass] or N for no [fail])				
		Warehouse	**Wholesale**	**Wholesale/ Retail**	**Retail Part I**
4.1.1	Layout (display, dispensing, and storage room accessible and well secured against unauthorised entry)				
4.1.2	Size/number of rooms (warehouse and stores: enough space to minimise mix-ups; retail: separate rooms for display, dispensing, and storage)				
4.1.3	Hygiene (clean and free from debris)				
4.1.4	State of repair (no cracks or crevices on the floor, smooth painted walls)				
4.1.5	Ventilation and cooling system (working and provides suitable temperatures for drug storage)				
4.1.6	Lighting (adequate to enable reading of labels)				
4.1.7	Display of drugs (only OTC drugs are displayed)				
4.1.8	Utilities: water, handwash basins, WC				
4.2	In case of nonconformity, explain: If space provided is not enough, please use continuation page(s).				

5. Security of Premises

5.1	Are the premises secure in respect to:				
		Warehouse	**Wholesale**	**Wholesale/Retail**	**Retail Part I**
5.1.1	External perimeter security (fencing, gates, walls, windows, etc.)				
5.1.2	Special secure cupboards for restricted (controlled) drugs				
5.1.3	Accessibility to unauthorised person(s)				
5.1.4	Documents/records-keeping				
5.2	In case of nonconformity, explain: If space provided is not enough, please use continuation page(s).				

6. Storage Conditions

6.1	Are the storage conditions suitable for the intended purpose in respect to:				
		Warehouse	**Wholesale**	**Wholesale/ Retail**	**Retail Part I**
6.1.1	Durability of floor and ease of cleaning				
6.1.2	Prevention of infestation by vermin and pests				
6.1.3	Adequate shelving (no medicines are kept on the floor)				
6.1.4	Pallets				
6.1.5	Execution of stock rotation/FEFO				
6.1.6	Storage of returned/recalled/ expired/quarantined goods				
6.1.7	Cold rooms/refrigerators for the storage of vaccines and/or biologicals				
6.2	In case of nonconformity, explain: If space provided is not enough, please use continuation page(s).				

7. Ancillary Items

7.1	Does the facility do compounding? If yes, go to #7.2. If no, go to 8.	Y / N (circle)			
7.2	Are suitable ancillary items available for the intended purpose in respect to the follow items:				
		Warehouse	**Wholesale**	**Wholesale/Retail**	**Retail Part I**
7.2.1	Hotplate or any other source of heat				
7.2.2	Weighing balance(s) and weights				
7.2.3	Dispensing measures (measuring cylinders, beakers, etc.)				
7.2.4	Source of clean and safe water				
7.2.5	Mortar and pestle, spatula, and dispensing tray				
7.3	In case of nonconformity, explain: If space provided is not enough, please use continuation page(s).				

8. Record-Keeping and Documentation

8.1	Are record-keeping and documentation suitable for the intended use in respect to:				
		Warehouse	**Wholesale**	**Wholesale/Retail**	**Retail Part I**
8.1.1	Prescription Book				
8.1.2	Poison Book				
8.1.3	Controlled Drugs Register				
8.1.4	Written procedures for maintenance of cold-chain product				
8.1.5	Import Permit				
8.1.6	Ledger Book or an appropriate inventory control system				
8.1.7	TFDA-endorsed Pro Forma Invoices				
8.1.8	Receipts/invoices				
8.1.9	Copies of delivery notes				
8.1.10	Accuracy of record-keeping				
8.1.11	Do the physical quantities of narcotic/psychotropic drugs match those on the Register?				
8.1.12	Are the prescriptions for narcotic/psychotropic drugs written by duly qualified medical personnel and properly kept?				
8.1.13	Endorsement of entries by authorised person(s)				

8.1.14	Written procedures for handling returned, recalled, and/or expired drugs				
8.1.15	Written procedures for dealing with complaints and/or adverse reaction reports				
8.2	In case of nonconformity, explain: If space provided is not enough, please use continuation page(s).				

9.0 Reference Materials

9.1	Are appropriate reference material(s) available?				
		Warehouse	**Wholesale**	**Wholesale/Retail**	**Retail Part I**
9.1.1	*Tanzania National Formulary* (TNF)				
	Indicate edition of TNF				
9.1.2	*Tanzania Pharmaceutical Handbook*				
9.1.3	Tanzanian Food, Drug and Cosmetics Act 2003 and its corresponding regulations and guidelines				
9.1.4	Standard treatment guidelines				
9.1.5	National essential drugs list				
9.1.6	Current list of registered drugs				
9.1.7	Pharmaceuticals and Poison Act 1978 and its corresponding regulations and guidelines				
9.1.8	*Good Dispensing Manual* (Swahili/English versions)				
9.1.9	*British National Formulary*				
9.1.10	*British Veterinary Codex*				
9.2	In case of nonconformity, explain: If space provided is not enough, please use continuation page(s).				

10. Legality of Stocked Products

Note: In case of nonconformity, stop the inspection, confiscate the products, and fill in the Confiscation/Quarantine Form.

	Yes	No	Number of Products Confiscated
10.1 Are there unregistered products stocked on the premises?			
10.2 Are there unauthorised products in stock?			

11. Product Label Examination

11.1	Closely examine the products in stock and evaluate the labels in respect to:				
		Warehouse	**Wholesale**	**Wholesale/Retail**	**Retail Part I**
11.1.1	Language of labels and package inserts				
11.1.2	Any signs of tampering				
11.1.3	Labelling requirements				
11.2	In case of nonconformity, explain: If space provided is not enough, please use continuation page(s).				

12. Samples for Examination

12.1	Conduct physical examination on pharmaceutical products stocked in the facility according to SOP No. TFDAINS 002 and take samples of batches of antimalaria and antibiotic drugs included in the drug quality surveillance programme for GPHF Minilab screening. For suspicious antimalarials and antibiotics, take samples in accordance with SPD 02-00, SPD 02-01, SPD 03-01, or SPD 05-01, as appropriate.	
12.2	Number of batches of products sampled under the surveillance programme	
12.3	Number of batches of suspicious products sampled	

13. Any Other Observations

If space provided is not enough, please use continuation page(s).

14. Recommendations

Name and Address of Facility:	
Items requiring attention:	Actions agreed to be taken and timeline:

15. Owner's/In-charge Declaration

I/we, ……..……., the in-charge/owner of the said premises, certify the information and observations made on this sheet during the inspection of the premises to be true and correct.

Signature: …….....	Date: …….....

16. Name(s) of Inspector(s): Signature(s) of Inspector(s)

1.	……	
2.	……	
3.	……	
Date:		