

**UNITED REPUBLIC OF TANZANIA  
MINISTRY OF HEALTH**



**TANZANIA FOOD AND DRUGS AUTHORITY**  
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**PART II DRUG DISPENSING OUTLET INSPECTION FORM  
(DUKA LA DAWA BARIDI AND MUHIMU) (TFDAINS Form 008)**

**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)					
	Duka la Dawa Muhimu		Duka la Dawa Baridi			
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):					

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

## 2. Personnel

### 2.1 Responsible Staff

2.1.1	Name:	
2.1.2	Qualification:	
2.1.3	Position/Title:	

### 2.2 Sales Persons

Are all sales persons qualified to operate a Duka la Dawa Baridi/Muhimu? Y / N (circle one)			
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 #9. If no, go to #4.
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## 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])		
		<b>Duka la Dawa Baridi</b>	<b>Duka la Dawa Muhimu</b>
4.1.1	Layout		
4.1.2	Size/number of rooms		
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		
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:		
		<b>Duka la Dawa Baridi</b>	<b>Duka la Dawa Muhimu</b>
5.1.1	External perimeter security (e.g., fencing, gates, walls, windows)		
5.1.2	Do unauthorised persons have access to the secure storage areas?		
5.1.3	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:		
		<b>Duka la Dawa Baridi</b>	<b>Duka la Dawa Muhimu</b>
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		
6.1.4	Pallets		
6.1.5	Execution of stock rotation/FEFO		
6.1.6	Storage of returned/recalled/spoiled/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. Record-Keeping and Documentation

7.1	Are record-keeping and documentation suitable for the intended use in respect to:		
		<b>Duka la Dawa Baridi</b>	<b>Duka la Dawa Muhimu</b>
7.1.1	Prescription Book		
7.1.2	Poison Book (for Duka la Dawa Muhimus only)		
7.1.3	Ledger Book or an appropriate Inventory Control System		
7.1.4	Receipts/Invoices		
7.1.5	Copies of delivery notes		
7.1.6	Accuracy of record-keeping		
7.1.7	Legality of the source(s) of supplies		
7.1.8	Written procedures for handling returned, recalled, and/or expired drugs		
7.1.9	Written procedures for dealing with complaints and/or adverse reaction reports		
7.2	In case of nonconformity, explain:  If space provided is not enough, please use continuation page(s).		

## 8. Reference Materials

8.1	Are appropriate reference material(s) available?		
		<b>Duka la Dawa Baridi</b>	<b>Duka la Dawa Muhimu</b>
8.1.1	<i>Tanzania National Formulary (TNF)</i>		
	Indicate edition of TNF		
8.1.2	<i>Tanzania Pharmaceutical Handbook</i>		
8.1.3	Tanzanian Food, Drug and Cosmetics Act 2003 and its corresponding regulations and guidelines		
8.1.4	<i>Good Dispensing Manual</i> (Swahili/English versions)		
8.2	In case of nonconformity, explain:  If space provided is not enough, please use continuation page(s).		

## 9. 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
9.1 Are there unregistered products stocked on the premises?			
9.2 Are there unauthorised products in stock?			

## 10. Product Label Examination

10.1	Closely examine the products in stock and evaluate the labels in respect to:		
		Duka la Dawa Baridi	Duka la Dawa Muhimu
10.1.1	Language of labels and package inserts		
10.2	In case of nonconformity, explain:  If space provided is not enough, please use continuation page(s).		

## 11. Samples for Examination

11.1	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.	
11.2	Number of batches of products sampled under the surveillance programme	
11.3	Number of batches of suspicious products sampled	

## 12. Any Other Observations

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

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**13. Recommendations**

<b>Name and Address of Facility:</b>	
Items requiring attention:	Actions agreed to be taken and timeline:

**14. 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: .....
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**15. Name(s) of Inspector(s):** **Signature(s) of Inspector(s)**

1.		
2.		
3.		

<b>Date:</b>
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