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Checklist for physical inspection of medicines to early detect and prevent Substandard and Falsified medical products

Dosage form: tablet and capsules

These checklists have been developed by Rwanda FDA, the tool is designed to help health care professionals to carry out physical inspection of medical products with signs of substandard and falsified during reception at pharmaceutical establishments.
All suspicious products should be reported to the Authority for further investigation using the suspected poor quality medicines reporting form.

1. Packaging

Any medical products should be packaged in a container, which can be anything from a glass bottle, blister pack, plastic or metal, carton bearing the label.
Check the type of packaging and compare it to known containers for the same product from the same manufacturer. The packaging and the labelling of pharmaceutical products is a very complex and an expensive business. Thus, the process and the quality of packaging material are difficult to counterfeit. This is why a thorough physical inspection could be an important screening step for product quality control.

	Yes	NO	N/A	Other observation
1.1. Container and Closure system				
Does the container and closure protect the product from the outside environment; e.g.is the container properly sealed?				
Do they assure that the medical products meet the proper specifications throughout its shelf life?				
Are the container and the closure appropriate for the product inside?				
1.2LABELLING The information written on the label is very important. The information can be printed on a label adhered to the container, or printed directly onto the container itself, but all information must be				

legible and indelible.				
If there is a carton protecting the container, does the label on the carton match the label on the container?				
Is all information on the label legible and indelible?				
Is the information on label written in at least one of official languages used in Rwanda?				
1.2.1 The trade (Brand)name	Yes	No	N/A	Other observation
Is the trade name spelled correctly?				
Is the medical product (trade name) registered by Rwanda FDA?				
Does the symbol® follow the trade name?				
For blister or foil strip packed products, is the trade name indelibly impressed or imprinted onto the strip?				
1.2.2 The active ingredients name (Scientific name/generic name)				
Is the active ingredient name spelt correctly?				
Do the trade name and the active ingredient names correspond to the registered product?				
1.2.3The manufacturer's name and logo				
Are the manufacturer's name and logo legible and indelible?				
1.2.4The manufacturer's full address: All manufacturers are required by international law to print their complete address on the label.				
Is the manufacturer's full address available and legible?				
Has the manufacturer or its LTR registered the product in the country?				
1.2.5 The medicine strength(mg/Unit):				
Is the strength - the amount of active ingredient per unit clearly stated on the label?				
For blister or foil strip packed products, is the medicine strength indelibly impressed or imprinted onto the strip?				
1.2.6 The dosage form (e.g., tablet/capsule):				
Is the dosage form clearly indicated on the container label?				
Does the dosage form stated on the label match the actual dosage form inside the container?				
1.2.7 The number of units per container: Does the number of dosage units listed on the label match the number of dosage units in the container?	Yes	No		Other observation
1.2.8 The batch (or lot) number:				
Is the Batch number on the outer package same as the one on the inner package?				

Is the batch number on the outer package the same as the one on the blister or foil strip packed products?				
For blister or foil strip packed medicines, is the batch number indelibly impressed or imprinted onto the strip?				
Is the manufacturing date clearly indicated on the label?				
Is the expiry date clearly indicated on the label?				
For blister or foil strip packed products, is the expiry date indelibly impressed or imprinted onto the strip?				
Does the manufacture and expiry date on the outer package the same as the one on the inner package?				
Does the manufacture and expiry date on the outer package the same as the one on blister or foil strip packed products?				
1.2.11 Storage condition information:	Yes	No	N/A	Other observation
Are the storage conditions indicated on the label?				
Has the product been properly stored?				
1.3 Leaflet or package insert: All product packs contain a leaflet explaining dosage, the medicine content, the adverse effects, the medicine's actions, and how the medicine should be taken. The only exceptions are where the packaging includes all the information that would otherwise be in the leaflet.				
Does the medicine has the leaflet inside?				
Is the information on leaflet written in at least one of official languages used in Rwanda?				
2.PHYSICAL CHARACTERISTICS OF TABLETS/CAPSULES Tablets or capsules can be checked for signs of moisture, dirty marks, erosion, cracks and any other adulteration.				
2.1Uniformity of shape:	NO	YES		Other Observation
Are the tablets/capsules uniform in shape?				
2.2Uniformity of size				
Are the tablets/capsules uniform in size?				
2.3Uniformity of colour				
Are the tablets/capsules uniform in colour?				
2.4 Uniformity of texture:				
Are the tablets uniformly polished, free of powder, and non-sticking?				
2.5Markings (scoring, letters, etc.):				
Are markings uniform and identical?				
2.6 Breaks, Cracks and Splits:				
Are the tablets/capsules free of breaks, cracks, splits or pinholes?				
2.8 Embedded surface spots or contamination:				

Are the tablets/capsules free of embedded surface spots and foreign particle contamination?				
2.9Presence of empty capsules and presence of particulate matters within the powder inside the capsules and tablet				
Is the sample examined free of empty capsules?				
Are the opened capsules contain particulate matters within the powder inside the capsules?				
2.9 Smell Does the medicine smell the same as the original (If available)? Does it smell peculiar?				