PHARMACEUTICAL SOCIETY OF UGANDA

Tool for Visual Inspection of Medicines

A checklist for visual inspection of medicines in order to identify suspicious products for further examination.

The tool is designed to help health professionals carry out a visual inspection of medicines for signs of counterfeiting such as improper packaging, labelling or description of dosage and suspected substandard products. All suspicious products with incorrect labels, missing information about the strength, dosage, or expiration date, signs of product discoloration or deterioration should be reported to National Drug Authority (NDA) copied to the Pharmaceutical Society of Uganda (PSU) for tracking purposes.

1. PACKAGING

Any medicine should be packaged in a container, which can be anything from a glass bottle to a blister pack, to a tube of glass, plastic or metal. A folding carton bearing the label very often protects the container. 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 visual inspection could be an important screening step for product quality control.

Item	Yes	No	Other Observations
1.1 Container and Closure			
Does the container and closure protect the product from the outside environment; e.g. is the container properly sealed?			
Do they assure that the product will meet the proper specifications throughout its shelf life?			
Are the container and the closure appropriate for the product inside?			
Is the container safely sealed?			

Item	Yes	No	Other Observations
1.2 Label 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?			
1.2.1 The trade (brand) name			
Is the trade name spelled correctly?			
Is the medicinal product (trade name) registered in the country by NDA?			
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 ingredient 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?			
1.2.3 The manufacturer's name and logo:			
Are the manufacturer's name and logo legible and correct?			
Does the logo or hologram (if applicable) look authentic?			
Does the logo or hologram (if applicable) change colour when viewed from different angles?			
1.2.4 The manufacturer's/Supplier's full address: All manufacturers are required by international law to print their complete address on the label. Many companies making or distributing substandard or counterfeit products do not have a traceable address on the label.			
Is the manufacturer's full address legible and correct?			
Is the supplier/LTR licensed by NDA ?			
Does the supplier have a verifiable physical address?			
Has this company or its agent 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?			

Item	Yes	No	Other Observations
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 of the medication?			
Is the indicated medicine under this dosage form registered?			
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 stated on the container. You may verify the quantity e.g in a blister?			
1.2.8 Dosage statement (if appropriate)			
Is the dosage clearly indicated on the label?			
Is the dosage stated on the label appropriate for the medicine in this form and strength?			
Is the product registered and authorized for sale in the manufacturer's country?			
1.2.9 The batch (or lot) number: Medicines with the same batch/lot number are expected to be equivalent. In a continuous process, a batch corresponds to a defined portion of the production, based on time or quantity. Products from the same batch number should have the same history of manufacturing, processing, packing, and coding. All product quality control testing should be based on batch/lot numbers.			
Does the numbering system on the package correspond to that of the producing company?			
For blister or foil strip packed medicines, is the batch number indelibly impressed or imprinted onto the strip?			
1.2.10 The date of manufacture and the expiry date: An expired product should not be sold under any circumstances.			
Are the manufacture and expiry dates clearly indicated on the label?			
For blister or foil strip packed products, is the expiry date indelibly impressed or imprinted onto the strip?			
1.2.11 Storage information:			
Are the storage conditions indicated on the label?			
Has the product been properly stored?			

Item	Yes	No	Other Observations
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			
Is the package insert printed on the same coloured or same quality paper as the original (If available to compare) or does it look familiar?			
Is the ink on the package insert or packaging smudge-proof?			
Does the information on the package insert match the information on the product container?			

2. PHYSICAL CHARACTERISTICS OF TABLETS/CAPSULES

Item	*Yes*	*No*	*Other Observations*
Tablets or capsules can be checked for signs of moisture, dirty marks, abrasion erosion, cracks, or any other adulteration.			
2.1 Uniformity of Shape:			
Are the tablets/capsules uniform in shape?			
2.2 Uniformity of Size:			
Are the tablets/capsules uniform in size?			
2.3 Uniformity of Colour:			
Are the tablets/capsules uniform in colour?			
2.4 Uniformity of Texture: Tablets can be film-coated, sugar-coated or enteric-coated.			
Do the tablets have a uniform coating?			
Is the base of the tablets fully covered?			
Are the tablets uniformly polished, free of powder, and non-sticking?			
2.5 Markings (scoring, letters, etc.):			
Are markings uniform and identical?			
Does the logo (if present) match that of the manufacturing company?			
2.6 Breaks, Cracks and Splits:			
Are the tablets/capsules free of breaks, cracks, splits or pinholes?			
2.7 Embedded surface spots or contamination:			
Are the tablets/capsules free of embedded surface spots and foreign particle contamination?			
2.8 Presence of empty capsules in the case of a sample of capsules:			
Is the sample examined free of empty capsules?			
2.9 Odour			
Does the medicine smell the same as the original (If available)?			
Does it smell peculiar?			

3. PHYSICAL CHARACTERISTICS OF SYRUPS/INJECTABLES/VACCINES

Item	*Yes*	*No*	*Other Observations*
Syrups, vaccines and injectables should be checks for signs of sedimentation, adulteration, microbial growth			
3.1 Sedimentation:			
Are any sediments or particles present?			
3.2 Discoloration:			
Are there any signs of discoloration?			
3.3 Microbial growth:			
Are there any signs of microbial growth such as a cloudy appearance?			
3.4 Odour			
Is there any unusual odor?			
3.5 Leakage and seals			
Is there any leakage?			
Are the seals intact and similar to the manufacturer's usual seals			
3.6 Uniformity of container size			
Are the container/vials uniform in size?			
3.7 Uniformity of fill levels:			
Are the fill levels uniform in comparison to the regular supplies?			
4.0 Efficacy and Safety			
4.1 Drug efficacy			
Have there been any complaints of lack of effect of the drug?			
4.2 Adverse effect			
Have any adverse effects been reported?			

NB*: An appropriate sampling criteria and frequency should be applied based on a risk assessment approach. A visual inspection chamber with sufficient lighting, black/white background and magnifying glass is needed to enable better visual analysis. This tool has been adapted from the FIP visual inspection tool.*