

Inspection Checklist for Drugs Received in the Warehouse:

Labeling:

1. Labeling should be **in English** and preferably one other official language of WHO.
2. All labels should display at least the following information:
 - ⇒ International Nonproprietary Name (INN) of the active ingredients
 - ⇒ Dosage form
 - ⇒ Quantity of active ingredient(s) in the dosage form (e.g. tablet, ampoule) and the number of units per package
 - ⇒ Batch number
 - ⇒ Date of manufacture
 - ⇒ Expiry date (in clear language, not in code)
 - ⇒ Pharmacopoeia standard (e.g. BP, USP,)
 - ⇒ Instructions for storage
 - ⇒ Name and address of the manufacturer
3. A printed label on each **ampoule** should contain the following:
 - ⇒ INN of the active ingredient(s)
 - ⇒ Quantity of the active ingredient
 - ⇒ Batch number
 - ⇒ Name of the manufacturer
 - ⇒ Expiry date

The full label should again appear on the collective package.
4. Directions for use, warnings and precautions may be given in **leaflets** (package inserts). However, such leaflets should be considered as a supplement to labeling and not as an alternative.
5. For articles requiring **reconstitution** prior to use (e.g. powders for injection) a suitable beyond-use time for the constituted product should be indicated.

Packaging:

1. **Tablets and capsules** should be packed in sealed waterproof containers with replaceable lid, protecting the contents against light and humidity.
2. **Liquids** should be packed in unbreakable leak-proof bottles or containers.
3. **Containers** for all pharmaceutical preparations must conform to the latest edition of internationally recognized pharmacopoeia standards.
4. **Ampoules** must have either break-off necks, or sufficient files must be provided.

Source: MSH 1997

3. DRUG PROCUREMENT

Expiry date:

At time of shipment the product shall have **at least 75% of its shelf life**. Write expiry date on the box in large letters and numbers, also on single containers put on the shelf. In case that the expiry date is unsatisfactory (calculate consumption until expiry date), return to supplier.

Appearance of the product:

All shipments:

Compare the goods with the supplier's invoice and original purchase order or contract. Note discrepancies on the Delivery Report. CHECK THAT:

- Number of containers delivered is correct
- Number of packages in each container is correct
- Quantity in each package is correct
- Drug is correct
- Dosage form is correct (tablet, liquid, other form)
- Strength is correct (milligrams, percentage concentration,)
- There is no visible evidence of damage (describe)

Take a sample for testing if required.

Tablets:

For each shipment, tablets of the same drug and dose should be consistent. CHECK THAT:

- Tablets are identical in size
- Tablets are identical in shape
- Tablets are identical in color (shade of color may vary from batch to batch)
- Tablet markings are identical (scoring, lettering, numbering)
- There are no defects (check for spots, pits, chips, breaks, uneven edges, cracks, embedded or adherent foreign matter, stickiness)
- There is no abnormal odor when a sealed bottle is opened

Source: MSH 1997

Appearance of the product, cont'd

Capsules:

For each shipment, tablets of the same drug and dose should be consistent.
CHECK THAT:

- Capsules are identical in size
- Capsules are identical in shape
- Capsules are identical in color (shade of color may vary from batch to batch)
- Capsule markings are identical
- There are no defects (check for holes, pits, chips, breaks, uneven edges, cracks, embedded or adherent foreign matter, stickiness)
- There are no empty capsules
- There are no open or broken capsules

Parenterals:

Parenterals are all products for injection (IV liquids, ampoules, dry solids, suspensions for injection). CHECK THAT:

Solutions are clear (solutions should be free from undissolved particles, within permitted limits)

- Dry solids for use in injections are entirely free from visible foreign particles
- There are no leaking containers (bottles, ampoules)

Source: MSH 1997