



BACHA KHAN MEDICAL COMPLEX
MEDICAL TEACHING INSTITUTE, SWABI



Policy on Multi-Dose Vials

POL/C/CEN/PHARM-003/v.1

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Original Date: June 2022	Revision Date: June 2025

1. PROCEDURE:

- 1.1 All open multiple dose vials shall be labeled as follows:
 - 1.1.1 The label should not cover the name of the drug and concentration.
 - 1.1.2 The label should indicate:
 - 1.1.2.1 The date and time the vial was opened or reconstituted, (e.g. Jan 01, 2008 at 2200h).
- 1.2 All open multi-dose vials shall be assigned an expiry date according to the manufacturer's recommendations or USP 797 guidelines.
- 1.3 Prior to use, the integrity of the stopper (**rubber-lid**) is checked. The content of the vial is also checked for any particulate matter. The stopper is swabbed with alcohol before the puncture.
- 1.4 All multi-dose vials shall be discarded if:
 - 1.4.1 when empty,
 - 1.4.2 when the manufacturer's expiration date is reached,

1.4.3 when the integrity of the **stopper (rubber-lid)** is suspected or visible contamination occurs,

1.4.4 when particulate matter is present,

1.4.5 when deterioration is suspected, or Found in improper storage specifications.

2. GUIDELINES:

Follow this procedure when multiple dose vials are used.

- 2.1 Wash hands thoroughly before handling injectable.
- 2.2 Determine if vial has been stored properly.
- 2.3 Check all multiple dose vials for evidence of contamination and deterioration. Color, clarity, and presence or absence of precipitate should resemble normal state.
- 2.4 Check all multiple dose vials for evidence of particulate matter: coring (residue from rubber diaphragm), floaters, etc.
- 2.5 Use appropriate aseptic technique. Swab with alcohol or povidone-iodine before puncturing.
- 2.6 Place bevel of needle at appropriate angle to prevent coring.
- 2.7 Use a sterile needle each time a multiple dose vial is entered.
- 2.8 If vial is unopened and if vial requires reconstitution, reconstitute according to manufacturer's guideline. Determine shelf-life date according to section below.
- 2.9 If vial is unopened and vial does not require reconstitution determine shelf life according to section below.
- 2.10 If vial is opened, determine if it can be reused according to guidelines below or contact Pharmacy.
- 2.11 Store properly according to manufacturer's recommendations; follow the directions on the vial or in the insert or contact Pharmacy.
- 2.12 Pictogram for nursing education placed in each medication room containing multi dose vials.

3. DETERMINING OF A SHELF LIFE:

- 3.1** Use the following guidelines to determine the shelf-life multiple dose vial:
- 3.1.1 Multi dose vials must be discarded.
 - 3.1.2 when empty.
 - 3.1.3 when the manufacturer's expiration date is reached.
 - 3.1.4 when the integrity of the stopper (rubber-lid) is suspected or visible contamination occurs.
 - 3.1.5 when particulate matter is present.
 - 3.1.6 when deterioration is suspected.
 - 3.1.7 Found in improper storage specifications
- 3.2** For commercially available solutions or suspensions, this date is generally the expiration stamped on the container.
- 3.3** For powders that are reconstituted, this date is calculated based on the manufacturer's recommendation stated on the vial or in the insert. When vials have been reconstituted, the recalculated expiration date and the person's shall place on the vial as follows: "Exp dd/ mm /yy".. The initial "X" shall not be used in place of "Exp".
- 3.4** All outdated / improperly stored multidose vials must be dispose.
- 3.4.1 **NOTE:** Assigned expiration dates may be shorter than that of the manufacturer. However, under no circumstance will an assigned expiration date exceed the manufacturer's expiration date.
 - 3.4.2 **Exceptions:** A multiple dose vial taken into the room of a patient undergoing hemodialysis can be used multiple times, **and the vial will be used for that patient only.**

4. DISPENSING:

All multi-dose (heparin vial, salbutamol sol, insulin regular vial and Heparin etc.) will be dispensed as per departmental dispensing procedure. (For details please see 'Service delivery procedure')

(Ref: Please also see Hospital formulary)

Pictogram

