Repackaging and Compounding

Chapter 11

Objectives

- List the steps in the repackaging of medications.
- List five reasons pharmacies often repackage bulk medications into unit dose packages.
- Describe the proper handling of medications during repackaging.

Objectives (cont'd)

- Describe the way in which ointments or creams should be packed into jars.
- Demonstrate how to fill out a repacking logbook with the necessary information.
- Explain the calculations used to determine beyond use date when repackaging.

Objectives (cont'd)

- List the common reasons behind using unit dose medications.
- Describe the types of containers used for repackaged and compounded medications.
- Define terms used in compounding procedures.
- List the common reasons why patients need compounded medications.

Objectives (cont'd)

- Describe the equipment used in repackaging drugs.
- Explain the considerations that must be given to storage and stability of compounded products.
- Differentiate between types of scales used to weigh compounds.

Objectives (cont'd)

- Demonstrate how to fill out a compounding sheet with the necessary information.
- Explain the correct methods in the preparation and cleanup of compounding areas.

Introduction

- Repackaging medication is common in hospital pharmacy.
- Compounding nonsterile products is common in community pharmacy.
- Repackaging also called *unit dosing.*

Repackaging

- FDA: FDA is responsible for guidelines for all manufacturers that package medications.
- Expiration dates are determined by tests run by manufacturers and FDA.
- Repackaging in hospitals: expiration date is set by state.

Repackaging (cont'd)

- Five reasons to repackage from bulk:
  - Drugs that cannot be bought from manufacturer
  - Cost of unit dosing may be cheaper
  - Speed and efficiency increased
  - Individual labels result in decrease in errors
  - Can be put back in stock if not used

Repackaging (cont'd)

- Hospitals save money by unit dosing.
- Good manufacturing practices are used.
- Guidelines:
  - Drugs and labels: all medications must be checked by a registered pharmacist.
  - Equipment: must be in good condition and clean.

Repackaging (cont'd)

- Guidelines (cont'd)
  - Expiration date: 6 months or ¼ of the manufacturer's expiration date
  - Package: Appropriate for the drug
  - Preparation: Not more than one item prepared at a time
  - Records: All repackaged items logged for referencing

Repackaging Equipment

- Packaging machines fill unit dose containers, make labels, and adhere the labels to containers.
- Less high-tech: process is done manually using blister packs.
- Equipment kept clean and in good condition.
- Gloves are worn.

Repackaging Techniques

- Non-sterile technique:
  - Lab coat
  - Hair tied back
  - Hands washed
  - Gloves if the tablets or capsules will be touched
  - Pill counting tray and spatula if the tablets will be dispensed from the tray

Repackaging Techniques (cont'd)

- Have enough packages and labels ready for use.
- Keep medications separate from one another.
- Prepack only one item at a time.
- Calculate accurate expiration date.
- Log in logbook.

Repackaging Techniques (cont'd)

- Two types of repackaged medications:
  - Unit dose
  - Monthly supply

Documentation

- Major step not to be overlooked is keeping track of products.
- For recalled drug, accurate count of repackaged unit doses needed with identifying mark.
- For an example of a record log sheet used for documentation, see Table 11-3.

Labeling & Checking Repackaged Medications

- Dosage forms that are repackaged: tablets, capsules, liquids
- Unit dose labels: computer generated
- Technician determines amount needed, calculates expiration date, documents components, generates labels, loads medication

Storage and Stability

- FDA responsible for providing guidelines for all manufacturers that package medications.
- Beyond use dates given to repackaged products is done by using USP guidelines.

Expiration Dates vs. Beyond Use Dating

- Opened bulk bottle: manufacturer's expiration date no longer valid.
- Expiration dates: assigned by the manufacturer.
- Beyond use dates: given by pharmacy when repackaging or compounding medications.

Expiration Dates vs. Beyond Use Dating (cont'd)

- Set expiration date to end of month.
- Method 1: life of repackaged product: 6 months or ¼ of manufacturer's expiration date.
- Method 2: maximum of 1 year as long as it does not exceed safety margin given by drug company.
- Documentation is very important

Compounding: History

- Medicinal mixtures using plants, animals, and minerals dates back 4000 years.
- 1820: 80% of prescriptions in the first U.S. pharmacopoeia were compounds.
- Premade dosages do not necessarily treat everyone.
  - Pediatric doses, hospice patients

Nonsterile Compounding

- Nonsterile compounding: done on countertop
- Common items: creams, ointments, oral suspensions
- Less common: capsules, suppositories, syringe
- Box 11-2

Compounding Area

- Area should be away from areas where normal prescription processing, chemicals, dust, or where open boxes are located.
- Sink should be located close to the compounding site for hand washing and cleanup.

Equipment

- Personal protective equipment: gloves, goggles, gown, hair cover, lab coat, mask, shoe covers
- Measuring devices: graduated cylinders, syringes, pipettes, electronic filling machines
- Mixing equipment: mortar and pestle

Equipment (cont'd)

- Weighing equipment: scales, electronic balances

Additional Supplies

- Mold forms: metal and rubber
- Excipients
- Flavorings: added to mask bad taste of ingredients

Personal Preparation

- Technician should tie back long hair and wear a lab coat and gloves.
- A technician who is sick or has any open wounds should not make any compounding products.

Weighing Techniques

- Components of typical balance:
  - Paper and weights
  - Tweezers for grasping metal weight
  - Arrest knob locking balance in place
  - Box 11-4

Weighing Techniques (cont'd)

- Pharmacy balances are sensitive
  - Airflow—keep to minimum
  - Glass lid cuts air currents
- Spatula: used to pick up small amounts; lightly tapping to flick few granules at a time
- Compounding: time-consuming, accuracy important

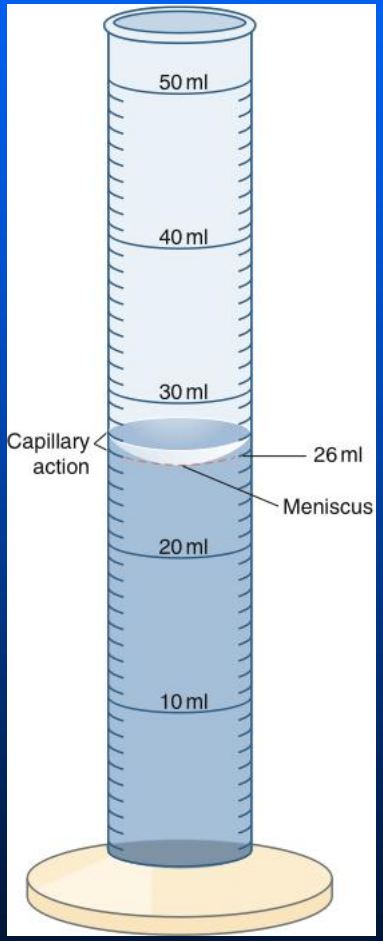
Weighing Techniques (cont'd)

When technician are using a class A or class III balance, each dial must be set accurately for precise measurement.

Measuring Liquids

- Liquids: there are simple steps to ensure proper volume.
  - Water molecules will cling to sides of container.
  - Have liquid at eye level.
  - Read at bottom of liquid line (meniscus).
- For maximum accuracy in measuring liquids use the 20% rule.

A 50-ml Graduate Showing the Meniscus and Proper Measurement of Solutions



Preparing Solutions

- Solutions comprise:
  - Solvent (larger part)
  - Solute (ingredient used in solvent)
- Measure carefully and mix thoroughly
- Solubility will dictate the type of dosage form that needs to be prepared.
- Reconstitution of premade oral suspensions may be done away from the compounding area.

Solids: Tablets, Capsules, & Lozenges

- Molds are used for forming these types of oral dosage forms.
- Molded tablets disintegrate quickly when they come into contact with moisture.
- Tablets or lozenges can be made one at a time or in multiple doses.

Solids: Tablets, Capsules, & Lozenges (cont'd)

- Capsules
  - Punch method techniques slow and arduous
  - Capsule machines load capsules quickly and accurately

Solids: Tablets, Capsules, & Lozenges (cont'd)

- Lozenges: normally made with flavors to enhance their taste
  - Hard
  - Soft
  - Chewable

Semi-solids: Ointments, Sticks and Suppositories

- Medication sticks
  - Applied directly to a site on the body that needs treatment
- Ointment: hydrophobic base
  - Petroleum jelly mixed with drug
  - Jars or tubes

Semisolids: Ointments, Sticks and Suppositories (cont'd)

- Suppositories
  - Oleaginous or water-soluble bases, glycerinated gelatins
- Preparing suppositories
  - Molds
  - Hand-rolled method

Nasal preparations: Ointments, Suspensions, Gels and Solutions

- Can be compounded into dosage forms such as:
  - Jellies, gels, and ointments that can be administered as a topical agent (ointment, gels, jellies)
  - Spray (solutions)
  - Drops (solutions, suspensions)
  - Nasal inhalers (volatiles)

Nasal preparations: Ointments, Suspensions, Gels and Solutions (cont'd)

- Preparing solutions:
  - Dissolve ingredients into ¾ of the total amount of sterile water for injection to be used, mix well.
  - qs the SW (sterile water) to the total volume required.
  - Determine pH, clarity and other quality control factors from a sample of solution.

Nasal preparations: Ointments, Suspensions, Gels and Solutions (cont'd)

- Preparing solutions (cont'd):
  - Filter through a sterile 0.2miron filter into a sterile nasal container.
  - Package and label.

Nasal preparations: Ointments, Suspensions, Gels and Solutions (cont'd)

- Preparing suspensions:
  - Repeat steps 1 & 3 in solutions.
  - Package in an appropriate container for autoclaving.
  - Autoclave, cool, then label (this step is optional depending on the recipe).
  - Choose a random sample to check for quality of product (sterility, pH, etc.).

Nasal preparations: Ointments, Suspensions, Gels and Solutions (cont'd)

- Preparing ointments:
  - Repeat step 1.
  - Sterilize each ingredient using an appropriate method.
  - Mix each of the ingredients with the sterile vehicle.
  - Perform quality control on a sample of the mixture.
  - Package and label.

Nasal preparations: Ointments, Suspensions, Gels and Solutions (cont'd)

- Preparing gels:
  - Repeat step 1.
  - Filter through a 0.2 micron filter into a sterile container.
  - Add the (sterilized) gelling agent and mix well.

Nasal preparations: Ointments, Suspensions, Gels and Solutions (cont'd)

- Preparing gels (cont'd):
  - Add SW for injection to volume/weight and mix well.
  - Perform Quality Assurance (QA) on sample.
  - Package and label.

Packaging

- Containers must:
  - Be appropriate size
  - Protect contents
  - Have childproof caps (not for jars and syringes)
  - Have appropriate labels

Stability

- Stability of drug is affected by light, air temperature, pH.
- Expiration date can be found from manufacturer's literature or compounding books.

Documentation

- Documentation of records under quality assurance of FDA guidelines
- For types of information documented (along with the recipe)
- Documents kept for 3 years from time medication was prepared

Documentation (cont'd)

- Label information:
  - Intended use of product
  - Storage requirements
  - Expiration dates

Safety

- All chemicals should be stored inside cabinets or behind shelf brackets to avoid spillage.
- Method of cleaning and disposing of agents or any equipment used depends on the type of agents used.

Sterile Compounding

- Sterile compounding is performed for most parenteral medications that are administered intravenously, intramuscularly, intrathecal, subcutaneously, intradermal, intranasal, otic, or ophthalmic routes of administration.
  - Must be sterile upon completion.

Opthalmic Agents

- The pH of both blood and tears is 7.4, therefore this is the pH at which ophthalmic agents should be close to.
  - Usually range from 6.5 to 8.5
- Must be made in a laminar flow hood using aseptic technique and packaged in sterile container.

Compounding Professionalism

- Pharmaceutical eloquence: the special use of finishing technique to give the final product a professional look

Regulatory and Quality Control

- Package medications that can degrade with UV exposure in amber containers.
- Compounded drugs may be made in limited quantities.
- Compounded products must be made from approved ingredients that meet manufacturing and safety standards.

Regulatory and Quality Control (cont'd)

- The drug product must not be identified by the FDA as a one that presents demonstrable difficulties for compounding in terms of safety or effectiveness.

Chemotherapeutic Agents

- Parenteral products or compounded creams, etc. should be prepared only in a safe environment such as a vertical flow barrier-hood.
- Some patients may need dosage prepared in various solutions, or in transdermal delivery systems.

Veterinary Medications

- Dosage in a form that avoids stress on the animal:
  - Medication may be mixed into a treat
  - Sticks to administer antibiotics to the inside of the ear
  - Liquids poured onto pet food

Compounding

- Specialized compounding pharmacies are becoming more popular due to the special needs of more people.

Personnel Training

- Training on compounding should include calculations, compounding equipment, dosage forms, interpretation of symbols, literature, safety, and techniques.

Compounding Calculations

- The final product may need to be prepared in a different strength or volume than what the recipe lists.
- Pharmacist or technician will need to perform calculations to attain the correct weights and/or volumes for the final product.