



GUIDELINES

GUIDELINES ON PREPACKAGING OF MEDICATIONS

Preamble

Certain precautions must be taken if the quality of prepackaged medication is to be maintained. The guidelines presented herein will assist the pharmacist in developing procedures for prepackaging drugs from the original manufacturer's container without compromising the quality of the product.

Definition

For the purpose of this guideline, prepackaging is the process by which the pharmacy transfers a medication manually, or by means of an automated system, from a manufacturer's original commercial container to another type of container in advance of actual, immediate need for dispensing of a prescriber's order. Such package may be a unit dose, single dose, or unit of issue package for use in a unit dose dispensing system, or in a container suitable for a traditional dispensing system.

Guidelines

- Prepackaging procedures must comply with federal and state laws and regulations. The more stringent of the laws shall apply.
- The prepackaging operations and area must be clean and separate from other pharmacy activities.
- Only one drug product at a time should be prepackaged in a specific work area. No drug products other than the one being packaged should be present in the immediate packaging area. Labels other than those for the product being packaged should not be present in the area.
- Before beginning a prepackaging run, a physical evaluation (color, odor, appearance, and markings) of the drug product being prepackaged should be made to assure product integrity. The bulk container should also be examined for evidence of water damage, contamination, and other deleterious effects.
- All prepackaging equipment and systems should be operated and used in accordance with the manufacturer's or other established instructions. There should

- be valid justification and authorization by the supervisor for any deviation from those instructions on the part of the operator.
- The pharmacist must use available data on the characteristics of all packaging material used to protect the integrity of the drug product. This information should include data on the chemical composition, light transmission, moisture permeability, size, thickness (alone or in laminate), recommended sealing temperature, and storage requirements.
 - Current federal and state label requirements, whichever is more stringent, must be adhered to. The desired components are as follows:
 1. Proprietary and non-proprietary name(s)
 2. Dosage form
 3. Strength
 4. Strength of dose and total contents delivered
 5. Beyond-use date
 6. Control number (lot number)
 - The beyond-use date applied to prepackaged medications should adhere to USP standards. An additional trained individual, other than the packaging operator, should verify that:
 1. The prepackaging system (drug, materials, and machines) is in correct working order
 2. All procedures have been performed properly
 - Control records of all packaging operations must be kept per state and federal guidelines, and include the following information:
 1. Complete descriptions of the drug, e.g. name, strength, dosage form
 2. The name of the product's manufacturer and distributor (as applicable)
 3. Manufacturer's control number (lot number)
 4. The pharmacy's control number, if different from the manufacturer's
 5. Expiration date of the manufacturer's original container and the beyond-use dating of the prepackaged product
 6. Number of units prepackaged, total contents delivered per unit, and the date(s) they were prepackaged
 7. Initials of the operator and the pharmacist responsible for packing of each individual run
 8. Description of the packaging materials and equipment used.
 - Upon completion of prepackaging, all unused drug stock and finished packages should be removed from the prepackaging area. The packaging machinery and related equipment should then be completely emptied, cleaned, and inspected before commencing the next prepackaging operation.
 - All unused labels (if separate labels are used) should be removed from the immediate prepackaging area and verified by the operator. If labels are prepared as part of the prepackaging operation, the label plate (or analogous part of the printing apparatus) should be removed or adjusted to "blank" upon completion of the run. This will help assure that the correct label is printed during any subsequent run. There should be a procedure to reconcile the number of packages produced with the number of labels used (if any) and destroyed (if any) and the number of units or volume of drug product set forth to be prepackaged.

- All prepackaged drugs should be stored in a temperature and humidity-controlled environment. Prepackaging materials should be stored and used in accordance with the manufacturer's instructions and any applicable state or federal regulations.
- Daily records of temperature and humidity shall be maintained.
- Written procedures (both general and product specific) governing prepackaging operations should be developed. A schedule for review and revision should be established.
- Quality control should be maintained and documented.
- Operators must be trained and must demonstrate proficiencies in equipment operation and prepackaging procedures, including proper hand washing technique.
- Applicable FDA and USP requirements concerning the type of package required for specific drug products must be followed.

References:

ASCP Standards of Practice

ASHP Technical Assistance Bulletin on Repackaging Oral Solids and Liquids in Single Unit and Unit Dose Packages

ASHP Technical Assistance Bulletin on Single Unit and Unit Dose Packaging

National Association of Boards of Pharmacy Model State Pharmacy Act and Model Rules

USP 22nd Edition, Storage and Expiration Dating

ASCP Fact Sheet on Beyond-Use Dating

These guidelines supercede guidelines previously approved by the ASCP Board of Directors in July 1992.

Approved by the ASCP Board of Directors, November 10, 1998. Developed by the Organizational Affairs Council.

American Society of Consultant Pharmacists
1321 Duke Street
Alexandria, VA. 22314-3563
(703) 739-1300
FAX: (703) 739-1321
<http://www.ascp.com>
e-mail: info@ascp.com