

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

To maximize the benefits of a unit dose drug distribution system, all drugs must be packaged in single unit or unit dose packages.<sup>a</sup> However, not all drugs are commercially available in single unit (or unit dose) packages. Therefore, the institutional pharmacist must often repackage drugs obtained in bulk containers (e.g., bottles of 500 tablets) into single unit packages so that they may be used in a unit dose system.

Certain precautions must be taken if the quality of drugs repackaged by the pharmacist is to be maintained. The guidelines presented herein will assist the pharmacist in developing procedures for repackaging drugs in a safe and acceptable manner:

1. The packaging operation should be isolated, to the extent possible, from other pharmacy activities.
2. Only one drug product at a time should be repackaged in a specific work area. No drug products other than the one being repackaged should be present in the immediate packaging area. Also, no labels other than those for the product being repackaged should be present in the area.
3. Upon completion of the packaging run, all unused stocks of drugs and all finished packages should be removed from the packaging area. The packaging machinery and related equipment should then be completely emptied, cleaned, and inspected before commencing the next packaging operation.
4. All unused labels (if separate labels are used) should be removed from the immediate packaging area. The operator should verify that none remains in the packaging machine(s). If labels are prepared as part of the packaging 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 set forth to be packaged.
5. Before beginning a packaging run, an organoleptic evaluation (color, odor, appearance, and markings) of the drug product being repackaged should be made. The bulk container should also be examined for evidence of water damage, contamination, or other deleterious effects.
6. All packaging 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.
7. The pharmacist should obtain data on the characteristics of all packaging materials used. 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.
8. Unit dose packages and labels should, to the extent possible, comply with the “ASHP Guidelines for Single Unit and Unit Dose Packages of Drugs.”<sup>1</sup>
9. Whenever feasible, a responsible individual, other than the packaging operator, should verify that (a) the packaging system (drug, materials, and machines) is set up correctly and (b) all procedures have been performed properly. Ultimate responsibility for all packaging operations rests with the pharmacist.
10. Control records of all packaging runs must be kept. These records should include the following information: (1) complete description of the product, i.e., name, strength, dosage form, route of administration, etc.; (2) the product’s manufacturer or supplier; (3) control number; (4) the pharmacy’s control number if different from the manufacturer’s; (5) expiration dates of the original container and the repackaged product; (6) number of units packaged and the date(s) they were packaged; (7) initials of the operator and checker (if any); (8) a sample of the label and, if feasible, a sample of the finished package, which should not be discarded until after the expiration date and which should be examined periodically for signs of deterioration; and (9) description (including lot number) of the packaging materials and equipment used.
11. It is the responsibility of the pharmacist to determine the expiration date to be placed on the package, taking into account the nature of the drug repackaged, the characteristics of the package, and the storage conditions to which the drug may be subjected. This date must not be beyond that of the original package.<sup>b</sup>
12. All drugs should be packaged and stored in a temperature- and humidity-controlled environment to minimize degradation caused by heat and moisture. A relative humidity of 75% at 23 °C should not be exceeded. Packaging materials should be stored in accordance with the manufacturer’s instructions and any applicable regulations.
13. Written procedures (both general and product specific) governing repackaging operations should be prepared and updated as required. Any deviation from these procedures should be noted and explained on the control record. Operators must understand the procedures (and operation of all packaging equipment) before commencing the run.
14. Applicable FDA and USP requirements concerning the type of package required for specific drug products must be followed.
15. Drugs and chemicals with high vapor pressures should be stored separately from other products to minimize cross contamination.

## References

1. American Society of Hospital Pharmacists. ASHP guidelines for single unit and unit dose packages of drugs. *Am J Hosp Pharm.* 1977; 34:613–4.
2. Stolar MH. Expiration dates of repackaged drug products. *Am J Hosp Pharm.* 1979; 36:170. Editorial.

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<sup>a</sup>A *single unit* package is one which contains one discrete pharmaceutical dosage form, e.g., one tablet or one 5-mL volume of liquid. A *unit dose* package is one which contains the particular dose of drug ordered for the patient. A *single unit* package is a *unit dose* (or *single dose*) package if it contains that particular dose of drug ordered for the patient.

<sup>b</sup>For specific recommendations on expiration date policy, see Reference 2.

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Developed originally by a joint working group of the American Society of Hospital Pharmacists and the American Society of Consultant Pharmacists and representatives of the drug packaging industry. The original document subsequently was approved officially by the Boards of Directors of ASHP and ASCP. FDA reviewed the original document and commended ASHP and ASCP for developing the guidelines.

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