COMPOUNDING 12

12.1 GENERAL INFORMATION

12.1-1 Are there some compounded nonsterile preparations (CNSPs) that I cannot compound?

Yes. The U.S. Food and Drug Administration (FDA) has details on what can and cannot be compounded.

State-licensed physicians and pharmacists who compound under section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) may only compound drug products using bulk drug substances that:

1. comply with an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph if one exists, and the USP chapter on pharmacy compounding;
2. are components of FDA-approved drug products if an applicable USP or NF monograph does not exist; or
3. appear on FDA's list of bulk drug substances that can be used in compounding (the 503A bulks list) if such a monograph does not exist and the substance is not a component of an FDA-approved drug product.

In addition, bulk drug substances must be accompanied by a valid certificate of analysis and must have been manufactured by an establishment registered with FDA under section 510 of the FD&C Act.[29]

12.1-2 Is prepackaging medications into unit-dose containers considered compounding?

These activities are repackaging, not compounding. See USP <1178> *Good Repackaging Practices*[6] and the FDA guidance documents concerning repackaging.[7]

12.1-3 Does ASHP have guidelines dealing with nonsterile compounding?

Yes. See the *ASHP Technical Assistance Bulletin on Compounding Nonsterile Products in Pharmacies.*[30] ***Note:*** This document pre-dates <795>, so the USP standard needs to be followed when it is more stringent than the information in the ASHP document.

DOI 10.37573/9781585286782.012

12.1-4 There are some compounding kits that are available and contain all the ingredients and supplies for making a compound. Is use of a kit like this considered compounding?

Yes, if it is labeled as a compounding kit, then <795> must be followed for compounding it.

12.1-5 Is reconstituting an oral antibiotic considered compounding?

No. That is considered reconstituting—not compounding—as long as it is for an individual patient and you follow the approved labeling for reconstitution and storage.

12.1-6 Do I need SDSs for every compound I make?

Safety data sheets (SDSs) (formerly called material safety data sheets, MSDSs) are required for active pharmaceutical ingredients (APIs). Some dosage forms are exempt from the requirement.

SDSs are required for:

- Drugs deemed hazardous by the manufacturer
- Solid medications that contain hazardous substances that are intended to be dissolved or crushed before administration

SDSs are not required for:

- Medications that don't contain hazardous substances
- Medications that are in solid, final form for direct administration to the patient
- Drugs packaged by the manufacturer for sale to consumers (like over-the-counter medications)

See the OSHA Hazard Communication Standard for further information.[20]

12.1-7 Do I need a Certificate of Analysis for every ingredient in a compound?

All APIs and chemicals used for compounding must have a lot-specific certificate of analysis (CoA). FDA-approved drugs do not need a CoA unless they are deemed hazardous by the manufacturer. This distinction is different from the National Institute for Occupational Safety and Health (NIOSH) hazardous drug distinction (which concerns drugs that are hazardous to the healthcare worker). Ingredients other than API or FDA-approved drugs should have a CoA.

12.1-8 If I crush tablets or open capsules to make a CNSP, is that API?

No. Crushing, splitting, opening, or otherwise manipulating an FDA-approved drug does not create API. API is the raw chemical that is used to produce the FDA-approved drug.