

CATEGORIES OF NONSTERILE COMPOUNDING

There are 3 types of nonsterile compounding described in USP Chapter 795: simple, moderate and complex.

SIMPLE: There are 3 types of simple nonsterile compounded preparations (NSCPs):

1. The NSCP has a USP compounding monograph. There are just over 170 USP compounding monographs.
2. The NSCP appears in a peer reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate Beyond Use Dates (BUDs).
3. Reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer. This type of simple NSCP does not require any further documentation such as a Compounding Record.

MODERATE: There are 2 types of moderate NSCPs:

1. The NSCP requires special calculations or procedures, such as calibration of dosage unit mold cavities, to determine quantities of components used in the NSCP or in individualized dosage units.
2. The NSCP does not have specific stability data available. For example, mixing two or more manufactured cream products when the stability of the mixture is not known.

COMPLEX: The NSCP requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes. Examples of complex NSCP may include some transdermal dosage forms, modified-release NSCPs, and some inserts and suppositories for systemic effects.