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TITLE: SCOPE OF NONSTERILE COMPOUNDING	
SOP NUMBER: 1.2	**VERSION NUMBER: 1**
Written By:	Date: MM/DD/YYYY
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SOP Sample from SOP Manual, Nonsterile (PCCA #45-2642)

1. PURPOSE

1.1 The purpose of this SOP is to define what is considered nonsterile compounding.

2. RESPONSIBILITY

2.1 The Designated Person(s) shall supervise this procedure.

2.1.1 Designated Person(s) – <Job Title>

3. REFERENCES

3.1 SOP 1.1 – Creating, Changing and Reviewing of SOPs

3.2 SOP 2.2 – Employee Training

3.3 SOP 5.0 – Component Selection and Use

3.4 SOP 7.2 – Out of Specification (OOS)

3.5 SOP Section 10 – Hazardous Drug Compounding

3.6 USP 795 – *Pharmaceutical Compounding — Nonsterile Preparations*

3.7 USP 800 – *Hazardous Drugs — Handling in Healthcare Settings*

3.8 USP 825 – *Radiopharmaceuticals — Preparation, Compounding, Dispensing and Repackaging*

3.9 USP 1178 – *Good Repackaging Practices*

4. DEFINITIONS

4.1 Compounded nonsterile preparation (CNSP): A preparation intended to be nonsterile created by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering of a drug or bulk drug substance.

5. FREQUENCY

5.1 Whenever determining if a preparation is considered nonsterile compounding.

6. EQUIPMENT & SUPPLIES

6.1 N/A

7. PROCEDURE

7.1 Nonsterile compounding must follow the requirements of USP 795 and, if applicable, USP 800.

7.1.1 Nonsterile compounding is defined as combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug or bulk drug substance to create a nonsterile medication.

7.1.2 The requirements of USP 795 are intended to minimize harm, including death, to human and animal patients that could result from excessive microbial contamination, variability from the intended strength of correct ingredients (e.g., ±10% of the labeled strength), physical and chemical incompatibilities, chemical and physical contaminants, and/or use of ingredients of inappropriate quality.

7.1.3 Handling of nonsterile hazardous drugs (HDs) must additionally comply with *Hazardous Drugs — Handling in Healthcare Settings*. See SOP Section 10 – Hazardous Drug Compounding.

7.1.4 CNSPs that must comply include, but are not limited to, the following dosage forms: Solid oral preparations, liquid oral preparations, rectal preparations, vaginal preparations, topical preparations (i.e., creams, gels, ointments), nasal and sinus preparations intended for local application (i.e., nasal sprays and nasal irrigation) and otic preparations (excluding use in perforated eardrums).

7.2 Some practices encountered by pharmacies may not be considered compounding and are not required to meet the requirements of USP 795.

7.2.1 Nonsterile radiopharmaceuticals: Compounding of nonsterile radiopharmaceuticals is subject to the requirements in USP 825 *Radiopharmaceuticals — Preparation, Compounding, Dispensing, and Repackaging*.

7.2.2 Reconstitution: Reconstitution of a conventionally manufactured nonsterile product in accordance with the directions contained in the manufacturer approved labeling.

7.2.3 Repackaging: Repackaging of conventionally manufactured drug products (see USP 1178 *Good Repackaging Practices* for recommendations).

7.2.4 Splitting tablets: Breaking or cutting a tablet into smaller portions.

7.2.5 Administration: Preparation of a single dose for a single patient when administration will begin within 4 h. This includes crushing a tablet(s) or opening a capsule(s) to mix with food or liquids to facilitate patient dosing.

7.3 The requirements of USP 795 apply to all persons who prepare CNSPs and all places where CNSPs are prepared.

7.4 Personnel engaged in the compounding of CNSPs must also comply with laws and regulations of the applicable regulatory jurisdiction.

7.5 The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of CNSPs.

7.5.1 The responsibilities of the designated person(s) include but are not limited to:

7.5.1.1 Overseeing a training program to ensure competency of personnel involved in compounding, handling and preparing CNSPs. (SOP 2.2 – Employee Training)

7.5.1.2 Selecting components (SOP 5.0 – Component Selection and Use)

7.5.1.3 Monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed. (SOP 1.1 – Creating,

Changing and Reviewing of SOPS, SOP 2.2 – Employee Training and SOP 7.2 – Out of Specification (OOS))

7.5.1.4 Ensuring that standard operating procedures (SOPs) are fully implemented. The designated person(s) must ensure that follow-up is carried out if problems, deviations or errors are identified. (SOP 1.1 – Creating, Changing and Reviewing of SOPS and SOP 7.2 – Out of Specification (OOS))

7.5.1.5 Establishing, monitoring and documenting procedures for the handling and storage of CNSPs and/or components of CNSPs. (SOP Section 5 – Components)

7.5.2 Each SOP will indicate the designated person(s) that are responsible ensuring compliance to that procedure.

8. ATTACHMENTS

8.1 N/A

9. HISTORY

Version Number	Date Effective	Description of Change
1		New SOP.

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