Pharmacy Quality Assurance Commission
GUIDANCE DOCUMENT

Title:	United States Pharmacopeia General Chapter <795> - Nonsterile Compounding – Information	**Number:**	61
Reference:	RCW 18.64.270(2); USP Chapter <795>		
Contact:	Steve Saxe, Executive Director		
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According to the United States Pharmacopeia:

> USP General Chapter <795> provides standards for compounding quality nonsterile preparations. The chapter describes requirements for the compounding process, facilities, equipment, components, documentation, quality controls and training. General Chapter <795> also provides general guidelines for assigning beyond-use dates to nonsterile preparations.
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> USP General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations

In 2013, United States Pharmacopeia General Chapter <795> (USP 795) was incorporated into Washington law (RCW 18.64.270(2)). This statutory provision requires full compliance with USP 795 when individuals and facilities licensed by the Pharmacy Quality Assurance Commission (Commission) are compounding nonsterile products, regardless of practice setting.

The exact requirements USP 795 places on licensees depends on the type of nonsterile compounding conducted at the facility. Relevant factors influencing USP requirements include, but are not limited to: (i) whether the facility compounds nonsterile products for animals, (ii) whether the facility compounds hazardous drugs, and (iii) whether the facility compounds nonsterile products according to a manufacturer's labeling instructions.

The following hypotheticals illustrate the impact of the factors listed above on applicable USP 795 requirements. Attached to this e-mail is the most recent copy of the USP self-inspection worksheet that has *not* been approved by the Commission. It currently contains sixty-three (63) questions.

Hypothetical#1: A pharmacy only compounds nonhazardous nonsterile products according to a manufacturer's labeling instructions for human patients (also does not compound sterile products). This pharmacy would be able to mark N/A to the following questions in the USP 795 self-inspection worksheet:

- Training and Training Procedures: 4
- Compounding Facilities: 20, 27, 28, 29
- Compounding Documentation: 56
- Compounding for Animal Patients: 59, 60, 61, 62, and 63.

Hypothetical#2: A pharmacy only compounds nonhazardous nonsterile products for human patients (also does not compound sterile products). This pharmacy would be able to mark N/A to the following questions in the self-inspection worksheet:

- Training and Training Procedures: 4
- Compounding Facilities: 20, 27, 28, 29
- Compounding for Animal Patients: 59, 60, 61, 62, and 63.

A determination as to the difficulty of compliance with USP 795 is a decision for each facility. While the above hypotheticals note some of the questions a facility may be able to mark "N/A", there may be others e.g. compounding equipment questions depending on the set up of each facility.

PLEASE NOTE: the USP 795 Self-Inspection Addendum has not been published yet. The Pharmacy Quality Assurance Commission Compounding Subcommittee will be meeting to discuss and make final recommendations on this worksheet for presentation at the July 2018 regularly schedule Commission business meeting.