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USP <795>

KEY CHANGES

The following represents key changes from the currently enforceable version of USP Chapter<795> (last major revision in 2014) to the revised USP Chapter <795> (official as of November 1, 2023). The following are the major changes and are not meant to be an exhaustive list of the entirety of all changes made. Some changes will be reported as direct text excerpts from the respective chapter (notated by quotation marks), while others will be reported as a general comment describing the text or change. *Note: Bolding has been added to the text below for emphasis.*

Category	USP <795>, 2014[1]	USP <795>, 2023[2]
01. INTRODUCTION AND SCOPE		
CNSPs subject to the requirements in this chapter	Did not specify specific dosage forms Includes reconstituting or manipulating conventionally manufactured products per manufacturer labeling.	Added information on types of CNSPs: solid oral, liquid oral, rectal, vaginal, topical (i.e., creams, gels, and ointments), nasal and sinus intended for local application (i.e., nasal sprays and nasal irrigation), otic (excluding use in perforated eardrums) Excludes reconstitution of a conventionally manufactured product per manufacturer labeling.
The designated person	Not addressed	"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."
Hazardous drugs	Covered throughout the chapter	Removed from chapter and references to follow USP <800>
02. PERSONNEL TRAINING AND EVALUATION		
Training and competencies	Was not specific on what was required for training	"All personnel who compound or have direct oversight of compounding CNSPs must be **initially trained and qualified by demonstrating knowledge and competency according to the requirements ... "** "Knowledge and competency must be demonstrated **initially and at least every 12 months ... "** List of core competencies
Steps of training procedure	Did not include what steps needed to be taken in the training procedure	Includes three steps that need to be included in the training procedures: 1. Understand requirements of Chapter <795> 2. Understand and interpret safety data sheets and certificates of analysis (if applicable) 3. Read/understand procedures related to compounding duties

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03. PERSONAL HYGIENE AND GARBING		
Risk of contamination	Not addressed	Prior to entering the compounding area, personnel who have a risk of contamination (e.g., rashes, oozing sores, recent tattoos) must notify the designated person Designated person is responsible to evaluate any risk of contamination
Hand hygiene procedures	Not addressed	Added a box on hand hygiene procedures
Garb and glove requirements	"As needed"	Gloves are required for **all** compounding activities "**Other garb must be appropriate for the type of compounding performed** and should be worn as needed for the protection of the personnel from chemical exposures and for prevention of CNSP contamination"
04. BUILDINGS AND FACILITIES		
Compounding area	Not addressed	Requires a designated area for nonsterile compounding
Storage area	Not addressed	Temperature in storage area(s) should be monitored at least daily
05. CLEANING AND SANITIZING		
Minimum frequency for cleaning and sanitizing	Not addressed	Table was added on minimum frequencies for cleaning and sanitizing surfaces include work surfaces, floors, walls, and ceilings
06. EQUIPMENT AND COMPONENTS		
Equipment	Not addressed	" ... components that could generate airborne chemical particles must be evaluated to determine if these activities must be performed in a closed-system processing device ... " Containment ventilated enclosures must be certified at least every 12 months
Components	Not addressed	APIs must be manufactured by an FDA-registered facility and must be accompanied by a valid certificate of analysis
07. MASTER FORMULATION AND COMPOUNDING RECORDS		
Master formulation record and compounding record	A MFR **should** be created before compounding a preparation for the first time. A CR **should** be completed each time a preparation is compounded Should = **recommended**	A MFR **must** be created for each unique formulation of a CNSP. A CR **must** be created for all CNSPs. Must = **required**
08. RELEASE INSPECTIONS AND TESTING		
Visual inspection	Not addressed	Before releasing and dispensing, the CNSP must be visually inspected

Category	USP <795>, 2014[1]	USP <795>, 2023[2]
09. LABELING		
No major changes	--	--
10. ESTABLISHING BEYOND-USE DATES		
BUDs	Used the term "water-containing" to help determine BUDs	Eliminated the term "water-containing" Now uses water activity levels to help determine BUDs Parameters to consider when assigning BUDs: water activity, chemical and physical stability, compatibility of container closure system, degradation of container closure system, potential for microbial proliferation, deviations from essential compounding steps and procedures
11. SOPS		
SOPs	Not addressed	"All personnel who conduct or oversee compounding activities must be trained in the facility's SOPs and be responsible for ensuring that they are followed." "One or more person(s) must be designated to ensure all SOPs are fully implemented."
12. QUALITY ASSURANCE AND QUALITY CONTROL		
No major changes	--	--
13. CNSP PACKAGING AND TRANSPORTING		
No major changes	--	--
14. DOCUMENTATION		
No major changes	--	--

References

1. United States Pharmacopeial Convention. General chapter <795> pharmaceutical compounding—nonsterile preparations. USP43-NF38. Rockville, MD: U.S. Pharmacopeial Convention; 2019.

2. United States Pharmacopeial Convention. General chapter <795> pharmaceutical compounding—nonsterile preparations. USP-NF 2023, Issue 1, November 1, 2022, official as of November 1, 2023.

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Kevin and Patti are members of the USP Compounding Expert Committee, but this resource is not affiliated with or endorsed by USP.