USP <795> Nonsterile Compounding — Customer Checklist

Disclaimer: These checklists are provided by SOSCleanroom for general educational use and operational planning only. They are recommendations and do not constitute legal, regulatory, clinical, or safety advice, and should not be treated as a statement of fact about your specific facility. SOSCleanroom does not certify compliance through this document. You are responsible for developing, approving, and maintaining your own SOPs, training, documentation, and validation based on the official USP–NF text, your state/federal requirements, and your organization's risk assessment. Always consult qualified professionals and the applicable authorities having jurisdiction (AHJ).

Use this checklist for a rapid internal self-assessment. Align each item to the currently applicable official USP–NF text and your jurisdiction's enforcement posture.

A) Governance and quality system

- [ ] Responsible individual(s) designated; oversight and review cadence defined.
- [ ] SOP set controlled (approvals, versioning, archived copies, change control).
- [ ] Deviation/CAPA process exists; investigations are documented and timely.
- [ ] Batch record system maintained (formulas, master records, component traceability, cleaning logs).

B) Personnel, hygiene, and workflow discipline

- [ ] Initial training documented before independent nonsterile compounding.
- [ ] Standard method for weighing/measuring and mixing is documented and followed.
- [ ] Ongoing competency schedule tracked; retraining triggers defined for failures/events.
- [ ] Supply staging supports consistency (same products, same locations, minimal improvisation).

C) Facilities, equipment, and component control

- [ ] Designated compounding area supports cleanliness, organization, and controlled access.
- [ ] Equipment is suitable; calibration/verification and maintenance records are current.
- [ ] Components controlled (identity/grade, lots, storage, expiration); traceability captured in records.
- [ ] Cross-contamination controls in place (segregation, dedicated tools, allergen awareness).

D) Cleaning and sanitation program

- [ ] Approved cleaning chemistries and contact times defined in SOPs; compatibility considerations documented.
- [ ] Wiping technique standardized (pattern, overlap, face control, change-out rules).
- [ ] Cleaning schedule implemented and logged; missed events are escalated and corrected.
- [ ] Tools are low-lint and appropriate (controlled packaging, consistent formats).

E) Quality checks and verification

- [ ] Calculations and measuring steps are verified (double-checks or validated controls as applicable).
- [ ] Final appearance/consistency check performed; targets documented where applicable.
- [ ] Label review performed; formula, strength, directions, and warnings match the record.

F) BUD, labeling, storage, transport, traceability

- [ ] BUD assignment approach defined; rationale documented and aligned to risk and stability basis.
- [ ] Labels support traceability (ingredients, lots, preparer, dates, storage conditions).
- [ ] Storage/transport conditions match BUD assumptions; deviations are documented and addressed.

Official USP references (source-of-truth):

- USP <795> portal: https://www.usp.org/compounding/general-chapter-795
- USP–NF notice on <795> publication/official status: https://www.uspnf.com/notices/795-pub-announcement-20221101
- USP FAQ – Identifying official text: https://www.usp.org/frequently-asked-questions/identifying-official-text
- USP FAQ hub: https://www.usp.org/frequently-asked-questions