Master Formula Audit

Drug Name: _____

Formula ID: _____

An MFR must include at least the following information:

- [ ] Name, strength or activity, and dosage form of the CNSP
- [ ] Identities and amounts of all components; if applicable, relative characteristics of components (e.g., particle size, salt form purity grade, solubility)
- [ ] Container closure system(s)
- [ ] Complete instructions for preparing the CNSP including equipment, supplies, and description of compounding steps
- [ ] Physical description of the final CNSP
- [ ] Beyond-use date (BUD) and storage requirements
- [ ] Reference source to support the assigned BUD
- [ ] If applicable, calculations to determine and verify quantities and/or concentrations of components and strength or activity of the API(s)
- [ ] Labeling requirements (e.g., shake well)
- [ ] Quality control (QC) procedures (e.g., pH testing, visual inspection) and expected results
- [ ] Other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature)

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