Suggested SOP For Development of a CSP Formula

1.0 PURPOSE

1.1 To establish a protocol for formulating, preparing and testing a CSP formula.
1.2 To outline all considerations required for developing a compounded sterile preparation (CSP) formula.

2.0 SCOPE

2.1 All CSP formulas are to be formulated and entered into the master formula database per this policy and procedure.

3.0 RESPONSIBILITY

3.1 It will be the responsibility of the Pharmacist-in-Charge or the sterile compounding pharmacist to oversee this procedure.

4.0 FREQUENCY

4.1 When new formula is requested, formulated, designed and entered into the database

5.0 EQUIPMENT & SUPPLIES

5.1 USP <797>
5.2 USP <71>
5.3 USP <85>
5.4 Beyond Use Dating Guidelines/SOPs
5.5 Trissel's Stability of Compounded Formulations
5.6 Handbook on Injectable Drugs
5.7 Reference Materials as needed

6.0 PROCEDURE

6.1 Each time a new CSP formula is requested, and before it is formulated and entered into the master formula database, all of the following must be followed & considered.

6.101 First, check if the preparation is a commercially available product. If so, check the ASHP & FDA drug shortage website to determine whether the product is currently unavailable. If it is determined to be on backorder/shortage – note this in the notes section of the formula, along with the date.

6.102 For compounds prepared for human use, Consult 21 CFR 216.24 "Drugs Products Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness" to ensure that the formula requested does not contain any ingredients on this list .

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6.102 Verify that the dose and/or concentration requested is clinically sound and will not exceed recommended dosing.

6.103 Determine the required ingredients and quantities through the use of the listed equipment/supplies, or package insert. Clearly describe the compounding process, in the notes section of the formula.

6.104 Determine the sterilization method by referencing the resources listed in the equipment section. Consider whether the final product will maintain desired potency following the sterilization method. Clearly describe the sterilization method in the compounding instructions.
-Filtration – indicate specifically what filter & size to use – base this on the manufacture's specifications/package insert for each filter type
-Steam Heat – consider the chemical stability when subjected to heat.
-Dry Heat – consider the chemical stability when subjected to heat. Clearly indicate the temperature & time required to adequately sterilize

6.105 Determine an appropriate Beyond Use Date, as per SOPs, USP <797> and available references, and indicate along with rational on the master formula. To extend a beyond use date further than indicated in USP <797>, sterility tests must be performed as per USP <71>.

6.106 Determine the typical and/or largest batch size and calculate the number of units needed to conduct method suitability testing per USP <71> and endotoxin testing per USP <85>.

6.106 Determine appropriate storage conditions, clearly indicate in the formula instructions and auxiliary labels. Reference appropriate materials.

6.107 Clearly tag the CSP formulation as the appropriate schedule if any ingredient is a scheduled medication, as per DEA & state board of pharmacy specs.

6.108 Clearly label the finished CSP according to SOPs, state and federal regulations and accrediting guidelines.

7.0 HISTORY

7.1 Original

Source: SOP review - LDT Health Solutions, Inc. 2014.