STERILE PREPARATION COMPOUNDING
SELF-ASSESSMENT REPORT
NMAC 16.19.36
USP <797>

INSTRUCTIONS

Each facility that produces compounded sterile preparation (CSP) must complete this assessment. The pharmacist-in-charge is responsible for the report, and must sign it. The completed report must be available for review by the New Mexico Board of Pharmacy (BOP) during facility inspections. Regulation citations are provided at the beginning of each section. Review NMAC 16.19.36, and USP <797> prior to answering if you are unsure of a statement on this assessment report. Comments about specific statements may be recorded on the last page of this report. Please record the statement number with your comment.

FACILITY NAME: _____ DATE: _____

ADDRESS: _____

CITY, ZIP CODE: _____

PHARMACY LICENSE NUMBER: _____ EXP. DATE: _____

PHARMACIST-IN-CHARGE: _____ LICENSE NUMBER: _____

PHYSICAL REQUIREMENTS [NMAC 16.19.36.9, 16.19.36.10]

	YES	NO	N/A
1. BUFFER ROOM IS 100 SQ. FT. OR LARGER.	____	____	____
2. A RETAIL PHARMACY CAPABLE OF PRODUCING CSP IS 340 SQ. FT. OR LARGER.	____	____	____
3. BUFFER AND ANTE ROOMS ARE AT APPROPRIATE RELATIVE POSITIVE AIR PRESSURES (FOR NONHAZARDOUS DRUGS)	____	____	____
4. CONTROLLED (ISO CLASSIFIED) AREAS ARE CERTIFIED TO USP <797> REQUIREMENTS AT LEAST EVERY SIX MONTHS	____	____	
5. USE OF CONTROLLED AREAS RESTRICTED TO COMPOUNDING-RELATED ACTIVITIES	____	____	
6. BUFFER AND ANTE ROOM: FLOORS, WALLS & CEILINGS ARE SMOOTH, NON-POROUS AND CLEANABLE	____	____	
7. CONTROLLED AREA LIGHTED AN AVERAGE 80-150 FOOTCANDLES.	____	____	

HAZARDOUS DRUG (HD) COMPOUNDING

	YES	NO	
8. DOES HD COMPOUNDING OCCUR AT THIS FACILITY?	____	____	(IF NO, SKIP TO NEXT SECTION)
9. BUFFER ROOM IS AT APPROPRIATE RELATIVE NEGATIVE AIR PRESSURE	____	____	
10. HD STORED UNDER REQUIRED NEGATIVE PRESSURE and AIR CHANGES PER HOUR	____	____	
11. HD COMPOUNDING ONLY IN BIOLOGICAL SAFETY CABINET OR COMPOUNDING ASEPTIC CONTAINMENT ISOLATOR	____	____	

PHARMACIST IN CHARGE [16.19.36.8]

	YES	NO	N/A
12. FACILITY HAS A DESIGNATED PHARMACIST IN CHARGE OF OPERATIONS, WHO IS RESPONSIBLE FOR:			
a) DEVELOPMENT, IMPLEMENTATION AND CONTINUING REVIEW AND MAINTENANCE OF WRITTEN POLICIES AND PROCEDURES WHICH COMPLY WITH USP/NF STANDARDS	____	____	
b) PROVIDING A PHARMACIST WHO IS AVAILABLE FOR 24 HOUR SEVEN-DAY-A-WEEK SERVICES	____	____	
c) ESTABLISHING A SYSTEM TO ENSURE THAT CSPS ARE ADMINISTERED BY LICENSED PERSONNEL OR PROPERLY TRAINED AND INSTRUCTED PATIENTS	____	____	
d) ESTABLISHING A SYSTEM TO ENSURE THAT CSPS ARE PREPARED IN COMPLIANCE WITH USP <797>	____	____	
e) ENSURING FACILITY PERSONNEL COMPLY WITH WRITTEN POLICIES AND PROCEDURES	____	____	
f) DEVELOPING AN APPROPRIATE AND INDIVIDUALIZED PLAN OF CARE WITH PATIENT OR CAREGIVER AND OTHER HEALTHCARE PROVIDERS FOR EACH PATIENT RECEIVING PARENTERAL PREPARATIONS IN A HOME SETTING	____	____	____

EQUIPMENT [16.19.36.10]

	YES	NO
13. REQUIRED EQUIPMENT IS AVAILABLE AND MAINTAINED [16.19.36.10(A), (B)]	____	____
14. CURRENT REFERENCES (HARD COPY OR ELECTRONIC) INCLUDE:		
a) USP/NF or USP ON COMPOUNDING: A GUIDE FOR THE COMPOUNDING PRACTITIONER	____	____
b) NM PHARMACY LAWS, RULES AND REGULATIONS	____	____
c) SPECIALTY REFERENCES (STABILITY AND COMPATIBILITY; STERILIZATION AND PRESERVATION; PEDIATRIC DOSING; AND DRUG MONOGRAPH) AS APPROPRIATE FOR SCOPE OF SERVICES PROVIDED	____	____

AUTOMATED COMPOUNDING DEVICES [16.19.36.10 (D)]

	YES	NO	
15. DOES THIS FACILITY UTILIZE AUTOMATED COMPOUNDING DEVICE(S)	____	____	(IF NO, SKIP TO NEXT SECTION)
16. SUCH DEVICES ARE OPERATED IN ACCORDANCE WITH ALL OF THE FOLLOWING:	____	____	
a) ACCURACY VERIFIED ROUTINELY AT LEAST EVERY 30 DAYS PER MANUFACTURER'S SPECIFICATIONS			
b) OBSERVED AT LEAST EVERY 30 DAYS BY THE OPERATOR DURING MIXING PROCESS TO ENSURE PROPER DEVICE FUNCTION			
c) DATA ENTRY VERIFIED BY RPH PRIOR TO COMPOUNDING OR ACCURATE FINAL DOCUMENTATION OF CSP TO ALLOW FOR RPH VERIFICATION OF INGREDIENTS PRIOR TO DISPENSING			
d) ACCURACY OF DELIVERY OF THE END PRODUCT IS VERIFIED ACCORDING TO WRITTEN POLICIES AND PROCEDURES			

POLICIES AND PROCEDURES [16.19.36.11]

	YES	NO
17. WRITTEN POLICIES AND PROCEDURES CONSISTENT WITH USP <797>, INCLUDING THOSE BELOW, ARE ESTABLISHED, IMPLEMENTED, FOLLOWED, AND AVAILABLE FOR INSPECTION AND REVIEW BY THE BOP	____	____
18. POLICIES AND PROCEDURES INCLUDE:		
a) CLEANING, DISINFECTION, EVALUATION, VALIDATION, TESTING, CERTIFICATION, AND MAINTENANCE OF CONTROLLED AREAS	____	____
b) PERSONNEL QUALIFICATIONS, TRAINING, ASSESSMENT AND PERFORMANCE VALIDATION	____	____
c) OPERATION, MAINTENANCE, VALIDATION, TESTING, AND CERTIFICATION OF FACILITY AND EQUIPMENT	____	____
d) COMPOUNDING, STORAGE, HANDLING, AND DISPENSING OF ALL COMPONENTS USED AND ALL CSPs	____	____
e) PROPER DISPOSAL OF PHYSICAL, CHEMICAL, HAZARDOUS, AND INFECTIOUS WASTE	____	____
f) QUALITY CONTROL GUIDELINES AND STANDARES	____	____
g) QUALITY ASSURANCE GUIDELINES AND STANDARDS	____	____
h) DETERMINATION OF STABILITY, INCOMPATIBILITIES, AND DRUG INTERACTIONS	____	____
i) ERROR PREVENTION AND INCIDENT REPORTING PER NMAC 16.19.25	____	____

RECORD KEEPING AND PATIENT PROFILE [NMAC 16.19.36.12]

	YES	NO	N/A
19. PATIENT PROFILES ARE MAINTAINED AND INCLUDE:			
a) RX RECORDS OR ORDERS INCLUDING THE ORIGINAL RX OR ORDER, REFILL AUTHORIZATION, ALTERATIONS IN THE ORIGINAL RX OR ORDER, AND INTERRUPTIONS IN THERAPY DUE TO HOSPITALIZATION	____	____	
b) PATIENT'S HISTORY INCLUDING ALLERGY OR ADVERSE DRUG REACTION INFORMATION	____	____	
c) PATIENTS RECEIVING PARENTERAL PREPARATIONS IN A HOME SETTING ARE CONTACTED AT A FREQUENCY APPROPRIATE TO THE COMPLEXITY OF THE PATIENT'S HEALTH PROBLEMS AND DRUG THERAPY AS DOCUMENTED ON CARE PLAN AND WITH EACH NEW RX, CHANGE IN THERAPY OR CONDITION	____	____	____
d) DOCUMENTATION THAT THE PATIENT RECEIVING PARENTERAL PREPARATIONS IN A HOME SETTING, OR THE PATIENT'S AGENT, HAS RECEIVED A WRITTEN COPY OF THE PLAN OF CARE AND TRAINING IN THE SAFE ADMINISTRATION OF MEDICATION	____	____	____

PERSONNEL TRAINING [NMAC 16.19.36.13]

	YES	NO	N/A
20. ALL COMPOUNDING PERSONNEL (RPh, INTERNS, TECHNICIANS) PREPARING OR SUPERVISING CSP PREPARATION HAVE COMPLETED ALL REQUIRED TRAINING [16.19.36.13 (A) – (D)]	____	____	
21. TRAINING RECORDS FOR ALL COMPOUNDING PERSONNEL ARE AVAILABLE FOR INSPECTION FOR THREE YEARS.	____	____	
22. COMPETENCY EVALUATIONS DOCUMENTED AND INCLUDE GLOVED FINGERTIP SAMPLING, AND MEDIA FILL TESTNG	____	____	
23. DOCUMENTATION OF TRAINING INCLUDES REQUIRED INFORMATION [16.19.36.13 (G)]	____	____	

QUALITY ASSURANCE
PATIENT OR CAREGIVER TRAINING FOR USE OF CSP IN A HOME SETTING [16.19.36.14]

	YES	NO	N/A
24. FACILITY PROVIDES CSPS FOR USE IN A HOME SETTING	____	____	(if no skip to next section)
25. RPH MAINTAINS DOCUMENTATION OF PROVIDED PATIENT TRAINING CONSISTENT WITH NMAC 16.19.4.16(F) NMAC	____	____	
26. THE FACILITY PROVIDES 24-HOUR TOLL FREE TELEPHONE NUMBER FOR PATIENTS	____	____	
27. THERE IS A DOCUMENTED, ONGOING QA PROGRAM THAT MONITORS PATIENT CARE AND PHARMACEUTICAL CARE OUTCOMES, INCLUDING:			
a) ROUTINE PROSPECTIVE DRUG USE REVIEW AND PATIENT MONITORING FUNCTIONS BY A PHARMACIST	____	____	
b) PATIENT MONITORING PLANS INCLUDE WRITTEN OUTCOME MEASURES AND SYSTEMS FOR ROUTINE PATIENT ASSESSMENT	____	____	
c) DOCUMENTATION OF PATIENT TRAINING	____	____	

QUALITY ASSURANCE OF COMPOUNDED STERILE PREPARATIONS [16.19.36.15]

	YES	NO	N/A
28. ALL PHARMACIES COMPOUNDING STERILE PREPARATIONS HAVE A DOCUMENTED, ONGOING PERFORMANCE IMPROVEMENT PROGRAM MONITORING PERSONNEL PERFORMANCE, EQUIPMENT AND FACILITIES BY:			
a) POLICIES AND PROCEDURES FOR ALL ASPECTS OF PREPARATION, STORAGE AND DISTRIBUTION OF CSP INCLUDING CLEANING MATERIALS AND DISINFECTANTS AND MONITORING EQUIPMENT ACCURACY	____	____	
b) FOR **HIGH RISK** COMPOUNDING, REQUIRED END PRODUCT TESTING IS CONDUCTED	____	____	____
c) REGULAR, PLANNED QUALITY ASSURANCE AUDITS.	____	____	
d) DOCUMENTED PLAN OR CORRECTIVE ACTION FOR IDENTIFIED PROBLEMS	____	____	

e) MECHANISM FOR RETRIEVING/TRACKING RECALLED PREPARATIONS, ____ ____

29. DOES BATCH COMPOUNDING OCCUR AT THIS FACILITY? [SEE DEFINITION OF BATCH, NMAC 16.19.36.7(D)] ____ ____ (IF NO, SKIP TO NEXT QUESTION)

I. THE BATCH LABEL OF EACH CSP CONTAINS:

a) DRUG PRODUCT NAME(S), DILUENT NAME(S) AND AMOUNT(S) OF EACH ____ ____
b) LOT OR CONTROL NUMBER ASSIGNED TO BATCH PRODUCT ____ ____
c) FINAL CONCENTRATION(S), AND VOLUME WHEN APPROPRIATE ____ ____
d) BEYOND-USE DATE, AND TIME WHEN APPLICABLE ____ ____
e) ROUTE OF ADMINISTRATION WHEN APPLICABLE ____ ____
f) DATE OF PREPARATION ____ ____
h) FACILITY IDENTIFIER ____ ____
i) IDENTITY OF PERSON PREPARING AND PHARMACIST CHECKING FINAL PRODUCT ____ ____
j) ANCILLARY INSTRUCTIONS WHEN APPROPRIATE, AND DEVICE INSTRUCTIONS WHEN NEEDED ____ ____

II. COMPOUNDING RECORD FOR EACH CSP BATCH IS USED TO VERIFY COMPOUNDING ACCURACY WITH RECIPE AND INCLUDES:

a) REFERENCE TO CSP FORMULATION RECORD ____ ____
b) NAME, STRENGTH, VOLUME, MANUFACTURER, AND MANUFACTURER LOT NUMBER FOR EACH COMPONENT ____ ____
c) NAME, STRENGTH, AND VOLUME OF FINISHED CSP ____ ____
d) RECONCILIATION OF ACTUAL YIELD WITH ANTICIPATED YIELD, AND TOTAL # OF CSP UNITS PRODUCED ____ ____
e) IDENTITY OF PERSON PREPARING, AND PHARMACIST THAT COMPLETED FINAL CHECK ____ ____
f) DATE OF PREPARATION ____ ____
g) LOT OR CONTROL NUMBER ASSIGNED TO BATCH PRODUCT ____ ____
h) ASSIGNED BEYOND-USE DATE, AND TIME WHEN APPLICABLE ____ ____
i) RESULTS OF APPLICABLE QUALITY CONTROL PROCEDURES ____ ____

30. THE PATIENT SPECIFIC LABEL CONTAINS THE FOLLOWING INFORMATION:

a) PATIENT NAME ____ ____
b) LOT OR CONTROL NUMBER FOR BATCH PROCESSING ____ ____ ____
c) SOLUTION, INGREDIENT NAME(S) AND AMOUNT(S) ____ ____
d) BEYOND-USE DATE (AND TIME WHEN APPLICABLE) ____ ____
e) ROUTE OF ADMINISTRATION ____ ____
f) DIRECTIONS FOR USE INCLUDING INFUSION RATE AND SCHEDULED TIMES ____ ____
g) IDENTIFIER OF PERSON PREPARING STERILE PRODUCT AND PHARMACIST PERFORMING FINAL CHECK ____ ____
h) ANCILLARY INSTRUCTIONS WHEN APPROPRIATE ____ ____
i) DEVICE INSTRUCTIONS WHEN APPROPRIATE ____ ____
j) IF DISPENSED FOR OTHER THAN INPATIENT USE, ALL OTHER REQUIRED INFORMATION ____ ____

31. A FORMULATION RECORD FOR CONSISTENT SOURCE DOCUMENT (RECIPE) FOR CSP PREPARATION IS USED AND INCLUDES:

a) NAME, STRENGTH, DOSAGE FORM, AND FINAL VOLUME OF THE COMPOUNDED PREPARATION ____ ____
b) ALL INGREDIENTS AND THEIR QUANTITIES ____ ____
c) EQUIPMENT NEEDED TO PREPARE THE CSP, WHEN APPROPRIATE, AND MIXING INSTRUCTIONS ____ ____
d) OTHER ENVIRONMENTAL CONTROLS, SUCH AS FACTORS FOR CONSISTENT PREPARATION ____ ____
e) BEYOND USE DATING, DISPENSING CONTAINER, STORAGE REQUIREMENTS, QUALITY CONTROL PROCEDURES ____ ____
f) INFORMATION FOR PROPER LABELING (E.G. SAMPLE LABEL) ____ ____

32. ALL STERILE COMPOUNDING IS PERFORMED WITH APPROPRIATE ASEPTIC TECHNIQUE ____ ____
33. ALL STERILE COMPOUNDING IS PERFORMED UTILIZING HAND HYGIENE IN ACCORDANCE WITH USP <797> ____ ____
34. HAND HYGIENE AND GARBING IS PERFORMED IN ACCORDANCE WITH USP <797> ____ ____

35. ARE CSPS FROM YOUR FACILITY SHIPPED/DELIVERED INTO OTHER STATES ____ ____
36. IF YES, IS YOUR FACILITY PROPERLY LICENSED TO SHIP CSPS INTO OTHER STATES ____ ____
37. DOES THE AMOUNT OF CSPS SHIPPED OUT OF STATE EXCEED 5% OF THE TOTAL PRESCRIPTIONS DISPENSED BY YOUR FACILITY ____ ____
38. WHAT PERCENT OF TOTAL PRESCRIPTIONS DISPENSED BY YOUR FACILITY CONSISTS OF CSPS SHIPPED OUT OF STATE? ____%
39. FACILITY HAS POLICIES AND PROCEDURES TO ENSURE PROPER STORAGE CONDITIONS OF CSPS DURING SHIPPING ____ ____

40. FACILITY DOES NOT COMPOUND REGULARLY OR IN INORDINATE AMOUNTS ANY DRUG PRODUCTS THAT ARE ESSENTIALLY COPIES OF COMMERCIALLY AVAILABLE DRUG PRODUCTS ____ ____

USP 797 STANDARDS FOR COMPOUNDED STERILE PREPARATIONS (CSP)

	YES	NO	N/A
41. IS USP < 797> USED IN DEVELOPING AND IMPLEMENTING THE POLICIES AND PROCEDURES?	____	____	
42. DO PERSONNEL HAVE THE POLICY AND PROCEDURE READILY AVAILABLE?	____	____	
43. INDICATE THE RISK LEVELS OF THE CSPS PRODUCED IN THIS FACILITY:			
IMMEDIATE USE	____	____	
LOW RISK	____	____	
MEDIUM RISK	____	____	
HIGH RISK	____	____	

ARE THE FOLLOWING ADDRESSED IN THE POLICY AND PROCEDURE USING USP <797> STANDARDS?

	YES	NO	N/A
44. CSP RISK LEVELS	____	____	
45. SINGLE AND MULTIPLE-DOSE CONTAINERS	____	____	
46. HAZARDOUS DRUGS AS CSPS	____	____	____
47. RADIOPHARMACEUTICALS AS CSP	____	____	____
48. ALLERGEN EXTRACTS	____	____	____
49. STERILIZATION	____	____	
STERILIZATION OF BY FILTRATION, AND FILTER INTEGRITY TESTING	____	____	____
STERILIZATION BY MOIST HEAT	____	____	____
STERILIZATION BY DRY HEAT	____	____	____
DEPYROGENATION	____	____	____
50. ENVIRONMENTAL QUALITY AND CONTROL ISSUES	____	____	
PRESSURE DIFFERENTIAL MONITORING	____	____	
EXPOSURE OF CRITICAL SITES	____	____	
ISO CLASS 5 PRIMARY ENGINEERING CONTROLS (PEC); BUFFER AREAS, AND ANTE-AREAS	____	____	
VIABLE AND NONVIABLE ENVIRONMENTAL SAMPLING	____	____	
SURFACE AND AIR SAMPLING FREQUENCY AND PROCESSES	____	____	
GROWTH MEDIA	____	____	
ACTION LEVELS, DOCUMENTATION, AND DATA EVALUATION	____	____	
FACILITY DESIGN AND ENVIRONMENTAL CONTROLS	____	____	
PLACEMENT OF PEC WITHIN ISO CLASS 7 BUFFER AREA	____	____	
CLEANING AND DISINFECTION OF ISO CLASSIFIED AREAS (SCHEDULES, AND PROCEDURES)	____	____	
51. PERSONNEL COMPETENCIES INCLUDE:			
HAND HYGIENE AND GARBING (WITH VISUAL OBSERVATION)	____	____	
CLEANING AND DISINFECTION	____	____	
ASEPTIC TECHNIQUE AND RELATED PRACTICES	____	____	
INITIAL COMPETENCY EVALUATION INCLUDES GLOVED FINTERTIP SAMPLING TIMES THREE	____	____	
INITIAL AND ONGOING COMPETENCY EVALUATION INCLUDES:			
GLOVED FINTERTIP SAMPLING	____	____	
MEDIA FILL TESTING	____	____	
SURFACE SAMPLING	____	____	
ADDITIONAL TESTING (E.G. WRITTEN)	____	____	
52. SAMPLING PROCEDURES	____	____	
53. INCUBATION PROCEDURES	____	____	
54. ACTION LEVELS, DOCUMENTATION AND DATA EVALUATION	____	____	
55. FINISHED PREPARATION RELEASE CHECKS AND TESTS	____	____	
INSPECTION OF PREPARATIONS AND REVIEW OF COMPOUNDING PROCEDURES	____	____	
IDENTITY AND STRENGTH VERIFICATION OF INGREDIENTS	____	____	
STERILITY TESTING	____	____	____
BACTERIAL ENDOTOXIN (PYROGEN) TESTING	____	____	____
56. DRUG STORAGE	____	____	
57. BEYOND-USE DATING DETERMINATION	____	____	
58. MAINTAINING STERILITY, PURITY AND STABILITY OF DISPENSED AND DISTRIBUTED CSPS	____	____	
59. REDISPENSED CSPS	____	____	____
60. PACKAGING AND TRANSPORTING CSPS	____	____	

COMMENTS

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PHARMACIST-IN-CHARGE SIGNATURE DATE