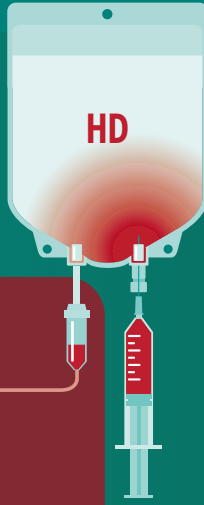
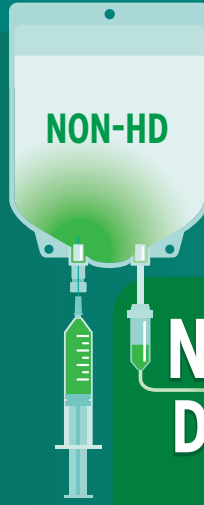


FLOW CHART FOR USP 797 AND USP 800 PEC REQUIREMENTS



NON-HAZARDOUS DRUG PREPARATION

STERILE

CATEGORY 1
Beyond Use Date (BUD)
BUD < 12 hrs
24 hrs if Refrigerated



CATEGORY 2
Beyond Use Date (BUD)
BUD > 12 hrs



SECONDARY ENGINEERING CONTROL (SEC) CONFIGURATION

SEGREGATED COMPOUNDING AREA
12 AIR CHANGES / HOUR
POS. PRESSURE .01" - .03" WC



SECONDARY ENGINEERING CONTROL (SEC) CONFIGURATION

ISO CLASS 7 CLEAN ROOM
30 AIR CHANGES / HOUR
POS. PRESSURE .01" - .03" WC



PRIMARY ENGINEERING CONTROL (PEC) REQUIREMENTS



LAMINAR AIRFLOW WORKBENCH (LAFW)

— OR —



CLASS II BIOLOGICAL SAFETY CABINET (BSC)

— OR —



NU-PR797

COMPOUNDING ASEPTIC ISOLATOR (CAI)

HAZARDOUS DRUG PREPARATION

STERILE

CATEGORY 1
Beyond Use Date (BUD)
BUD < 12 hrs
24 hrs if Refrigerated

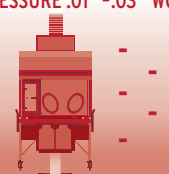


CATEGORY 2
Beyond Use Date (BUD)
BUD > 12 hrs



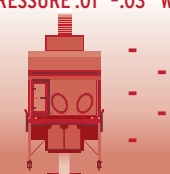
CONTAINMENT SECONDARY ENGINEERING CONTROL (C-SEC) CONFIGURATION

CONTAINMENT SEGREGATED COMPOUNDING AREA
12 AIR CHANGES / HOUR
NEG. PRESSURE .01" - .03" WC



CONTAINMENT SECONDARY ENGINEERING CONTROL (C-SEC) CONFIGURATION

ISO CLASS 7 CLEAN ROOM
30 AIR CHANGES / HOUR
NEG. PRESSURE .01" - .03" WC



NON-STERILE

CONTAINMENT SECONDARY ENGINEERING CONTROL (C-SEC) CONFIGURATION

CONTAINMENT SEGREGATED COMPOUNDING AREA
12 AIR CHANGES / HOUR
NEG. PRESSURE .01" - .03" WC



CONTAINMENT PRIMARY ENGINEERING CONTROL (C-PEC) REQUIREMENTS



EXTERNALLY VENTED CLASS II BIOLOGICAL SAFETY CABINET (BSC)

— OR —



COMPOUNDING ASEPTIC CONTAINMENT ISOLATOR (CACI)

CONTAINMENT PRIMARY ENGINEERING CONTROL (C-PEC) REQUIREMENTS

EXTERNALLY VENTED (PREFERRED) OR REDUNDANT HEPA FILTER



CLASS I BIOLOGICAL SAFETY CABINET (BSC)

— OR —



CLASS II BIOLOGICAL SAFETY CABINET (BSC)

— OR —



COMPOUNDING ASEPTIC CONTAINMENT ISOLATOR (CACI)



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