Employee's Printed Name: _____ **Month: _____ Year: _____**

Competency Evaluation Checklist for Sterile Compounding *(Biannual Testing)* No Log – Parasol Medical

Required Elements (Initial and Date)	**Completion of Task**			**Confirmation**	
	Employee Initials	**Date of completion**	**Observer Initials**	**Confirmation Initials**	**Date Passed**
Complete and Pass Pharmacy Compounding Sterile Preparations Competency CBL with Net Learning Test – *Annually*					
Complete & Pass Garbing Competency Evaluation with Gloved Fingertip and Thumb (GFT) Sampling After Garbing *-Biannually* (GFT Test Log – Biannual Testing)					
Complete & Pass Aseptic Manipulation Competency Evaluation with Observed Aseptic Technique Media-Fill Testing, followed by GFT and Surface Sampling of Direct Compounding Area (DCA) *- Biannually* (Aseptic Manipulation Competency Evaluation)					

FINAL Biannual Employee Competency Confirmed by:
(All above complete and assessment form complete.)

_____
Signature of Pharmacist

_____
Printed Name of Pharmacist

_____
Date

COMMENTS (i.e. applicable retest dates and results):

_____

_____

_____

_____

_____

EMPLOYEE NAME:

Gloved Fingertip and Thumb Test (Biannual Testing)

EMPLOYEE POST GARBING GFT

Test Observer Name: _____

Test Date: _____ Test Time: _____

☐ *Check box to confirm you collected certificate of analysis (CoA) for growth media. Keep a copy of the CoA(s) on file.*

GFT Test: LEFT HAND	GFT Test: RIGHT HAND
Component No.: T-D100 Media Type: TSA with L&T, Sterile Media Manufacture: Parasol Medical Media Exp. Date: _____ Media Lot # _____	Component No.: T-D100 Media Type: TSA with L&T, Sterile Media Manufacture: Parasol Medical Media Exp. Date: _____ Media Lot # _____
INTERVAL 1 2023 USP <797> 30-35ºC for no less than 48 hr	**INTERVAL 2** 2023 USP <797> 20-25ºC for no less than 5 additional days
Start Date: _____ End Date: _____	Start Date: _____ End Date: _____

GFT TEST RESULTS

Report any growth greater than action levels

Visual Observation of Proper Garbing and Hand Hygiene ☐ PASS ☐ FAIL

Name of Person Reading the Results: _____

Growth Results: ☐ POSITIVE ☐ NEGATIVE

Colony Forming Unit Count (total of both sides): _____

Test Results *(must pass both visual and growth test)*: ☐ PASS ☐ FAIL

EMPLOYEE POST GARBING GFT SAMPLING OVERVIEW

Sign-off after successful completion of test.

Report any growth greater than action levels to appropriate management.

☐ PASS

☐ FAIL Pharmacist Signature: _____ Date: _____

CORRECTIVE ACTION SUMMARY / COMMENTS:

Action Levels for Gloved Fingertip and Thumb Sampling, per 2023 USP <797>

Gloved Fingertip and Thumb Sampling	Action Levels *(cfu, total from both hands*
After garbing	>0

Action levels are based on the total cfu count on both hands

USP 797 Hand Hygiene, Garbing, & Aseptic Technique Assessment Form for Compounding Personnel

Qualified evaluator will mark an 'X' in each space for which person being assessed has acceptably completed described activity. Write 'N/A' if activity is not applicable or 'N/O' if activity was not observed. Employee being assessed is **immediately** informed of all unacceptable activities and shown correct procedure.

HAND HYGIENE AND GARBING PRACTICES

_____ **Ante-/Clean Room:** Wearing no cosmetics or jewelry (watches, rings, earrings, etc.) upon entry into ante-area.

_____ **All Other Compounding Areas:** Wearing no cosmetics or jewelry (watches, rings, earrings, etc.) upon preparation for compounding.

_____ Aware of line of demarcation separating clean and dirty sides.

_____ Dons shoe covers one at a time, placing covered shoe on clean side of line of demarcation, as appropriate (Ante-Room).

_____ Dons beard cover if applicable.

_____ Dons head cover (bonnet) assuring that all hair is covered.

_____ Dons face mask to cover bridge of nose down to include chin.

_____ Performs hand hygiene procedure by wetting hands and forearms up to elbows and washing using approved soap for at least 30 seconds.

_____ Dries hands and forearms using lint-free towel.

_____ Dons appropriately sized gown and ensures full closure (Ante-Room).

_____ In compounding (buffer) area, disinfects hands again using waterless alcohol-based surgical hand scrub with persistent activity and allows hands to dry thoroughly.

_____ Dons appropriately sized sterile gloves and examines for defects, holes or tears.

_____ During sterile compounding activities, routinely disinfects gloves with sterile 70% IPA prior to work in direct compounding area (DCA) and after touching potentially contaminated items or surfaces.

_____ When exiting compounding (buffer) area, removes gown and hangs on hook provided in ante room if not visibly soiled and is to be re-donned that day.

_____ All garb (unless saving gown as specified above) will be removed in Pharmacy and discarded appropriately.

_____ Hands must be washed after removing gloves.

ASEPTIC TECHNIQUE

_____ Disinfects ISO Class 5 device surfaces with an appropriate agent.

_____ Disinfects components/vials with an appropriate agent prior to placing into ISO Class 5 work area.

_____ Introduces only essential material in proper arrangement in the ISO Class 5 work area.

_____ Does not interrupt, impede, or divert flow of first-air to critical sites.

_____ Ensures syringes, needles, and tubing remain in their individual packaging and are only opened in ISO Class 5 work area.

_____ Does not expose critical sites to contact contamination or worse than ISO Class 5 air.

_____ Disinfects stoppers and injection ports by wiping with sterile 70% IPA; Performs Gloved GFT Test (no immediate application of 70% IPA to gloves before test).

_____ Affixes needles to syringes without contact contamination.

_____ Punctures vial stoppers and spikes infusion ports without contact contamination.

_____ Disinfects sterile gloves routinely by wiping with sterile 70% IPA during prolonged compounding manipulations.

_____ Understands and demonstrates proper cleaning procedures for sterile compounding environments per daily checklists and cleaning logs.

Signature of Employee Being Assessed	Printed Name	Date
Signature of Observer	Printed Name	Date

EMPLOYEE NAME:

Aseptic Manipulation Competency Evaluation

ASEPTIC COMPETENCY - MEDIA-FILL TEST

Test Observer Name: _____

Test Date: _____ Test Time: _____

☐ *Check box to confirm you collected certificate of analysis (CoA) for growth media. Keep a copy of the CoA(s) on file.*

MEDIA-FILL PRODUCT INFO

Item: 3mL Ampule Component #: T-A003
Media Type: TSB, Red Dye, Sterile Media Manufacture: Parasol Medical
Media Exp. Date:_____ Media Lot #: _____

Item: 20mL Multidose Vial Component #: T-V020
Media Type: TSB, Sterile Media Manufacture: Parasol Medical
Media Exp. Date:_____ Media Lot #: _____

Item: 100mL Mini-bag, underfilled Component #: T-B100
Media Type: TSB, Sterile Media Manufacture: Parasol Medical
Media Exp. Date:_____ Media Lot #: _____

Additional Components (optional)

Item: _____ Component #: _____
Media Type: _____ Media Manufacture: _____
Media Exp. Date:_____ Media Lot #: _____

INTERVAL 1 2023 USP <797> 30-35ºC for 7 days	INTERVAL 2 2023 USP <797> 20-25ºC for 7 additional days
Start Date: _____ End Date: _____	Start Date: _____ End Date: _____

MEDIA-FILL TEST RESULTS

Any growth / turbidity indicates a failed media-fill evaluation

Name of Person Reading the Results: _____

Growth Results: ☐ POSITIVE ☐ NEGATIVE

Media-fill Test Results: ☐ PASS ☐ FAIL

ASEPTIC COMPETENCY - POST GFT TEST

Test Date: _____ Test Time: _____

☐ *Check box to confirm you collected certificate of analysis (CoA) for growth media. Keep a copy of the CoA(s) on file.*

GFT TEST: LEFT HAND	GFT TEST: RIGHT HAND
Component No.: T-D100 Media Type: TSA with L&T, Sterile Media Manufacture: Parasol Medical Media Exp. Date: _____ Media Lot # _____	Component No.: T-D100 Media Type: TSA with L&T, Sterile Media Manufacture: Parasol Medical Media Exp. Date: _____ Media Lot # _____
INTERVAL 1 2023 USP <797> 30-35ºC for no less than 48 hr	**INTERVAL 2** 2023 USP <797> 20-25ºC for no less than 5 additional days
Start Date: _____ End Date: _____	Start Date: _____ End Date: _____

POST GFT TEST RESULTS

Report any growth greater than action levels to Pharmacy Manager

Visual Observation of Proper Garbing and Hand Hygiene ☐ PASS ☐ FAIL

Name of Person Reading the Results: _____

Growth Results: ☐ POSITIVE ☐ NEGATIVE

Colony Forming Unit Count (total of both sides): _____

Test Results *(must pass both visual and growth test)*: ☐ PASS ☐ FAIL

GFT Sampling Action Levels, per 2023 USP <797>

Gloved Fingertip and Thumb Sampling	Action Levels *(cfu, total from both hands)*
After media-fill	>3

Action levels are based on the total cfu count on both hands

ASEPTIC COMPETENCY - POST SURFACE SAMPLE TEST

Test Date: _____ Test Time: _____

☐ *Check box to confirm you collected certificate of analysis (CoA) for growth media. Keep a copy of the CoA(s) on file.*

SURFACE SAMPLE TEST PRODUCT INFO

Component No.: T-D100
Media Type: TSA with L&T, Sterile Media Manufacture: Parasol Medical

Media Exp. Date: _____ Media Lot # _____

INTERVAL 1 2023 USP <797> 30-35ºC for no less than 48 hr	INTERVAL 2 2023 USP <797> 20-25ºC for no less than 5 additional days
Start Date: _____ End Date: _____	Start Date: _____ End Date: _____

POST SURFACE SAMPLE TEST RESULTS

Report any growth greater than action levels

Name of Person Reading the Results: _____

Growth Results: ☐ POSITIVE ☐ NEGATIVE

Colony Forming Unit Count (total of both sides): _____

Surface Sample Test Results: ☐ PASS ☐ FAIL

If cfu count exceeds action levels, identify microorganism(s) to the genus level:

_____

Surface Sampling Action Levels, per 2023 USP <797>

ISO Class	Surface Sampling Action Levels (cfu/device or swab)
5	>3

Action levels are based on the total cfu count for both sides of paddle

EMPLOYEE ASEPTIC MANIPULATION COMPETENCY EVALUATION OVERVIEW

Sign-off after successful completion of all three test.

☐ PASS
☐ FAIL Pharmacist Signature: _____ Date: _____

CORRECTIVE ACTION SUMMARY / COMMENTS:

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