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Participant Name:		Date:	
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Validator Name:	Mayur Vibhakar/	State, License/Registration #:	

### Process Validation Evaluation Checklist **Aseptic Handwashing**

Procedure Evaluated	YES	NO	
Removed all jewelry and objects up to elbow (including rings)			
Did not have cuts, sunburn, nail polish or false nails	🗖		
Turned on water and adjusted temperature correctly	🗖		
Avoided unnecessary splashing during washing process	🗖		
Cleaned nails First using soap & nail pick under warm running water	🗖		
Used plenty of antibacterial soap during cleaning process	🗖		
Cleaned all four surfaces of each finger	🗖		
Cleaned all surfaces of hands, wrist and arms up to the elbow using a circular motion for at least 30 seconds	🗖		
Did not touch the sink, faucet or other objects which would contaminate the hands during the process	🗖		
Rinsed hands holding them upright and allowing water to drip down to elbow	🗖		
Rinsed all soap residue off hands and arms	🗖		
Dried hands properly and did not contaminate hands in process	🗖		
Did NOT turn off water until hands were completely dry			
Turned water off with dry, sterile, lint-free, disposable towels			
Did not touch the faucet while turning water off	🗖		
Healthcare Training Center OR  I certify on at that that Particle    Date	cipant's Name		
is 100% competent at the above task.			
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Participant Name:		Date:
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Validator Name:	Mayur Vibhakar/	State, License/Registration #:

### Process Validation Evaluation Checklist

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Procedure Evaluated	YES	NO	
Removed outer lab jacket, make-up, & jewelry before entering ante room	🗖		
Applied non-shedding shoe covers over clean shoes properly	🗖		
Non-shedding hair covered was placed over all hair	🗖		
Non-shedding beard cover applied appropriately over face if needed	🗖		
Applied non-shedding face cover or mask over face covering both nose and chin	🗖		
Washed hands properly prior to beginning process	🗖		
Made sure hands/forearms were completely dry before donning gown	🗖		
Correctly donned appropriate size non-shedding disposable, enclosed neck gown	🗖		
Gown sleeves long and fit snugly at the wrists	🗖		
Gown zipped, snapped, or tied to assure front was closed	🗖		
Prior to applying sterile gloves, antiseptic hand cleansing was performed using a			
waterless alcohol-based surgical hand scrub with persistent rubbing activity	🗖		
Made sure hands and arms were completely dry before applying gloves	🗖		
Correct size non-shedding, sterile, powder-free gloves applied in clean room			
Sterile gloves were applied over the outer cuff of the gown without contamination			
Sterile gloves were disinfected as needed with Sterile 70% isopropyl			
alcohol throughout the entire compounding procedure	🗖		
Gown and garb were applied properly and removed in correct sequence	🗖		
Healthcare Training Center OR I certify on that			
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is 100% competent at the above task.			
EVALUATOR'S SIGNATURE:Mayur Vibhakar/			

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Participant Name:		Date:
Validator Name:	Mayur Vibhakar/	State, License/Registration #:

## Process Validation Evaluation Checklist Ampule Preparation

Procedure Evaluated	YES	NO
Did not wear jewelry, false nails, makeup, etc. inside the hood		
Donned appropriate apparel as required by US 797		
Washed hands & cleaned hood correctly before beginning compounding process		
Correctly performed all required calculations before entering clean room	🗖	
Brought correct supplies, drugs, and drug concentrations into the hood	🗖	
Did not bring unnecessary supplies into clean room or hood area	🗖	
All supplies & drugs were cleaned prior to bringing them into the clean room area	🗖	
Supplies were placed in the hood using proper aseptic technique	🗖	
Ampule neck was cleared of fluid and cleaned with sterile alcohol before breaking	🗖	
Ampule neck was wrapped with gauze and broke properly	🗖	
Filter device was used to withdraw contents of ampule	🗖	
Did not spill contents of ampule when drawing up liquid	🗖	
Filter device was removed and proper needle/syringe device was used to measure		
correct amount of drug	🗖	
If needle was recapped the proper device or scooping method was used to prevent sticks	🗖	
Syringe was checked to assure correct amount of drug was drawn up (no bubbles, etc.)	🗖	
Additive port on container was cleaned with sterile alcohol before adding drug	🗖	
Did not core or puncture side of additive port when adding drug to container	🗖	
Properly mixed contents of container and inspected for incompatibilities or particulates	🗖	
Additive port was cleaned with sterile alcohol & tamperproof seal placed over port	🗖	
Glass and sharps were placed in the appropriate disposal container	🗖	
Did not utilize outer 6 inches of hood or work too close to sides/back of hood	🗖	
Did not contaminate needle, syringe, vial, ampule, or other sterile components	🗖	
Disinfected sterile gloves routinely by wiping with sterile 70% Isopropyl alcohol during compounding process	П	
Did not take hands out of hood or leave the clean room during the mixing process		
Did not contaminate the hood by coughing, sneezing, chewing gum, or excessive talking		_
Healthcare Training Center OR		
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is 100% competent at the above task.		
EVALUATOR'S SIGNATURE: Mayur Vibhakar/		

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Participant Name:		Date:	
Validator Name:	Mayur Vibhakar/	State, License/Registration #:	

### Process Validation Evaluation Checklist **Vial Preparation**

Procedure Evaluated	YES	NO
Did not wear jewelry, false nails, makeup, etc. inside the hood		
Donned appropriate apparel as required by USP 797		
Washed hands & cleaned hood correctly before beginning compounding process		
Correctly performed all required calculations prior to entering the clean room		
Brought correct supplies, drugs, and drug concentrations into the hood		
All supplies & drugs were cleaned prior to bringing them into the clean room area		
Supplies were placed in the hood using proper aseptic technique		
Removed dust cover and cleaned rubber diaphragm with sterile alcohol swab		
Attached needle to syringe without contaminating sterile components or blocking first air		
Inserted needle correctly into diaphragm to prevent coring & used proper		
milking technique to withdraw contents		
Did not remove needle from vial until all air bubbles were removed and volume verified		
Removed air bubbles correctly and did not spill any liquid or aspirate contents		
Needle was withdrawn correctly from vial to prevent spilling or aspirating		
Withdrew correct amount of diluent if reconstituting a powder vial		
Recleaned diaphragm with sterile alcohol swab prior to reinserting needle, if powder vial		
Mixed powder with liquid correctly without shaking vial contents, if reconstituting		
Checked (reconstituted) liquid for incompatibilities or particulate matter		
& correct volume before injecting		
If needle was recapped the proper device or scooping method was used		
Additive port was cleaned with sterile alcohol and was not cored or	_	_
punctured when adding drug to container		
Properly mixed the contents of container & inspected for incompatibilities/particulates		
Additive port was cleaned with sterile alcohol & tamperproof seal placed over port		
Properly affixed IV label to IV bag without blocking fluid measurements on bag		
Disinfected sterile gloves by routinely wiping with sterile 70% Isopropyl		
alcohol during mixing process		
Did not contaminate needle, syringe, vial, or other sterile components		
Did not contaminate the hood by coughing, sneezing, chewing gum, or excessive talking		
Did not utilize outer 6 inches of hood or work too close to sides/back of hood		
I certify onatthatthat		
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is 100% competent at the above task.		
EVALUATOR'S SIGNATURE: Mayur Vibhakar/		

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Participant Name:	Date:
Validator Name: Mayur Vibhakar/	State, License/Registration #:

## Process Validation Evaluation Checklist **TPN Preparation**

1es =100% compilant 140 = < 100% compilant)		
Procedure Evaluated	YES	NO
Did not wear jewelry, false nails, makeup, etc. inside the hood	🗖	
Donned appropriate apparel as required by USP 797	🗖	
Washed hands & cleaned hood properly before beginning compounding process	🗖	
Correctly performed all required calculations prior to entering clean room	🗖	
Brought correct supplies, drugs, and drug concentrations into the hood	🗖	
Did not bring unnecessary supplies into clean room or hood area	🗖	
All supplies & drugs were cleaned prior to bringing them into the clean room area	🗖	
Correct base solution and other TPN supplies brought into clean room	🗖	
Supplies were placed in the hood using proper aseptic technique, added port saver if facility policy		
Removed all dust covers and cleaned rubber diaphragms with sterile alcohol swabs	🗖	
Attached needles to syringes without contaminating sterile components or blocking first air	🗖	
Inserted needles correctly into diaphragms to prevent coring & used proper milking		
technique to withdraw contents	🗖	
Did not remove needles from vial until all air bubbles were removed and volume verified	🗖	
Removed air bubbles correctly, did not spill any liquid or aspirate contents when removing needles	🗖	
Withdrew correct amount of each electrolyte or additive	🗖	
Added electrolytes containing phosphate first to prevent precipitate formation	🗖	
Added electrolytes containing calcium after additive port was sufficiently cleared of phosphate	🗖	
Checked all liquid for incompatibilities/ particulate matter & correct volume before injecting	🗖	
Added colored minerals/vitamins and other additives last	🗖	
If needle was recapped the proper device or scooping method was used to prevent needle sticks	🗖	
Additive port was cleaned with sterile alcohol, was not cored/punctured when adding drug to container	🗖	
Properly mixed the contents of container and inspected for incompatibilities or particulates	🗖	
Additive port was cleaned with sterile alcohol & tamperproof seal placed over port	🗖	
Properly affixed IV label to IV bag without blocking fluid measurements on bag	🗖	
Disinfected sterile gloves by routinely wiping with sterile 70% Isopropyl		
alcohol during mixing process	🗖	
Did not contaminate needle, syringe, vial, or other sterile components	🗖	
Did not contaminate the hood by coughing, sneezing, chewing gum, or excessive talking	🗖	
Did not utilize outer 6 inches of hood or work too close to sides/back of hood during manipulations  Healthcare Training Center OR	🗖	
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is 100% competent at the above task.		
EVALUATOR'S SIGNATURE: Mayur Vibhakar/		

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Participant Name:		Date:
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Validator Name:	Mayur Vibhakar/	State. License/Registration #:

### Process Validation Evaluation Checklist **Horizontal Airflow Hood Cleaning**

(Please place a check in the appropriate column while observing participants performance:

Procedure Evaluated	YES	NO
Hood was turned on and let run for at least 30 minutes prior to use		
Did not wear makeup, jewelry, false nails, or lab coat, etc. inside the hood		
Donned appropriate apparel as required by USP 797		
All items were removed from the hood areas to be cleaned		
All hood surfaces were first cleaned with sterile water and non-shedding Sterile wipes		
All hood Surfaces were cleaned second with Sterile 70% Isopropyl Alcohol & non-shedding Sterile wipes		
The IV pole was first surface cleaned if applicable		
The sides of hood were cleaned second, beginning at the top and working in a horizontal outward motion from back to front of the hood with overlapping strokes		
The bottom surface of the hood was cleaned last, beginning with the back and working horizontally from side to side with overlapping strokes		
Did not clean back wall HEPA filter (must be done by certified technician)		
Did not use spray bottles inside hood		
Did not contaminate previously cleaned surfaces at any time during cleaning		
Did not block first air from HEPA filter with hands, or other objects inside hood		
Did not utilize outer 6 inches of hood opening or work too close to sides or back of hood during manipulations		
Did not contaminate hood by coughing, sneezing, chewing gum, or excessive talking		
Did not leave hood during cleaning process		
Did not dispose of trash until end of hood cleaning process		
Changed or cleaned prefilter as required by institution		
I certify on at that that	Participant's Na	me
is 100% competent at the above task.	-	
EVALUATOR'S SIGNATURE:Mayur Vibhakar/		

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Participant Name:		Date:	
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Validator Name:	Mayur Vibhakar/	State, License/Registration #:	

#### Process Validation Evaluation Checklist Vertical Airflow Hood Cleaning

(Please place a check in the appropriate column while observing participants performance: Yes = 100% compliant No = < 100% compliant)

Yes = 100% compliant No = < 100% compliant)		
Procedure Evaluated	YES	NO
Hood was turned on and let run for at least 30 minutes prior to use	🗖	
Did not wear jewelry, false nails, or lab coat, etc. inside the hood	🗖	
Donned appropriate apparel as required by USP 797	🗖	
All items were removed from the hood areas to be cleaned	🗖	
All hood surfaces were first cleaned with sterile water and non-shedding Sterile wipes	🗖	
All hood Surfaces were cleaned second with Sterile 70% Isopropyl Alcohol		
& non-shedding sterile wipes	🗖	
The back wall inside of the hood was cleaned first beginning at the top and working side to side in a		
horizontal motion until you reach the bottom with overlapping strokes	🗖	
The IV pole was cleaned second if applicable	🗖	
The side walls inside the hood were cleaned third beginning at the top and working side to side in a		
horizontal motion until you reach the bottom with overlapping strokes	🗖	
The bottom surface of the hood was cleaned fourth, beginning with the back working		
horizontally from side to side with overlapping strokes	🗖	
The inside of the glass shield was cleaned fifth beginning at the top and working side to side in a		
horizontal motion until you reach the bottom with overlapping strokes	🗖	
Lower glass shield, so the opening was not > or < 8 inches, after cleaning inside front shield		
The outside of the glass shield was cleaned last beginning at the top and working side to side in a	<b>–</b>	
horizontal motion until you reach the bottom with overlapping strokes (new materials used)	🗖	
Did not use spray bottles inside hood		
Did not contaminate previously cleaned surfaces at any time during cleaning		_
Did not clean top of hood HEPA filter (must be done by certified technician)		_
Did not leave hood during cleaning process		_
Did not block first air from HEPA filter with hands, or other objects inside hood		_
Did not utilize outer 6 inches of hood opening or work too close to sides/back/top of hood		
Did not block air-intake grills at anytime.		
Changed or cleaned prefilter as required by institution	<del>-</del>	$\overline{\Box}$
Changed of eleaned prefitter as required by institution		_
Healthcare Training Center OR		
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Participant Name:	Date:
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Validator Name: Mayur Vibhakar/	State, License/Registration #:

## Process Validation Evaluation Checklist **Sterile Solution Label Preparation**

Procedure Evaluated	YES	NO
Label followed the appropriate format as approved by state board of pharmacy		NO
Label contained name, amount, & strength of all solutions		
Label contained name, amount, & strength of all additives	🗖	
Label contained name and identification number (or room number) of patient		
Label contained rate of administration/directions for use		
Label contained device specific instructions if applicable		
Label contained proper storage information as required and auxiliary labels		
Label contained date and time for drug administration		
Label contained appropriate beyond use (exp.) date/time information		
Label contained appropriate identification of person preparing and pharmacist who checked preparation		
Label was properly affixed to IV container	🗖	
Label did not contain any error, typos, or corrections		
Performed appropriate calculations as required to prepare label information		
Information on label was transcribed correctly from physicians order		
Healthcare Training Center OR  I certify on that		
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is 100% competent at the above task.		
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Participant Name:		Date: _	
Validator Name:	State, License	/Registration #:	

## Process Validation Evaluation Checklist **Biological Safety Cabinet Cleanining**

$Yes = 100\% \ compliant \ No = < 100\% \ compliant)$		
Procedure Evaluated	YES	NO
Procedure Evaluated  Hood was turned on and let run for at least 30 minutes prior to use		
Did not wear jewelry, false nails, or lab coat, etc. inside the hood		
Donned appropriate apparel as required by USP 800		
All items were removed from the hood areas to be cleaned		
All hood surfaces were first cleaned with sterile water and non-shedding sterile wipes		
All hood surfaces were cleaned second with sterile 70% Isopropyl Alcohol & non-shedding sterile wipes		
The back wall inside of the hood was cleaned first beginning at the top and working side to side in a horizontal motion until you reach the bottom with overlapping strokes		
The IV pole was cleaned second if applicable		
The side walls inside the hood were cleaned third beginning at the top and working side to side in a horizontal motion until you reach the bottom with overlapping strokes		
The bottom surface of the hood was cleaned fourth, beginning at the back and working side to side in a horizontal motion until you reach the bottom with overlapping strokes		
The inside of the glass shield was cleaned fifth beginning at the top and working side to side in a horizontal motion until you reach the bottom with overlapping strokes		
Lower glass shield, so the opening was not $>$ or $<$ 8 inches, after cleaning inside front shield		
The outside of the glass shield was cleaned last beginning at the top and working side to side in a horizontal motion until you reach the bottom with overlapping strokes		
Did not use spray bottles inside hood		
Did not contaminate previously cleaned surfaces at any time during cleaning		
Did not clean top of hood HEPA filter (must be done by certified technician)		
Did not leave hood during cleaning process		
Did not block first air from HEPA filter with hands, or other objects inside hood		
Did not utilize outer 6 inches of hood opening or work too close to sides/back/top of hood		
Did not block air-intake grills at any time		
Changed or cleaned prefilter as required by institution	🗖	
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#### Process Validation Evaluation Checklist

### **Hazardous Drug Ampule Preparation**

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Procedure Evaluated	YES	NO
Did not wear jewelry, false nails, or long sleeves, etc. inside the biological safety cabinet (BSC)		
Donned appropriate apparel as required by USP 800 (i. e. gown, gloves, etc.)		
Washed hands, cleaned BSC, and put on appropriate gloves before beginning process		
Correctly performed all required calculations before entering negative pressure clean room		
Brought the correct supplies, drugs and concentrations into the BSC for preparations		
Primed administration set with appropriate solution if applicable		
Placed plastic-backed paper drape on BSC counter surface prior to beginning preparations and		_
performed all work on this drape		<u> </u>
Made sure glass shield was only open 8 inches and no more		
Ampule neck was cleared of fluid before breaking	🗖	
Ampule neck was cleaned correctly before breaking	🗖	
Ampule neck was wrapped correctly prior to breaking	🗖	
Ampule was broken correctly, without spilling	🗖	
Correct size of luer-lock syringe was utilized	🗖	
Filter device attached to syringe correctly	🗖	
Ampule drawn up correctly, without spilling		
Cleared all liquid from needle and hub prior to removing filter needle device		
Removed filter needle and replaced with closed system vented needle		
Air bubbles removed and excess drug injected into sterile closed vial/container		
Cleared all liquid from needle and hub prior to removing needle from closed vial/container and did not spill or aspirate contents		_
Drew up the correct amount of drug & checked measurement before injecting into IV bag		
Cleaned additive port on container prior to injecting drug		
Did not core or puncture side of additive port when adding drug to container		
Properly mixed contents of container and inspected for incompatibilities or particulate matter		
Cleaned additive port with sterile alcohol swab to remove any drug residue		
Placed appropriate hazardous drug tamperproof seal on additive port		
IV bag was placed in hazardous plastic zip-lock bag before removing from hood		
Second hazardous plastic zip-lock bag placed over first bag after removed from hood		
Appropriate hazardous drug labels placed on container & bag as required by USP 800		
Glass and sharp items placed in appropriate hazardous drug disposal containers		
Other hazardous waste placed in bags and appropriately labeled containers	🗖	
Did not bring unnecessary items into hood	🗖	
Did not utilize outer 6 inches of hood opening or work too close to air-intake grills	🗖	
Did not contaminate needle, plunger, syringe during preparation	🗖	
Did not block airflow from HEPA filter with hands, or other objects inside hood		
Did not take hands out or leave the hood during preparations		
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### Process Validation Evaluation Checklist

### **Hazardous Drug Vial Preparation**

Yes = 100% compliant No = < 100% compliant)				
Procedure Evaluated	YES	NO		
Did not wear jewelry, false nails, or lab coat, etc. inside biological safety cabinet (BSC)	. 🗆			
Donned appropriate apparel as required by USP 800 (i.e. gown, gloves, etc.)				
Washed hands, cleaned BSC and put on appropriate gloves before beginning process				
Correct supplies were brought into the biological safety cabinet				
Primed administration set with appropriate solution if applicable				
Placed plastic-backed non-shedding drape on counter surface prior to beginning compounding				
preparations and performed all work on this drape	. 🗖			
Glass shield was only open 8 inches and no more				
Removed dust cover and cleaned rubber diaphragm correctly				
Correct size of luer-lock syringe was utilized (can NOT be more than ¾ full)				
Inserted needle correctly to prevent coring				
Used proper closed system venting device, and did not aspirate at any time				
Did not remove needle from vial until all air bubbles were removed and volume verified				
Removed air bubbles correctly and did not spill any liquid		_		
Cleared all liquid from needle and hub prior to removing needle from closed vial system				
Withdrew needle correctly from vial to prevent spilling or aspirating on drape/counter/BSC		_		
Withdrew the correct amount of diluent if needed to reconstitute powder		_		
If reconstituting powder, did not remove needle while mixing contents		_		
If reconstituting powder, mixed powder with liquid correctly without shaking vial contents				
Drew up the correct amount of drug and checked measurement before withdrawing from vial				
Cleared all liquid from needle and hub prior to removing needle from closed vial system	. —	_		
and did not spill or aspirate the contents of reconstituted drug on drape/BSC/counter	П			
Did not contaminate needle, syringe, plunger, preparer during preparation				
Checked reconstituted liquid for incompatibilities or particulate matter prior to injecting				
Cleaned additive port on container prior to injecting drug		_		
Did not core or puncture side of additive port when adding drug to container				
Properly mixed contents of container and inspected for incompatibilities or particulate matter				
Cleaned additive port with sterile alcohol swab to remove drug residue				
Placed appropriate hazardous drug tamperproof seal on additive port	. 🗖			
Cleaned entire IV bag with sterile alcohol swabs to remove any drug residue				
		_		
IV container was placed in plastic zip-lock bag before removing from hood				
Appropriate hazardous drug label placed on container as required by institution				
Second hazardous plastic zip-lock bag placed over first bag after removed from hood				
Appropriate hazardous drug labels placed on container & bag as required by USP 800				
Glass and sharp items placed in appropriate hazardous drug disposal containers				
Did not contaminate needle, plunger, syringe during preparation	. 🗖			
Did not block airflow from HEPA filter with hands, or other objects inside hood				
Did not take hands out or leave the hood during preparations				
Did not bring unnecessary items into hood		ā		
Did not utilize outer 6 inches of hood opening or work too close to air-intake grills				
ALL hazardous waste placed in appropriately labeled bags and containers				
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is 100% competent at the above task.				
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## Process Validation Evaluation Checklist Sterile Ophthalmic Solution Label Preparation

Procedure Evaluated	YES	NO
Did not wear jewelry, false nails, makeup, etc. inside the hood		
Donned appropriate apparel as required by USP 797	🗖	
Washed hands & cleaned hood correctly before beginning compounding process	🗖	
Horizontal Laminar Airflow Hood was used or other form of ISO CLASS 5 environment	🗖	
All containers, closures, droppers and equipment used were sterile	🗖	
Appropriate container and closure were selected	🗖	
Appropriate preservative and buffer were selected if required	🗖	
Appropriate filter device was utilized for assuring clarity and sterility of solution	🗖	
Proper technique was followed to prevent contamination of needles, syringes,		
and any containers that might affect final product	🗖	
Filter device was utilized correctly	🗖	
Solution securely closed and sealed prior to removing from sterile environment	🗖	
Label contained appropriate beyond use (exp.) date/time information	🗖	
Appropriate labels placed on final product, including auxiliary labeling if necessary	🗖	
Appropriate procedures were utilized if sterilizing final solution in autoclave	🗖	
Did not remove hands from hood or leave hood at any time during preparation process	🗖	
Brought the correct supplies and equipment to hood	🗖	
Did not block HEPA filter or airflow in hood	🗖	
Did not work in outer six inches of hood where room air mixes, or if using vertical hood, did not open glass cover beyond 8 inches		
Product stored appropriately if not dispensed immediately	🗖	
I certify on at that that	articipant's Nan	 me
is 100% competent at the above task.	1	
EVALUATOR'S SIGNATURE:		