PHARMASOL

FILLING & PACKAGING BATCH RECORD
PROPOSED COMMERCIAL RECORD

LOT NO_____

Pharmasol Item #	**8012020**	Customer	**Aucta Pharmaceuticals, Inc.**	DCO	**20-0182**	Rev No.	**0**
Customer Part #	**N/A**	Description	**Clobetasol Propionate Foam 0.05%**	Size	**100g**	Page 1 of 26	

Initiated By / Date	Operations Approval / Date	QA Approval / Date
07/07/20	07/07/20	07/08/20

Instructions for Issuing Batch Record:
1. Record Work Order number and QTY.
2. Sign and date below indicating batch record has been properly issued. A second individual must sign and date to verify batch record was properly issued.

Work Order No._____ Batch Record Issued By:_____ Date:_____

Work Order Qty._____ Batch Record Verified By: _____ Date:_____

Signatures of Personnel NOTE: *A signature on this record indicates that you have read and understood the process entailed within this record and are trained in all functions that are performed. All personnel who write on this batch record are required to sign below.*

Name (Print)	Signature	Initials	Date

Comments:

BILL OF MATERIAL

Item	Description	Qty Per Unit
01915	Can 45 x 110mm, Aluminum, Plain White	1.00000 ea
8112010	Clobetasol Foam 0.05% Concentrate	0.10050 kg
05813	Valve S90, Aluminum Cup	1.00000 ea
43070	Propellant AP-70	0.00529 kg
13665	Actuator - Mars White Spout w/ Assembled Natural Overcap	1.00000 ea
XXXX	Wrap Label Rev.XXX	1.00000 ea
XXXX	Unit Carton Rev.XXX	1.00000 ea
XXXX	Patient Insert Rev.XXX	1.00000 ea
XXXX	Master Carton X12	0.08333 ea
N/A	Master Carton Label (printed on demand)	0.08333 ea
N/A	Pallet Label (printed on demand)	0.00000 ea

FORMS REQUIRED

1. 090-3-007 In-Process Testing

Comments:

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PROCESS SPECIFICATIONS			
Concentrate fill (gm):	100.5 ± 0.5 g	Heat Tank Temp (°F):	NLT 130°F
Propellant fill [AP-70] (gm):	5.29 ± 0.2 g	Vacuum:	NLT 15 inHg
Pressure @ 25°C:	Record Results	Crimp Depth (in.):	0.190" – 0.200"
Extrusion:	NLT 100g	Crimp Radial (in.):	1.065" – 1.075"
Heat Tank Dwell:	NLT 60 Seconds		

LOT NUMBER SPECIFICATIONS			
Character	**Format**	**Designation**	**Lot Number Example**
1st Line (Batch Number)	XXXXX	Pharmasol 5 Digit Batch Number	99999 EXP 01/2022
2nd Line (Expiration Date)	EXP MM/YYYY	2 Years from Date of Compound Manufacture	

MAJOR / CRITICAL EQUIPMENT LIST			
EQUIPMENT	**RECORD ASSET #**	**CALIBRATION DUE DATE**	**FUNCTION**
Inkjet Coder			Prints lot number on the bottom of can.
Filling Station (Filamatic filler with FUS 130 pistons)			Fill concentrate
Crimping Station			Crimp valve to unit
Gassing Station			Charge propellant
Heat Tank			Units submerged in hot water and blown dry
Thermometer			Monitor water temperature
TQS-LM / TQS-SP			Handling serialization of single unit cartons
TQS-CP / TQS-MP			Handling serialization of cases and pallets

Comments:

Startup			**Performed Initial / Date**	**Verified Initial / Date**
	LINE CLEARANCE CHECK LIST			
	Time Performed:_____ am / pm Date: _ _ / _ _ /_ _ Prior Work Order #: _____ Prior Lot#: _____ Line# _____		(Line Supervisor)	
1.	Filling station is cleared and clean.	☐ Complete		
	Gassing station is cleared and clean.	☐ Complete		
	Waterbath is cleared and clean.	☐ Complete		
	All prior product has been cleared from the line.	☐ Complete		
	All components not applicable to this lot are removed from the line.	☐ Complete		
	Entire line, and work area has been cleaned for start-up.	☐ Complete		
	Cleaning verification of previous product is acceptable	☐ Complete		
	Verify all equipment and the filling line is clean, and the Production Line Usage Logbook is completed.	☐ Complete	(Line Supervisor)	
2.	Verify that all measuring equipment, scales, etc. has current calibration stickers and is functioning properly.		(Line Supervisor)	

Comments:

Startup						Performed Initial / Date	Verified Initial / Date
3.	CONCENTRATE VERIFICATION ATF (Approval To Fill) is not Necessary to start filling						
	Tank#	Batch#	Date Batched	Approx. Time	Performed Initials / Date	Verified Initials / Date	Verified Initials / Date
					(Line Supervisor)	(Engineering)	(Technician)
					(Line Supervisor)	(Engineering)	(Technician)
	PROPELLANT VERIFICATION						
	Propellant Item#	Propellant Type	Flag Color	Propellant Lot#	Performed Initials / Date	Verified Initials / Date	Verified Initials / Date
					(Line Supervisor)	(Engineering)	(Technician)
					(Line Supervisor)	(Engineering)	(Technician)
4.	Maintain the batch temperature at 45 ± 5°C throughout the filling process. Ensure concentrate is mixing (20 ± 5 RPM) throughout the filling process. Use **Attachment 1** to record results throughout the filling process.						
5.	Set up the filler. • Set up the Filamatic Filling Unit with FUS-130 pistons. • Connect the tank to the piston's inlet via disposable **Teflon** tubing • Attach tubing to the piston's outlet and connect to the filling nozzle. • Record Line Speed _____					(Engineering)	
6.	Set up the crimper & gasser.					(Engineering)	

Comments:

Startup		**Performed Initial / Date**	**Verified Initial / Date**
7.	Prior to startup of the production line ensure the following forms are completed, signed by the appropriate individuals, and attached to the record: LABEL / PACKAGING USAGE & VERIFICATION SCALES & CRIMP GAUGES VERIFICATION OVERALL WEIGHT LIMITS FORM	(Line Supervisor)	
8.	Verify all components and materials are correct per Bill of Material, and BOM is fully complete.	(Line Supervisor)	
9.	Verify that the lot number on the bottom of the can is legible and attach a photocopy to the record. Record lot number _____	(Line Supervisor)	
10.	Record START date and time of production run. Start Time_____am / pm Date_____	(Line Supervisor)	
11.	Record STOP date and time of production run. Stop Time_____am / pm Date_____	(Line Supervisor)	
12.	At the completion of the production run, prior to the submitting the record to QA ensure the following forms are completed, signed by the appropriate individuals, and attached to the record: 090-3-007 In-Process Testing CONTROL CHARTS & WARNING LIMITS VARIABLES INSPECTION FORM ATTRIBUTES INSPECTION FORM	(Line Supervisor)	

Comments:

FILLING INSTRUCTIONS

1. Place the cans inside the pucks on the conveyor.
2. Apply lot number to bottom of can. Lot number must be clear and legible.
3. Charge concentrate. Notify mechanic immediately of any problems related to filling (low, high, overflow, spillage, etc.)
4. Verify vacuum is on. Place valve onto cans. Use caution, so there is no damage, or bending to the Valve Stem. Crimp the Valve to can under vacuum. Notify mechanic immediately of any problems related to crimping.
5. Charge propellant. Notify mechanic immediately of any obvious problems (i.e. spillage).
6. Weigh 100% of the units and discard all units that fall outside of the gross weight limits.
7. Inspect the can / valve for leaks while units are submerged in the heat tank. The formation of a constant stream of bubbles coming from the crimped area of the container or around the stem of the valve should be considered a leaking unit. Identify and segregate any rejected units. Notify the mechanic immediately of any rejects.
8. Apply actuator to the unit.
9. Monitor and record product variables and product attributes on the appropriate section of the record.
10. Monitor and record weights on the appropriate section of the record.
11. Monitor and record in-process testing on form 090-3-007.

Comments:

PACKAGING INSTRUCTIONS

1. Apply 2D Serialized datamatrix barcode to the bottom flap of the unit carton on the unvarnished area.
   1.1. If the code is distorted or unreadable, remove the contents of the unit carton and place them into a new unit carton.
2. Each item level serialization system includes a GS1 2D data matrix with the following Application Identifiers (AI) in the following order:

   (01) GTIN (XXXXXXXXXXXXXX) - Static Field)
   - (21) Serial Number (Dynamic Field)
   - (17) Expiration date (Format: MMM YYYY)
   - (10) Lot Number (Format: XXXXX)

   Figure 1 (2D Datamatrix Example)

   Enter Example Here

3. Assemble master cartons right side-up and place 12 unit cartons into the master carton.

Comments:

4. Aggregate the 12 units present in the master carton and a master carton label will be printed.
   4.1. The printed label is a 3" x 5" and the Case Level serialization includes a GS1 2D data matrix and two linear barcodes with the following Application Identifiers (AI) in the following order: **(See Figure 2)**

   GS1 2D data matrix:
   - (01) GTIN (Encoded)
   - (21) Serial Number (Encoded)
   - (17) Expiration date (Encoded)
   - (10) Lot Number (Encoded)

   Figure 2 (Case Label Example)

   Enter Example Here

   Linear Barcode 1:
   - (17) Expiration date (Encoded and Human Readable)
     - Format (YYMMDD) confirm the day is the last day of the month
   - (10) Lot Number (Encoded and Human Readable)
   - (30) Quantity (Encoded and Human Readable)

   Linear Barcode 2:
   - (01) GTIN (Encoded and Human Readable)
     - (XXXXXXXXXXXXXX - Static Field)
   - (21) Serial Number (Encoded and Human Readable)
5. Apply case label to the long panel on bottom left corner of the case.
6. With the handheld computer, scan each case 2D datamatrix to aggregate the cases. A 4 x 6" pallet label will be printed. ***(See Figure 3)***
7. The Pallet Level serialization system will print and encode a linear barcode with the following Application Identifier (AI) in the following order:

   Linear Barcode 1:
   - (00) 5 Series SSCC18 Number (Encoded and Human Readable)
     - 20807105 is static and all following digits are the unique identifiers.

   Figure 3 (Pallet Label Example)

   Enter Example Here

Comments:

8. Place cases on pallet per pallet configuration below.
   8.1. Pallet Configuration, XX Cases per Layer, X Layers, Total of XX Cases. **(See Figure 4)**
   8.2. Pallets must be heat treated.
   8.3. Place corner posts on all four corners of the pallet.

Figure 4 (Pallet Configuration)

Enter Example Here

Comments:

Refer to 070-3-002 Label / Packaging Usage & Verification for detailed instructions.

LABEL / PACKAGING USAGE & VERIFICATION

Place one sample below for each printed material (i.e. wrap label, patient insert, unit carton, shipper label, pallet label).

Comments:

DOWNTIME RECORD

Record downtime for minor event such as breaks, and shift changes occurring during the run. Refer to SOP 070-2-012 for additional details.

TIME OF OCCURRENCE	EXPLANATION (with initials and date at end of each entry)	TIME LINE RESTARTED

Reviewed by: _____ Date: _____

Comments:

ADJUSTMENT RECORD

Downtime: Record why line is down, what was done to correct the stoppage.
Adjustment: Record a detailed description of the adjustment, including why it was needed.
OOS: If an OOS is found, confirm that the results are documented, and the product is quarantined to the last good check.
Other: Describe in space provided.
Refer to 070-2-012, Downtime and Adjustment Procedure for additional details.

DATE & TIME OF OCCURRENCE	Date: _____ Time: _____ Initials:_____
DESCRIPTION OF EVENT (Initial and date at end of each entry. Mechanics must initial and date for mechanical adjustments)	Mark the all that apply: ☐ Downtime ☐ Adjustment ☐ OOS Found ☐ Other (Explain Below) Description: _____ _____ _____ Mark Action Taken: ☐ N/A ☐ *Quarantined Product (NCMR#) _____ ☐ Other (Explain):_____
DATE & TIME LINE RESTARTED	Date: _____ Time: _____ Initials:_____
DATE & TIME OF OCCURRENCE	Date: _____ Time: _____ Initials:_____
DESCRIPTION OF EVENT (Initial and date at end of each entry. Mechanics must initial and date for mechanical adjustments)	Mark the all that apply: ☐ Downtime ☐ Adjustment ☐ OOS Found ☐ Other (Explain Below) Description: _____ _____ _____ Mark Action Taken: ☐ N/A ☐ *Quarantined Product (NCMR#) _____ ☐ Other (Explain):_____
DATE & TIME LINE RESTARTED	Date: _____ Time: _____ Initials:_____

*If product is quarentined, clear the line back to the last acceptable inspection and obtain NCMR#.

Reviewed by: _____ Date:_____

Comments:

Refer to SOP 090-3-009 Verification of Scales / Crimp Gauges & Other Major Equipment for detailed instructions.

SCALES & CRIMP GAUGES VERIFICATION FORM

Scale ID #	Cal Due Date	Weight ID#	Specification	Reading	Deviation

Gauge#	Block ID #	Cal Due Date	Specification	Reading	Deviation
Radial:					
Depth:					
Radial:					
Depth:					

Performed by: _____ Date: _____

Comments:

Refer to SOP 090-3-004 Overall Weight Limits for detailed instructions.

OVERALL WEIGHT LIMITS FORM

Component	**Lot#**	**LOW**	**AVERAGE**	**HIGH**
Can (g):				
Concentrate (g):		100.0g	100.5g	101.0g
Valve (g):				
Propellant (g):		5.09g	5.29g	5.49g
Other (g):				
(A) (Sum of columns above) Total:		_____(g) **Lowest Limit**	_____(g) **Average**	_____(g) **Highest Limit**

Performed By: _____ **Date:** _____

Verified By: _____ **Date:** _____

Comments:

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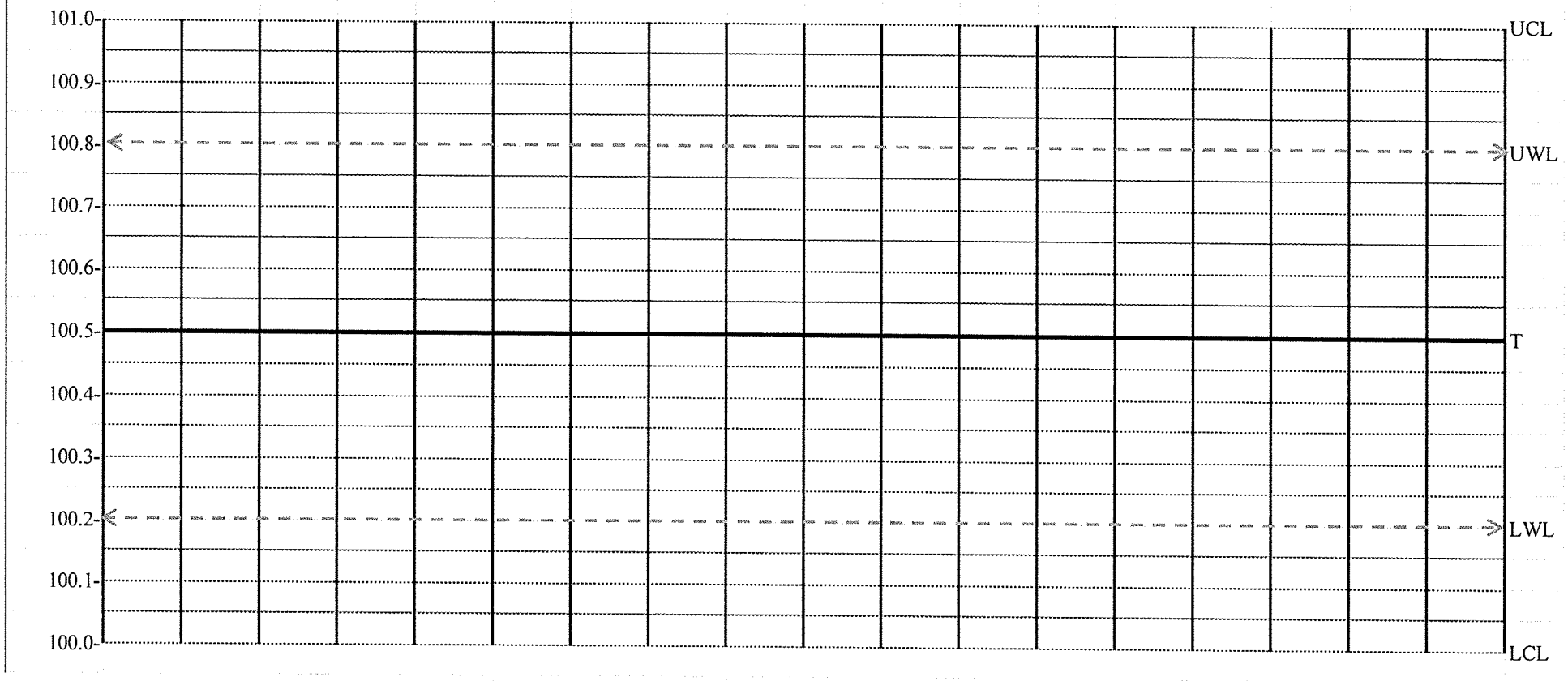
Customer Part #	**N/A**	Description	**Clobetasol Propionate Foam 0.05%**	Size	**100g**	Page 16 of 26	

Concentrate Filler Chart - Refer to SOP 090-2-009 Control Charts & Warning Limits for detailed instructions. **Filler #** _____ **Date:**

Time:																		
Intials:																		
Final/Wt																		
Tare/Wt																		
Net/Wt																		



Reviwed By / Date:_____

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Comments:

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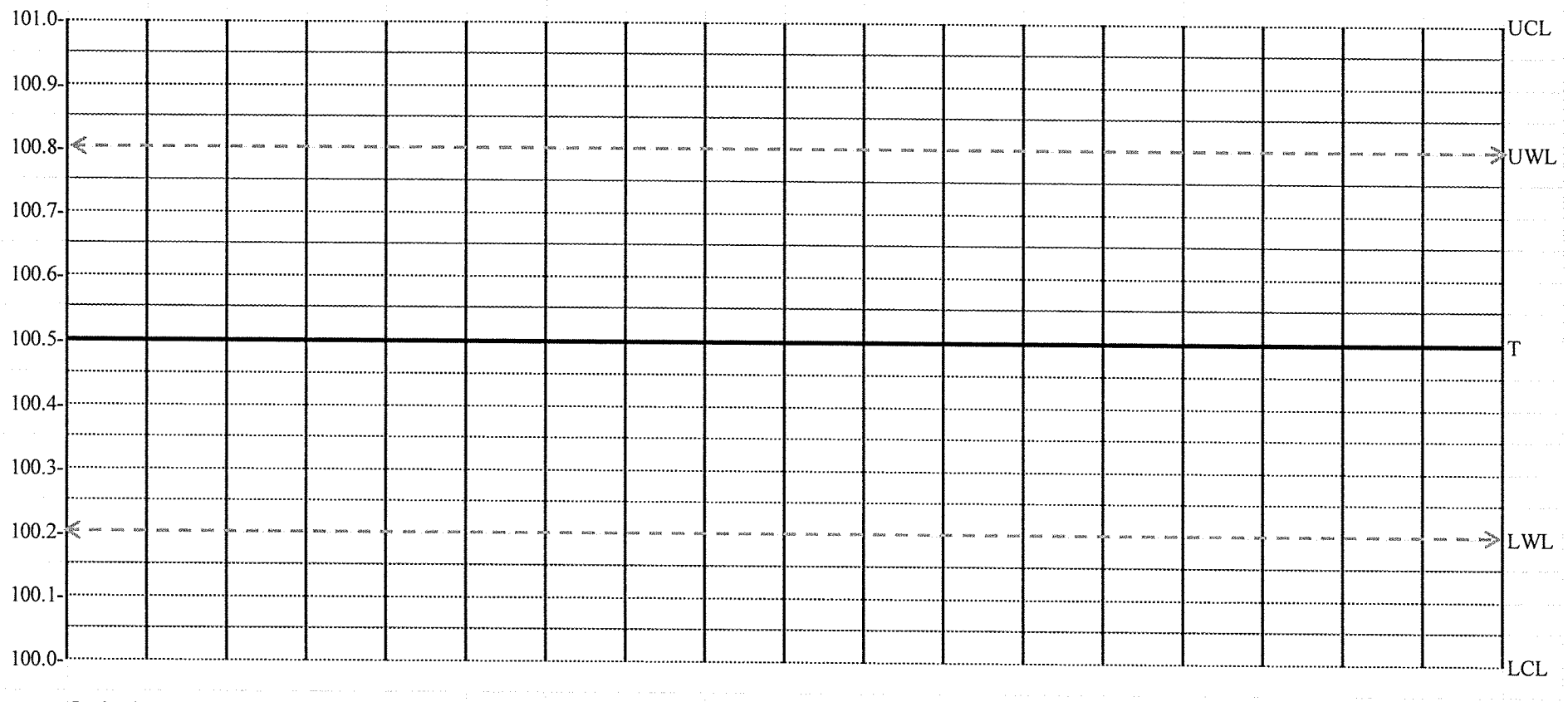
Concentrate Filler Chart - Refer to SOP 090-2-009 Control Charts & Warning Limits for detailed instructions. **Filler #** _____ **Date:**

Time:																			
Intials:																			
Final/Wt																			
Tare/Wt																			
Net/Wt																			



Reviwed By / Date:_____

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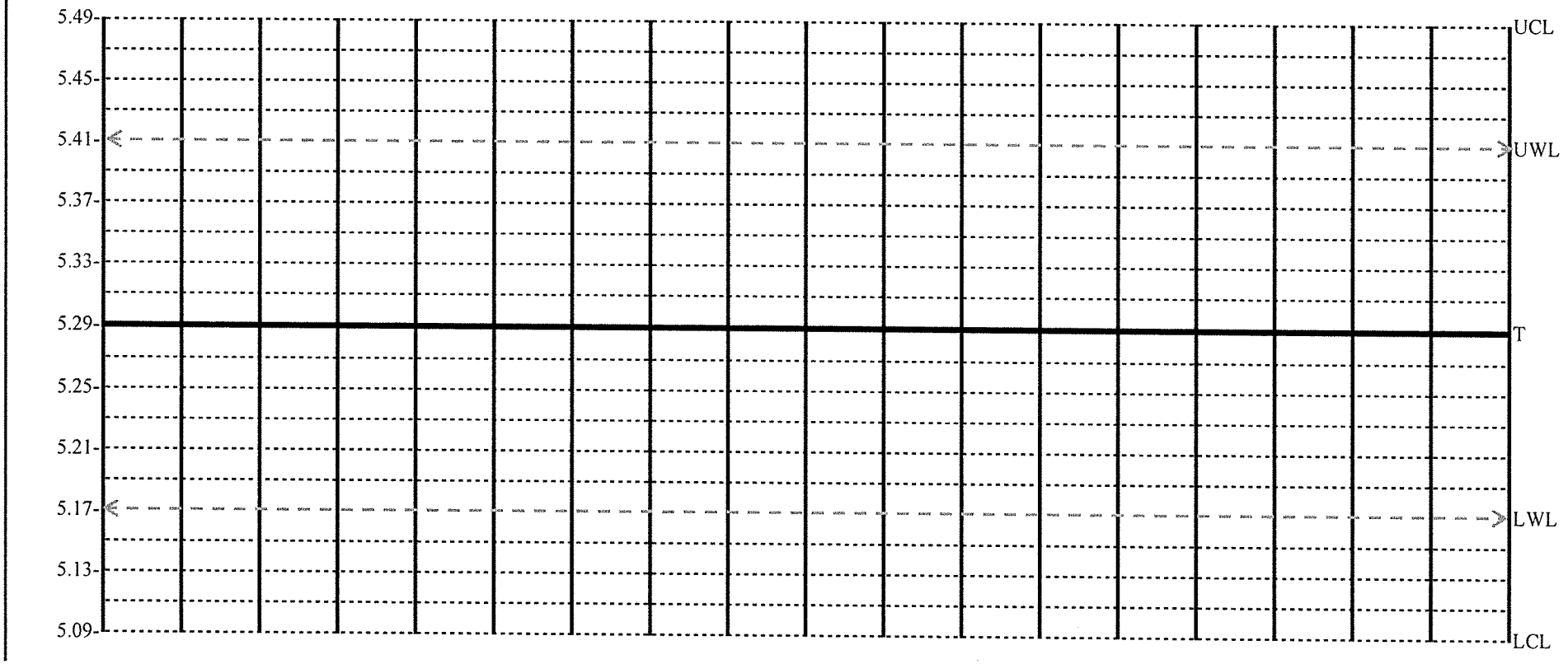
Gasser Chart - Refer to SOP 090-2-009 Control Charts & Warning Limits for detailed instructions. **Gasser#** _____ **Date:**

Time:																		
Intials:																		
Final/Wt																		
Tare/Wt																		
Net/Wt																		



Reviwed By / Date:_____

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Comments:

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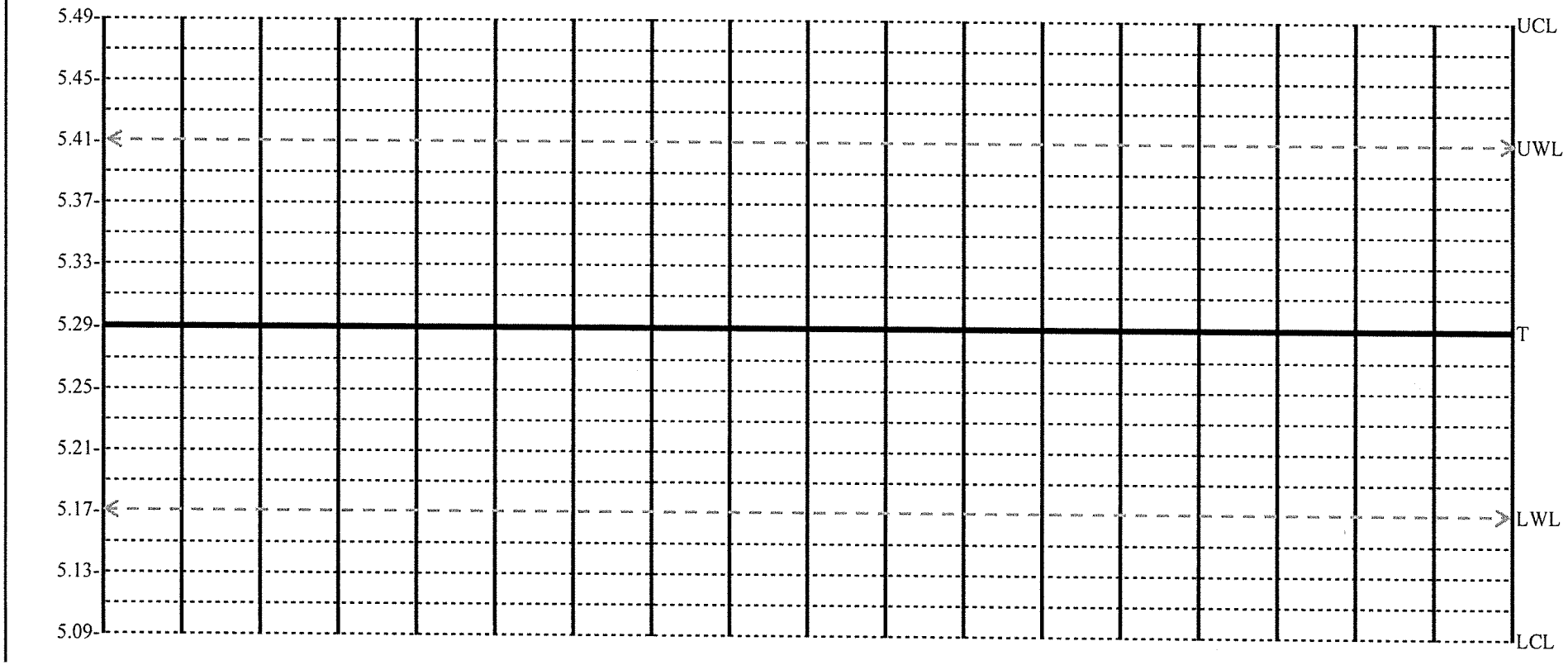
Gasser Chart - Refer to SOP 090-2-009 Control Charts & Warning Limits for detailed instructions. Gasser#_____ Date:

Time:																		
Intials:																		
Final/Wt																		
Tare/Wt																		
Net/Wt																		



Reviwed By / Date:_____

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Customer Part #	**N/A**	Description	**Clobetasol Propionate Foam 0.05%**	Size	**100g**		

Refer to SOP 090-3-011 Variables/Attributes Inspection for detailed instructions.

VARIABLES INSPECTION FORM

Time:										
Performed By Initials:										
Variables Inspections (4 pcs / Hourly)										
Crimp Depth (in.): 0.190" – 0.200"										
Crimp Diameter (in.): 1.065" – 1.075"										
Vacuum: NLT 15 inHg										
Heat Tank Dwell: NLT 60 Seconds										
Heat Tank Temp (°F): NLT 130°F										
Air Blower Operational A ✓ represents no defects found										

Reviewed by: _____ Date: _____

Comments:

Refer to SOP 090-3-011 Variables/Attributes Inspection for detailed instructions.

ATTRIBUTES INSPECTION FORM

Time:											
Performed By Initials:											
	A/R	**Exterior Attributes Inspections** (Final Pack 1 cases / Hourly)									
Wrong Drug Name or Lot Number (Case Label)	0/1										
GTIN, Lot, & EXP Date (Case Label) (Present, Correct, & Legible)	0/1										
Incorrect Number of Unit Packaged	0/1										
Correct Pallet Pattern (Record Pallet#) A ✓ represents no defects found.											
	A/R	**Unit Package Inspections** (Final Pack 8 pcs / Hourly)									
GTIN, Lot, & EXP Date (Unit Carton) (Present, Correct, & Legible)	0/1										
Lot Number (Unit) (Present, Correct, & Legible)	0/1										
Label Rev. XXXX (Present & Correct)	0/1										
Insert Rev. XXXX (Present & Correct)	0/1										
Unit Carton Rev. XXXX (Present & Correct)	0/1										

Reviewed by: _____ Date: _____

Comments:

SAMPLING PLAN

Reason	Beginning		Middle		End		Sub-Total
Pharmasol Retain Samples: 81 Samples Total. 27 Beginning, 27 Middle, & 27 End.	Case# / Time	(Qty) / Initials/Date	Case# / Time	(Qty) / Initials/Date	Case# / Time	(Qty) / Initials/Date	
QC Analytical Samples: 40 Samples Total. 13 Beginning, 13 Middle, & 14 End.	Case# / Time	(Qty) / Initials/Date	Case# / Time	(Qty) / Initials/Date	Case# / Time	(Qty) / Initials/Date	
Stability Samples: Refer to current stability protocol	Case# / Time	(Qty) / Initials/Date	Case# / Time	(Qty) / Initials/Date	Case# / Time	(Qty) / Initials/Date	
Other: (Otherwise N/A)	Case# / Time	(Qty) / Initials/Date	Case# / Time	(Qty) / Initials/Date	Case# / Time	(Qty) / Initials/Date	
In-Process Samples: (Destructive Test Samples)	N/A		N/A		N/A		
						Total:	

1. Pull samples as described above.
2. Enter the quantity pulled for each segment at the time of occurrence and record that time with initials and date in the boxes provided.
3. Enter the case # present on the line when samples are pulled (where applicable).
4. Label each unit to identify when and from what point in the production run the samples were taken.
5. Fill in blank section(s) for extra samples pulled. Include description/explanation.
6. Submission samples will be forwarded to the respective departments in accordance with SOP 100-3-152.

Comments:

COMPONENT RECONCILIATION

Record N/A for any item that is not applicable and explain in comments.

	Item Number	01737	05813	13665				
	Lot Numbers							
	Description	Can	Valve	Actuator	Wrap Label	Unit Carton	Patient Insert	Master Carton
A	Quantity Issued							
B	Quantity Produced							
C	Scrap / Waste							
D	Samples							
E	Total Used (B + C +D)							
F	Theoretical Balance (A - E)							
G	Actual Returned (Physical Count)							
H	Variance (F – G)							
I	% Variance (H ÷ A) x 100							
* Tolerance		3%	3%	3%	3%	3%	3%	3%

Reconciliation Performed By (Prod)	Date:
Reconciliation Verified By (QA)	Date:

* Any Variances that exceed specified tolerance must be explained below.

Comments:

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Customer Part #	**N/A**	Description	**Clobetasol Propionate Foam 0.05%**	Size **100g**	Page 24 of 26

CONCENTRATE RECONCILIATION

Target Concentrate Fill Weight.	100.5 g	÷ 1000	0.1005 kg

A.	Quantity of Concentrate Issued		_____ kg	
B.	Quantity Produced	(Number of units = _____ x Target Fill Wt. per unit)	_____ kg	
C.	Samples	(Number of units = _____ x Target Fill Wt. per unit)	_____ kg	
D.	Rejected Units	(Number of units = _____ x Target Fill Wt. per unit)	_____ kg	
E.	Process Scrap / Waste Concentrate		_____ kg	
F.	Tailings		_____ kg	
G.	Total Quantity Used	(B + C + D + E+ F)	_____ kg	
H.	Quantity of Concentrate Remaining		_____ kg	Disposition: _____
I.	Quantity of Concentrate Accounted For (G + H)		_____ kg	
J.	% Product **Concentrate** Yield (I / A) x 100 If % yield exceeds requirement, explain below.		_____ %	Requirement is 95% - 105%

Reconciliation Performed By: _____ (Production) Date _____ Verified By _____ (QA) Date _____

Comments:

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Customer Part #	N/A	Description	Clobetasol Propionate Foam 0.05%	Size	100g	Page 25 of 26	

ATTACHMENT 1 – TEMPERATURE / MIXING SPEED MONITORING FORM

Maintain the batch temperature at 45 ± 5°C throughout the filling process. Ensure concentrate is mixing (20 ± 5 RPM) throughout the filling process.

Record approximately every 15 minutes.

Start Date: ______________ Filling Start Time: __________am/pm Filling Stop Time: __________am/pm

Mixer Speed	Temperature	Time	Mixer Speed	Temperature	Time	Mixer Speed	Temperature	Time
_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM
_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM
_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM
_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM
_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM
_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM
_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM
_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM
_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM
_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM
_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM
_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM	_______ RPM	_______ °C	_______ AM / PM

Performed By: ____________________ Date: ______________ Reviewed by: ____________________ Date: ______________

Comments:

DEVIATIONS

Record all deviations, QIRs and other abnormalities that occur during the process below.

Page Number	Deviation, QIR Number or Observation and Description	Initials & Date	Initials & Date

Final Batch Record Review:

Production Review by: _____ Date: _____

QA Review by: _____ Date: _____

Comments: