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PHARMASOL

COMPOUNDING BATCH RECORD
PROPOSED COMMERCIAL RECORD

Batch No.: _____
Batch Size: **500 kg**

Pharmasol Item #	**8112010-250J**	Customer	**Aucta Pharma**	DCO	**20-0059**	Rev No.	**0**
Customer Part #	**N/A**	Description	**Clobetasol Propionate Foam, 0.05% – Bulk Liquid**			Page 1 of 19	

Initiated By / Date	Compounding Approval / Date	QA Approval / Date
Christine Eaton 07/14/20	07/14/20	07/15/20

Instructions for Issuing Batch Record:
1. Record WO # below per production schedule.
2. Sign and date below indicating Batch Record have been properly issued. A second signature is required to verify batch record is properly issued.

Process Validation Included (Yes / No):_____ if yes, write the PVP number: _____ MFG Date:_____

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

Cleaning: **Alcohol Based** Batch Record Verified By:_____ Date:_____

Extra Pages Issued:

Pages	Date	QA Initials / Date of Issuer	Initials / Date of Receiver

Comments

Signatures of Personnel NOTE: *All personnel who write on this batch record are required to sign below.*

Name (Print)	Signature	Initials	Date

Comments

Equipment List

Identify asset #'s and PM/calibration due dates. If additional spots are needed, record in the comments section.

Equipment	Asset / PM & Cal Due Date	Description	Performed By (Initials & Date)	Witnessed By (Initials & Date)
Main Mixing Vessel. (Tank 250J)	ID: _____ PM Due Date:_____	Manufacture of product		
Tank 250J Load Cells	ID: _____ Cal Due Date:_____	Weighing ingredients		
Secondary Mixing Vessel. (80J)	ID: _____ PM Due Date:_____	Manufacture of product		
Tank 80J Load Cells	ID: _____ Cal Due Date:_____	Weighing ingredients		
Balance/Scales	ID: _____ Cal Due Date:_____ ID: _____ Cal Due Date:_____ ID: _____ Cal Due Date:_____	Weighing ingredients		
Analytical Balance, accurate to 3 decimal places	ID: _____ Cal Due Date:_____	Weighing of API		
Nitrogen	ID: _____ Cal Due Date:_____	Blanket Tank 250J prior to filling procedure		
Tachometer	ID: _____ Cal Due Date:_____	Measure mixer speed (RPM)		
Thermometer	ID: _____ Cal Due Date:_____	Measure temperature (°C)		

Comments

Item #	PHASE	W/O Qty. (kg)	500.00	PRE-WEIGH WORKSHEET - MUST BE PERFORMED IN HEPA BOOTH								
		Item Code / Part Number	Description	Formula (%)	Qty. Req'd (a)		Scale ID	Gross Weight	Tare Weight	Net Weight	Issued By (Initials & Date)	Witnessed By (Initials & Date)
1	A	42073	Dehydrated Alcohol, USP	58.05	290.25	kg		kg	kg	kg		
								kg	kg	kg		
								kg	kg	kg		
2		45523	Polysorbate 60	0.41	2.05	kg		kg	kg	kg		
3		42073	Dehydrated Alcohol, USP (d)	1.33	6.65	kg		kg	kg	kg		
4		45357P	Cetyl Alcohol, NF	1.14	5.70	kg		kg	kg	kg		
5		45522	Stearyl Alcohol, NF	0.51	2.55	kg		kg	kg	kg		
6		45356P	Propylene Glycol, USP	2.09	10.45	kg		kg	kg	kg		
7		**45561**	**Clobetasol Propionate, USP (b)**	**0.05**	**250.00**	**g**		**g**	**g**	**g**		
8		42073	Dehydrated Alcohol, USP (d)	1.33	6.65	kg		kg	kg	kg		
9	B	44205	Purified Water, USP	34.88	174.40	kg		kg	kg	kg		
10		44797	Citric Acid Anhydrous Powder, USP	0.08	0.40	kg		kg	kg	kg		
11		45560	Potassium Citrate Monohydrate Granular, USP	0.13	0.65	kg		kg	kg	kg		
			Total	**100.00**	**500.00**	kg						
12		42073	Dehydrated Alcohol, USP (c)	-	15.00	kg		kg	kg	kg		

(a) Algorithm rounds Qty. to 2 places after decimal.
(b) Pre-weigh the Clobetasol Propionate, USP into a stainless steel beaker after completion of all excipients weighing.
(c) Use only if required for compensation of alcohol due to evaporation in step # 14. Quantity greater than 15 kg may be used if required.
(d) For rinsing containers post addition of materials.

Comments

Item #	PHASE	W/O Qty. (kg)	500.00	BILL OF MATERIAL								
		Item Code / Part Number	Description	Formula (%)	Qty. Req'd (a)		Qty. Issued	Lot Number	Drum Number	COA Exp. Date	PHMS Exp. Date	Issued By (Initials & Date)	Witnessed By (Initials & Date)
1	A	42073	Dehydrated Alcohol, USP	58.05	290.25	kg	kg						
2		45523	Polysorbate 60	0.41	2.05	kg	kg						
3		42073	Dehydrated Alcohol, USP (d)	1.33	6.65	kg	kg						
4		45357P	Cetyl Alcohol, NF	1.14	5.70	kg	kg						
5		45522	Stearyl Alcohol, NF	0.51	2.55	kg	kg						
6		45356P	Propylene Glycol, USP	2.09	10.45	kg	kg						
7		**45561**	**Clobetasol Propionate, USP (b)**	**0.05**	**250.00**	**g**	**g**						
8		42073	Dehydrated Alcohol, USP (d)	1.33	6.65	kg	kg						
9	B	44205	Purified Water, USP	34.88	174.40	kg	kg						
10		44797	Citric Acid Anhydrous Powder, USP	0.08	0.40	kg	kg						
11		45560	Potassium Citrate Monohydrate Granular, USP	0.13	0.65	kg	kg						
			Total	**100.00**	**500.00**	kg							
12		42073	Dehydrated Alcohol, USP (c)	-	15.00	kg	kg						

(a) Algorithm rounds Qty. to 2 places after decimal.
(b) Pre-weigh the Clobetasol Propionate, USP into a stainless steel beaker after completion of all excipients weighing.
(c) Use only if required for compensation of alcohol due to evaporation in step # 14. Quantity greater than 15 kg may be used if required.
(d) For rinsing containers post addition of materials.

Comments

Clobetasol Propionate, USP Quantity Calculation:

Note: Use 100.0% as assay value in the below calculation if reported assay is 100.0% or more than 100.0%

Note: If two lots are required, N/A Part A and proceed to Part B

Part A:
Current 1st Lot of Clobetasol Propionate, USP: _____ Assay on dried basis (%): _____

Total Amount of Clobetasol Propionate, USP of 1st lot to be dispensed:

$$\left(\frac{Amount\ (g) Required\ from\ page\ 5\ [Item\#45561] \times 100}{\%Assay\ on\ dry\ basis}\right) = \_\_\_\_\_ \text{ g (Qty 1)}$$

Part B: Total Quantity added to Batch
Current 1st Lot of Clobetasol Propionate, USP: _____ Assay on dried basis (%): _____
Current 2nd Lot of Clobetasol Propionate, USP: _____ Assay on dried basis (%): _____

Amount of first lot weighed: _____ g (Qty 1)

$$\left(\frac{Amount\ of\ first\ lot\ weighed\ (Qty\ 1) \times Assay of\ 1st\ lot}{100}\right) = \_\_\_\_\_ \text{ g (Qty 2)}$$

2nd lot theoretical amount:
Amount (g) required from page 5 [Item #45561] – Qty 2 = _____ g (Qty 3)

Total Amount of Clobetasol Propionate, USP of 2nd lot to be dispensed:

$$\left(\frac{(Qty\ 3) \times 100}{Assay\ of\ 2nd\ lot}\right) = \_\_\_\_\_ \text{ g (Qty 4)}$$

Checked By / Date: _____ Verified By / Date: _____

Comments

RAW MATERIAL DATA SHEET

	ITEM #	Tare Weight (kg)	Net Weight (kg)	Container Number	Lot Number	COA Expiration Date	PHMS Expiration Date	Issued By (Initial & Date)	Witnessed By (Initial & Date)
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									

- Zero the scale and place empty weighing container. Record weight from scale readout.
- Zero the scale again, and charge the quantity required from the compounding record.
- Record total issuances on Bill of Material table of batch record

Comments

RAW MATERIAL DATA SHEET

	ITEM #	Tare Weight (kg)	Net Weight (kg)	Container Number	Lot Number	COA Expiration Date	PHMS Expiration Date	Issued By (Initial & Date)	Witnessed By (Initial & Date)
11									
12									
13									
14									
15									
16									
17									
18									
19									
20									

- Zero the scale and place empty weighing container. Record weight from scale readout.
- Zero the scale again, and charge the quantity required from the compounding record.
- Record total issuances on Bill of Material table of batch record

Comments

Step #	Step Description		Performed By (Initials & Date)	Witnessed By (Initials & Date)
N/A	Verify all equipment, utensils; tanks, pumps and tubing have been thoroughly cleaned according to SOP 030-2-019 Rev # _____			
N/A	Record expiration date of all chemicals in the BOM.			
N/A	Note: **Do NOT proceed** beyond this step until calibration of all equipment to be used has been recorded and confirmed to be within calibration interval.			
Alcohol Phase – Main Mixing Vessel (Tank 250J)				
1.	Record Compounding start Date & Time. Ensure the tank is **completely empty** zero load cells on 250J and record tare weight.	Start Date: _____ Start Time: _____ AM/PM Tank ID: _____ Tank tare weight: _____ kg		
2.	Into **Tank 250J**, add **290.25 kg** of **Dehydrated Alcohol**, USP (Item # 1, Item Code: **42073**). Begin center propeller mixing at **90 ± 5 rpm**. Begin side scraper mixing at **20 ± 10 rpm**	Amount Added: _____ kg Time of Addition: _____ AM/PM Mixing Start Time: _____ AM/PM Record Center Mixing Speed: _____ RPM Record Side Scraper Speed: _____ RPM		

Comments

Step #	Step Description		Performed By (Initials & Date)	Witnessed By (Initials & Date)
3.	Add **2.05 kg** of **Polysorbate 60, NF** (Item #2, Item Code: **45523**) and continue center mixing at **90 ± 5 rpm**, and side scraper mixing at **20 ± 10 rpm** Rinse the container with **6.65 kg** of **Dehydrated Alcohol, USP** (Item # 3, Item Code: **42073**)	Amount Added: _____ kg Time of Addition: _____ AM/PM Record Center Mixing Speed: _____ RPM Record Side Scraper Speed: _____ RPM Amount of Alcohol used to rinse: _____ kg		
4.	Add **5.7 kg** of **Cetyl Alcohol, NF** (Item # 4, Item Code: **45357P**) and continue center mixing at **90 ± 5 rpm,** and side scraper mixing at **20 ± 10 rpm**.	Amount Added: _____ kg Time of Addition: _____ AM/PM Record Center Mixing Speed: _____ RPM Record Side Scraper Speed: _____ RPM		
5.	Add **2.55 kg** of **Stearyl Alcohol, NF** (Item # 5, Item Code: **45522**) and continue center mixing at **90 ± 5 rpm,** and side scraper mixing at **20 ± 10 rpm**.	Amount Added: _____ kg Time of Addition: _____ AM/PM Record Center Mixing Speed: _____ RPM Record Side Scraper Speed: _____ RPM		
6.	Add **10.45 kg** of **Propylene Glycol, USP** (Item # 6, Item Code: **45356P**) and continue center mixing at **90 ± 5 rpm,** and side scraper mixing at **20 ± 10 rpm**.	Amount Added: _____ kg Time of Addition: _____ AM/PM Record Center Mixing Speed: _____ RPM Record Side Scraper Speed: _____ RPM		

Comments

Step #	Step Description		Performed By (Initials & Date)	Witnessed By (Initials & Date)
7.	Heat the contents of step 6 to **45 ± 5°C** Continue center mixing at **90 ± 5 rpm,** and side scraper mixing at **20 ± 10 rpm**. Collect ~5kg of bulk from the bottom valve of the tank and pour back into the top. Repeat this 3 times and continue mixing until the contents becomes clear. Maintain temperature at 45 ± 5°C. Solution recirculated 3 times:(Circle One) YES NO Solution is clear: (Circle One) YES NO	Heat Start time: _____ AM/PM Record Center Mixing Speed: _____ RPM Record Side Scraper Speed: _____ RPM 1st recirc. Time: _____ AM/PM 2nd recirc. Time: _____ AM/PM 3rd recirc. Time: _____ AM/PM Record Temperature: _____ °C Time Temp. reached: _____ AM/PM Time solution is clear: _____ AM/PM		

Comments

Step #	Step Description		Performed By (Initials & Date)	Witnessed By (Initials & Date)
8.	Add **250.00 g** (or the **calculated amount from Page 6**) of **Clobetasol Propionate, USP** (Item # 7; Item Code: **45561**) Continue center mixing at **90 ± 5 rpm** and side scraper mixing at **20 ± 10 rpm** for **NLT 30 minutes** while maintaining the temperature at **45 ± 5°C**. Check the solution for clarity and record below. Rinse the container with **6.65 kg** of **Dehydrated Alcohol, USP** (Item # 8, Item Code: **42073**) Solution is clear:(**Circle One**) YES NO **NOTE: Proceed to starting Phase B while mixing for 30 minutes.**	Amt of API Added: _____ **g** Time of Addition: _____ AM/PM Record Center Mixing Speed: _____ RPM Record Side Scraper Speed: _____ RPM Record Temperature: _____ °C Mixing Start Time: _____ AM/PM Amount of Alcohol used to rinse: _____ kg Mixing End Time: _____ AM/PM		
9.	Monitor and record the temperature of the solution **every 10 minutes** while manufacturing Phase B. Ensure the temperature is being maintained at **45 ± 5°C**			

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

Comments

Step #	Step Description		Performed By (Initials & Date)	Witnessed By (Initials & Date)
Aqueous Phase – Side Mixing Vessel (Tank 80J)				
10.	Take the tare weight of Tank 80J and record. Into Tank 80J, add **174.40 kg** of **Purified Water, USP** (Item # 9; Item Code: **44205**). Begin mixing at **250 ±50 rpm**, and heat to **45 ± 5°C.**	Tare Weight: _____ kg Amount Added: _____ kg Time of Addition: _____ AM/PM Record Speed: _____ RPM Record Temperature: _____ °C Time Temp. reached: _____ AM/PM		
11.	Once the water is at **45 ± 5°C**, add 0.**40 kg** of **Citric Acid Anhydrous Powder, USP** (Item # 10; **44797**) Continue mixing at **250 ±50 rpm**.	Amount Added: _____ kg Time of Addition: _____ AM/PM Record Speed: _____ RPM Record Temperature: _____ °C		
12.	Add 0.**65 kg** of **Potassium Citrate Monohydrate Granular, USP** (Item # 11, Item Code: **45560**) Continue mixing at **250 ±50 rpm** for **10 minutes** or until dissolved. Maintain temperature at **45 ± 5°C**. Completely dissolved: (**Circle One**) YES NO	Amount Added: _____ kg Time of Addition: _____ AM/PM Record Speed: _____ RPM Record Temperature: _____ °C Mixing Start Time: _____ AM/PM Mixing End Time: _____ AM/PM		

Comments

Step #	Step Description		Performed By (Initials & Date)	Witnessed By (Initials & Date)
Phase AB – Main Mixing Vessel Tank 250J				
13.	Record the initial temp of Tank 250J **prior** to the transfer. Transfer the Aqueous Phase from tank 80J into Tank 250J (Alcohol Phase). Mix the contents of Tank 250J at center mixing speed **90 ± 5 rpm**, and side scraper mixing at **20 ± 10 rpm** for not less than **20 minutes**; maintain temperature at **45 ± 5°C**.	Temp. of Tank 250J before transfer: _____ °C Time of Addition: _____ AM/PM Temp. of Tank 250J after transfer: _____ °C Record Center Mixing Speed: _____ RPM Record Side Scraper Speed: _____ RPM Mixing Start Time: _____ AM/PM Mixing End Time: _____ AM/PM		
14.	Check batch weight, compensate using additional **Ethyl Alcohol 200 Proof, USP** (Item # 12; Item Code: **42073**) if necessary to get the theoretical batch weight.	A. Tank tare wt (step 1): _____ kg B. Batch + tare: _____ kg C. Actual (B – A): _____ kg D. Theor. batch wt: _____ kg E. Amount of Alcohol to add (D – C): _____ kg Amount of Alcohol Added: _____ kg		

Comments

Step #	Step Description		Performed By (Initials & Date)	Witnessed By (Initials & Date)
15.	Collect **2-3 times** the small portion of the liquid (≈ 5.0 kg) from the tank outlet and add back into the same bulk solution tank. Solution collected 2 - 3 times:(**Circle One**) YES NO	1st Portion collected: _____ AM/PM 2nd Portion collected: _____ AM/PM 3rd Portion collected: _____ AM/PM Record Speed: _____ RPM		
16.	Mix at center mixing speed of **90 ± 5 rpm**, and side scraper mixing at **20 ± 10 rpm** for an additional **5 minutes** to form a uniform liquid.	Mixing Start Time: _____ AM/PM Mixing End Time: _____ AM/PM Final batch weight W_b:_____ kg		
17.	Record the batch completion time.	Stop Time: _____ AM/PM		

Comments

<table>
<tr><th>Step #</th><th>Step Description</th><th>Performed By (Initials & Date)</th><th>Witnessed By (Initials & Date)</th></tr>
<tr><td>18.</td><td>Into amber glass bottles, obtain Two (2) sets of 2 oz. samples from the top, middle and bottom of the mixing vessel. Identify samples with Item #, Batch #, Name of the Batch, Date, Time and operator's Initials and submit to the QC for testing.
<table>
<tr><th>Location#</th><th>Gross Weight. (g)</th><th>Tare Weight (g) of container</th><th>Net Sample Weight (g).</th></tr>
<tr><td>Top 1</td><td></td><td></td><td></td></tr>
<tr><td>Top 2</td><td></td><td></td><td></td></tr>
<tr><td>Middle 1</td><td></td><td></td><td></td></tr>
<tr><td>Middle 2</td><td></td><td></td><td></td></tr>
<tr><td>Bottom 1</td><td></td><td></td><td></td></tr>
<tr><td>Bottom 2</td><td></td><td></td><td></td></tr>
<tr><td colspan="3">Total Weight of In process bulk samples only (W_s)</td><td></td></tr>
</table></td><td></td><td></td></tr>
<tr><td colspan="4">Concentrate Yield Determination</td></tr>
<tr><td>19.</td><td>Calculate % Yield = (Actual Yield) ÷ (Theoretical Batch Size) x 100%

Actual Yield (W_y)= (W_b-W_s): _____ kg
Sample Quantity (W_s): _____ kg
Theoretical Batch Size: _____ kg
% Yield: _____%
Acceptance Range: 98-102%</td><td></td><td></td></tr>
</table>

Comments

Pharmasol Item #	**8112010-250J**	Customer	**Aucta Pharma**	DCO	**20-0059**	Rev No.	**0**
Customer Part #	**N/A**	Description	**Clobetasol Propionate Foam, 0.05% – Bulk Liquid**			Page 17 of 19	

Step #	Step Description	Performed By (Initials & Date)	Witnessed By (Initials & Date)
20.	**Blanket Tank 250J with Nitrogen**. The remaining bulk in the Tank 250J (main tank) shall maintain the temperature at approximately **45°±5C** while mixing at center mixing speed of **80 ± 10 rpm**, and side scraper mixing speed of **20 ± 10 RPM**. Monitor the temperature and speed **every 15 minutes** until the start of the filling operation. Temperature and mixing speeds recorded post manufacturing will be recorded in the approved fill and pack record.		

Mixer Speed	Temp.	Time	Mixer Speed	Temp.	Time	Mixer Speed	Temp.	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

Comments

Step #	Step Description			Performed By (Initials & Date)	Witnessed By (Initials & Date)
21.	**Tank # 250J**	**Quantity (kg)**	**Time**		
	A. Empty Tank (Tare)				
	B. Filled Tank (Gross)				
	C. Amt Issued to Prod. (Net after samples)				
	D. Returned weight after filling				
	E. Tailings				

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

Batch Record Review

Compounding Review by: _____ Date: _____

QA Review by: _____ Date: _____

Comments