BATCH PRODUCTION AND CONTROL RECORD			
PRODUCT TRIAL BATCH	**PRODUCT CODE**	**EFFECTIVE DATE**	
MFR No. NA	**BPCR No.** NA	**BATCH No.**	
REVISION No. 00	**SUPERSEDE BPCR No.** NIL	**PAGE No.** 1 of 41	

BATCH MANUFACTURING RECORD

PRODUCT NAME : **TRIAL BATCH FOR PROCESS SIMULATION/LINE SUITABIILITY (OINTMENT LINE)**

LABEL CLAIM : **Composition:**

Linseed Oil BP	3.00%w/w
Methyl Salicylate IP	10.00% w/w
Menthol IP	5.00% w/w
Preservative:	
Benzyl Alcohol IP	1.00% w/w
Gel Base	q. s.

STANDARD BATCH SIZE : 200.0 kg
ACTUAL BATCH SIZE :
SHELF LIFE : NA
MARKET : NA
MANUFACTURING LICENSE No. :
MANUFACTURING DATE :
EXPIRY DATE : NA
DATE OF COMMENCEMENT :
DATE OF COMPLETION :
BATCH YIELD (%) : NA
PRODUCT OF (Company Name) : NA
BMR ISSUED BY :
DATE :

	Prepared By Executive QA	Checked By Manager Production	Approved By Head - QA	Authorized By Head – Operations
Sign				
Date				
Name				

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
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BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BPCR No.** NA	**BATCH SIZE**	**PAGE No.** 3 of 41	

A. BILL OF RAW MATERIALS:

S.No.	Material No.	Material Name.	O.A. (%)	Std. Qty. (200.0 kg)
1.		VIRGIN LINSEED OIL BP	-	6.000 kg
2.		METHYL SALICYLATE IP	-	20.000 kg
3.		MENTHOL IP	-	10.000 kg
4.		BENZYL ALCOHOL IP	-	2.000 kg
5.		STEARIC ACID IP	-	1.000 kg
6.		GLYCERYL MONOSTEARATE IP	-	1.000 kg
7.		PROPYLENE GLYCOL IP	-	2.000 kg
8.		TRIETHANOLAMINE BP	-	0.320 Kg
9.		ACRYPOL -940	-	1.400 kg
10.		METHYL PARABEN IP	-	0.400 kg
11.		PROPYL PARABEN IP	-	0.040 kg
12.		BUTYLATED HYDROXY TOLUENE IP	-	0.100 kg
13.	------	PURIFIED WATER IP/USP	*2%	q.s

Note: Required Qty.= Std. Qty. +(Std. Qty.x overages)
100

*** 2% Overage taken to compensate the loss due to evaporation.**

B. DISPENSING :

Instructions:

1. During process check environmental conditions to be within limits (i.e. Temperature NMT 25°C & RH NMT 55%) and record in environment monitoring record at the time of start of dispensing, after every one hour and after every breakdown as per QA **SOP.**
2. Ensure all Equipments are cleaned and affixed with **"CLEANED"** Status Label.
3. Gowning Procedure shall be followed while entering into the Dispensing Area as per Warehouse respective SOP.
4. Take Line clearance from QA before starting the Dispensing Activity as per **SOP.**
5. Dispense the material as per the Bill of material**.**
6. All Analytical Weighing Balance shall be calibrated as per Quality Assurance **SOP.**
7. Take raw materials to dispensing area and weight the first excipients and then active ingredients in double polyethylene bags under RLAF by operating the RLAF as per Warehouse **SOP.**

1.1 OPERATIONAL CHECKS:

Instrument Name	Identification No.	Calibration Status (Ok/Not Ok)	Checked By Sign / Date Warehouse Officer/Executive
Electronic Weighing Balance			
Electronic Weighing Balance			
Electronic Weighing Balance			
Electronic Weighing Balance			

1.2 ENVIRONMENTAL MONITORING: At the time of start of Dispensing, after **Every One Hour** and after Every Breakdown.

Date/ Time	Room No. /Name	Temp. (°C) (Limit 25°C)	% RH (Limit 55 %)	Done By Sign/Date	Checked By Sign/Date	Remarks

1.3 CALCULATION:

$$\text{Potency} = \frac{(100\text{-LOD}) \times \text{Assay}}{100}$$

$$\text{Qty. Required} = \frac{\text{Label Claim} \times \text{Batch Size}}{\text{Potency}}$$

Calculation Done By Production Officer / Executive Sign & Date

Calculation Checked By IPQA Officer / Executive Sign & Date

1.4 LINE CLEARANCE FOR DISPENSING: (Refer SOP No.:……..)

(To Be Performed by Warehouse & Verified by QA persons)

LINE CLEARANCE CHECK LIST – DISPENSING

Previous Product		**Area**	
Batch No.		**Date / Time**	

S. No.	Check Points	Status (OK / Not OK)	Done By (Warehouse Officer/Exe.)	Checked By (IPQA Officer/Exec)
1.	Check the **"Status Board"** of the dispensing area for following details: Product Name, Batch No., Mfg. Date, Exp. Date, Batch Size and ensure that the details are matching with the BMR of present batch to be processed			
2.	Check the cleanliness of the room and ensure that it is free from the remains of the previous batch.			
3.	Check the cleanliness of the RLAF unit and ensure that it is free from the remains of the previous batch.			
4.	Check and Ensure that the RLAF is switched ON minimum 30 minutes before start of the activity and the pressure differential across HEPA filter is within limit.			
5.	Check the Temperature and Relative Humidity (RH) of the dispensing room (It should be within specified range).			
6.	Check the Calibration Status of the Weighing Balance.			
7.	Ensure all logbooks of the area (RLAF Usage Log Book, Balance Calibration Log Book, Cleaning Log Book and Environmental Monitoring Log Book etc.) are filled regularly.			
8.	Inspect the waste bins and ensure that it is free from remains of the previous batch.			
9.	Check the availability of online BMR			
10.	Check the approval of Raw Materials from QC by pasted Approved Labels on containers.			
11.	Check and Verify the identity of raw materials by Item code & A.R. No. to be used are as per BMR.			
12.	Check and Ensure the dispensed Raw Materials are kept in a separate SS trolley with proper status label.			
13.	Check and Ensure the Liquid Raw Materials are dispensed in clean SS container with proper status label. (If Liquid Raw Material is in BOM)			
14	Ensure proper cleaning of filters of RLAF, Returned Riser and grill of filters.			
15	Check and Ensure the availability of Cleaned Dispensing Tools			

Note: Write 'NA' where not Applicable

After complete checking as per checklist QA Officer/Executive shall give the line clearance of the area by signing on 'Line Clearance Label'

Checked By Sign / Date _____ **Line Clearance Given By Sign / Date_____**
(Warehouse Officer/Executive) **(QA Officer/Executive)**

AFFIX DISPENSING AREA LINE CLEARANCE LABEL

1.5 RAW MATERIAL DISPENSING RECORD:

S.No.	Material Name	Material No.	Std. Qty. (200 kg)	O.A. (%)	Issued Qty. (……Kg)	A.R. No.	Gross Wt.	Tare Wt.	Net Wt. Issued	Issued By Sign/Date (Warehouse)	Verified By Sign/Date (IPQA)
1.	Linseed Oil BP		6.000	….							
2.	Methyl Salicylate IP		20.000	….							
3.	Menthol IP		10.000	….							
4.	Benzyl Alcohol IP		2.000	….							
5.	Stearic Acid IP		1.000	….							
6.	Glyceral Monostearate IP		1.000	….							
7.	Propylene Glycol IP		2.000	….							
8.	Triethanolamine BP		0.320	….							
9.	Acrypol -940		1.400	….							
10.	Methyl Paraben IP		0.400	….							
11.	Propyl Paraben IP		0.040	….							
12.	Butylated Hydroxy Toluene IP		0.100	….							

Raw Material Dispensing Started at (Date/ Time)	Raw Material Dispensing Completed at (Date/ Time)	Dispensed By (Operators) (Sign & Date)	Checked By (Warehouse Officer/Executive) (Sign & Date)	Verified By (QA Officer/Executive) (Sign & Date)

BATCH PRODUCTION AND CONTROL RECORD				
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AFFIX THE RAW MATERIALS DISPENSING LABELS

BATCH PRODUCTION AND CONTROL RECORD				
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MFR No. NA	**BPCR No.** NA	**BATCH SIZE**	**PAGE No.** 12 of 41	

AFFIX THE RAW MATERIALS DISPENSING LABELS

1.6 VERIFICATION OF DISPENSED RAW MATERIALS

(To Be Performed at Manufacturing Area)

1. Balance ID No.:…… Calibration Status (Ok/Not Ok):_____

2. Balance ID No.:……. Calibration Status (Ok/Not Ok):_____

S. No.	Material Name	Material No.	Std. Qty. (200 kg)	Issued Qty. (……..kg)	A. R. No.	Gross Weight	Units	Checked By Sign/Date (Production)	Verified By Sign/Date (IPQA)
1.	Linseed Oil BP		6.000				kg		
2.	Methyl Salicylate IP		20.000				kg		
3.	Menthol IP		10.000				kg		
4.	Benzyl Alcohol IP		2.000				kg		
5.	Stearic Acid IP		1.000				kg		
6.	Glyceral Monostearate IP		1.000				kg		
7.	Propylene Glycol IP		2.000				kg		
8.	Triethanolamine BP		0.320				kg		
9.	Acrypol -940		1.400				kg		
10.	Methyl Paraben IP		0.400				kg		
11.	Propyl Paraben IP		0.040				kg		
12.	Butylated Hydroxy Toluene IP		0.100				kg		

C. MANUFACTURING PROCEDURE:

Instructions:

1. Read the BMR thoroughly before proceeding with operation and follow it strictly.
2. Carry out all the activities related to equipment cleaning and material handling strictly as per respective Standard Operating Procedures.
3. Label all Equipments and Areas with status and product label and display prominently.
4. All Raw Materials Dispensing Labels, In-process Status Labels, Line Clearance Labels and Equipment Cleaning Status Labels to be retained with the Batch Production and Control Record.
5. Get Line Clearance before beginning of every operation from QA as per **SOP.**
6. Protective Mask, Hand Gloves and any other safety provisions must be followed.
7. The persons working in area must follow proper gowning as per Production respective SOP.
8. Any deviation from the BMR must be done with prior approval of QA.
9. In case of any non compliance is observed, stop the operation and report to the officer concerned.
10. Ensure that all the Raw Material Weights are counter checked before Processing.
11. Ensure that all the Containers containing Raw Material, Intermediate and Final Product Containers are clean before carrying out operations.
12. Check the Identification Tags and Weights of the Dispensed Materials and Transfer the Material to Receiving Bay of Production.
13. Ensure complete Dissolution of Ingredients at every step before processing for next step.
14. Recommended Environmental Conditions are to be observed strictly during manufacturing process as per QA **SOP**.
15. Bulk & Finished Product should be least exposed to Atmosphere.

BATCH PRODUCTION AND CONTROL RECORD				
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MANUFACTURING AREA:

1.1 LINE CLEARANCE FOR MANUFACTURING AREA: (Refer SOP No.: ……)

Previous Product		**Batch No.**	
Area		**Date / Time**	

S. No.	Check Points	Status (OK / Not OK)	Done By Sign/Date (Production)	Checked By Sign/Date (IPQA)
1.	Check the Area is Visually Clean and Free From Dust Particles and ensure that there are no Previous Product Materials/Unwanted Materials.			
2.	Ensure the "**Status Board**" of the area is Neatly and Duly written with **'Batch Details'** as per mentioned in BMR like Product Name, Batch No., Batch Size, Mfg. Date, Best Before.			
3.	Check the cleanliness of all Equipments which are used in Manufacturing are done as per Respective Cleaning SOP.			
4.	Ensure that all Equipments which are used in Manufacturing are free from any remains of the Previous Batch / Product material.			
5.	Ensure the Waste Bins are properly Cleaned and Placed in Proper Place.			
6.	Check and Ensure that the Temperature and Relative Humidity of the Area are within the Specified Limit as per mentioned in BMR.			
7.	Check and Ensure that the Machine Log Book, Cleaning Log Book and Environmental Monitoring Log Book are filled correctly.			
8.	Check the proper status labeling on the machines. Ensure that the machine in Cleaning Area has appropriate **Status Label – To Be Cleaned / Cleaned**.			
9.	Check and Ensure that the Wash Water / Swab are released from Quality Control and Report attached with BMR before signing as 'Released' on Cleaned label.			
10.	Check and Ensure that the Purified Water Report is attached with BMR.			

BATCH PRODUCTION AND CONTROL RECORD				
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S. No.	Check Points	Status (OK / Not OK)	Done By Sign/Date (Production)	Checked By Sign/Date (IPQA)
11.	Check the Cleaning and Calibration Status of Weighing Balance.			
12.	Check and Verify the Item Code and Weight of Dispensed Raw Material with BMR.			
13.	Check the BMR is filled up to Dispensing Stage.			

After complete checking as per checklist QA Officer/Executive shall give the line clearance of the area by signing on 'Line Clearance Label'.

Checked By Sign / Date _____
(Prod. Officer/Executive)

Line Clearance Given By Sign / Date_____
(QA Officer/Executive)

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BPCR No.** NA	**BATCH SIZE**	**PAGE No.** 17 of 41	

AFFIX MANUFACTURING AREA LINE CLEARANCE LABEL

1.2 ENVIRONMENTAL MONITORING: At the time of start of Manufacturing, Initial/End and after every **4 Hour** and **After Every Breakdown**.

Date/Time	Room No./Name	Dry Bulb Temp. (°C) Limit (25°C)	Wet Bulb Temp. (°C)	% RH Limit (NMT 55%)	Done By Sign/Date (Operator)	Checked By Sign/Date (Production)	Remarks

1.3 RINSE WATER ANALYSIS:

If Product Change, Production Department shall give the Intimation to QA for Rinse Water Collection. After Sampling, QA shall send the Sample along-with Intimation to QC for Analysis.

If Batch Change, Production Department shall give the Intimation to QA for Rinse Water Collection after Consecutive 5 Batches of Same Product. After Sampling, QA shall send the sample along-with intimation to QC for analysis.

Intimation No.	Intimated By Sign/Date/Time (Production)	Intimation Received By Sign/Date/Time (QA)	Quantity Sampled	Sampled By Sign/Date/Time (QA)

After Receiving the Analysis Report from QC, fill the A.R. No_____

The Equipment Release / Not Release for Manufacturing.

QA Officer/Executive Sign _____ Date _____ Time _____

1.4 EQUIPMENT DETAILS:

Name of Equipment	Equipment ID No.	Previous Product	Batch No.	Cleanliness (OK/Not OK)	Checked by Sign/Date (Production)	Verified by Sign/Date (IPQA)
Multimixture vessel						
Wax phase vessel						
Water phase vessel						
Holding Vessel						
Holding Vessel						
Holding Vessel						
Holding Vessel						
Transfer pump(lobe pump)						
Filling & Sealing Machine						
Auto Cartonator						

1.5 PREPARATION OF GEL:

- **VERIFICATION OF DISPENSED RAW MATERIALS:** Verify the Weight of Dispensed Raw Material against the Quantity mentioned in the Bill of Raw Materials. Verify the A. R. No. of Dispensed Raw Materials as per mentioned in the Bill of Raw Materials.
- Quantity mentioned for **Standard Batch Size 200 kg** in blank column quantity to be filled for Actual Batch Size taken.
- **Instruction:** Water phase & Oil phase are the process to go parallel in order to complete the phases at a right time & to shorten the time. So will start the water phase first as it takes more time to complete the process.

BATCH PRODUCTION AND CONTROL RECORD				
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STEP -1 WATER PHASE PREPARATION:

Addition & Mixing of Acropol in Purified water:

a) Transfer manually total qty (_____ Kg) of **Purified water** required in steam Jacketed Multi-mixer at Room temperature (Temperature NMT 40^0C) and record the weight in the following table

b) Add slowly, **Acrypol -940**, (____ Kg) in **Purified Water** (____ Kg**)** while sifting through 18 # , over a period of 20 minutes in Jacketed Multi Mixer with homogenizer at 2800 RPM

Stage	Process Variables	Process Time		Acceptance Criteria	Observation	Production	QA
		From	To				
Water Phase Preparation (Dispersion of Acrypol 940) **Addition executed with Open Lid**	Heating Temperature			NA			
	Homogenizer Speed			2800 RPM			
	Anchor I			OFF			
	Mixing Time			20 Minutes			
	Sieve used			18 #			
	Sieve integrity – Before Sifting			Should be integral			
	Sieve integrity – After Sifting			Should be integral			

c) Mix the Acrypol in water with Anchor I 'ON' at 30 rpm & Homogenizer "ON'' at 2800 RPM for 30 minutes at room temperature

Stage	Process Variables	Process Time		Acceptance Criteria	Observation	Production	QA
		From	To				
Mixing of Acrypol in water	Heating Temperature			NA			
	Homogenizer Speed			2800 RPM			
	Anchor I			30 RPM			
	Mixing Time			30 Minutes			

d) Mix the Acrypol in water with Anchor I 'ON' at 30 rpm , Anchor II 'ON' at 15 rpm & Homogenizer "ON'' at 2800 RPM for 10 minutes at room temperature

Stage	Process Variables	Process Time		Acceptance Criteria	Observation	Production	QA
		From	To				
Mixing of Acrypol in water	Heating Temperature			NA			
	Homogenizer Speed			2800 RPM			
	Anchor I			30 RPM			
	Mixing Time			10 Minutes			

e) Observe the lumps if any and clarity of solution

Stage	Process Variables	Observation Time		Acceptance Criteria	Observation	Production	QA
		From	To				
Clarity of Acrypol 940 solution	Observe the clarity			Clear, no Lump observed			

f) In case Lump observed or solution is not clear further mix for 10 minutes using the following parameters

Stage	Process Variables	Process Time		Acceptance Criteria	Observation	Production	QA
		From	To				
Mixing of Acrypol in water	Heating Temperature			NA			
	Homogenizer Speed			2800 RPM			
	Anchor I			30 RPM			
	Mixing Time			10 Minutes			

g) Observe the lumps if any and clarity of solution

Stage	Process Variables	Observation Time		Acceptance Criteria	Observation	Production	QA
		From	To				
Clarity of Acrypol 940 solution	Observe the clarity			Clear, no Lump observed			

h) Lump Breaking

Lumps formed during the process were broken by stopping the machine, opening the lid and crushing with long handle SS scoop along the wall of vessel

Stage	Process Variables	Process Time		Acceptance Criteria	Observation	Production	QA
		From	To				
Lump Breaking	NA			No lump observed			

i) Final Mixing

After breaking the lumps of Acrypol 940, Lid is closed and solution was mixed for 30 minutes with Anchor I ON and Homogenizer ON

Stage	Process Variables	Process Time		Acceptance Criteria	Observation	Production	QA
		From	To				
Mixing	Heating Temperature			NA			
	Homogenizer Speed			2800 RPM			
	Anchor I			30 RPM			
	Mixing Time			30 Minutes			

j) Water Phase - Heating

Heating Process to be started after maintaining the steam pressure 2.5 Kg/cm^2.

Heat the resulting Acrypol solution to maintain the temperature up to 70±2^{0}C in Jacketed Multi Mixer by using the same condition i.e. steam at pressure 2-2.5kg/cm², Homogenizer ON at 2800 rpm and Anchor I 'ON'.

Stage	Process Variables	Process Time		Acceptance Criteria	Observation	Production	QA
		From	To				
Heating	Heating Temperature			Set Temp 60°C Acceptance Criteria Product temp 70 °C+/- 2°C			
	Anchor I			10 RPM			
	Mixing Time			30 Minutes			
	Steam Pressure			2.0 – 2.5 kg/cm^2			

STEP-2 OIL PHASE PREPARATION:

Manufacturing of Oil Phase:

(Process to be started after water phase heating is put ON)

a) Oil Phase Jacketed Vessel is set at Temperature 45 °C temperature and steam at pressure 2.0 - 2.5kg/cm^2. Once PLC indicated 70^{o}C temperature, following raw materials were added in oil phase jacketed vessel (350kg capacity) with manual mixing using S.S. ladle,

Stearic acid IP (____ Kg)

Glyceryl mono Stearate (____ Kg)

b) Once molten mass is observed , following material is added to dissolve in molten mass

Methyl paraben IP (____ Kg)

Propyl paraben IP (____ Kg)

Butylated Hydroxy Toluene (____ Kg)

Mix with S.S. ladle till it solubilize in the solution.

Stage	Process Variables	Process Time From	Process Time To	Acceptance Criteria	Observation	Production	QA
Heating	Heating Temperature			Set Temp 45°C Acceptance Criteria Product temp 70 °C+/- 2°C			
	Melting Time			NMT 15 min			
	Steam Pressure			2.0 – 2.5 kg/cm^2			
	Time required for MP,PP,BHT to dissolve			NMT 5 minutes			

STEP-3 EMULSIFICATION:

a) Transferred Step no.2 oil phase into Step no .1 water phase, using pump and using SS filter 100# at 70±2^{0}C temperature creating vacuum 300-400mm of Hg in approx. 1-2 minutes with 3 times rinsing of (____ Kg) Purified Water, Further mixed for 10 minutes.

Stage	Process Variables		Process Time From	Process Time To	Acceptance Criteria	Observation	Production	QA
Emulsification **Addition of Oil Phase to Water Phase**	Integrity of Sieve	Before Use			Should be integral			
		After Use			Should be integral			
	Mesh Size				100#			
	Product Temperature				Set at PLC 70 °C			
					Actual product temp 70 °C ± 2°C			
	Vacuum				Set 300 – 400 mm of Hg			
	Transfer Time				2 minutes (1 – 3 Minutes)			
	Anchor I Speed				30 RPM			
	Rinsing with 2 kg water X 3 times				2 minutes (1 – 3 Minutes)			
	Mixing Time				10 Minutes			
	Homogenizer Speed				OFF			

b) Emulsion Homogenization:

Homogenizer was run with 2800 rpm along with anchor stirrer at 30 rpm for 4 minutes.

Stage	Process Variables	Process Time		Acceptance Criteria	observation	Production	QA
		From	To				
Emulsion Homogenization	Heating Temperature			Set at PLC 70 °C +/- 2°C			
	Homogenizer Speed			2800 rpm			
	Anchor Speed			30 RPM			
	Mixing Time			4 Minutes			
	Steam Pressure			2.0 – 2.5 kg/cm^2			
	Vacuum			300-400 mm of Hg			
	Actual product temp			70 °C ± 2°C			

STEP-4 COOLING:

Circulate the Soft Water for approx. 20 min. into Jacketed Multi Mixer with stirrer "ON" at 30 RPM by applying vacuum at 300mmHg to reduce Product Temperature from 70^{0}C to 40±2^{0}C. As Product Temperature reduces to 40±2^{0}C release the vacuum completely.

Stage	Process Variables	Process Time		Acceptance Criteria	Observation	Production	QA
		From	To				
Cooling	Soft water Circulation Time			Approx. 20 Minutes			
	Anchor Speed			30 RPM			
	Mixing Time			20 Minutes			
	Applied Vacuum			300 – 400 mm of Hg			
	Product Temperature			40 ± 2°C			

STEP-5. TRIETHANOLAMINE PREPARATION & NEUTRALIZATION OF EMULSION:

a) Transfer manually total qty (____ Kg) of Purified water required for Triethanolamine solution preparation and (____ Kg) for rinsing the container after addition of Triethanolamine solution in different SS Container Capacity – (___ Ltr and ___ Ltr) at and record the weight in the following table

S.No.	Gross weight in Kg	Tare weight in Kg	Net Weight in Kg

b) Add **Triethanolamine** (____ Kg) in **Purified Water** (____ Kg) in SS 5 Ltr Container capacity & mix manually for 5 Minutes to get a clear solution.

Stage	Process Variables	Process Time		Acceptance Criteria	observation	Production	QA
		From	To				
Triethanolamine solution Preparation	Manual Mixing Time			Clear solution			

c) Add Triethanolamine solution to Manufacturing Tank containing emulsion over a period of 1-2 Minute (Including rinsing of container using (____ Kg) **Purified Water** by mixing with Anchor Speed I at 30 rpm product temp. 40 ± 2^0C).
Continue mixing with stirrer at Anchor I at 30 rpm with homogenizer at 2800 rpm, product temp. 40 ± 2^0C for 3 minutes.

Stage	Process Variables	Process Time		Acceptance Criteria	Observation	Production	QA
		From	To				
Addition of Triethanolamine to Manufacturing Tank along with Rinsing	Addition Started at			1 to 2 min			
	Addition Completed At			---			
	Product Temperature			40°C ± 2°C			
	Anchor Speed			30 RPM			
	Homoginization Speed			2800 rpm			
	Continued Homoginization and Mixing Time			3 min			

STEP-6 ADDITION OF LINSEED OIL & MENTHOL, METHYL SALICYLATE AND BENZYL ALCOHOL SOLUTION:

a) Preparation of Menthol, Methyl Salicylate and Benzyl Alcohol Solution:

Dissolve **Menthol** (____ Kg) in **Methyl Salicylate** (____ Kg) and **Benzyl alcohol** (____ Kg) in Water phase vessel with stirrer for 60 min. to Benzyl alcohol solution and then was added with Stirrer RPM 600 for 60 minutes.

Stage	Process Variables	Process Time		Acceptance Criteria	Observation	Production	QA
		From	To				
Preparation of Menthol, Methyl Salicylate, Benzyl alcohol	Mixing Time with stirrer			60 Minutes			
	Solution description			Clear			

b) Warming & addition of linseed Oil in Gel:

Warm Linseed oil (____ Kg) (*Warmed to 40^0C) in Wax phase vessel & note the temperature by using Thermo gun & transfer into Multi-mixer of Step 6 using pump and using SS filter 100# mixing with Anchor I at 30 rpm for 5 min. along with homogenizer at 2800 rpm for 3 min. at temp. 40 ± 2^0C using vacuum.

Stage	Process Variables		Process Time		Acceptance Criteria	Observation	Production	QA
			From	To				
Warming of Linseed oil	Warming Temperature				40 °C			
Addition of Linseed Oil to Gel of Multi-mixer	Applied Vacuum				300 – 400 mm of Hg			
	Integrity of Sieve	Before Use			Should be integral			
		After Use			Should be integral			
	Mesh Size				100#			
	Product Temperature				40 ± 2^0C			
	Anchor Speed				30 RPM			
	Homogenization Speed				2800 rpm			
	Homogenization Time				3 min			
	Mixing Time				5 min			

c) Addition of Menthol, Methyl Salicylate and Benzyl Alcohol Solution:

Transfer slowly the Menthol, Methyl Salicylate and Benzyl Alcohol Solution into Gel of Multi-mixer of Step 6(Transfer time approx. 20 min.) using pump and using SS filter 100# mixing with Anchor I at 30 rpm along with homogenizer at 2800 rpm at temp. 40 ± 2^0C using vacuum.

Stage	Process Variables		Process Time		Acceptance Criteria	Observation	Production	QA
			From	To				
Addition of Menthol, Methyl Salicylate and Benzyl Alcohol Solution	Applied Vacuum				300 – 400 mm of Hg			
	Integrity of Sieve	Before Use			Should be integral			
		After Use			Should be integral			
	Mesh Size				100#			
	Product Temperature				40 ± 2^0C			
	Anchor Speed				30 RPM			
	Homoginization Speed				2800 rpm			
	Transfer time				Approx. 20 min.			

STEP-7 FINAL MIXING OF BULK:

a) Mix bulk by using Anchor at 30 rpm for 10 minutes along with homogenizer at 2800 rpm for 5 min.

Stage	Process Variables	Process Time		Acceptance Criteria	Observation	Production	QA
		From	To				
Final Bulk Mixing	Product Temperature			40°C ± 2°C			
	Anchor Speed			30 RPM			
	Mixing Time			10 min			
	Homogenization Speed			2800 rpm			
	Homogenization Time			5 min			

b) Holding of the Bulk:

Hold the bulk aside for at least one hour to see that there is no separation of oil layer

Stage	Process Variables	Process Time		Acceptance Criteria	Observation	Production	QA
		From	To				
Holding Time	Oil Separation			No Separation			
	Time			60 min			

c) Final bulk to be checked for pH between **5.5 – 7.5**.

Process Start Time / Date	Process Completed Time / Date	Checked By (Sign/ Date) (Production)	Verified By (Sign / Date) (IPQA)

- Label the storage tanks with proper identification w.r.t. Product Name, Batch No. Mfg Date,

  use before, Batch Size & Status Intimate quality control department to arrange collect the sample for analysis.
- After completion of mixing send 150 gm of bulk to QC department for analysis.

1.6 SAMPLE REQUEST FOR QC ANALYSIS:

a. Send Test Request Form to IPQA for Sampling.

b. After Sampling, IPQA shall send the Sample along-with Intimation to QC for Analysis.

Intimation No.	Intimated By Sign/Date/Time (Production)	Intimation Received By Sign/Date/Time (IPQA)	Quantity Sampled	Sampled By Sign/Date/Time (IPQA)

c. After receiving the Analysis Report from QC, fill the A. R. No._____

d. The Gel is Release / Not Release for Filling.

QA Officer/Executive Sign _____ Date _____ Time _____

1.7 BULK RECONCILIATION:

S.No.	Particulars	Results
a.	Actual Batch Size	Kg
b.	Batch Quantity Received for Filling	Kg
c.	Bulk Sample send to QC for Analysis	Kg
d.	Bulk Received for Filling Process	Kg
e.	Percentage Yield	$\frac{(c + d) \times 100}{a} = \frac{\quad}{\quad} \times 100$ = _____%.
Calculation Done By Sign/Date (Production)		**Calculation Checked By Sign/Date (IPQA)**

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BPCR No.** NA	**BATCH SIZE**	**PAGE No.** 30 of 41	

1.8 IN – PROCESS OBSERVATIONS (To be Filled by QA only):

S. No.	Date / Time	Shift	Observations	Informed To Production (Officer/ Executive)	Observed By IPQA (Officer / Executive)	Action Taken By Production (Officer/ Executive)	Verified By IPQA (Officer/ Executive)

1.9 VERIFICATION OF BPCR UP-TO MANUFACTURING STAGE:

Checked By Sign / Date Production Officer / Executive	Reviewed By Sign / Date IPQA Officer / Executive

2.0 RINSE WATER ANALYSIS:

In case of Type B cleaning Production Department shall give the Intimation to QA for Rinse Water sampling. After Sampling, QA shall send the Sample along-with Intimation to QC for Analysis.

Intimation No.	Intimated By Sign / Date / Time (Production)	Intimation Received By Sign / Date / Time (QA)	Quantity Sampled	Sampled By Sign/ Date / Time (QA)

After Receiving the Analysis Report from QC, fill the A.R. No_____

The Equipment Release / Not Release for Filling.

QA Officer/Executive Sign _____ Date _____ Time _____

3.0 EQUIPMENT DETAILS:

Name of Equipment	ID. No.	Previous Product	Batch No.	Checked by Sign/Date (Production)	Verified by Sign/Date (QA)
Tube Filling & Sealing Machine					
Conveyer Belt					
Weighing Balance					
Shrink Machine					
Weighing Balance					

4.0 LINE CLEARANCE FOR FILLING AND SEALING: (Refer SOP No.: ……..)

(To Be Performed By Production person and Verified by IPQA Person)

LINE CLEARANCE CHECK LIST

Previous Product		**Batch No.**	
Area		**Date / Time**	

S. No.	Check Points	Status (OK/Not OK)	Done by Sign Production	Checked by Sign QA
1.	Check the Area is Visually Clean and Free From Dust Particles and Ensure that there are no Previous Product Materials/Unwanted Materials.			
2.	Ensure the **"Status Board"** of the area is Neatly and Duly written with Batch Coding Details as per mentioned in BMR like Product Name, Batch No., Batch Size, Mfg. Date, Exp Date.			
3.	Check the Cleaning of Filling Line is done as per Respective Cleaning SOP.			
4.	Ensure the Filling Line is Free From any remains of the Previous Product.			
5.	Ensure the Duly Labeled Containers for Non – Recoverable Rejects are properly cleaned.			
6.	Ensure the Waste Bins are properly Cleaned and Placed in Proper Place.			
7.	Check and Ensure that the Temperature, RH and Differential Pressure of the area are within the Specified Limit as per mentioned in BMR.			
8.	Check and Ensure that the Machine Logbook, Cleaning Logbook, and Environmental Monitoring Logbook are filled correctly.			
9.	Ensure the cleaning of Return Air Riser; it should be clean and free from remains of the previous product.			
10.	Check the proper Status Labeling on the Machines.			
11.	Check and Ensure that the Wash Water/Swab are released from Quality Control and Report attached with BMR.			
12.	Check and Ensure that the Bulk Cream is Release from Quality Control and Released Report attached with BMR			

Note: Write 'NA' where Not Applicable

After complete checking as per checklist QA Officer/Executive shall give the Line Clearance of the area by signing on 'Line Clearance Label'

Checked By Sign / Date _____ **Line Clearance Given By Sign / Date_____**
(Prod. Officer/Executive) **(QA Officer/Executive**

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BPCR No.** NA	**BATCH SIZE**	**PAGE No.** 33 of 41	

Affix the Line Clearance Label for Filling and Sealing Area

5.0 ENVIRONMENTAL MONITORING: At the time of Initial/End and, after **Every 4 Hour** and **After Every Breakdown**.

Date & Time	Shift I/II/III	Room No./Name	Temp.(°C) (Limit: NMT 25°C)	% RH (Limit: NMT 55%)	Done By Operator Sign & Date	Checked By Production Sign & Date	Verified By QA Sign & Date

6.0 TUBES DE-CARTONING:

Process Start Time & Date	Process Completion Time & Date	No. of Tubes De-cartoned	Done By Sign / Date (Operator)	Checked By Sign / Date (Production)

7.0 INSPECTION OF EMPTY TUBES:

a. The Empty Tubes are checked for Defectiveness like Breakage, Fiber or any other Foreign Particles.

Process Start Time & Date	Process Completion Time & Date	No. of Tubes Inspected	Done By Sign / Date (Operator)	Checked By Sign / Date (Production)

8.0 IN-PROCESS CHECKS DURING INSPECTION OF EMPTY TUBES:

(**Frequency:** Initial by both Production/IPQA, After Every **One Hour** by Production and IPQA alternatively and End of the batch)

Date	Time	No. of Tubes Checked	Optical Check				Quantity Passed	Checked By Production / QA
			Printing	Colored Particles	White Particles	Cracks/Dents		

9.0 FILLING & SEALING OF TUBES:

9.1 INSTRUCTIONS:

- Before Starting the Filling, Check the Cleanliness of the Machine, Container & Area.
- Ensure all Equipments are cleaned and affixed with **"CLEANED"** Status Label.
- Proper Gowning Procedure shall be followed while entering into the Filling and Sealing Room as per **Production respective SOP.**
- Before start of Filling and Sealing Process, check environmental conditions to be within limits and record in the Environmental Monitoring Record.
- Get Line Clearance before beginning of operation from QA as per **SOP**.
- Protective Mask, Hand Gloves and any other safety provisions must wear during process.
- All Weighing Balance shall be calibrated as per Quality Assurance **SOP**.
- Charge the Gel in Vessel of Filling Machine.
- Set the Machine for Weight.
- Always fill the weight in such a way that it should not be less than the weight to be filled.
- Once the weight is set and is found proper then start Filling Operation.
- During filling, check weight after every 1 hour by Production and after every 1 hours by QA and after every breakdown.
- Check after Starting the Machine, after **1 hour** and after every breakdown for Quality of Sealing.

9.2 MACHINE OPERATION DETAILS:

Filling & Sealing Machine No.	Filling & Sealing Started At Date / Time	Filling & Sealing Completed At Date / Time	Total Time	Checked By Sign/Date (Production)	Verified By Sign / Date (QA)

9.3 MACHINE SETTING PARAMETERS:

Filling Parameters	**Settings Required**
Fill Weight	30 + 0.5 g
Targeted Fill Weight	NLT 30 g
Weight of Empty Tube/Container (Min. 20 Nos)	____ , _____, ____ , ____ , ____ , ____ , ____ , ___ , ____ , ____ , ____ , ___ , ___ , ___ ____ , ____ , ____ , ____ , ____ , ____
Avg. Wt. of Empty Tube	**……..g**
Wt.Variation of Empty Tube **(Limit NMT 5.0%)**	$\frac{\text{min wt. of empty tube – Avg.wt of empty tube}}{\text{Avg.wt of empty tube}}$ X 100 = **…….. %**
	$\frac{\text{max wt.of empty tube – Avg.wt of empty tube}}{\text{Avg.wt of empty tube}}$ X 100 = **…….. %**
Crimp sealing Temperature	
Batch No. on sealed crimp	

Crimp sealing height (mm)		
Height after filling and sealing		
Air Pressure		

Crimp sealing Temperature	**Set temperature**	**Observed temperature**
Heater-1 (450°C - 510°C) Target Sealing Temp. 480°C		
Heater-2 (450°C - 510°C) Target Sealing Temp. 480°C		

Batch Coding detail on sealed crimp				
Machine Speed (80-120 tubes/minute) Targeted Machine Speed (100 tubes/minute)		Machine Speed (30-60tubes/minute) Targeted Machine Speed (40 tubes/minute)		

9.4 INITIAL FILLING/SEALING RECORD:

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BPCR No.** NA	**BATCH SIZE**	**PAGE No.** 37 of 41	

By Production Officer/Executive			**By QA Officer/Executive**		
Tube No.	**Fill Weight (Limit:** 30 + 0.5 gm**)**	**Leak Test (Ok/Not Ok)**	**Tube No.**	**Fill Weight (Limit:** 30 + 0.5gm**)**	**Leak Test (Ok/Not Ok)**
1			1		
2			2		
3			3		
4			4		
5			5		
6			6		
7			7		
8			8		
9			9		
10			10		
Checked By Sign/Date Production			**Verified By Sign/Date QA**		

9.5a). INPROCESS CONTROL DURING FILLING/SEALING 1:

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BPCR No.** NA	**BATCH SIZE**	**PAGE No.** 38 of 41	

(Frequency: Initial by both Production/IPQA, After Every **One Hour** by Production and IPQA alternatively and End of the batch)

Date Time				**Date Time**				**Date Time**				**Date Time**			
Tube No.	**Weight (gm)**			**Tube No.**	**Weight (gm)**			**Tube No.**	**Weight (gm)**			**Tube No.**	**Weight (gm)**		
	Gross wt.	**Tare wt.**	**Net wt.**		**Gross wt.**	**Tare wt.**	**Net wt.**		**Gross wt.**	**Tare wt.**	**Net wt.**		**Gross wt.**	**Tare wt.**	**Net wt.**
1				1				1				1			
2				2				2				2			
3				3				3				3			
4				4				4				4			
5				5				5				5			
6				6				6				6			
7				7				7				7			
8				8				8				8			
9				9				9				9			
10				10				10				10			
11				11				11				11			
12				12				12				12			
13				13				13				13			
14				14				14				14			
15				15				15				15			
16				16				16				16			
17				17				17				17			
18				18				18				18			
19				19				19				19			
20				20				20				20			
Avg.wt.				Avg.wt.				Avg.wt.				Avg.wt.			
Uniformity of Weight				Uniformity of Weight				Uniformity of Weight				Uniformity of Weight			

Note: Net weight = Gross weight – Tare weight

Done by		**Done by**		**Done by**		**Done by**	
Checked By PRD/QA		**Checked By PRD/QA**		**Checked By PRD/QA**		**Checked By PRD/QA**	

Remark:

b). INPROCESS CONTROL DURING FILLING/SEALING 2:

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BPCR No.** NA	**BATCH SIZE**	**PAGE No.** 39 of 41	

(**Frequency:** Initial by both Production/IPQA, After Every **One Hour** by Production and IPQA alternatively and End of the batch)

Date Time				**Date Time**				**Date Time**				**Date Time**			
Tube No.	**Weight (gm)**			**Tube No.**	**Weight (gm)**			**Tube No.**	**Weight (gm)**			**Tube No.**	**Weight (gm)**		
	Gross wt.	**Tare wt.**	**Net wt.**		**Gross wt.**	**Tare wt.**	**Net wt.**		**Gross wt.**	**Tare wt.**	**Net wt.**		**Gross wt.**	**Tare wt.**	**Net wt.**
1				1				1				1			
2				2				2				2			
3				3				3				3			
4				4				4				4			
5				5				5				5			
6				6				6				6			
7				7				7				7			
8				8				8				8			
9				9				9				9			
10				10				10				10			
11				11				11				11			
12				12				12				12			
13				13				13				13			
14				14				14				14			
15				15				15				15			
16				16				16				16			
17				17				17				17			
18				18				18				18			
19				19				19				19			
20				20				20				20			
Avg.wt.				Avg.wt.				Avg.wt.				Avg.wt.			
Uniformity of Weight				Uniformity of Weight				Uniformity of Weight				Uniformity of Weight			

Note: Net weight = Gross weight – Tare weight

Done by		**Done by**		**Done by**		**Done by**	
Checked By PRD/QA		**Checked By PRD/QA**		**Checked By PRD/QA**		**Checked By PRD/QA**	

Remark:

c. INPROCESS CONTROL RECORD DURING FILLING/SEALING:

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BPCR No.** NA	**BATCH SIZE**	**PAGE No.** 40 of 41	

Leak Test record:

(Frequency: Initial by both Production/IPQA, After Every **One Hour** by Production and IPQA alternatively and End of the batch)

Date Time		**Date Time**		**Date Time**		**Date Time**	
Tube No.		Tube No.		Tube No.		Tube No.	
1		1		1		1	
2		2		2		2	
Done by		Done by		Done by		Done by	
Checked By PRD/QA		Checked By PRD/QA		Checked By PRD/QA		Checked By PRD/QA	
Date Time		Date Time		Date Time		Date Time	
Tube No.		Tube No.		Tube No.		Tube No.	
1		1		1		1	
2		2		2		2	
Done by		Done by		Done by		Done by	
Checked By PRD/QA		Checked By PRD/QA		Checked By PRD/QA		Checked By PRD/QA	
Date Time		Date Time		Date Time		Date Time	
Tube No.		Tube No.		Tube No.		Tube No.	
1		1		1		1	
2		2		2		2	
Done by		Done by		Done by		Done by	
Checked By PRD/QA		Checked By PRD/QA		Checked By PRD/QA		Checked By PRD/QA	

Remarks:

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BPCR No.** NA	**BATCH SIZE**	**PAGE No.** 41 of 41	

10. FILLED AND SEALED TUBE RECONCILIATION: (as per Production respective SOP.)

S.No.	Particulars	Results
a.		
b.		
c.		
d.		
e.		
f		
e.		
Calculation Done By Sign/Date (Production)		**Calculation Checked By Sign/Date (IPQA)**

IN – PROCESS OBSERVATIONS (To be filled by IPQA only):

S.No.	Date/ Time	Shift	Observations	Informed To Production (Officer/ Executive)	Observed By QA (Officer/ Executive)	Action Taken By Production (Officer/ Executive)	Verified By QA (Officer/ Executive)

a.VERIFICATION OF BPCR UP-TO FILLING AND SEALING STAGE:

Checked By Sign/Date Production Officer/Executive	Reviewed By Sign/Date IPQA Officer/Executive

D. REVISION HISTORY:

Revision No.	Details of Changes	Reason for Change	Effective Date	Updated By
00	NA	NA		