BATCH PRODUCTION AND CONTROL RECORD									
PRODUCT	PRODUCT COD	E EFFECTIVE DA	TE						
TRIAL BATCH	DD CD N	D A TO CHA NA							
MFR No.	BPCR No.	BATCH No.							
REVISION No.	SUPERSEDE BPCR	No. PAGE No.							
00	NIL	1 of 41							
BATCH MANUFACTURING RECORD									
PRODUCT NAME	: TRIAL BA	TCH FOR PROCESS S	IMULATION/LINE						
	SUITABII	LITY (OINTMENT LIN	NE)						
LABEL CLAIM	: Compositio	n:							
	Linseed Oil	BP	3.00% w/w						
	Methyl Sali	cylate IP	10.00% w/w						
	Menthol IP		5.00% w/w						
	Preservative Benzyl Alco	: hol 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	e) : NA								
BMR ISSUED BY	:								
DATE	•								
	•								
Prepared By	Checked By	Approved By	Authorized By						
Executive QA	Manager Product	ion Head - QA	Head – Operations						
Sign									
Date									
Name									

FORMAT No.:

	BATCH PRODUCTION AND CONTROL RECORD									
]	PRODUCT	EXP. DATE								
	MFR No.	PAGE No.	-							
	NA	2 of 41								
	CONTENTS									
S.No.	Dill of Door Mode	Title			Page No.					
A	Bill of Raw Mate	rials			3					
В	Dispensing				4					
1.1	Operational Che	ecks			5					
1.2	Environmental N	Monitoring			5					
1.3	Calculation				6					
1.4	Line Clearance f	for Dispensing			7					
1.5	Raw Material D	ispensing Record			10					
1.6	Verification of D	ispensed Raw Mate	rials		13					
С	Manufacturing l	Procedure			14					
1.1	Line Clearance	for Manufacturing A	rea		15					
1.2	Environmental N		18							
1.3	Rinse water ana		18							
1.4	Equipment Deta	ils			19					
1.5	Preparation of C	Gel			19					
1.6	Sample Request	for QC Analysis			30					
1.7	Bulk Reconciliat	ion			30					
1.8	In – process Obse	ervations (To be Fille	d by QA only)		31					
1.9	Verification of B	PCR up-to Manufact	uring Stage		31					
2.0	Rinse Water Ana	lysis			32					
3.0	Equipment Detai	ls			32					
4.0	Line Clearance for	or Filling and Sealing			33					
5.0	Environmental M	Ionitoring			35					
6.0	Tubes De-Carton	ing			35					
7.0	Inspection of Em	pty Tubes			35					
8.0	In-Process Check	s During Inspection	of Empty Tubes		36					
9.0	Filling & Sealing	of Tubes			36					
10.0	Filled & sealed to	ibes reconciliation			40					
D	Revision History				41					

BATCH PRODUCTION AND CONTROL RECORD									
P	RODUCT	BATCH No.	MFG. DATE	EXP. DATE					
	RIAL BATCH				_				
N	AFR NO.	BPCR NO.	BATCH SIZE	PAGE NO. $3 \text{ of } 41$					
Δ				5 01 41					
A. BILL OF KAW MATEKIALS:									
S.No.	Material No.	Material	Name.	O.A.	Std. Qty.				
				(%)	(200.0 kg)				
1.		VIRGIN LINSEED	OIL BP	-	6.000 kg				
2.		METHYL SALICY	YLATE IP	-	20.000 kg				
3.		MENTHOL IP		-	10.000 kg				
4.		BENZYL ALCOH	OL IP	-	2.000 kg				
5.		STEARIC ACID II	P	-	1.000 kg				
6.		GLYCERYL MON IP	IOSTEARATE	-	1.000 kg				
7.		PROPYLENE GLY	YCOL IP	-	2.000 kg				
8.		TRIETHANOLAM	IINE BP	-	0.320 Kg				
9.		ACRYPOL -940		-	1.400 kg				
10.		METHYL PARAB	EN IP	-	0.400 kg				
11.		PROPYL PARABI	EN IP	-	0.040 kg				
12.		BUTYLATED HY TOLUENE IP	DROXY	-	0.100 kg				
13.		PURIFIED WATE	R IP/USP	*2%	q.s				

Note: Required Qty.= Std. Qty. +(<u>Std. Qty.x overages</u>) 100

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

]	BATCH PRODUCTION AND CONTROL RECORD							
PRODUCT	BATCH No.	MFG. DATE	EXP. DATE					
TRIAL BATCH								
MFR No.	BPCR No.	BATCH SIZE	PAGE No.					
NA	NA		4 of 41					

B. DISPENSING :

Instructions:

- 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**.

BATCH PRODUCTION AND CONTROL RECORD							
PRODUCT	BATCH No.	MFG. DATE	EXP. DATE				
TRIAL BATCH							
MFR No.	BPCR No.	BATCH SIZE	PAGE No.				
NA	NA		5 of 41				

1.1 OPERATIONAL CHECKS:

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

	BATCH PRODUCTIO	ON AND CONTR	OL RECORD	
PRODUCT	BATCH No.	MFG. DATE	EXP. DATE	
TRIAL BATCH			DA GE N	
MFR No. NA	BPCR No.	BATCH SIZE	PAGE No.	
INA	INA		0 01 41	
1.3 CALCULATION:				
(100-LOD) Potoney –	X Assay			
100 I otency –				
Lab	el Claim x Batch Size			
Qty. Required =				
	Potency			
Calculation Dana By Dr	oduction		Calculation Chas	zad Ry IDAA
Officer / Executiv	ve		Officer / Ex	ecutive
Sign & Date			Sign &	Date

	B	BATCH PRODUCTI	ON AN	D CONTR	ROL RECOR	D	
	PRODUCT BATCH No. MFG. DATE				EXP. DAT	E	
	TRIAL BATCH						
	MFR No.	CH SIZE	PAGE No).			
	NA	NA			7 of 41		
1.4	LINE CLEARANCE	FOR DISPENSING	; :		(Refei	r SOP No.:)
(T	o Be Performed by War	ehouse & Verified by	QA per	sons)			
		LINE CLEARANC	E CHEC	CK LIST –	DISPENSIN	G	
Pre	evious Product			Area			
Bat	tch No.			Date / Ti	me		
							1
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 dist	bensing	area for			
	following details: Proc	luct Name, Batch No.	, Mfg. D	ate, Exp.			
	Date, Batch Size and	ensure that the deta	ails are	matching			
	with the BMR of prese	ent batch to be process	sed				
2.	Check the cleanliness	of the room and ens	ure that	it is free			
	from the remains of the	e previous batch.					
3.	Check the cleanliness	of the RLAF unit and	d ensure	that it is			
4	free from the remains of	of the previous batch.	1.01				
4.	Check and Ensure tha	t the RLAF is switch	ied ON 1	minimum			
	differential across HE	$\Delta filter is within limit$	and the	pressure			
5.	Check the Temperatur	re and Relative Hum	idity (R)	H) of the			
0.	dispensing room (It sh	ould be within specifi	ed range	a), of the			
6.	Check the Calibration	Status of the Weighin	g Balanc	ce.			
7.	Ensure all logbooks of	of the area (RLAF U	Jsage Lo	og Book,			
	Balance Calibration	Log Book, Cleaning	, Log B	look and			
	Environmental Moni	toring Log Book	etc.) a	re filled			
	regularly.						
8.	Inspect the waste bins	and ensure that it is f	free from	n remains			
	of the previous batch.						
9.	Check the availability	of online BMR	0.0.1	. 1			
10.	Check the approval of Approval I abala at	or Raw Materials fro	m QC b	by pasted			
11	Approved Labels on co	ontainers.	iala by I	tom anda			
11.	$\& \Delta R$ No to be used	are as per RMP	iais by I	tem code			
12	Check and Ensure the	dispensed Raw Mate	rials are	kept in a			
	separate SS trollev wit	h proper status label.	iiuis uiv	rt in u			
13.	Check and Ensure the	Liquid Raw Material	s are dis	pensed in			
	clean SS container wi	th proper status label	uid Raw				
	Material is in BOM)						
14	Ensure proper cleaning	g of filters of RLAF,					
1-	Returned Riser and gri	ll of filters.					
15	Check and Ensure th	e availability of Cle	eaned D	ispensing			
►T.	100ls	not Ameliashi					
INC	Jue: write INA Where	not Applicable					

	BATCH PRODUCT	ION AND CONTR	UL KECOKD	
PRODUCT	BATCH No.	MFG. DATE	EXP. DATE	
TRIAL BATCH			DAGEN	
MFR No.	BPCR No.	BATCH SIZE	PAGE No.	
NA After seventeter	INA		8 0I 41	1
After complete t	mecking as per check	list QA Olicei/Exe	cutive shall give the m	
area by signing o	on 'Line Clearance Lab	pel'		
Shookod By Sign / Doto		Line Cleare	ngo Ciyon By Sign / D	oto
Warehouse Officer/Exec	cutive)	(QA Officer/	Executive)	ate

	BATCH PRODUCTI	ON AND CONTR	OL RECORD						
PRODUCT TRIAL BATCH	BATCH No.	MFG. DATE	EXP. DATE						
MFR No.	BPCR No.	BATCH SIZE	PAGE No.						
<u>NA</u>	<u>NA</u>		9 of 41						
AFFIX DISPENSING AREA LINE CLEARANCE LABEL									

	BATCH PRODUCTION AND CONTROL RECORD										
	PRODUCT		BA	ТСН	No.	MFG. D	ATE	EXP. DA	TE		
	TRIAL BATC	Ж									
	MFR No.		BI	PCR N	No.	BATCH	SIZE	PAGE N	No.		
	NA			NA				10 of 4	1		
1.5	RAW MATE	RIAL I	DISPEN	ISING	G RECO	RD:					
S.No	. Material Name	Material No.	Std. Qty. (200 kg)	O.A. (%)	Issued Qty. (Kg)	A.R. No.	Gross W	t. 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.	Triethanolamin e 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	Raw Material Dispensing	Dispensed By	Checked By	Verified By
Dispensing Started at	Completed at	(Operators)	(Warehouse Officer/Executive)	(QA Officer/Executive)
(Date/ Time)	(Date/ Time)	(Sign & Date)	(Sign & Date)	(Sign & Date)

	BATCH PRODUCTI	ON AND CONTR	OL RECORD	
PRODUCT TRIAL BATCH	BATCH No.	MFG. DATE	EXP. DATE	
MFR No.	BPCR No.	BATCH SIZE	PAGE No.	
NA	NA		11 of 41	
Al	FFIX THE RAW MA	TERIALS DISPEN	ISING LABELS	

	BATCH PRODUCT	ION AND CONTR	OL RECORD	
PRODUCT TRIAL BATCH	BATCH No.	MFG. DATE	EXP. DATE	
MFR No.	BPCR No.	BATCH SIZE	PAGE No.	
NA	NA		12 of 41	
А	FFIX THE RAW MA	TERIALS DISPEN	NSING LABELS	

		DA	BATCH PRODUCTION AND CONTROL RECORD							
	PRODUCT		BATCH	H No.	MFG. DATE	EXP	. DAT	E		
	TRIAL BATCH	[
	MFR No.		BPCR	No.	BATCH SIZE	E PA	GE No.	•		
1 (13	of 41			
1.0	VERIFICATIO	JN OF D	ISPENSI	ED KAW	VIATERIALS					
Γ)	To Be Performed a	at Manufa	acturing A	Area)						
l.Ba	alance ID No.:	•••••			Calibration Sta	tus (Ok/N	ot Ok):			_
2.Ba	alance ID No.:				Calibration Sta	tus (Ok/N	ot Ok):			_
S. No.	Material Name	Material No.	Std. Qty. (200 kg)	Issued Qty.	A. R. No.	Gross Weight	Units	Cho Sig	ecked By gn/Date	Verified By Sign/Date
1.	Linseed Oil BP		6.000	(Kg)			kg	(11)	buuction)	
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			

BATCH PRODUCTION AND CONTROL RECORD						
PRODUCT	BATCH No.	MFG. DATE	EXP. DATE			
TRIAL BATCH						
MFR No.	BPCR No.	BATCH SIZE	PAGE No.			
NA	NA		14 of 41			

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									
PRODUCT	BATCH No.	MFG	. DATE	EXP. DA	TE				
TRIAL BATCH									
MFR No.	BPCR No.	BATC	H SIZE	PAGE N	No.				
NA	NA			15 of 4	1				
MANUFACTURING A	REA:								
1.1 LINE CLEARANC Previous Product	E FOR MANUFACT	URING .	AREA: Batch No	(Refer	SOP No.:)			
Area			Date / Ti	me					
S. Check Points Status Done By Checked By									
No. (OK / Not Sign/Date Sign/Date									
OK) (Production) (IPOA)									

		UK)	(Production)	(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 PRODUCTIO	ON AND CONTR	OL RECO	RD	
	PRODUCT	BATCH No.	MFG. DATE	EXP. DA	ТЕ	
	MFR No.	BPCR No.	BATCH SIZE	PAGE	No.	
	NA NA	NA	D ATCH SIZE	16 of 4	1	
S.		Check Points		Status	Done By	Checked By
No.				(OK / Not	Sign/Date	Sign/Date
11	Chaolt the Cleanin	a and Calibration Sta	tug of Waighing	OK)	(Productio	n) (IPQA)
11.	Balance.	ig and Canoration Sta	tus of weighing			
12.	Check and Verify Raw Material with	the Item Code and Wei BMR.	ght of Dispensed			
13.	Check the BMR is	filled up to Dispensing	Stage.			
Check (Prod.	xed By Sign / Date _ . Officer/Executive)	I ((Line Clearance Gi QA Officer/Exect	iven By Sign ıtive)	n / Date	

	BATCH PRODUCTI	ON AND CONTR	OL RECORD	
PRODUCT	BATCH No.	MFG. DATE	EXP. DATE	
MFR No.	BPCR No.	BATCH SIZE	PAGE No.	
NA	NA		17 of 41	
AFFIX	MANUFACTURING	G AREA LINE CI	LEARANCE LAB	EL

	BATCH PRODUCTION AND CONTROL RECORD									
PROI	DUCT	BATCH No.		MFG.	DATE	EXP.	DATE			
TRIAL	BATCH									
MFR	No.	BPCR No.]	BATC	H SIZE	PAG	E No.			
N	A	NA				18 c	of 41			
1.2 ENVIR	ONMENTA	L MONITORING	G: At th	ne time	of start of	Manufa	cturing, Ini	tial/End and	after	
every 4	Hour and A	fter Every Breakd	own.				-			
Date/Time	Room No./Name	Dry Bulb Temp. (°C) Limit (25°C)	Wet Temp	et Bulb np. (°C) % RH Limit (NMT 55%) Done By Sign/Date (Operator)		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 Recei	ving the Analysis Rep	port from QC, fill the A	.R. No	

The receiving the rmarysis report from Qe, in the rait.

The Equipment Release / Not Release for Manufacturing.

QA Officer/Executive Sign _____ Date _____ Time _____

BATCH PRODUCTION AND CONTROL RECORD									
PRODUCT	BATCH	No. M	FG. DATE	EXP. DA	ATE				
TRIAL BATC	H								
MFR No.	BPCR N	Io. BA	BATCH SIZE PAGE No.		No.				
NA	NA			19 of 4	41				
1.4 EQUIPMEN	.4 EQUIPMENT DETAILS:								
Name of Equipment	Name of Equipment Equipment Previous Ratch No Cleanliness Checked by Sign/Data Sign/Data								

Name of Equipment	Equipment ID No.	Previous Product	Batch No.	Cleanliness (OK/Not OK)	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								
PRODUCT	BATCH No.	MFG. DATE	EXP. DATE						
TRIAL BATCH									
MFR No.	BPCR No.	BATCH SIZE	PAGE No.						
NA	NA		20 of 41						

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^oC) 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	Proces	ss Time	Acceptance	Observation	Production	QA
	Variables	From	То	Criteria			
Water Phase	Heating Temperature			NA			
(Dispersion of	Homogenizer Speed			2800 RPM			
Acrypol 940)	Anchor I			OFF			
Addition	Mixing Time			20 Minutes			
executed with Open Lid	Sieve used			18#			
Open Liu	Sieve integrity –			Should be			
	Before Sifting			integral			
	Sieve integrity – After			Should be			
	Sifting			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	Process Time		Acceptance	Observation	Production	QA
	Variables	From	То	Criteria			
Mixing of	Heating Temperature			NA			
water	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 Process T		ss Time	Acceptance	Observation	Production	QA
	Variables	From	То	Criteria			
Mixing of	Heating			NA			
Acrypol in	Temperature						
water	Homogenizer			2800 RPM			
	Speed						
	Anchor I			30 RPM			
	Mixing Time			10 Minutes			

FORMAT No.:

	BATCH PRODUCTION AND CONTROL RECORD								
PRODUCT	BATCH No.	MFG. DATE	EXP. DATE						
TRIAL BATCH									
MFR No.	BPCR No.	BATCH SIZE	PAGE No.						
NA	NA		21 of 41						

e) Observe the lumps if any and clarity of solution

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

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

Stage	Process	Process Time		Acceptance	Observation	Production	QA
	Variables	From	То	Criteria			
Mixing of	Heating Temperature			NA			
Acrypol in water	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	То				
Clarity of	Observe the			Clear, no			
Acrypol 940	clarity			Lump			
solution				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	То				
Lump	NΔ			No lump			
Breaking				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

]	BATCH F	PRODU	CTION	AND CONTRO	DL RECORD		
PROE	DUCT	BATCH N		MFG. DATE		EXP. DATE		
TRIAL	BATCH							
MFR	No.	BPC	CR No.	B	ATCH SIZE	PAGE No.		
NA	4	1	NA			22 of 41		
Stage	Proce	Process		ss Time	Acceptance	Observation	Production	QA
	Varia	bles	From	То	Criteria			
Mixing	Heating Tem	perature			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/cm². 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	Proces	ss Time	Acceptance	Observation	Production	QA
	Variables	From	То	Criteria			
Heating	Heating			Set Temp 60°C			
	Temperature			Acceptance			
				Criteria			
				Product temp			
				70 °C+/- 2°C			
	Anchor I			10 RPM			
	Mixing Time	1		30 Minutes			
	Steam Pressure	1		$2.0 - 2.5 \text{ kg/cm}^2$			

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/cm². Once PLC indicated 70°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.

	BATCH PRODUCTION AND CONTROL RECORD										
PRO	PRODUCT BAT		CH No.		M	FG. DATE	EXP. DATE				
TRIA	L BATCH							_			
MF	'R No.	BPC	CR No.		BA	TCH SIZE	PAGE No.				
]	NA]	NA				23 of 41	-			
Stage	Proces	S	Process Tim		ie	Acceptance	Observation	Production	QA		
	Variabl	les	From	To)	Criteria					
						Set Temp 45°C					
						Acceptance					
	Heating Tempe	rature				Criteria Product					
Heating						temp 70 °C+/-					
g	Melting Time					2°C					
						NMT 15 min					
	Steam Pressure					2.0 - 2.5 kg/cm	2				
	Time required f MP,PP,BHT to	for 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°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	Proc	ess	Proces	ss Time	Acceptance	Observation	Production	QA
	Varia	bles	From	То	Criteria			
Emulsification		Before			Should be			
	Integrity	Use			integral			
Addition of	of Sieve	After			Should be			
Oil Phase to		Use			integral			
Water Phase	Mesh Size				100#			
	Product Temperature				Set at PLC 70			
					°C			
					Actual product			
					temp 70 °C \pm			
					2°C			
					Set 300 – 400			
	vacuum				mm of Hg			
	Transfer Ti	me			2 minutes $(1-3)$			
					Minutes)			
	Anchor I S	peed			30 RPM			
	Rinsing wi	th 2 kg			2 minutes $(1-3)$			
	water X 3 t	imes			Minutes)			
	Mixing Time				10 Minutes			
	Homogeniz Speed	zer			OFF			

BATCH PRODUCTION AND CONTROL RECORD							
PRODUCT	BATCH No.	MFG. DATE	EXP. DATE				
TRIAL BATCH							
MFR No.	BPCR No.	BATCH SIZE	PAGE No.				
NA	NA		24 of 41				

b) Emulsion Homogenization:

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

Stage	Process	Proces	ss Time	Acceptance	observation	Production	QA
	Variables	From	То	Criteria			
	Heating			Set at PLC			
Emulsion	Temperature			70 °C +/- 2°C			
Homogenization	Homogenizer			2800 rpm			
	Speed						
	Anchor Speed			30 RPM			
	Mixing Time			4 Minutes			
	Steam Pressure			$2.0 - 2.5 \text{ kg/cm}^2$			
	Vacuum			300-400 mm of Hg			
	Actual product	1		$70 \degree C \pm 2\degree C$			
	temp						

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° C to $40\pm2^{\circ}$ C. As Product Temperature reduces to $40\pm2^{\circ}$ C release the vacuum completely.

Stage	Process Pro		ss Time	Acceptance	Observation	Production	QA
	Variables	From	То	Criteria			
Cooling	Soft water			Approx. 20			
	Circulation Time			Minutes			
	Anchor Speed	hor Speed		30 RPM			
Mixing Time			20 Minutes				
	Applied Vacuum			300 – 400 mm of Hg			
	Product			$40 \pm 2^{\circ}C$			
	Temperature						

BATCH PRODUCTION AND CONTROL RECORD								
PRODUCT	BATCH No.	MFG. DATE	EXP. DATE					
TRIAL BATCH								
MFR No.	BPCR No.	BATCH SIZE	PAGE No.					
NA	NA		25 of 41					

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	Proces	ss Time	Acceptance	observation Production	QA	
	Variables	From	То	Criteria			
Triethanolamine	Monual Mixing			Clear solution			
solution							
Preparation							

 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±2⁰C).

Continue mixing with stirrer at Anchor I at 30 rpm with homogenizer at 2800 rpm, product temp. 40 ± 2^{0} C for 3 minutes.

Stage	Process	Process Tin		Acceptance	Observation	Production	QA
	Variables	From	То	Criteria			
	Addition Started at			1 to 2 min			
Addition of	Addition						
Triethanolamine	Completed At						
to Manufacturing	Product			$40^{\circ}C \pm 2^{\circ}C$			
Tank along with	Temperature						
Rinsing	Anchor Speed			30 RPM			
	Homoginization			2800 rpm			
	Speed						
	Continued			3 min			
	Homoginization						
	and Mixing Time						

BATCH PRODUCTION AND CONTROL RECORD							
PRODUCT	BATCH No.	MFG. DATE	EXP. DATE				
TRIAL BATCH							
MFR No.	BPCR No.	BATCH SIZE	PAGE No.				
NA	NA		26 of 41				

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	Proce	ss Time	Acceptance	Observation	Production	QA
	Variables	From	То	Criteria			
Preparation of	Mixing Time			60 Minutes			
Menthol, Methyl	with stirrer						
Salicylate, Benzyl	Solution			Clear	-		
alcohol	description						

b) Warming & addition of linseed Oil in Gel:

Warm Linseed oil (____ Kg) (*Warmed to 40^{0} C) 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^{0} C using vacuum.

Stage	Pro	ocess	Proces	ss Time	Acceptance	Observation	Production	QA
	Var	iables	From	То	Criteria			
Warming of Linseed oil	Warming Temperature				40 °C			
Addition of Linseed Oil	Applied Vacuum				300 – 400 mm of Hg			
to Gel of Multi-mixer	Integrity	Before Use			Should be integral			
	of Sieve	After Use			Should be integral			
	Mesh Size				100#			
	Product T	emperature			40±2°C			
	Ancho	r Speed			30 RPM			
	Homogenization Speed Homogenization Time				2800 rpm			
					3 min			
	Mixin	g Time			5 min			

	BATCH PRODUCTION AND CONTROL RECORD							
PRODUCT	PRODUCTBATCH No.MFG. DATEEXP. DATE							
TRIAL BATCH	TRIAL BATCH							
MFR No.	BPCR No.	BATCH SIZE	PAGE No.					
NA	NA		27 of 41					

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. $40\pm2^{\circ}$ C using vacuum.

Stage	Proc	Process		ss Time	Acceptance	Observation	Production	QA
	Varia	ables	From	То	Criteria			
Addition of	Applied	Applied Vacuum			300 - 400 mm			
Menthol,	Applied Vacuum				of Hg			
Methyl	Before				Should be			
Salicylate and	Integrity	IntegrityUseof SieveAfter			integral			
Benzyl Alcohol	of Sieve				Should be			
Solution	Use Mesh Size Product Temperature				integral			
					100#			
					40±2°C			
	Anchor	Speed			30 RPM			
	Homoginization Speed Transfer time				2800 rpm			
					Approx. 20 min.			

		BATCH PI	RODU	CTION	AND CO	NTRO	L RECORD		
PRO	DUCT	BATC	CH No.	N	IFG. DAT	E	EXP. DATE		
TRIA ME	BATCH B No	BPC	R No	B	ATCH SI	ZE	PAGE No		
	NA	N	A	D			28 of 41		
STEP-7 FI	NAL MIXI	NG OF BULK	:	ľ					
a) 1	Mix bulk b min.	y using Ancho	r at 30	rpm for	10 minute	es along	g with homoger	nizer at 2800 :	rpm for 5
Stage	Pr	ocess	Proces	ss Time	Accept	ance	Observation	Production	QA
	Va	riables	From	То	Crite	eria			
Final	Product	Temperature			$40^{\circ}C \pm 2$	2°C			
Bulk	Anch	or Speed			30 RPM	[
Mixing	Mixi	ng Time			10 min				
	Homogen	ization Speed			2800 rpi	n			
	Homogen	ization Time			5 min				
Stage	Hold the bui	k aside for at le Process Variables	east one Proces	e hour to ss Time	see that the Accep	nere is n otance ceria	o separation of Observation	oil layer Production	QA
			From	То					
Holding Ti	me Oil	Separation			No Sepa	aration			
	Time	;			60 min				
c) I	Final bulk to	be checked fo	r pH be	tween 5.	.5 – 7 . 5.				
Process Start	t Time / Date	Process Comple	eted Tim	ne / Date	Checked By (Sign/ Date) (Production)			Verified By (Sign / Date) (IPQA)	
Label use be analys	the storage efore, Batch sis.	tanks with prop	ber iden 8 Intima	tification ate quali	n w.r.t. Pro ty control	oduct N departi	ame, Batch No. nent to arrange	Mfg Date, collect the sa	ample for
> After	completion	of mixing send	l 150 gr	n of bull	to QC de	epartme	nt for analysis.		
1.6 SAMI	PLE REQU	UEST FOR Q	C ANA	LYSIS:					
a. Se	and Test Rec	uest Form to I	PQA for	r Sampli	ng.				
b. Af	fter Samplin	g, IPQA shall s	send the	Sample	along-wit	th Intim	ation to QC for	Analysis.	
Intimation N	No. Sig	ntimated By gn/Date/Time Production)		nation Re Sign/Date (IPQA	cceived By /Time A)	Qu	antity Sampled	Sample Sign/Dat (IPQ	ed By e/Time A)

]	BATCH PRODUCT	ION A	ND CONTR	OL RECORD						
	PRODUCT	BATCH No.	MF	G. DATE	EXP. DATE						
	TRIAL BATCH					_					
	MFR No.	BPCR No.	BA	FCH SIZE	PAGE No.						
	NA	NA			29 of 41						
c. A	After receiving the A	nalysis Report from Q	C, fill	the A. R. No.	·	_					
d. T	The Gel is Release / N	Not Release for Filling									
Ç	A Officer/Executiv	ve Sign	D	ate	Time						
1.7 E	.7 BULK RECONCILIATION:										
S.No.	I	Particulars			Results	5					
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			$\frac{(c+d) x}{a}$	100 =	<u>X 100</u>					
					%.						
	Calculati Sign/Date	on Done By (Production)		Calculation Checked By Sign/Date (IPQA)							

]	BATCH	PRODU	CTION A	ND CONTR	OL RECORD)	
	PROI	DUCT	Ŧ	BA	ГСН №.	MF	G. DATE	G. DATE EXP. DATE		
	TRIAL MER	BATCH	1	RP	CR No	BAT	CH SIZE	PACE No		
	NA			NA			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 Take By Productio (Officer/ Executive)	n 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

		BATCH PF	RODUCTIO	ON AND CO	ONTR	OL REC	ORD			
PRODUC	CT	BATC	CH No.	MFG. DA	TE	EXP. I	DATE			
IRIAL BAICH MFR No		BPCI	2 No	BATCH S	IZE	PAGE	E No			
NA	•	N.	A	brichs		31 of	f 41			
2.0 RINSE	WATER	R ANALYSI	S:							
In case of	Туре В с	cleaning Pro	duction De	partment sh	all giv	e the Inti	mation to	QA f	for Rinse Water	
sampling. A	sampling. After Sampling, QA shall send the Sample along-with Intimation to QC for Analysis.									
	Intin	nated By	Intimation	Received By					Sampled By	
Intimation No.	Sign / 1 (Pro	Date / Time duction)	Sign / Da	ate / Time (A)	Q	Quantity Sa	mpled	Si	gn/ Date / Time (QA)	
After Recei	ving the A	Analysis Rep	oort from Q	C, fill the A.	R. No					
The Equipn	nent Rele	ase / Not Re	lease for Fil	lling.						
OA Officer	r/Executi	ve Sign		Date		Tir	ne			
30 EOUPME	NT DET	AILS								
Name of Fauj	nment	ID No	Previo	ous Product	R	atch No	Checker	d hv	Verified by	
Name of Equi	pinent	ID. 140.	ITEVIC	Jus I I Juuci			Sign/D	ate	Sign/Date	
	2 1'						(Product	tion)	(QA)	
Machine	Sealing									
Conveyer Belt										
Weighing Balan	ce									
Shrink Machine										
Weighing Balan	ce									
									II	

BATCH PRODUCTION AND CONTROL RECORD											
	PRODUCT	BATCH No.	MFG. DA	TE	EXP. DA	ГЕ					
	TRIAL BATCH										
	MFR No.	BPCR No.	No. BATCH SIZE		PAGE N	0.					
4.0	LINE CLEARAN	CE FOR FILLING AN	D SEALIN	G:	(Refer S	SOP No.:)				
((To Be Performed By Production person and Varified by IDOA Derson)										
(10 be renormed by rioduction person and vermed by if QA Person)											
Dravious Draduat Datab Na											
Previ	lous Product			Batc	n 1 NO .						
Area				Date	/ Time						
					G ()						
S.		Check Points			Status	Done by	Checked by				
190.						Production	OA				
1.	Check the Area	is Visually Clean and	Dust		Troduction						
	Particles and Ens	sure that there are no I	Previous Pro	oduct							
	Materials/Unwante	ed Materials.									
2.	Ensure the "Statu	s Board" of the area is	Neatly and	Duly							
	written with Batc	ch Coding Details as p	ed in								
	BMR like Produc	ct Name, Batch No., E	Mfg.								
2	Date, Exp Date.										
5.	Respective Cleani	ng SOP	is done as	per							
4.	Ensure the Filling	g Line is Free From an	v remains o	f the							
	Previous Product.	,	<i>, , , , , , , , , ,</i>								
5.	Ensure the Du	ly Labeled Container	s for No	n –							
	Recoverable Reject	cts are properly cleaned.									
6.	Ensure the Waste	Bins are properly Clean	ed and Plac	ed in							
	Proper Place.	1 1	DII								
7.	Check and Ens	ure that the Temper	ature, RH	and							
	L imit as per menti	oned in BMR	in the spec	inea							
8.	Check and Ensur	e that the Machine Lo	gbook. Clea	ning							
	Logbook, and E	nvironmental Monitorir	ig Logbook	are							
	filled correctly.										
9.	Ensure the cleanin	ng of Return Air Riser; i	t should be	clean							
	and free from rema	ains of the previous prod	luct.								
10.	Check the proper S	Status Labeling on the M	lachines.	1							
11.	from Quality Cart	that the Wash Water/Sw	ab are relea	sed							
12	Check and Ensure	that the Rulk Cream is I	viui DIVIK. Release from								
12.	Quality Control ar	d Released Report attac	hed with BN	íR							
L	Control un				I	1	I				
Note	e: Write 'NA' who	ere Not Applicable									
	After complete o	checking as per checklis	t OA Office	r/Exec	cutive shall of	ive the Line C	learance 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	BATCH No.	MFG. DATE	EXP. DATE					
TRIAL BATCH								
MFR No.	BPCR No.	BATCH SIZE	PAGE No.					
NA NA SALATION DIFFICULTURE 11102 1001 NA 33 of 41								

Affix the Line Clearance Label for Filling and Sealing Area

BATCH PRODUCTION AND CONTROL RECORD									
PRODUCTBATCH No.MFG. DATEEXP. DATE									
TRIAL BATCH									
MFR No.	BPCR No.	BATCH SIZE	PAGE No.						
NA	NA		34 of 41						

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	Checked By Production	Verified By QA
					Sign & Date	Sign & Date	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		Optica	Quantity	Checked By		
		Checked	Printing	Colored	White	Cracks/Dents	Passed	Production / QA
				Particles	Particles			

	BATCH PRODUCTION AND CONTROL RECORD									
PRODUCT	BATCH No.	MFG. DATE	EXP. DATE							
TRIAL BATCH										
MFR No.	BPCR No.	BATCH SIZE	PAGE No.							
NA	NA		35 of 41							

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)

	BATC	CH PRODUCTIO	ON AND CONTR	OL RECORD					
PRODUCT]	BATCH No.	MFG. DATE	EXP. DATE					
TRIAL BATCH									
MFR No.		BPCR No.	BATCH SIZE	PAGE No.					
NA		NA		36 of 41					
9.3 MACHINE SE	TTINC	FPARAMETER	S:						
Filling Parameters			Settings Ro	equired					
Fill Weight	30 + 0.	5 g							
Targeted Fill Weight	NLT 3	0 g							
Weight of Empty Tube/Container (Min. 20 Nos)	,	,,	,,,,	· , , ,	,,,,				
Avg. Wt. of Empty Tube	•••••	g							
Wt.Variation of Empty	$\frac{\min \text{ wt. of empty tube } - \text{ Avg.wt of empty tube}}{\text{Avg.wt of empty tube}} X \ 100 = \dots \%$								
(Limit NMT 5.0%)	max w	t.of empty tube – A Avg.wt of en	vg.wt of empty tube	X 100 =	%				
Crimp sealing Temperature									
Batch No. on sealed crimp									
Crimp sealing height (mm)								
Height after filling and sea	ling								
Air Pressure									
Crimp sealing Temper	ature	Set temp	perature	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 sea crimp	aled								
Machine Speed (80-120 tubes/minute) Targeted Machine Speed (100 tubes/minute)			Machine Speed (30-60tubes/minute Targeted Machine (40 tubes/minute)	e) Speed					

9.4 INITIAL FILLING/SEALING RECORD:

	BATCH PRODUCTION AND CONTROL RECORD											
PRODU	CT BATCH No. M			M	FG. DATE	EXP. DATE						
TRIAL BA	ATCH DDGD N			D 4		D. CE M	-					
	o. BPC		K NO.	BA	TCH SIZE	PAGE No.						
NA	7	N N	A			3/ of 41		•				
By Pro	oduction (Dfficer/Exe	cutive			By QA Officer/Ex	xecut	ive				
Tube No.	Fill V	Veight	Leak Tes	t	Tube No.	Fill Weight		Leak Test				
	(Limit: 30	+0.5 gm)	(Ok/Not O	K)		(Limit: $30 + 0.5$	ogm)	(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	7						

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

]	BATCH	I PRC	DUC	TIO	N AND	CON	FROL	RECO	RD			
P	RODI	JCT		BA	АТСН	No.		MFG. I	DATE	E	XP. DA	TE			
TF	RIAL B	ATCH	ł												
N	AFR N	lo.		BPCR No. E		BATCH	SIZE	E I	PAGE N	lo.					
	NA NA 38 of 41								1						
	(Frequency: Initial by both Production/IPQA, After Every One Hour by Production and IPQA														
ć	alternatively and End of the batch)														
Date				Date				Date				Date			
Time				Time				Time				Time			
Tubo	We	eight (g	gm)	Tubo	We	eight (g	(m)	Tubo	V	Veight (gm)	Tubo	W	/eight (g	m)
No.	Gross wt.	Tare wt.	Net wt.	No.	Gross wt.	Tare wt.	Net wf.	No.	Gross wt.	Tare wt.	Net wt.	No.	Gross wt.	Tare wt.	Net wf.
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.	r		
of Weight				of Weight				of Weight				of Weight			

Done byDone byDone byDone byChecked
By
PRD/QAChecked
By
PRD/QAChecked
By
PRD/QAChecked
By
PRD/QA

Remark:

b). INPROCESS CONTROL DURING FILLING/SEALING 2:

				BATCH	I PRC	DUC	TIO	N AND	CON	FROL	RECO	RD			
P	RODI	JCT		BA	АТСН	[No.		MFG. I	DATE	E	XP. DA	ТЕ			
TF	RIAL B	ATCH	I												
Ν	AFR N	No.		B	PCR I	No.		BATCH SIZE PAGE No		l o.					
	NA				NA						39 of 4	1			
(Fre	quenc	y: Init	tial by End (both Pr	oduct	ion/IP	QA, A	After Ev	ery O	ne Hou	r by Pro	oductior	and I	PQA	
		ly and	Linu (D (1			D (1		
Date Time				Date Time				Date Time				Date Time			
Tube	We	eight (g	gm)	Tube	We	eight (g	m)	Tube	V	Veight (g	gm)	Tube	W	/eight (g	m)
No.	Gross wt.	Tare wt.	Net wt.	No.	Gross wt.	Tare wt.	Net wt.	No.	Gross wt.	Tare wt.	Net wt.	No.	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	r		

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 PRODU	CTION AND CONT	ROL RECORD	
PRODUCT	BATCH No.	MFG. DATE	EXP. DATE	
TRIAL BATO	СН			
MFR No.	BPCR No.	BATCH SIZE	PAGE No.	
NA	NA	Diffender	40 of 41	
Look Tost moo	and		40 01 41	
Leak Test rec	oru:			
(Frequency: Initial by	both Production/IPQA, After H	Every One Hour by Produ	ction and IPQA alternativ	vely and End of the bate
Date	Date	Date	Date	
Time	Time	Time	Time	
Tube	Tube	Tube	Tube	
No.	No.	No.	No.	
1	1	1	1	
2		2	2	
	Done	- L Done		+
by	by	by	by	
Checked	Checked	Checked	Checker	d
By	By	By	By	
PRD/QA	PRD/QA	PRD/QA	PRD/QA	A
Date	Date	Date	Date	
Time	Time	Time	Time	
Tube	Tube	Tube	Tube	
No.	No.	No.	No.	
1	1	1	1	
2	2	2	2	
Done	Done	Done	Done	
by	by	by	by	
Checked	Checked	Checked	Checke	d
By	By	By	By	
PRD/QA	PRD/QA	PRD/QA	PRD/QA	A
Date	Date	Date	Date	
Time	Time	Time	Time	
Tube	Tube	Tube	Tube	
No.	No.	No.	No.	
1	1	1	1	
2	2	2	2	
Done	Done	Done	Done	
by	by	by	by	
Checked	Checked	Checked	Checke	d
Ву	Ву	Ву	By	
PRD/QA	PRD/QA	PRD/QA	PRD/QA	A

Remarks:

		BATCH PRODUCTI	ON A	ND CONTR	OL RECORD				
P	RODUCT	BATCH No.	MF	G. DATE	EXP. DATE				
]	MFR No.	BPCR No.	BAT	ATCH SIZE PAGE No.					
10. FI	LLED AND SEA	LED TUBE RECONC	CILIA	TION: (as p	er Production res	pective SOP.)			
S.No.		Particulars			Results				
a.									
b.									
с.									
d.									
e.									
f									
e.									
	Calculati Sign/Date	on Done By (Production)		Calculation Ch Sign/Date (I	ecked By PQA)				

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

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