BATCH PRODUCTION AND CONTROL RECORD								
PRODUCT NAME	PRODUCT NAME PRODUCT CODE EFFECTIVE DATE							
Placebo Batch (for Vitamin								
D3 60,000 IU) for								
equipment Qualification								
MFR No.	BMR No.	BATCH No.						
REVISION No.	SUPERSEDE BMR No.	PAGE No.						
00	NIL	1 of 45						

BATCH MANUFACTURING RECORD

PRODUCT NAME : Placebo Batch (for Vitamin D3 60,000 IU) for

Equipment Qualification

GENERIC NAME :

LABEL CLAIM : Each Soft Gelatin Capsule contains:

Placebo (except Cholecalciferol (Vitamin D₃) IP 60,000 IU)

Methyl Paraben IP & Propyl Paraben IP used as

preservatives

Colour: Approved colors used in gelatin shell.

STRENGTH :

MFG. LIC. No.

STANDARD BATCH SIZE : 1,00,000 Capsules **ACTUAL BATCH SIZE** : 1,00,000 Capsules

PACK SIZE :

MANUFACTURING DATE :

EXPIRY DATE :

SHELF LIFE : 24 Months

BLOCK/PRODUCTION LINE

MARKET : Not for sale for Equipment Qualification

DATE OF COMMENCEMENT :

DATE OF COMPLETION :

BATCH YIELD (%) : PRODUCT OF (Company Name) :

BMR ISSUED BY (QA) : DATE :

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

FORMAT No.:

	BATCH PRODUCTION AND CONTROL RECORD						
PRODUCT NAME BATCH No. MFG. DATE EXP. DATE							
Placebo Batch (for							
Vitamin D3 60,000							
IU) for equipment							
Qualification							
MFR No.	BMR No.	BATCH SIZE	PAGE No.				
			2 of 45				

1.0 DISPENSING:

Instructions:

- 1. During process check environmental conditions to be within limits (i.e. Temp. NMT 25°C & RH 30-55%) and record in environment monitoring record at the time of start of dispensing, after every one hour and after every breakdown.
- 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
- 4. Take Line clearance from QA before starting the Dispensing Activity.
- 5. Dispense the material as per the Bill of material.
- 6. All Analytical Weighing Balance shall be calibrated.
- 7. Take raw materials to dispensing area and weight the first excipients and active ingredients in double polyethylene bags under RLAF by operating the RLAF.

1.1 OPERATIONAL CHECKS:

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

FORMAT No.:		
-------------	--	--

	BATCH PRODUCTION AND CONTROL RECORD					
PRODUCT NAME BATCH No. MFG. DATE EXP. DATE						
Placebo Batch (for						
Vitamin D3 60,000						
IU) for equipment						
Qualification						
MFR No.	BMR No.	BATCH SIZE	PAGE No.			
			3 of 45			

1.2 ENVIRONMENTAL MONITORING: (FOR DISPENSING OF ACTIVE PHARMACEUTICALS INGREDIENTS)

At the time of start of Dispensing, after every one hour and after every breakdown.

Date/ Time (Hrs.)	Room No. /Name	Temp. (°C) Limit (NMT 25°C)	% RH Limit (30 to 55 %)	Done By Warehouse Sign/Date	Checked By QA Sign/Date	Remarks

1.3 ENVIRONMENTAL MONITORING: (FOR DISPENSING OF EXCIPIENTS)

At the time of start of Dispensing, after every one hour and after every breakdown.

Date/ Time (Hrs.)	Room No. /Name	Temp. (°C) Limit (NMT 25°C)	% RH Limit (30 to 55 %)	Done By Warehouse Sign/Date	Checked By QA Sign/Date	Remarks

FORMAT No.:

BATCH PRODUCTION AND CONTROL RECORD							
PRODUCT NAME BATCH No. MFG. DATE EXP. DATE							
Placebo Batch (for							
Vitamin D3 60,000							
IU) for equipment							
Qualification							
MFR No. BMR No. BATCH SIZE PAGE No.							
			4 of 45				

1.4 LINE CLEARANCE FOR DISPENSING: FOR ACTIVE PHARMACEUTICALS INGREDIENTS

(To be performed by Warehouse Officer/Executive & QA Officer/Executive)

LINE CLEARANCE CHECK LIST – DISPENSING

Pre	evious Product		I	Area		
Bat	tch No.		Date / T	ime (Hrs.)		
S. No.		Check Points		Status (OK / Not OK)	Done By (Warehouse Officer/Exe.) Sign/Date	Checked By (QA Officer/Exec) Sign/Date
1.	details: Product	us Board " of the dispensing area for for Name, Batch No., Mfg. Date, Exp. Dat that the details are matching with the be processed.	e, Batch			
2.		liness of the room and ensure that it is far previous batch.	ree from			
3.		liness of the RLAF Unit and ensure that nains of the previous batch.	that it is			
4.	Check and ensur 30 minutes bet	re that the RLAF is switched "ON" ne fore start of the activity and the set HEPA filter is within limit.				
5.	Check the Tem Dispensing Roor	perature and Relative Humidity (RH m (It should be within specified range).) of the			
7.	Ensure all logboo Balance Calibrat	ne Calibration Status of the balance. Ill logbooks of the area (RLAF Usage Log Book, Calibration Log Book, Cleaning Log Book and mental Monitoring Log Book etc.) are filled regularly.				
8.	Inspect the Wast the previous batc	e Bins and ensure that it is free from reach.	mains of			
9.	Ensure that the Labels is affix or	raw material is QC approved and A n each container.	pproved			
	A.R. No. to be us	y the identity of raw materials by Item sed are as per BMR.				
11.	filters.	leaning of filters of RLAF, Riser and				
12.		re the availability of Cleaned Dispensin	g Tools			

Note: Write 'NA' where not Applicable

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

	BATCH PRODUCTION AND CONTROL RECORD						
PRODUCT NAME BATCH No. MFG. DATE EXP. DATE							
Placebo Batch (for							
Vitamin D3 60,000							
IU) for equipment							
Qualification							
MFR No. BMR No. BATCH SIZE PAGE No.							
			5 of 45				

1.5 LINE CLEARANCE FOR DISPENSING: FOR EXCIPIENTS

(To be performed by Warehouse Officer/Executive & QA Officer/Executive)

LINE CLEARANCE CHECK LIST – DISPENSING

Pre	evious Product		1	Area		
Bat	ch No.		Date / T	ime (Hrs.)		
S. No.		Check Points		Status (OK / Not OK)	Done By (Warehouse Officer/Exe.) Sign/Date	Checked By (QA Officer/Exec) Sign/Date
1.	details: Product l	us Board" of the dispensing area for following Name, Batch No., Mfg. Date, Exp. Date that the details are matching with the Bl be processed.	, Batch			
2.		liness of the room and ensure that it is from previous batch.	ee from			
3.	free from the ren	liness of the RLAF Unit and ensure that mains of the previous batch.				
4.	30 minutes before	re that the RLAF is switched "ON" min re start of the activity and the pressure ss HEPA filter is within limit.	imum			
5.	Dispensing Room	erature and Relative Humidity (RH) of m (It should be within specified range).	the			
6.7.	Ensure all logboo Balance Calibrat	ration Status of the balance. oks of the area (RLAF Usage Log Book tion Log Book, Cleaning Log Book and Monitoring Log Book etc.) are filled reg				
8.	Inspect the Wast the previous bate	te Bins and ensure that it is free from reach.	mains of			
9.	Labels is affix or					
10.		y the identity of raw materials by Item c sed are as per BMR.	ode &			
	Ensure proper clefilters.	eaning of filters of RLAF, Riser and gri	ll of			
12.	Check and Ensur	re the availability of Cleaned Dispensing	g Tools			

Note: Write 'NA' where not Applicable

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

FORMAT	No.	•								

BATCH PRODUCTION AND CONTROL RECORD							
PRODUCT NAME	BATCH No.	MFG. DATE	EXP. DATE				
Placebo Batch (for							
Vitamin D3 60,000							
IU) for equipment							
Qualification							
MFR No.	BMR No.	BATCH SIZE	PAGE No.				
			6 of 45				

AFFIX DISPENSING AREA LINE CLEARANCE LABEL

FORMAT No.:

	BATCH PRODUC	FION AND CONTR	ROL RECORD	
PRODUCT NAME	BATCH No.	MFG. DATE	EXP. DATE	
Placebo Batch (for				
Vitamin D3 60,000				
IU) for equipment				
Qualification				
MFR No.	BMR No.	BATCH SIZE	PAGE No.	
			7 of 45	

1.6 RAW MATERIAL DISPENSING RECORD:

S.	Mat. No.	Material Name	Std. Qty.	Required	Actual	A.R. No.	Gross	Tare	Net	Issued By	Verified By
No.			(1.0 Lac)	Qty.	Qty. Issued		Wt.	Wt.	Wt.	(Warehouse	(QA Officer/Exe.)
			kg	(Capsules)	Issueu					(Sign/Date)	(Sign/Date)
GE	LATIN M	ASS PART								(2-8-3-555)	(=-8
		Gelatin IP (Soft									
1.		Shell 40 Mesh)	27.000								
		150-180 BLO									
2.		Glycerin IP	7.700								
		Sorbitol Solution									
3.		70% non	5.100								
		crystalline IP									
4.		Methyl Paraben IP	0.130								
5.		Propyl Paraben IP	0.065								
6.		Purified Water IP	22.100 ltr.								
ME	DICAMEN	NT PART									
		Butylated									
7.		Hydroxy Anisole IP	0.010								
		Butylated									
8.		Hydroxy Toluene	0.005								
		IP									
9.		Refined Soya Oil	24.745								

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

BATCH PRODUCTION AND CONTROL RECORD								
PRODUCT NAME	BATCH No.	MFG. DATE	EXP. DATE					
Placebo Batch (for								
Vitamin D3 60,000								
IU) for equipment								
Qualification								
MFR No.	BMR No.	BATCH SIZE	PAGE No.					
			8 of 45					

IU) for equipment Qualification MFR No. BMR No. BATCH SIZE PAGE No. 8 of 45 AFFIX THE RAW MATERIALS DISPENSING LABELS
MFR No. BMR No. BATCH SIZE PAGE No. 8 of 45
8 of 45
AFFIX THE RAW MATERIALS DISPENSING LABELS
MITIM THE KAW MATERIALS DIST ENSING EMBELS

BATCH PRODUCTION AND CONTROL RECORD							
PRODUCT NAME	BATCH No.	MFG. DATE	EXP. DATE				
Placebo Batch (for							
Vitamin D3 60,000							
IU) for equipment							
Qualification							
MFR No.	BMR No.	BATCH SIZE	PAGE No.				
			9 of 45				

AFFIX THE RAW MATERIALS DISPENSING LABELS

FORMAT No.:

	BATCH PRODUCTION AND CONTROL RECORD							
PRODUCT NAME	BATCH No.	MFG. DATE	EXP. DATE					
Placebo Batch (for								
Vitamin D3 60,000								
IU) for equipment								
Qualification								
MFR No.	BMR No.	BATCH SIZE	PAGE No.					
			10 of 45					

2.0 MANUFACTURING 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.
- 6. Protective Mask, Hand Gloves and any other safety provisions must be followed.
- 7. The persons working in area must follow proper gowning.
- 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. Recommended Environmental Conditions are to be observed strictly during manufacturing process
- 14. Bulk & Finished Product should be least exposed to Atmosphere.

FORMAT No.:	 	

	BATCH PRODUCTION AND CONTROL RECORD								
PRODUCT NAME	BATCH No.	MFG. DATE	EXP. DATE						
Placebo Batch (for									
Vitamin D3 60,000									
IU) for equipment									
Qualification									
MFR No.	BMR No.	BATCH SIZE	PAGE No.						
			11 of 45						

3.0 MANUFACTURING –GELATIN MASS PREPARATION: 3.1 LINE CLEARANCE FOR GELATIN MASS AREA:

Previous Product			Batch 1	No.		
Area			Date /	Time		
S.No.		Check Points		Status (OK/Not OK)	Done By Production Officer/Exe. Sign/Date	Checked By QA Officer/Exe. Sign/Date
1.	and ensure that there materials/unwanted r		les			
2.	written with 'Batch d	Board " of the area is neatly and duly letails' as per mentioned in BMR like No., Batch Size, Mfg. Date, Best B				
3.	Check the cleanliness cleaning SOP.	s of Equipments are done as per resp	ective			
4.	Ensure the Equipmer previous Batch / Prod	nts are free from any remains of the duct material.				
5.	Ensure the duly label rejects are properly c	led containers for Non – Recoverable leaned.				
6.	place.	are properly cleaned and placed in p	_			
7.		at the Temperature and Relative Hum a the specified limit as per mentioned	•			
8.	Check and ensure that Book and Environme correctly.					
9.	Ensure that Return A	ir Riser are properly clean.				
10.	Check the proper status labeling on the machines. Ensure that the machine in cleaning Area has appropriate status label – To Be Cleaned / Cleaned.					
11.	Check and ensure that Quality Control and as 'Released' on Clea	ning				
12.		nd calibration status of weighing bal				
13.	material with BMR.	item code and weight of dispensed i	aw			
14.	Check the BMR is fil					

Not5: 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'.

BATCH PRODUCTION AND CONTROL RECORD						
PRODUCT NAME	BATCH No.	MFG. DATE	EXP. DATE			
Placebo Batch (for						
Vitamin D3 60,000						
IU) for equipment						
Qualification						
MFR No.	BMR No.	BATCH SIZE	PAGE No.			
			12 of 45			

AFFIX GELATIN AREA LINE CLEARANCE LABEL

RMAT No.:	-

BATCH PRODUCTION AND CONTROL RECORD							
PRODUCT NAME	BATCH No.	MFG. DATE	EXP. DATE				
Placebo Batch (for							
Vitamin D3 60,000							
IU) for equipment							
Qualification							
MFR No. BMR No. BATCH SIZE PAGE No.							
			13 of 45				

3.2 ENVIRONMENTAL MONITORING: At the time of start of Gelatin Mass Preparation, after every one hour and after every breakdown.

Date/Time	Room No./Name	Temp. (°C) (NMT 25°C)	% RH (NMT 65%)	Done By Sign/Date	Checked By Sign/Date	Remarks

3.3 EQUIPMENT DETAILS:

Name of Equipment	ID. No.	Previous Product	Batch No.	Cleanliness (OK/Not OK)	Checked by Sign / Date (Production Officer/Exe.)	Verified by Sign / Date (QA Officer/Exe.)

BATCH PRODUCTION AND CONTROL RECORD							
PRODUCT NAME BATCH No. MFG. DATE EXP. DATE							
Placebo Batch (for							
Vitamin D3 60,000							
IU) for equipment							
Qualification							
MFR No.	BMR No.	BATCH SIZE	PAGE No.				
			14 of 45				

3.4 VERIFICATION OF DISPENSED RAW MATERIALS:

(To be performed at manufacturing area)	
1. Balance ID. No.:	Calibration Status (Ok/Not Ok):
. Balance ID. No.:	Calibration Status (Ok/Not Ok):

S.	Mat. No.	Material Name	Std. Qty.	Required		A.R. No.	Gross			Checked By	
No.			(1.0 Lac)	Qty.	Qty. Issued		Wt.	Wt.	Poly	(Production	(QA Officer/Exe.)
			kg	(Capsules)	Issueu				bags	(Sign/Date)	(Sign/Date)
Gl	ELATIN M	IASS PART		cupsures)						(Sign/Dute)	(Sign/Dute)
1.		Gelatin IP									
		(Soft Shell 40	27.00								
		Mesh) 150-180	27.00								
		BLO									
2.		Glycerin IP	7.700								
3.		Sorbitol Solution									
		70% non	5.100								
		cyrstalline IP									
4.		Methyl	0.130								
		Paraben IP	0.130								
5.		Propyl Paraben IP	0.065								
6.		Purified Water IP	22.100								
			ltr.								
	EDICAME	NT PART									
7.		Butylated									
		Hydroxy	0.010								
		Anisole IP									
8.		Butylated									
		Hydroxy	0.005								
		Toluene IP					1				
9.		Refined Soya Oil	24.745								

FORMAT No.:	

BATCH PRODUCTION AND CONTROL RECORD					
PRODUCT NAME	BATCH No.	MFG. DATE	EXP. DATE		
Placebo Batch (for					
Vitamin D3 60,000					
IU) for equipment					
Qualification					
MFR No.	BMR No.	BATCH SIZE	PAGE No.		
			15 of 45		

3.5 MANUFACTURING PROCESS OF GELATIN MASS:

- **a.** Take 0.500 kg (Batch Qty.....kg) of Glycerin into a clean S.S. container.
- **b.** Add 0.130 kg (Batch Qty.....kg) of Methyl Paraben and 0.065 kg (Batch Qty.....kg) of Propyl Paraben to step (a) and heat it up-to 50-60°Cto get homogenous clear solution.

Process Start	Temp. of Solution	Mixing	g Time	Stirrer	Process Completed	Checked By	Verified By
Time / Date		From	To	Speed	Time / Date	(Sign/ Date)	(Sign / Date)
						(Production)	(QA)

- c. Take @ 7.200 ltr.(Batch Qty.....) of Purified Water into a cleaned SS Vessel and add 7.200 kg (Batch Qty.....kg) of Glycerin and 5.100 kg (Batch Qty.....kg) of Sorbitol Solution 70% and mix vigorously.
- **d.** Filter the solution through 100 mesh sieve and collect in another SS Vessel.
- e. Load filtered Solution into the Gelatin Melter by operating the Gelatin Melter as per SOP No.

Process Start Time / Date	Integrity of Filter (OK/Not OK)				Checked By (Sign / Date)	Verified By (Sign / Date)
	Before	After			(Production)	(QA)

- **f.** Start the Stirrer of Melter and heating Supply in the Gelatin Melter.
- **g.** Then add cool preservative solution of step b in the Gelatin Melter with Stirring.
- **h.** Add 27.000 kg (Batch Qty.....kg) of Gelatin at temperature 55-60°C. Add @ 14.900 ltr.(Batch Qty.....) of Purified Water and then mix for 15 minutes.

Process Start Time / Date	Mixir	ng Time	Total Mixing Time	Process Completed Time / Date	Checked By (Sign / Date)	Verified By (Sign / Date)
	From	To			(Production)	(QA)

- i. Rise the temperature up to 62° C (.............°C)
- **j.** At this temperature, allow the gelatin to cook for 45-60 minutes.

Process Start Time / Date	Temperature of Gelatin Mass	Cooking Time	Process Completed Time / Date	Checked By (Sign / Date) (Production)	Verified By (Sign / Date) (QA)

k. Start the vacuum pump and open inlet valve for incoming supply of vacuum slowly in the Melter for 10 minutes.

FORMAT No.:

]	BATCH PRODU	CTION A	ND CONTI	ROL RECORD	
PRODUCT NAM Placebo Batch (fo Vitamin D3 60,00 IU) for equipmen Qualification	or 00	BATCH No.	MF	G. DATE	EXP. DATE	
MFR No.		BMR No.	BAT	CH SIZE	PAGE No.	
					16 of 45	
Process Start Time	/ Date	Process Complete Date	ed Time /	(Sign	cked By n / Date) duction)	Verified By (Sign / Date) (QA)
complete in n. Open the slowly. o. Draw the melted material material send Test Recomplete in n. Open the slowly.	um on mass in outlet versample ass completes the complete	Melting Stage. ralve of Gelatin N of mass in plate oletely. T FOR QC ANA orm to QA for sar	Melter slower and observates: The analysis is a second observation of the second observation observation of the second observation obse	vly to release erve the Gela	e vacuum outside atin Mass for abs	perature 58 – 62°C to get from the Gelatin Melter sence of air bubble from
sampling, send	Iı Sigı	process sample watimated By In / Date / Time etion Officer/Exe.)	Intimation Sign / D	Received By ate / Time ficer/Exe.)	ept. for analysis. Quantity Sampled	Sampled By Sign / Date / Time (QA Officer/Exe.)
	(11000)	CHOII Officer/Exc.)	(lo Ay)	ilecti/EAC.)		(QA OHICE/EAC.)
The Gelatin M QA Officer/E	lass is I	alysis report from Release / Not Rele re Sign	ease for Er	ncapsulation. Date		
Chec	cked By	Sign / Date ficer / Executive			Reviewed By S QA Officer / I	Sign / Date

BATCH PRODUCTION AND CONTROL RECORD									
PRODUCT NAME BATCH No. MFG. DATE EXP. DATE									
Placebo Batch (for									
Vitamin D3 60,000									
IU) for equipment									
Qualification									
MFR No.	BMR No.	BATCH SIZE	PAGE No.						
			17 of 45						

6.0 MANUFACTURING -MEDICAMENT PREPARATION:

6.1 LINE CLEARANCE FOR MEDICAMENT PREPARATION AREA:

Product		Batch No.				
Area			Date / Tir	ne		
S.No.			Status (OK / Not OK)	Done By Production Officer/Exe. Sign/Date	Checked By QA Officer/Exe. Sign/Date	
1.	ensure that there are materials.	isually clean and free from dust particles are no previous product materials/unwanted				
2.	'Batch details' as po No., Batch Size, Ma	Board " of the area is neatly and duly writer mentioned in BMR like Product Name, fg. Date, Best Before.	Batch			
3.	Check the cleanline cleaning SOP.	ess of Equipments are done as per respective	ve			
4.	Ensure the Equipme Batch / Product man	ents are free from any remains of the previterial.				
5.	Ensure the duly lab properly cleaned.	eled containers for Non – Recoverable rejo	ects are			
6.	Ensure the waste bi	n are properly cleaned and placed in prope	er place.			
7.	Check and ensure the	hat the Temperature and Relative Humidit specified limit as per mentioned in BMR.				
8.		hat the Machine Log Book, Cleaning Log Monitoring Log Book are filled correctly.				
9.		Air Riser are properly clean.				
10.	machine in cleaning Cleaned / Cleaned.	atus labeling on the machines. Ensure that g Area has appropriate status label – To Be	e			
11.		hat the Rinse water / swab are released fro I report attached with BMR before signing ned label.				
12.	Check the cleaning	and calibration status of weighing balance	e			
13.		e item code and weight of dispensed raw				
14.	Check the BMR is	filled up to Gelatin Mass Preparation Stage	e.			

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'.

BATCH PRODUCTION AND CONTROL RECORD									
PRODUCT NAME BATCH No. MFG. DATE EXP. DATE									
Placebo Batch (for									
Vitamin D3 60,000									
IU) for equipment									
Qualification									
MFR No.	BMR No.	BATCH SIZE	PAGE No.						
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AFFIX MEDICAMENT PREPARATION AREA LINE CLEARANCE LABEL

ORMAT No.:	RMAT No.:	

BATCH PRODUCTION AND CONTROL RECORD									
PRODUCT NAME BATCH No. MFG. DATE EXP. DATE									
Placebo Batch (for									
Vitamin D3 60,000									
IU) for equipment									
Qualification									
MFR No.									
			19 of 45						

6.2 ENVIRONMENTAL MONITORING: At the time of start of Medicament Preparation, after every one hour and after every breakdown.

Date/Time	Room No./Name	Temp. (°C) (NMT 25°C)	% RH (NMT 50%)	Done By Sign/Date	Checked By Sign/Date	Remarks

6.3 EQUIPMENT DETAILS:

Name of Equipment	ID. No.	Previous Product	Batch No.	Cleanliness (OK/Not OK)	Checked by Sign / Date (Production Officer/Exe.)	Verified by Sign / Date (QA Officer/Exe.)

BATCH PRODUCTION AND CONTROL RECORD										
PRODUCT NAME BATCH No. MFG. DATE EXP. DATE										
Placebo Batch (for										
Vitamin D3 60,000										
IU) for equipment										
Qualification										
MFR No.	BMR No.	BATCH SIZE	PAGE No.							
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6.4 MEDICAMENT MANUFACTURING PROCEDURE:

6.4.1 MANUFACTURING PROCESS OF MEDICAMENT:

a. Take @ 24.745 kg (Batch Qty.....kg) of Refined Soya Oil & filtration through # 100mesh SS sieve and collect into a clean Medicament Preparation Vessel. Keeping aside @ 3.500 kg (Batch Qty._____ oil for rinsing purpose of containers.

S	5.	Material Name	Sieve	Sieve Integ	grity Test	Sifting	Sifting	Done By	Checked by
N	0.		Size	Before	After	Started at	Completed at	(Sign/Date)	(Sign/Date)
				Use	Use	Date/Time	Date/Time	(Operator)	(Production)
]	1.	Refined Soya Oil	100#						

- **b.** Dissolve 0.010 kg (Batch Qty._____ kg) of Butylated Hydroxy Anisole, 0.005 kg (Batch Qty.____ kg) of Butylated Hydroxy Toluene in 1.500kg (Batch Qty.____ kg) Refined Soya Oil .(if required apply heat up to 60°C.)
- c. Cool down the step-(b) at 30°C & add into step-(a) and dissolve in it 1.000 kg (Batch Qty.____kg) of Refined Soya Oil & warmed at 30°C and then add to step-(a),
- **d.** Rinse the above with remaining Qty. of Refined Soya Oil 1.000 kg & add to step-(a) & mix for 15-30 minutes in Homogenizer Stirrer.
- e. Then transfer material from medicament tank to PLM & mix for 30 minutes.

Process Start	Mixing Time		Total Mixing Time		Checked By	Verified By
Time / Date				Time / Date	(Sign / Date)	(Sign / Date)
	From	To			(Production)	(QA)

FORMAT No.:		

BATCH PRODUCTION AND CONTROL RECORD								
PRODUCT NAME	EXP. DATE							
Placebo Batch (for								
Vitamin D3 60,000								
IU) for equipment								
Qualification								
MFR No.	BMR No.	BATCH SIZE	PAGE No.					
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6.4.2 WEIGHT OF MEDICAMENT:

Gross wt (kg)	Tare wt (kg)	Net wt (kg)	Checked By Sign / Date (Production Officer)	Verified By Sign /Date (QA Officer)
Total Weight of Medic	ament:	Kg		

		BATCH PRODU	CTION A	ND CONTI	ROL RECORD			
PRODUCT NAM	ME	BATCH No.	MFO	G. DATE	EXP. DATE			
Placebo Batch (fo								
Vitamin D3 60,0								
IU) for equipme								
Qualification		DMD M	D A TD		DACEN			
MFR No.		BMR No.	BAT	CH SIZE	PAGE No.			
					22 of 45			
6.4.3 RECONC	CILIAT	TION OF MEDIC	CAMENT:					
A. Theoretical we	eight of	Medicament:	kg.					
B. Actual weight	of Med	licament:	kg.					
C. Process Loss:		kg.						
D. QC Sample:		_						
E. Percentage yiel		A			100 =	%.		
(If the yield is less	than 99	9.00%, investigate	the matter)				
If Less yield Spec	ify the	reason:						
• •	·							
70 SAMDLE I	DEOLII							
7.0 SAMPLE REQUEST FOR QC ANALYSIS: Send Test Request Form to QA for Medicament Sampling for analysis. QA Officer / Executive after								
	•	•		t Sampling	for analysis. OA (Officer / Executive after		
Send Test Re	equest I	•	Medicament			Officer / Executive after		
Send Test Re	equest I	Form to QA for Natural for Nat	Medicament	ion to QC de				
Send Test Re	equest Ind the in	Form to QA for N	Medicament vith intimat Intimation Sign / Da			Officer / Executive after Sampled By Sign / Date / Time (QA Officer/Exe.)		
Send Test Re sampling, sen	equest Ind the in	Form to QA for Ma-process sample volumented By on / Date / Time	Medicament vith intimat Intimation Sign / Da	ion to QC do Received By ate / Time	ept. for analysis.	Sampled By Sign / Date / Time		
Send Test Resampling, sen Intimation No.	equest Ind the indicate Indica	Form to QA for Ma-process sample valued By (n / Date / Time action Officer/Exe.)	Medicament vith intimat Intimation Sign / Da (QA Off	ion to QC do Received By ate / Time icer/Exe.)	ept. for analysis. Quantity Sampled	Sampled By Sign / Date / Time		
Send Test Resampling, sen Intimation No. After receiving	equest Ind the indicate of the	Form to QA for Ma-process sample valued By (m / Date / Time action Officer/Exe.)	Medicament vith intimat Intimation Sign / Da (QA Off 1 QC, fill the	Received By ate / Time icer/Exe.)	ept. for analysis. Quantity Sampled	Sampled By Sign / Date / Time		
Send Test Resampling, sen Intimation No. After receiving	equest Ind the indicate of the	Form to QA for Ma-process sample valued By (n / Date / Time action Officer/Exe.)	Medicament vith intimat Intimation Sign / Da (QA Off 1 QC, fill the	Received By ate / Time icer/Exe.)	ept. for analysis. Quantity Sampled	Sampled By Sign / Date / Time		
Send Test Resampling, sen Intimation No. After receiving	equest Ind the indicate of the	Form to QA for Ma-process sample valued By (m / Date / Time action Officer/Exe.)	Medicament vith intimat Intimation Sign / Da (QA Off 1 QC, fill the	Received By ate / Time icer/Exe.)	ept. for analysis. Quantity Sampled	Sampled By Sign / Date / Time		
Send Test Resampling, sen Intimation No. After receiving The medicam	equest I and the in Sig (Produ	Form to QA for Ma-process sample value of the process samp	Medicament vith intimat Intimation Sign / Da (QA Off ase for Enc	Received By ate / Time icer/Exe.)	Quantity Sampled	Sampled By Sign / Date / Time (QA Officer/Exe.)		
Send Test Resampling, sen Intimation No. After receiving The medicam	equest I and the in Sig (Produ	Form to QA for Ma-process sample value of the process samp	Medicament vith intimat Intimation Sign / Da (QA Off ase for Enc	Received By ate / Time icer/Exe.)	ept. for analysis. Quantity Sampled	Sampled By Sign / Date / Time (QA Officer/Exe.)		
Send Test Resampling, sen Intimation No. After receiving The medicant QA Officer/	equest I and the in Sig (Produ	Form to QA for Ma-process sample value of the process of	Medicament vith intimat Intimation Sign / Do (QA Off ase for Enc	Received By ate / Time icer/Exe.) The A.R. No_capsulation.	Quantity Sampled	Sampled By Sign / Date / Time (QA Officer/Exe.)		
Send Test Resampling, sen Intimation No. After receiving The medicam QA Officer/ 8.0 VERIFICAT	equest I and the in Sig (Produ	Form to QA for Ma-process sample value of the process of	Medicament vith intimat Intimation Sign / Do (QA Off ase for Enc	Received By ate / Time icer/Exe.) The A.R. No_capsulation.	Quantity Sampled Time	Sampled By Sign / Date / Time (QA Officer/Exe.)		
Send Test Resampling, sen Intimation No. After receiving The medicam QA Officer/ 8.0 VERIFICAT Che	equest I and the in Sig (Production of the arms of the arms of the arms of the Execution of	Form to QA for Ma-process sample von the process sample von the proc	Medicament vith intimat Intimation Sign / Do (QA Off ase for Enc	Received By ate / Time icer/Exe.) The A.R. No_capsulation.	Quantity Sampled Time PARATION STA	Sampled By Sign / Date / Time (QA Officer/Exe.) GE:- gn / Date		
Send Test Resampling, sen Intimation No. After receiving The medicam QA Officer/ 8.0 VERIFICAT Che	equest I and the in Sig (Production of the arms of the arms of the arms of the Execution of	Form to QA for Ma-process sample value of the process samp	Medicament vith intimat Intimation Sign / Do (QA Off ase for Enc	Received By ate / Time icer/Exe.) The A.R. No_capsulation.	Quantity Sampled Time PARATION STATE Reviewed By Si	Sampled By Sign / Date / Time (QA Officer/Exe.) GE:- gn / Date		
Send Test Resampling, sen Intimation No. After receiving The medicam QA Officer/ 8.0 VERIFICAT Che	equest I and the in Sig (Production of the arms of the arms of the arms of the Execution of	Form to QA for Ma-process sample value of the process samp	Medicament vith intimat Intimation Sign / Do (QA Off ase for Enc	Received By ate / Time icer/Exe.) The A.R. No_capsulation.	Quantity Sampled Time PARATION STATE Reviewed By Si	Sampled By Sign / Date / Time (QA Officer/Exe.) GE:- gn / Date		
Send Test Resampling, sen Intimation No. After receiving The medicam QA Officer/ 8.0 VERIFICAT Che	equest I and the in Sig (Production of the arms of the arms of the arms of the Execution of	Form to QA for Ma-process sample value of the process samp	Medicament vith intimat Intimation Sign / Do (QA Off ase for Enc	Received By ate / Time icer/Exe.) The A.R. No_capsulation.	Quantity Sampled Time PARATION STATE Reviewed By Si	Sampled By Sign / Date / Time (QA Officer/Exe.) GE:- gn / Date		
Send Test Resampling, sen Intimation No. After receiving The medicam QA Officer/ 8.0 VERIFICAT Che	equest I and the in Sig (Production of the arms of the arms of the arms of the Execution of	Form to QA for Ma-process sample value of the process samp	Medicament vith intimat Intimation Sign / Do (QA Off ase for Enc	Received By ate / Time icer/Exe.) The A.R. No_capsulation.	Quantity Sampled Time PARATION STATE Reviewed By Si	Sampled By Sign / Date / Time (QA Officer/Exe.) GE:- gn / Date		
Send Test Resampling, sen Intimation No. After receiving The medicam QA Officer/ 8.0 VERIFICAT Che	equest I and the in Sig (Production of the arms of the arms of the arms of the Execution of	Form to QA for Ma-process sample value of the process samp	Medicament vith intimat Intimation Sign / Do (QA Off ase for Enc	Received By ate / Time icer/Exe.) The A.R. No_capsulation.	Quantity Sampled Time PARATION STATE Reviewed By Si	Sampled By Sign / Date / Time (QA Officer/Exe.) GE:- gn / Date		
Send Test Resampling, sen Intimation No. After receiving The medicam QA Officer/ 8.0 VERIFICAT Che	equest I and the in Sig (Production of the arms of the arms of the arms of the Execution of	Form to QA for Ma-process sample value of the process samp	Medicament vith intimat Intimation Sign / Do (QA Off ase for Enc	Received By ate / Time icer/Exe.) The A.R. No_capsulation.	Quantity Sampled Time PARATION STATE Reviewed By Si	Sampled By Sign / Date / Time (QA Officer/Exe.) GE:- gn / Date		
Send Test Resampling, sen Intimation No. After receiving The medicam QA Officer/ 8.0 VERIFICAT Che	equest I and the in Sig (Production of the arms of the arms of the arms of the Execution of	Form to QA for Ma-process sample value of the process samp	Medicament vith intimat Intimation Sign / Da (QA Off ase for Enc	Received By ate / Time icer/Exe.) The A.R. No_capsulation.	Quantity Sampled Time PARATION STATE Reviewed By Si	Sampled By Sign / Date / Time (QA Officer/Exe.) GE:- gn / Date		
Send Test Resampling, sen Intimation No. After receiving The medicam QA Officer/ 8.0 VERIFICAT Che	equest I and the in Sig (Production of the arms of the arms of the arms of the Execution of	Form to QA for Ma-process sample value of the process samp	Medicament vith intimat Intimation Sign / Da (QA Off ase for Enc	Received By ate / Time icer/Exe.) The A.R. No_capsulation.	Quantity Sampled Time PARATION STATE Reviewed By Si	Sampled By Sign / Date / Time (QA Officer/Exe.) GE:- gn / Date		
Send Test Resampling, sen Intimation No. After receiving The medicam QA Officer/ 8.0 VERIFICAT Che	equest I and the in Sig (Production of the arms of the arms of the arms of the Execution of	Form to QA for Ma-process sample value of the process samp	Medicament vith intimat Intimation Sign / Da (QA Off ase for Enc	Received By ate / Time icer/Exe.) The A.R. No_capsulation.	Quantity Sampled Time PARATION STATE Reviewed By Si	Sampled By Sign / Date / Time (QA Officer/Exe.) GE:- gn / Date		
Send Test Resampling, sen Intimation No. After receiving The medicant QA Officer/I	equest I and the in Sig (Production of the arms of the arms of the arms of the Execution of	Form to QA for Ma-process sample value of the process samp	Medicament vith intimat Intimation Sign / Da (QA Off ase for Enc	Received By ate / Time icer/Exe.) The A.R. No_capsulation.	Quantity Sampled Time PARATION STATE Reviewed By Si	Sampled By Sign / Date / Time (QA Officer/Exe.) GE:- gn / Date		

BATCH PRODUCTION AND CONTROL RECORD								
PRODUCT NAME BATCH No. MFG. DATE EXP. DATE								
Placebo Batch (for								
Vitamin D3 60,000								
IU) for equipment								
Qualification								
MFR No.	BMR No.	BATCH SIZE	PAGE No.					
			23 of 45					

9.0 MANUFACTURING - ENCAPSULATION: 9.1 LINE CLEARANCE FOR ENCAPSULATION:

Previous Product			Batch No.			
Area			Date / Tin			
S. No.		Check Points		Status (OK / Not OK)	Done By Production Officer/Exe. Sign/Date	Checked By QA Officer/Exe. Sign/Date
1.		s visually clean and free from dust pare no previous product material				
2.	'Batch details' as p	Board " of the area is neatly and duly very per mentioned in BMR like Product North Eng. Date, Best Before.				
3.	Check the cleanliness of Capsule Filling Machine is done as per respective cleaning SOP.					
4.	Ensure the Capsule Filling Machine is free from any remains of the previous Batch / Product material.					
5.		peled containers for Non – Recoverable	rejects are			
6.	Ensure the waste by	in are properly cleaned and placed in pr	oper place.			
7.		that the Temperature and Relative Hum specified limit as per mentioned in BM				
8.		that the Machine Log Book, Cleaning Monitoring Log Book are filled correct				
9.	Check the proper status labeling on the machines. Ensure that the machine in cleaning Area has appropriate status label – To Be Cleaned / Cleaned.					
10.	Check and ensure that the Rinse water / swab are released from Quality Control and report attached with BMR before signing as 'Released' on Cleaned label.					
11.	Check the cleaning	and calibration status of weighing bala	nce.			
12.	Check and Ensure released report atta	that the Blend is release from Quality C ched with BMR	Control and			
14.	Check the BMR is	filled up to Medicament Preparation Sta	ige.			

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'.

BATCH PRODUCTION AND CONTROL RECORD								
PRODUCT NAME BATCH No. MFG. DATE EXP. DATE								
Placebo Batch (for								
Vitamin D3 60,000								
IU) for equipment								
Qualification								
MFR No.	BMR No.	BATCH SIZE	PAGE No.					
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AFFIX CAPSULE FILLING AREA LINE CLEARANCE LABEL

FORMAT No.:	

BATCH PRODUCTION AND CONTROL RECORD									
PRODUCT NAME BATCH No. MFG. DATE EXP. DATE									
Placebo Batch (for									
Vitamin D3 60,000									
IU) for equipment									
Qualification									
MFR No.	BMR No.	BATCH SIZE	PAGE No.						
			25 of 45						

9.2 ENVIRONMENTAL MONITORING: At the time of start of encapsulation, after every one hour and after every breakdown.

Date/Time	Room No./Name	Temp. (°C) (NMT 20°C)	% RH Limit (43-47%)	Done By Sign/Date	Checked By Sign/Date	Remarks

9.3 EQUIPMENT DETAILS:

Name of Equipment	ID. No.	Previous Product	Batch No.	Cleanliness (OK/Not OK)	Checked by Sign / Date (Production Officer/Exe.)	Verified by Sign / Date (QA Officer/Exe.)
Encapsulation						
Machine						
						_

	BATCH PRODUCTION AND CONTROL RECORD			
PRODUCT NAME	BATCH No.	MFG. DATE	EXP. DATE	
Placebo Batch (for				
Vitamin D3 60,000				
IU) for equipment				
Qualification				
MFR No.	BMR No.	BATCH SIZE	PAGE No.	
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9.4 ENCAPSULATION INSTRUCTIONS:

- **a.** Operate the Encapsulation Machine.
- **b.** Check and maintain the heating of Gelatin Mass Tank at 50-54^oC.
- c. Before feeding of gelatin mass in Spreader Box maintain heating of Spreader Box at 53-57°C.
- d. Open the Gelatin Mass Holding Tank Valve and feed the Gelatin into the Spreader Box Full.
- e. Fill 0.5 kg of Light Liquid Paraffin into the medicament Hopper.
- **f.** Start the Machine and chilled air supply in Drum 8-12^oC.
- g. Collect ribbon of both side put in between Die Roll and Passing through chute.
- **h.** Measure the thickness of ribbon using gauge 0.75 mm 0.85 mm.
- i. Start heating of segment at 36-44°C
- **j.** Do pressure on Die and allow to cutting.
- **k.** Observe lubrication of circulation over ribbon.
- **l.** If sealing and cutting if OK, start inject of filling.
- m. Filled capsules of Light Liquid Paraffin will come in shape.
- **n.** Observe shape sealing and cutting of filled capsule.
- **o.** Draw the capsules from each horizontal row and take the fill weight.
- **p.** If fill weight of Light Liquid Paraffin is OK, remove extra Light Liquid Paraffin from Hopper and put off injection the Light Liquid Paraffin will go back outside.
- **q.** Now on complete emptying, feed the QC approved medicament into the Medicament Hopper.
- **r.** On good sealing cutting, start injection of setup valve for Encapsulation. Inform to QA Department to receive the Sample of Capsules for Fill Weight.

FORMAT No.:

	BATCH PRODUCTION AND CONTROL RECORD			
PRODUCT NAME	BATCH No.	MFG. DATE	EXP. DATE	
Placebo Batch (for				
Vitamin D3 60,000				
IU) for equipment				
Qualification				
MFR No.	BMR No.	BATCH SIZE	PAGE No.	
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9.5 ENCAPSULATION MACHINE SETTING PARAMETERS:

Perform the in-process checks after every one hour by Production and QA.

S.No.	Parameter	Limits
1.	Description	Light Pale Yellow coloured transparent Soft Gelatin Capsules containing clear colourless oily liquid.
2.	Average Fill Weight	250 mg ±3%
3.	Uniformity of Fill Weight	± 5% of Average Fill Weight
4.	Ribbon Thickness	0.75 - 0.85 mm
5.	Drum Temperature	8-12 ^o C
6.	Segment Temperature	36-44 ⁰ C
7.	Die Size	7.5 minim
8.	Shape	Oval
9.	Spreader Box Temp. (Left)	53-57 ⁰ C
10.	Spreader Box Temp. (Right)	53-57 ⁰ C
11.	Disintegration Time	NMT 30 minutes

9.6 ENCAPSULATION OPERATION DETAILS:

Date	Started at	Completed at	Output in Nos.	Operated By	Checked By Prod
		Total			

	BATCH PRODUC	TION AND CONTI	ROL RECORD	
PRODUCT NAME BATCH No. MFG. DATE EXP. DATE				
Placebo Batch (for				
Vitamin D3 60,000				
IU) for equipment				
Qualification				
MFR No.	BMR No.	BATCH SIZE	PAGE No.	
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9.7 INITIAL CHECKS OF ENCAPSULATION PARAMETERS:

Parameters	Std. Limits	Observed	Checked By Verified By
Dilla an Thialana	0.75 0.95		(Production) (QA)
Ribbon Thickness	0.75 - 0.85 mm		
Drum	8-12 ⁰ C		
Temperature			
Segment	36-44 ⁰ C		
Temperature			
Spreader Box	53-57 ⁰ C		
Temp. (Left)			
Spreader Box	53-57 ⁰ C		
Temp. (Right)			
Die Size	7.5 minim		
Capsule Colour	Light Pale Yellow		
	colored transparent		
Capsule Shape	Oval		
	Light Pale Yellow		
Description	colored transparent		
Description	Soft Gelatin Capsules		
	containing clear		
	colorless oily liquid.		
Average Fill	250 mg ±3%		
Weight			
Uniformity of Fill	± 5 % of Average Fill		
Weight	Weight		

NOTE: Initially after setting the machine, check the all in-process Checks of the initial capsule and record in the in-process checking record. Initial capsules during machine setting will be treated as non-recoverable.

	BATCH PRODUCTION AND CONTROL RECORD			
PRODUCT NAME	BATCH No.	MFG. DATE	EXP. DATE	
Placebo Batch (for				
Vitamin D3 60,000				
IU) for equipment				
Qualification				
MFR No.	BMR No.	BATCH SIZE	PAGE No.	
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9.8 IN -PROCESS CONTROL RECORD FOR ENCAPSULATION: (Frequency After every 30 minutes)

Parameters	Limits	Observations
	Date	
	Time	
Ribbon Thickness	0.75 - 0.85 mm	
Drum Temperature	8-12°C	
Segment Temperature	36-44 ⁰ C	
Spreader Box Temp. (L)	53-57 ⁰ C	
Spreader Box Temp. (R)	53-57 ⁰ C	
Capsule Colour	Light Pale Yellow coloured transparent	
Description	OK/Not OK	
Average Fill Weight	250 mg ±3%	
Disintegration Time	NMT 30 Minutes	
Sign (Production / QA)		

UNIFORMITY FILL WEIGHT RECORD OF CAPSULE (Frequency After every 60 minutes)

Capsule No.	Wt of filled	Wt of empty	Net wt. of fill	Capsule No.	Wt of filled	Wt of empty	Net wt. of fill	Capsule No.	Wt of filled	Wt of empty	Net wt. of fill
	Capsule	capsule			Capsule	capsule			Capsule	capsule	
1.				1.				1.			
2.				2.				2.			
3.				3.				3.			
4.				4.				4.			
5.				5.				5.			
6.				6.				6.			
7.				7.				7.			
8.				8.				8.			
9.				9.				9.			
10.				10.				10.			
11.				11.				11.			
12				12.				12.			
13.				13.				13.			
14.				14.				14.			
15.				15.				15.			
16.				16.				16.			
17.				17.				17.			
18.				18.				18.			
19.				19.				19.			
20.				20.				20.			
Total Fill	Wt.			Total Fill	Wt.			Total Fill	Wt.		
Avg. Fill	Wt.			Avg. Fill	Wt.			Avg. Fill	Wt.		
Max. Fill.		_ Min. Fill.	%	Max. Fill.		Min. Fill. 9	6	Max. Fill		Min. Fill. 9	б
Remark				Remark				Remark			
Done by				Done by				Done by			

	BATCH PRODUCTION AND CONTROL RECORD			
PRODUCT NAME	BATCH No.	MFG. DATE	EXP. DATE	
Placebo Batch (for				
Vitamin D3 60,000				
IU) for equipment				
Qualification				
MFR No.	BMR No.	BATCH SIZE	PAGE No.	
			30 of 45	

IN -PROCESS CONTROL RECORD FOR ENCAPSULATION: (Frequency After every 30 minutes)

Parameters	Limits	Observations
	Date	
	Time	
Ribbon Thickness	0.75 - 0.85 mm	
Drum Temperature	8-12 ⁰ C	
Segment Temperature	36-44 ⁰ C	
Spreader Box Temp. (L)	53-57 ⁰ C	
Spreader Box Temp. (R)	53-57 ⁰ C	
Capsule Colour	Light Pale Yellow colored transparent	
Description	OK/Not OK	
Average Fill Weight	250 mg ±3%	
Disintegration Time	NMT 30 Minutes	
Sign (Production / QA)		

UNIFORMITY FILL WEIGHT RECORD OF CAPSULE (Frequency After every 60 minutes)

Capsule	Wt of	Wt of	Net wt. of	Capsule	Wt of		Net wt. of		Wt of	Wt of	Net wt.
No.	filled Capsule	empty capsule	fill	No.	filled Capsule	empty capsule	fill	No.	filled Capsule	empty capsule	of fill
1.	•	•		1.	•			1.	•		
2.				2.				2.			
3.				3.				3.			
4.				4.				4.			
5.				5.				5.			
6.				6.				6.			
7.				7.				7.			
8.				8.				8.			
9.				9.				9.			
10.				10.				10.			
11.				11.				11.			
12				12.				12.			
13.				13.				13.			
14.				14.				14.			
15.				15.				15.			
16.				16.				16.			
17.				17.				17.			
18.				18.				18.			
19.				19.				19.			
20.				20.				20.			
Total Fill	Wt.			Total Fill	Wt.			Total Fill	Wt.		
Avg. Fill	Wt.			Avg. Fill	Wt.			Avg. Fill	Wt.		
Max. Fill.		Min. Fill.	%	Max. Fill.		Min. Fill. 9	6	Max. Fill		Min. Fill. 9	о́
Remark			_	Remark				Remark			
Done by				Done by				Done by			

	BATCH PRODUCTION AND CONTROL RECORD								
PRODUCT NAME BATCH No. MFG. DATE EXP. DATE									
Placebo Batch (for									
Vitamin D3 60,000									
IU) for equipment									
Qualification									
MFR No. BMR No. BATCH SIZE PAGE No.									
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IN -PROCESS CONTROL RECORD FOR ENCAPSULATION: (Frequency After every 30 minutes)

Parameters	Limits	Observations					
	Date						
	Time						
Ribbon Thickness	0.75 - 0.85 mm						
Drum Temperature	8-12 ⁰ C						
Segment Temperature	36-44 ⁰ C						
Spreader Box Temp. (L)	53-57°C						
Spreader Box Temp. (R)	53-57 ⁰ C						
Capsule Colour	Light Pale Yellow coloured transparent						
Description	OK/Not OK						
Average Fill Weight	250 mg ±3%						
Disintegration Time	NMT 30 Minutes						
Sign (Production / QA)							

UNIFORMITY FILL WEIGHT RECORD OF CAPSULE (Frequency After every 60 minutes)

Cl-	VV/4 - C	XX74 - C	NT-44 - C	C1-				C			Net wt.
Capsule	Wt of	Wt of	Net wt. of	Capsule	Wt of		Net wt. of		Wt of		
No.	filled	empty	fill	No.	filled	empty	fill	No.	filled	empty	of fill
4	Capsule	capsule			Capsule	capsule		4	Capsule	capsule	
1.				1.				1.			
2.				2.				2.			
3.				3.				3.			
4.				4.				4.			
5.				5.				5.			
6.				6.				6.			
7.				7.				7.			
8.				8.				8.			
9.				9.				9.			
10.				10.				10.			
11.				11.				11.			
12				12.				12.			
13.				13.				13.			
14.				14.				14.			
15.				15.				15.			
16.				16.				16.			
17.				17.				17.			
18.				18.				18.			
19.				19.				19.			
20.				20.				20.			
Total Fill	Wt.			Total Fill	Wt.		•	Total Fill	Wt.		
Avg. Fill	Wt.	_		Avg. Fill	Wt.			Avg. Fill	Wt.	_	
Max. Fill.		Min. Fill.	%	Max. Fill.		Min. Fill. 9	6	Max. Fill		Min. Fill. 9	о́
Remark				Remark				Remark			
Done by				Done by				Done by			

	BATCH PRODUC	TION AND CONTR	ROL RECORD					
PRODUCT NAME BATCH No. MFG. DATE EXP. DATE								
Placebo Batch (for								
Vitamin D3 60,000								
IU) for equipment								
Qualification								
MFR No.	BMR No.	BATCH SIZE	PAGE No.					
			32 of 45					

IN -PROCESS CONTROL RECORD FOR ENCAPSULATION: (Frequency After every 30 minutes)

Parameters	Limits	Observations					
	Date						
	Time						
Ribbon Thickness	0.75 - 0.85 mm						
Drum Temperature	8-12°C						
Segment Temperature	36-44 ⁰ C						
Spreader Box Temp. (L)	53-57 ⁰ C						
Spreader Box Temp. (R)	53-57°C						
Capsule Colour	Light Pale Yellow coloured transparent						
Description	OK/Not OK						
Average Fill Weight	250 mg ±3%						
Disintegration Time	NMT 30 Minutes						
Sign (Production / QA)							

UNIFORMITY FILL WEIGHT RECORD OF CAPSULE (Frequency After every 60 minutes)

	ONFORMITT FILE WEIGHT RECORD OF CATSOLE (Frequency Arter every 60 minutes)										
Capsule No.	Wt of filled Capsule	Wt of empty capsule	Net wt. of fill	Capsule No.	Wt of filled Capsule	Wt of empty capsule	Net wt. of fill	Capsule No.	Wt of filled Capsule	Wt of empty capsule	Net wt. of fill
1	Capsule	Capsule		1	Capsule	capsule		1	Capsule	capsule	
1.				1.				1.			
2.				2.				2.			
3.				3.				3.			
4.				4.				4.			
5.				5.				5.			
6.				6.				6.			
7.				7.				7.			
8.				8.				8.			
9.				9.				9.			
10.				10.				10.			
11.				11.				11.			
12				12.				12.			
13.				13.				13.			
14.				14.				14.			
15.				15.				15.			
16.				16.				16.			
17.				17.				17.			
18.				18.				18.			
19.				19.				19.			
20.				20.				20.			
Total Fill	Wt.		l	Total Fill	Wt.		1	Total Fill	Wt.		L
Avg. Fill	Wt.			Avg. Fill	Wt.			Avg. Fill	Wt.		
Max. Fill.		Min. Fill.	%	Max. Fill.		Min. Fill. %	ó	Max. Fill		Min. Fill. 9	6
Remark				Remark				Remark			
Done by				Done by				Done by			

	BATCH PRODUC	TION AND CONTR	ROL RECORD						
PRODUCT NAME BATCH No. MFG. DATE EXP. DATE									
Placebo Batch (for									
Vitamin D3 60,000									
IU) for equipment									
Qualification									
MFR No.	BMR No.	BATCH SIZE	PAGE No.						
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10.0 SEMI DRYING OF SOFT GELATIN CAPSULES:

- i. After Encapsulation, the filled capsules are directly goes into the semi dryer & rotate the semi dryer for 15-20 minutes.
- ii. Put about 4-5 pieces of lint free cloth in 2nd & 3rd tumbler (semi dryer) for oil adsorption.
- iii. After that immediately spread the capsules in a tray for drying.

11.0 DRYING OF SOFT GELATIN CAPSULES:

- **a.** Transfer the filled capsules by spreading in the SS cleaned trays in the single layer putting in S.S. clean trolley and put into Drying area after one hour of Encapsulation.
- **b.** Do shuffling and pair separation after every 2 hours putting the trolley in the Dryer and record the environmental data after every one hour and shuffling record after every two hours in the following table.

Dryin	Drying Room No. : Date & Time of Loading :							
No. of	f Trolleys :		Da	te & Time	of Remo	oval :		
Date	Time	Temp. (°C)	% RH Limit	Checked by	Sh	uffling	Checked by	Remarks
		Limit (22-24°C)	(NMT 25%)		Time	Done by		

			BATCH PRODU	ICTION AND	CONTR	OL REC	CORD		
Place Vitan IU) f	DUCT Nobo Batch nin D3 6 for equipualificati	n (for 60,000 ment	BATCH No.	MFG. D	DATE	EXP. DATE			
	AFR No.		BMR No.	ВАТСН	SIZE		E No. f 45		
Date	Time	Lin	Temp. (°C) nit (NMT 25°C)	% RH Limit (NMT 25%)	Checked by	Shuffling Time Done by		Checked by	Remarks
Se sa	end Test	Request send the	TEST FOR QC ANA Form to QA for san in-process sample v	npling of Dried	-		_		
ntim	ation No	h	Intimated By ign / Date / Time Irs.) (Production Officer/Exe.)	Intimation I By Sign / Time (F (QA Office	Date / Irs.)	_	antity apled	Sample Sign/Date (Hr (QA Office	e / Time s.)
		_	e analysis report fron e / Not Release for V	=	R. No				

	1	
FORMAT No.:		

Reviewed By Sign / Date

QA Officer / Executive

13.0 VERIFICATION OF BMR UP-TO DRYING STAGE:-

Checked By Sign / Date

Production Officer / Executive

	BATCH PRODUCTION AND CONTROL RECORD							
PRODUCT NAME BATCH No. MFG. DATE EXP. DATE								
Placebo Batch (for								
Vitamin D3 60,000								
IU) for equipment								
Qualification								
MFR No. BMR No. BATCH SIZE PAGE No.								
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14.0 VISUAL INSPECTION OF DRIED CAPSULES: (Inspect the 100 % Batch) **14.1 LINE CLEARANCE FOR VISUAL INSPECTION AREA:**

Previous	Product		Batch No	0.		
Area			Date / Ti	ime		
S. No.		Check Points		Status (OK / Not OK)	Done By Production Officer/Exe. Sign/Date	Checked By QA Officer/Exe. Sign/Date
1.		visually clean and free from dust pa are no previous product materials				
2.	'Batch details' as p	Board " of the area is neatly and duly we mentioned in BMR like Product Nafg. Date, Best Before.				
3.	Check the Cleanline	ess of Equipments as per respective clea	ning SOP.			
4.	Ensure the Equipm Batch / Product ma	nents are free from any remains of the terial.	e previous			
5.	Ensure the duly lab properly cleaned.	eled Containers for Non – Recoverable	rejects are			
6.	Ensure the waste bi	n are properly cleaned and placed in pro	per place.			
7.		hat the Temperature and Relative Humi specified limit as per mentioned in BMF				
8.		that the Machine Log Book, Cleaning Monitoring Log Book are filled correct				
9.		status labeling on the Machines. Ensuring Area has appropriate Status Label NED.				
10.	Quality Control an 'Released' on Clean		signing as			
11.		and Calibration Status of Weighing Ba	lance.			
12.	Check the BMR is	filled up to Drying Stage.				

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'.

FORMAT	No.	•								

BATCH PRODUCTION AND CONTROL RECORD								
PRODUCT NAME	BATCH No.	MFG. DATE	EXP. DATE					
Placebo Batch (for								
Vitamin D3 60,000								
IU) for equipment								
Qualification								
MFR No.	BMR No.	BATCH SIZE	PAGE No.					
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AFFIX VISUAL INSPECTION AREA LINE CLEARANCE LABEL

BATCH PRODUCTION AND CONTROL RECORD									
PRODUCT NAME	BATCH No.	MFG. DATE	EXP. DATE						
Placebo Batch (for									
Vitamin D3 60,000									
IU) for equipment									
Qualification									
MFR No.	BMR No.	BATCH SIZE	PAGE No.						
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14.2 ENVIRONMENTAL MONITORING: At the time of start of Visual Inspection, after every one hour and after every breakdown.

Date/Time	Room No./Name	Temp. (°C) (NMT 25°C)	% RH Limit (30-40%)	Done By Sign/Date	Checked By Sign/Date	Remarks

14.3 EQUIPMENT DETAILS:

Name of Equipment	ID. No.	Previous Product	Batch No.	Cleanliness (OK/Not OK)	Checked by Sign/Date (Production)	Verified by Sign/Date (QA)

BATCH PRODUCTION AND CONTROL RECORD									
PRODUCT NAME	BATCH No.	MFG. DATE	EXP. DATE						
Placebo Batch (for									
Vitamin D3 60,000									
IU) for equipment									
Qualification									
MFR No.	BMR No.	BATCH SIZE	PAGE No.						
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14.4 PROCEDURE:

a. Visually inspect the defected dried soft gelatin capsules subsequent storage of good capsules in labeled double polythene bags.

Date	Inspection Time		Done By	Checked By
	From	To	Sign/Date	Sign/Date

Record weight of rejected Capsules Kg.	
Rejected Capsules destroyed by: (Production)	
Rejected Capsules destruction checked by: (QA)	

15.0 VERIFICATION OF BMR UP-TO INSPECTION STAGE:-

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

BATCH PRODUCTION AND CONTROL RECORD									
PRODUCT NAME	BATCH No.	MFG. DATE	EXP. DATE						
Placebo Batch (for									
Vitamin D3 60,000									
IU) for equipment									
Qualification									
MFR No.	BMR No.	BATCH SIZE	PAGE No.						
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16.0 CAPSULE POLISHING:

16.1 LINE CLEARANCE FOR CAPSULE POLISHING AREA:

Previous Product			Batch N	No.		
Area				Time		
S.No.		Check Points		Status (OK / Not OK)	Done By Production Officer/Exe. Sign/Date	Checked By QA Officer/Exe. Sign/Date
1.	ensure that there materials.	visually clean and free from dust are no previous product mate	rials/unwanted			
2.	'Batch details' as p No., Batch Size, M	Board " of the area is neatly and du per mentioned in BMR like Producting. Date, Best Before.	t Name, Batch			
3.	cleaning SOP.	ness of Equipments is done as				
4.	Batch / Product ma		•			
5.	Ensure the duly lab properly cleaned.	eled Containers for Non – Recovera	able rejects are			
6.	Ensure the waste bi	n are properly cleaned and placed in	proper place.			
7.		that the Temperature and Relative H specified limit as per mentioned in H				
8.		are that the Machine Log Boo Environmental Monitoring Lo				
9.	that the Machine	er status labeling on the Mach e in Cleaning Area has approp CLEANED / CLEANED.				
10.	released from Q	sure that the Rinse water Auality Control and Report at ning as 'Released' on Cleaned	tached with			
11.		ning and Calibration Status of				
12.	Check the BMR	is filled up to Inspection Stag	je.			

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'.

FORMAT	No.:	 	 	

BATCH PRODUCTION AND CONTROL RECORD						
PRODUCT NAME	BATCH No.	MFG. DATE	EXP. DATE			
Placebo Batch (for						
Vitamin D3 60,000						
IU) for equipment						
Qualification						
MFR No.	BMR No.	BATCH SIZE	PAGE No.			
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AFFIX CAPSULE POLISHING AREA LINE CLEARANCE LABEL

FORMAT No.:		

BATCH PRODUCTION AND CONTROL RECORD						
PRODUCT NAME	BATCH No.	MFG. DATE	EXP. DATE			
Placebo Batch (for						
Vitamin D3 60,000						
IU) for equipment						
Qualification						
MFR No.	BMR No.	BATCH SIZE	PAGE No.			
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16.2 ENVIRONMENTAL MONITORING: At the time of start of Capsule Polishing, after every one hour and after every breakdown.

Date/Time	Room No./Name	Temp. (°C) (NMT 25°C)	% RH Limit (30-40%)	Done By Sign/Date	Checked By Sign/Date	Remarks

16.3 EQUIPMENT DETAILS:

Name of Equipment	ID. No.	Previous Product	Batch No.	Cleanliness (OK/Not OK)	Checked by Sign/Date (Production)	Verified by Sign/Date (QA)

BATCH PRODUCTION AND CONTROL RECORD						
PRODUCT NAME	BATCH No.	MFG. DATE	EXP. DATE			
Placebo Batch (for						
Vitamin D3 60,000						
IU) for equipment						
Qualification						
MFR No.	BMR No.	BATCH SIZE	PAGE No.			
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16.4 PROCEDURE:

- 9.1 Start Air Dispensing Unit and set the speed of 70 80 RPM / Minutes of Capsule Polishing Machine.
 - 9.2 Start supply of compressed air at pressure NMT 2.0 kg/cm².
 - 9.3 Feed inspected capsules in the Capsule Polishing Machine and polish the capsules.
 - 9.4 After completion of polishing, unload the polished capsules in cleaned Polybag with Identification Slip.

Note: Pack NMT 10.0 kg polished capsules in one polybag.

Date	Polishing Time		Machine	Compressed	Done By	Checked By
	From	To	Speed	Air Pressure	Sign / Date	Sign / Date

16.5 POLISHED CAPSULES CONTAINER RECORD:

17.0 RECONCILIATION OF POLISHED CAPSULES:

Weighing Balance ID	Weighing Balance ID No.:		Calibration Status (Ok/Not Ok):			
Container No.	Gross wt (kg)	Tare wt (kg)	Net wt (kg)			
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
		Total Net Weight	kg			

A. Weight of 100 Polished C	osules:gm			
B. Average Weight	$\frac{A}{100} = \underline{\qquad} =$	gm		
C. Total Number of Polished	$Capsules = \underline{Total\ weight\ of\ Polishe}$	d Capsules =	_=	Nos.
EODMAT No.				

	BATCH PROD	UCTION AND CONT	ROL RECORD	
PRODUCT NAM Placebo Batch (fo Vitamin D3 60,00 IU) for equipmer Qualification	or 00	MFG. DATE	EXP. DATE	
MFR No.	BMR No.	BATCH SIZE	PAGE No. 43 of 45	
		Average Weight		
D. Quality Control	Sample :			
E. Actual Batch Siz	ze :	Nos.		
F. Percentage yield		Е	<u>X 100</u> =	<u></u> %.
	than 98.0%, investigate	the matter)		
If Less yield Speci	iy tne reason:			
After completi	•	ALYSIS: Test Request Form to Q the in-process sample v		1 0 1
Intimation No.	Intimated By Sign / Date / Time (Production Officer/Exe.)	Intimation Received By Sign / Date / Time (QA Officer/Exe.)	Quantity Sampled	Sampled By Sign / Date / Time (QA Officer/Exe.)
After receiving	g the analysis report fro	m QC, fill the A.R. No_		
The Inspected	Capsules are Release /	Not Release for Capsul	le packing.	
Checked By Sign/D (Prod. Officer/Execu	Pate: utive)		By Sign / Date cer/Executive)	
19.0 VERIFICAT	ION OF BMR UP-TO	POLISHING STAGE	:	
	eked By Sign / Date ion Officer / Executive	e	Reviewed By Sig QA Officer / Ex	
		-		
FORMAT No.:				

BATCH PRODUCTION AND CONTROL RECORD					
PRODUCT NAME	BATCH No.	MFG. DATE	EXP. DATE		
Placebo Batch (for					
Vitamin D3 60,000					
IU) for equipment					
Qualification					
MFR No.	BMR No.	BATCH SIZE	PAGE No.		
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20.0 BATCH CONVERSION:

Product Name	Material Code	Batch No.	Qty.	Remark
Total Qty.				

Checked By (Production Officer / Executive) Sign. & Date Verified By (QA Officer / Executive) Sign. & Date

BATCH PRODUCTION AND CONTROL RECORD					
PRODUCT NAME	BATCH No.	MFG. DATE	EXP. DATE		
Placebo Batch (for					
Vitamin D3 60,000					
IU) for equipment					
Qualification					
MFR No.	BMR No.	BATCH SIZE	PAGE No.		
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IN-PROCESS OBSERVATIONS

(To Be Filled by OA)

S.No.	Date / Time	Observations	Observed By (Sign/Date) (QA)	Inform To (Production)	Action Taken By (Production)	Verified By Sign / Date (QA)

21.0 Revision History:

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