BATCH PRODUCTION AND CONTROL RECORD			
PRODUCT NAME Placebo Batch (for Vitamin D3 60,000 IU) for equipment Qualification	**PRODUCT CODE**	**EFFECTIVE DATE**	
MFR No.	**BMR No.**	**BATCH No.**	
REVISION No. 00	**SUPERSEDE BMR No.** NIL	**PAGE No.** 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 D_3) 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				

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			
Balance			
Balance			
Balance			

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

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

Previous Product		**Area**	
Batch No.		**Date / Time (Hrs.)**	

S. No.	Check Points	Status (OK / Not OK)	Done By (Warehouse Officer/Exe.) Sign/Date	Checked By (QA Officer/Exec) Sign/Date
1.	Check the **"Status Board"** of the dispensing area for following details: Product Name, Batch No., Mfg. Date, Exp. Date, Batch Size and ensure that the details are matching with the BMR of present batch to be processed.			
2.	Check the cleanliness of the room and ensure that it is free from the remains of the previous batch.			
3.	Check the cleanliness of the RLAF Unit and ensure that it is free from the remains of the previous batch.			
4.	Check and ensure that the RLAF is switched **"ON"** minimum 30 minutes before start of the activity and the pressure differential across **HEPA filter** is within limit.			
5.	Check the Temperature and Relative Humidity (RH) of the Dispensing Room (It should be within specified range).			
6.	Check the Calibration Status of the balance.			
7.	Ensure all logbooks of the area (RLAF Usage Log Book, Balance Calibration Log Book, Cleaning Log Book and Environmental Monitoring Log Book etc.) are filled regularly.			
8.	Inspect the Waste Bins and ensure that it is free from remains of the previous batch.			
9.	Ensure that the raw material is QC approved and Approved Labels is affix on each container.			
10.	Check and verify the identity of raw materials by Item code & A.R. No. to be used are as per BMR.			
11.	Ensure proper cleaning of filters of RLAF, Riser and grill of filters.			
12.	Check and Ensure the availability of Cleaned Dispensing 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'.

1.5 LINE CLEARANCE FOR DISPENSING: FOR EXCIPIENTS

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

LINE CLEARANCE CHECK LIST – DISPENSING

Previous Product		**Area**	
Batch No.		**Date / Time (Hrs.)**	

S. No.	Check Points	Status (OK / Not OK)	Done By (Warehouse Officer/Exe.) Sign/Date	Checked By (QA Officer/Exec) Sign/Date
1.	Check the **"Status Board"** of the dispensing area for following details: Product Name, Batch No., Mfg. Date, Exp. Date, Batch Size and ensure that the details are matching with the BMR of present batch to be processed.			
2.	Check the cleanliness of the room and ensure that it is free from the remains of the previous batch.			
3.	Check the cleanliness of the RLAF Unit and ensure that it is free from the remains of the previous batch.			
4.	Check and ensure that the RLAF is switched **"ON"** minimum 30 minutes before start of the activity and the pressure differential across **HEPA filter** is within limit.			
5.	Check the Temperature and Relative Humidity (RH) of the Dispensing Room (It should be within specified range).			
6.	Check the Calibration Status of the balance.			
7.	Ensure all logbooks of the area (RLAF Usage Log Book, Balance Calibration Log Book, Cleaning Log Book and Environmental Monitoring Log Book etc.) are filled regularly.			
8.	Inspect the Waste Bins and ensure that it is free from remains of the previous batch.			
9.	Ensure that the raw material is QC approved and Approved Labels is affix on each container.			
10.	Check and verify the identity of raw materials by Item code & A.R. No. to be used are as per BMR.			
11.	Ensure proper cleaning of filters of RLAF, Riser and grill of filters.			
12.	Check and Ensure the availability of Cleaned Dispensing 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 Placebo Batch (for Vitamin D3 60,000 IU) for equipment Qualification	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No.	**BMR No.**	**BATCH SIZE**	**PAGE No.** 6 of 45	

AFFIX DISPENSING AREA LINE CLEARANCE LABEL

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

1.6 RAW MATERIAL DISPENSING RECORD:

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

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

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

AFFIX THE RAW MATERIALS DISPENSING LABELS

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

AFFIX THE RAW MATERIALS DISPENSING LABELS

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.

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT NAME Placebo Batch (for Vitamin D3 60,000 IU) for equipment Qualification	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
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 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.	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 Equipments are done as per respective cleaning SOP.			
4.	Ensure the Equipments are free from any remains of the previous Batch / Product material.			
5.	Ensure the duly labeled containers for Non – Recoverable rejects are properly cleaned.			
6.	Ensure the waste bin are properly cleaned and placed in proper place.			
7.	Check and ensure that the Temperature and Relative Humidity of the area are within the specified limit as per mentioned in BMR.			
8.	Check and ensure that the Machine Log Book, Cleaning Log Book and Environmental Monitoring Log Book are filled correctly.			
9.	Ensure that Return Air 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 the Rinse water / swab are released from Quality Control and report attached with BMR before signing as 'Released' on Cleaned label.			
12.	Check the cleaning and calibration status of weighing balance.			
13.	Check and verify the item code and weight of dispensed raw material with BMR.			
14.	Check the BMR is filled up to Dispensing Stage.			

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 Placebo Batch (for Vitamin D3 60,000 IU) for equipment Qualification	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No.	**BMR No.**	**BATCH SIZE**	**PAGE No.** 12 of 45	

AFFIX GELATIN AREA LINE CLEARANCE LABEL

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.)

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

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^{0}Cto get homogenous clear solution.

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

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)		Process Completed Time / Date	Filtration Done By	Checked By (Sign / Date) (Production)	Verified By (Sign / Date) (QA)
	Before	After				

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^{0}C. Add @ 14.900 ltr.(Batch Qty…….) of Purified Water and then mix for 15 minutes.

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

i. Rise the temperature up to 62^{0}C (……^{0}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.

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

l. After 10 minutes, stop the vacuum pump and close the inlet valve for incoming supply for vacuum in the Melter.

m. Start vacuum on reaching 650-715 mm of Hg for 1 hour and reaching temperature 58 – 62^{0}C to get complete mass in Melting Stage.

n. Open the outlet valve of Gelatin Melter slowly to release vacuum outside from the Gelatin Melter slowly.

o. Draw the sample of mass in plate and observe the Gelatin Mass for absence of air bubble from melted mass completely.

4.0 SAMPLE REQUEST FOR QC ANALYSIS:

Send Test Request Form to QA for sampling of Gelatin Mass for analysis. QA officer / Executive after sampling, send the in-process sample with intimation to QC dept. for analysis.

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 the analysis report from QC, fill the A.R. No_____

The Gelatin Mass is **Release / Not Release** for Encapsulation.

QA Officer/Executive Sign _____ Date _____ Time _____

5.0 VERIFICATION OF BMR UP-TO GELATIN MASS PREPARATION STAGE:-

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

6.0 MANUFACTURING –MEDICAMENT PREPARATION:

6.1 LINE CLEARANCE FOR MEDICAMENT PREPARATION AREA:

Product		**Batch 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.	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 Equipments are done as per respective cleaning SOP.			
4.	Ensure the Equipments are free from any remains of the previous Batch / Product material.			
5.	Ensure the duly labeled containers for Non – Recoverable rejects are properly cleaned.			
6.	Ensure the waste bin are properly cleaned and placed in proper place.			
7.	Check and ensure that the Temperature and Relative Humidity of the area are within the specified limit as per mentioned in BMR.			
8.	Check and ensure that the Machine Log Book, Cleaning Log Book and Environmental Monitoring Log Book are filled correctly.			
9.	Ensure that Return Air 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 the Rinse water / swab are released from Quality Control and report attached with BMR before signing as 'Released' on Cleaned label.			
12.	Check the cleaning and calibration status of weighing balance.			
13.	Check and verify the item code and weight of dispensed raw material with BMR.			
14.	Check the BMR is filled up to Gelatin Mass Preparation 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'.

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT NAME Placebo Batch (for Vitamin D3 60,000 IU) for equipment Qualification	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No.	**BMR No.**	**BATCH SIZE**	**PAGE No.** 18 of 45	

AFFIX MEDICAMENT PREPARATION AREA LINE CLEARANCE LABEL

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

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. No.	Material Name	Sieve Size	Sieve Integrity Test		Sifting Started at Date/Time	Sifting Completed at Date/Time	Done By (Sign/Date) (Operator)	Checked by (Sign/Date) (Production)
			Before Use	After Use				
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 30ºC 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 Time / Date	Mixing Time		Total Mixing Time	Process Completed Time / Date	Checked By (Sign / Date) (Production)	Verified By (Sign / Date) (QA)
	From	To				

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 Medicament:		**Kg**		

6.4.3 RECONCILIATION OF MEDICAMENT:

A. Theoretical weight of Medicament: _____kg.

B. Actual weight of Medicament: _____kg.

C. Process Loss: _____kg.

D. QC Sample: _____kg.

E. Percentage yield : $\frac{(B+D) \times 100}{A}$ = _____X 100 = _____%.

(If the yield is less than 99.00%, investigate the matter)

If Less yield Specify the reason:

7.0 SAMPLE REQUEST FOR QC ANALYSIS:

Send Test Request Form to QA for Medicament Sampling for analysis. QA Officer / Executive after sampling, send the in-process sample with intimation to QC dept. for analysis.

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 the analysis report from QC, fill the A.R. No_____

The medicament is **Release / Not Release** for Encapsulation.

QA Officer/Executive Sign _____ Date _____ Time _____

8.0 VERIFICATION OF BMR UP-TO MEDICAMENT PREPARATION STAGE:-

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

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT NAME Placebo Batch (for Vitamin D3 60,000 IU) for equipment Qualification	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
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 / Time	

S. No.	Check Points	Status (OK / Not OK)	Done By Production Officer/Exe. Sign/Date	Checked By QA Officer/Exe. Sign/Date
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 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.	Ensure the duly labeled containers for Non – Recoverable rejects are properly cleaned.			
6.	Ensure the waste bin are properly cleaned and placed in proper place.			
7.	Check and ensure that the Temperature and Relative Humidity of the area are within the specified limit as per mentioned in BMR.			
8.	Check and ensure that the Machine Log Book, Cleaning Log Book and Environmental Monitoring Log Book are filled correctly.			
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 balance.			
12.	Check and Ensure that the Blend is release from Quality Control and released report attached with BMR			
14.	Check the BMR is filled up to Medicament Preparation 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'.

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT NAME Placebo Batch (for Vitamin D3 60,000 IU) for equipment Qualification	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No.	**BMR No.**	**BATCH SIZE**	**PAGE No.** 24 of 45	

AFFIX CAPSULE FILLING AREA LINE CLEARANCE LABEL

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						

9.4 ENCAPSULATION INSTRUCTIONS:

- **a.** Operate the Encapsulation Machine.
- **b.** Check and maintain the heating of Gelatin Mass Tank at 50-54^{0}C.
- **c.** Before feeding of gelatin mass in Spreader Box maintain heating of Spreader Box at 53-57^{0}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^{0}C.
- **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^{0}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.

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^{0}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					

9.7 INITIAL CHECKS OF ENCAPSULATION PARAMETERS:

Parameters	Std. Limits	Observed	Checked By (Production)	Verified By (QA)
Ribbon Thickness	0.75 - 0.85 mm			
Drum Temperature	8-12^{0}C			
Segment Temperature	36-44^{0}C			
Spreader Box Temp. (Left)	53-57^{0}C			
Spreader Box Temp. (Right)	53-57^{0}C			
Die Size	7.5 minim			
Capsule Colour	Light Pale Yellow colored transparent			
Capsule Shape	Oval			
Description	Light Pale Yellow colored transparent Soft Gelatin Capsules containing clear colorless oily liquid.			
Average Fill Weight	250 mg ±3%			
Uniformity of Fill Weight	± 5 % of Average Fill 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 Placebo Batch (for Vitamin D3 60,000 IU) for equipment Qualification	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No.	**BMR No.**	**BATCH SIZE**	**PAGE No.** 29 of 45	

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^{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 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 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.				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. % _____				Max. Fill. % _____ Min. Fill. % _____			
Remark				Remark				Remark			
Done by				**Done by**				**Done by**			

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT NAME Placebo Batch (for Vitamin D3 60,000 IU) for equipment Qualification	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
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 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.				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. % _____				Max. Fill. % _____ Min. Fill. % _____			
Remark				Remark				Remark			
Done by				**Done by**				**Done by**			

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT NAME Placebo Batch (for Vitamin D3 60,000 IU) for equipment Qualification	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No.	**BMR No.**	**BATCH SIZE**	**PAGE No.** 31 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 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 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.				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. % _____				Max. Fill. % _____ Min. Fill. % _____			
Remark				Remark				Remark			
Done by				**Done by**				**Done by**			

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT NAME Placebo Batch (for Vitamin D3 60,000 IU) for equipment Qualification	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
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^{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 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 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.				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. % _____				Max. Fill. % _____ Min. Fill. % _____			
Remark				Remark				Remark			
Done by				**Done by**				**Done by**			

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.

Drying Room No. : **Date & Time of Loading :**

No. of Trolleys : **Date & Time of Removal :**

Date	Time	Temp. (°C) Limit (22-24°C)	% RH Limit (NMT 25%)	Checked by	Shuffling		Checked by	Remarks
					Time	Done by		

Date	Time	Temp. (°C) Limit (NMT 25°C)	% RH Limit (NMT 25%)	Checked by	Shuffling		Checked by	Remarks
					Time	Done by		

12.0 SAMPLE REQUEST FOR QC ANALYSIS:

Send Test Request Form to QA for sampling of Dried Capsules for analysis. QA officer / Executive after sampling, send the in-process sample with intimation to QC dept. for analysis of Moisture content. (Limit: 8-12%)

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

After receiving the analysis report from QC, fill the A.R. No_____

Capsule is **Release / Not Release** for Visual Inspection.

QA Officer/Executive Sign _____ Date _____ Time(Hrs.) _____

13.0 VERIFICATION OF BMR UP-TO DRYING STAGE:-

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

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT NAME Placebo Batch (for Vitamin D3 60,000 IU) for equipment Qualification	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No.	**BMR No.**	**BATCH SIZE**	**PAGE No.** 35 of 45	

14.0 VISUAL INSPECTION OF DRIED CAPSULES: (Inspect the 100 % Batch)

14.1 LINE CLEARANCE FOR VISUAL INSPECTION AREA:

Previous Product		**Batch 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.	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 Equipments as per respective cleaning SOP.			
4.	Ensure the Equipments are free from any remains of the previous Batch / Product material.			
5.	Ensure the duly labeled Containers for Non – Recoverable rejects are properly cleaned.			
6.	Ensure the waste bin are properly cleaned and placed in proper place.			
7.	Check and Ensure that the Temperature and Relative Humidity of the area are within the specified limit as per mentioned in BMR.			
8.	Check and Ensure that the Machine Log Book, Cleaning Log Book and Environmental Monitoring Log Book are filled correctly.			
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 Balance.			
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'.

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT NAME Placebo Batch (for Vitamin D3 60,000 IU) for equipment Qualification	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No.	**BMR No.**	**BATCH SIZE**	**PAGE No.** 36 of 45	

AFFIX VISUAL INSPECTION AREA LINE CLEARANCE LABEL

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)

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 Sign/Date	Checked By Sign/Date
	From	To		

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

16.0 CAPSULE POLISHING:

16.1 LINE CLEARANCE FOR CAPSULE POLISHING AREA:

Previous Product		**Batch 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.	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 Equipments is done as per respective cleaning SOP.			
4.	Ensure the Equipments are free from any remains of the previous Batch / Product material.			
5.	Ensure the duly labeled Containers for Non – Recoverable rejects are properly cleaned.			
6.	Ensure the waste bin are properly cleaned and placed in proper place.			
7.	Check and Ensure that the Temperature and Relative Humidity of the area are within the specified limit as per mentioned in BMR.			
8.	Check and Ensure that the Machine Log Book, Cleaning Log Book and Environmental Monitoring Log Book are filled correctly.			
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 Balance.			
12.	Check the BMR is filled up to Inspection 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'.

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT NAME Placebo Batch (for Vitamin D3 60,000 IU) for equipment Qualification	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No.	**BMR No.**	**BATCH SIZE**	**PAGE No.** 40 of 45	

AFFIX CAPSULE POLISHING AREA LINE CLEARANCE LABEL

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT NAME Placebo Batch (for Vitamin D3 60,000 IU) for equipment Qualification	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No.	**BMR No.**	**BATCH SIZE**	**PAGE No.** 41 of 45	

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 Placebo Batch (for Vitamin D3 60,000 IU) for equipment Qualification	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No.	**BMR No.**	**BATCH SIZE**	**PAGE No.** 42 of 45	

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/cm^2.

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

16.5 POLISHED CAPSULES CONTAINER RECORD:

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

17.0 RECONCILIATION OF POLISHED CAPSULES:

A. Weight of 100 Polished Capsules : ……gm

B. Average Weight : $\frac{A}{100}$ = _____ = _____gm

C. Total Number of Polished Capsules = Total weight of Polished Capsules = _____ = _____Nos.

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT NAME Placebo Batch (for Vitamin D3 60,000 IU) for equipment Qualification	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No.	**BMR No.**	**BATCH SIZE**	**PAGE No.** 43 of 45	

Average Weight

D. Quality Control Sample :

E. Actual Batch Size : _____Nos.

F. Percentage yield : $\frac{C+D \times 100}{E}$ = _____X 100 = _____%.

(If the yield is less than 98.0%, investigate the matter)

If Less yield Specify the reason:

18.0 SAMPLE REQUEST FOR QC ANALYSIS:

After completion of Inspection, send Test Request Form to QA for Polished Capsules sampling. QA officer/Executive after sampling send the in-process sample with intimation Slip to QC dept. for analysis.

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 the analysis report from QC, fill the A.R. No_____

The Inspected Capsules are **Release / Not Release** for Capsule packing.

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

Verified By Sign / Date _____ (QA Officer/Executive)

19.0 VERIFICATION OF BMR UP-TO POLISHING STAGE:

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

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT NAME Placebo Batch (for Vitamin D3 60,000 IU) for equipment Qualification	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No.	**BMR No.**	**BATCH SIZE**	**PAGE No.** 44 of 45	

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 Placebo Batch (for Vitamin D3 60,000 IU) for equipment Qualification	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No.	**BMR No.**	**BATCH SIZE**	**PAGE No.** 45 of 45	

IN-PROCESS OBSERVATIONS

(To Be Filled by QA)

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