PROCESS VALIDATION PROTOCOL OF CALCITRIOL & MULTIVITAMINS SOFTGEL CAPSULES

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1.0 PROTOCOL APPROVAL:

Function	Department	Name	Signature	Date
Prepared By	Quality Assurance			
Reviewed By	Production			
	Quality Control			
	Engineering			
Approved By	Head - Production			
	Head - QA			

2.0 VALIDATION TEAM:

The Production, Quality Assurance, Quality Control, Engineering, and Technical support department are responsible for the overall adherence to the protocol. Individuals to be named in validation report.

BATCHES UNDER VALIDATION:

Three consecutive successful batches, Batch details with batch number, manufacturing and expiry date to be mentioned in validation report.

3.0 INTRODUCTION:

Calcitriol & Multivitamins Soft Gelatin capsules has been developed using the Soft Gel Encapsulation Technology.

OBJECTIVE:

The objective of this exercise is to develop a **PROCESS VALIDATION PROTOCOL** to validate the process and have documented evidence to ensure that critical process variables established during Validation. Also to demonstrate the process capability on equipment and utility ensuring that the product meets its predetermined specifications and quality attributes

SCOPE:

This protocol for the Process Validation of Calcitriol & Multivitamins Softgelatin capsules formulation defines the procedural aspects to be followed while carrying out Process validation activity that includes prerequisites before commencing the actual work like, Master formula and process, approved vendors and characteristics of raw materials. Also it defines the acceptance criteria, revalidation criteria and justification for critical process parameters.

VALIDATION CRITERIA:

- Process validation batch shall be manufactured as per process steps given in the Master Manufacturing Formula.
- The batches manufactured during process validation shall meet the criteria defined in product specification.

REVALIDATION CRITERIA:

The process shall be revalidated whenever there shall be changes in:

- Manufacturing process and the product formula.
- Manufacturing site or location.
- Change in critical equipment in manufacturing process
- Change in batch size

REASON FOR VALIDATION:

The product Calcitriol & Multivitamins will be manufactured as validation batch due to new product in Sikkim location, which has been transferred/ change in facility from another location.

TYPE OF VALIDATION:

Type of validation to be recorded in validation report.

4.0 PRODUCT PROFILE:

Name of the Product	**Calcitriol & Multivitamins**
Composition :	Each Soft Gelatin Capsule contain: Calcitriol IP 0.25 mcg Calcium carbonate IP 1250 mg Vitamin K2-7 45 mcg Mecobalamin JP 1500 mcg Zinc 7.5 mg Magnesium 50 mg L-Methyl Folate 800 mcg Excipient q.s. Colour : Approved Colours used in capsule shell Appropriate overages added.
Shelf Life :	24 months

Appearance	**:**	Red coloured, oval shaped Soft gelatin capsules containing pale brown to pink coloured viscous oily paste.
Storage	**:**	Store in a cool and dry place. Protect from direct sunlight.

5.0 MASTER FORMULA:

S.No.	Components	Specification	Qty/Capsule (in mg)
Gelatin Mass Manufacturing			
1.	Gelatin IP (200 Bloom)	IP	826.477
2.	Glycerin IP	IP	226.19
3.	Sorbitol Solution (70 %) (Non-Crystallising) IP	IP	160.957
4.	Methyl Paraben IP	IP	2.646
5.	Propyl Paraben IP	IP	0.659
6.	Fumaric Acid IP	IP	15.030
7.	Colour Ponceau 4R Supra IHS	IHS	10.683
8.	Titanium Dioxide IP	IP	3.74
9.	Purified Water IHS*	IHS	636.952
Medicament Manufacturing			
10.	Calcitriol IP @	IP	0.35 mcg
11.	Calcium Carbonate IP (BD-NLT 1g/ml)	IP	1250.00
12.	Vitamin K2-7 IHS #	IHS	29.35
13.	Mecobalamin JP £	JP	2.610
14.	Magnesium oxide heavy IP	IP	82.93
15.	Zinc Sulphate Monohydrate BP	BP	20.58
16.	L-Methyl Folate Calcium IHS $	IHS	1.83
17.	Natural Vitamin E IHS	IHS	10.00
18.	Methyl Paraben IP	IP	1.00
19.	Propyl Paraben IP	IP	0.10
20.	White Bees Wax IP	IP	0.50
21.	Hydrogenated Vegetable Oil BP (Lubritab)	BP	0.50
22.	Butylated Hydroxytoluene IP	IP	0.30
23.	Butylated Hydroxyanisole BP	BP	0.30
24.	Lecithin USP-NF	USP-NF	30.00
25.	Disodium Edetate IP	IP	1.00
26.	Citric Acid IP (Anhydrous)	IP	15.00
27.	Refined Soya Oil BP	BP	150.00
28.	Medium Chain Triglycerides BP (Hariol-538)	BP	279.00
Miscellaneous			
29.	Refined Soya Oil BP (For Fill Weight Setting & Machine Flush)	BP	33.30
30.	Light Liquid Paraffin IP (For Machine Lubrication & Ribbon Lubrication)	IP	40.00

Note: * 5.0 Kg extra amount of Purified water to be included in a lot (565.0 Kg for 300000 capsules) of gelatin mass preparation and will be removed during manufacturing process.
@ Include 40 % overage.
# Include 50 % overage.
£ Include 50 % overage.
$ Include 50 % overage.

6.0 RESPONSIBILITIES OF VALIDATION TASK FORCE:

The Production, QA/QC, Technical support department are responsible for the overall adherence to the protocol. Specific duties will include the following:

Monitoring protocol completeness, accuracy, technical content and applicability.

Scheduling and carrying out the Validation activity.

Data Review

Preparation of the Validation protocol and report

Approval of the report and / or recommendations of further work required.

The responsibilities of Production, QA/QC are

a. To facilitate the timely execution of this protocol by provision of personnel, equipment and materials as required.

b. Ensure compliance with cGMP and in house SOP's.

It is the responsibility of QA / QC Departments to record all results for the Validation exercise in the form of reports at each step of operation.

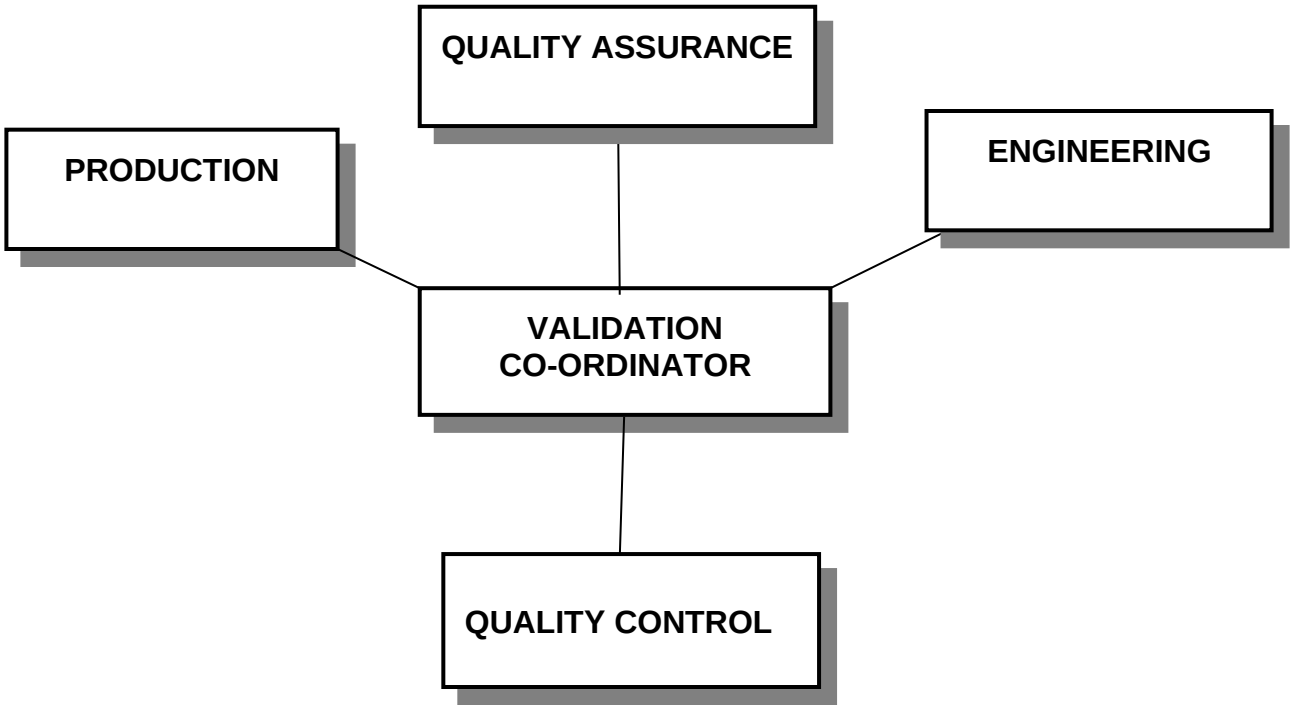
Note: All work carried out shall be in accordance with SOP's and in accordance to the Finished Product Specification.

It is responsibility of the Validation team to review test results and documentation and determine the success of the Validation execution. A member of the Validation team or QA/QC as appropriate shall check all cross-referencing and numerical results.

To ensure complete validation of the process each step of the protocol shall pass the acceptance criteria. Where problems occur with analytical results, SOP on OOS shall be followed. Any problem that occurs during the manufacturing process shall be documented in Batch Manufacturing Record. Any deviations or deficiencies, which occurred when carrying out of the validation testing, shall be

documented. All deficiencies and deviations shall be addressed before completing the Validation Report.

VALIDATION TASK FORCE:



7.0 RISK ANALYSIS:

The product Calcitriol & Multivitamins shall be manufactured in General block with batch size of 300000 capsule as a validation batch.

Calcitriol & Multivitamins shall be manufacturing by using the Softgel encapsulation Technology. Raw materials of approved vendor source shall be used for processing.

- **Dispensing:** Dispensing of all raw material is done by using calibrated balance, all raw material are procured from approved vendor, there is no critical parameter identified for validation during dispensing stage.
- **Gelatin mass manufacturing :** Preparation of Gelatin mass manufacturing is performed by laid down procedure with heating & stirring arrangement under vacuum and during mixing critical parameters are temperature, Applied vacuum, description presence of air bubble & RPM to be monitored for record purpose as part of validation.
- **Medicament preparation :**

  Preparation of medicament is performed by laid down procedure under heating & stirring arrangement and during mixing critical parameters are temperature, time of mixing, description & RPM to be monitored for record purpose as part of validation.

- **Encapsulation process:** During Encapsulation process physical parameter, Description, Assay to be check at different challenges, at maximum speed, minimum speed, optimum speed, full hopper, half hopper, end hopper, at initial stage, middle stage & at end stage. This process will cover critical process variable like effect of speed. After completion of Encapsulation process composite sample to be withdrawn for analysis as per QC in process specification.
- **Capsule degreasing:** Degreasing of capsule done in degreasing pan with addition of 6-8 numbers of MBPP Wipes. There is no critical parameter identified for validation during dispensing stage.
- **Drying:** In drying stage Spread capsule on ss tray & dried at specified temperature till desired LOD achieve process cover critical parameter like drying temperature and time of drying.

8.0 SAMPLING PROCEDURE:

1. All validation samples of Softgel manufacturing shall be as per sampling plan and placed in clean container and labeled as follows:

   - Product: Batch Number:
   - Batch Size: Stage:
   - MFG.: EXP.:

   Sampled By / Date

2. **BULK SAMPLE:**

   These samples shall be taken in accordance with SOP for "**Procedure for Cleaning and Operation of sampling thief".**

   The samples shall be placed in container or sampling poly bag and labelled as follows:

   - Product Name
   - Batch Number
   - Sample Location Number (Ref. Sample Summary)
   - Sample Type
   - Sign / Date

PROCESS VALIDATION PROTOCOL OF CALCITRIOL & MULTIVITAMINS SOFTGEL CAPSULES

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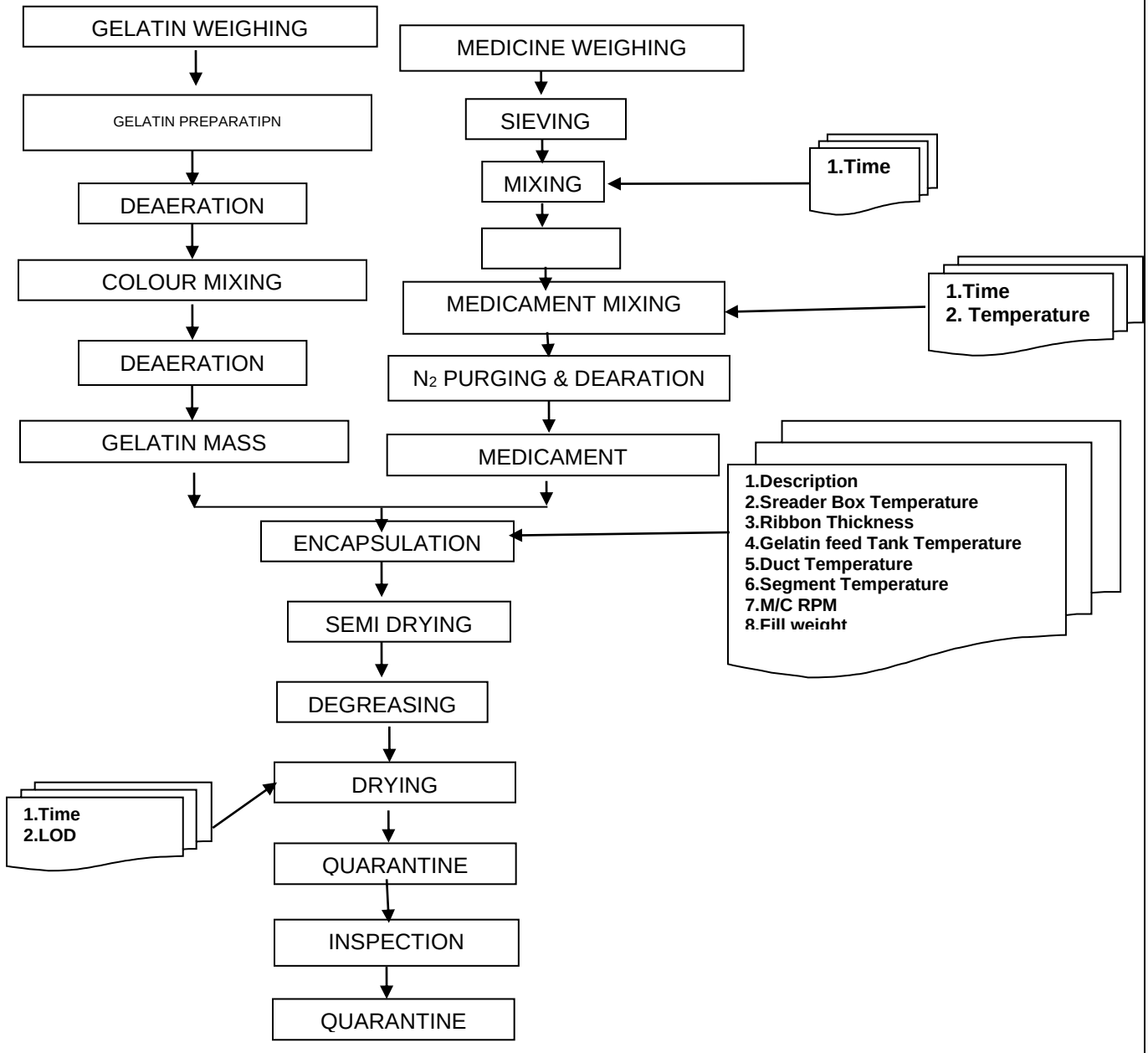
9.0 FLOW DIAGRAM



10.0 MANUFACTURING PROCESS

10.1	**Gelatin mass manufacturing**
10.1.1	Start the Hot water Circulation in jacket of gelatin cooking vessel and set the temperature at 65°C–80°C.
10.1.2	Transfer Glycerine 60.357 Kg, Sorbitol 48.287 Kg , Purified Water 161.086 Kg and extra amount of water into Gelatin cooking vessel by applying vacuum and start stirring at fast speed to attain the temperature 65ºC - 80ºC.
10.1.3	Add Fumaric Acid 4.509 Kg, Methylparaben 0.794 Kg, Propylparaben 0.198 Kg into Gelatin cooking vessel and mix for 15 -20 minutes.
10.1.4	Transfer Gelatin 247.943 Kg into Gelatin cooking vessel by applying vacuum with with continuous stirring at fast speed for 30 – 40 mins. Maintain the temperature of inside material at 65ºC + 5ºC.
10.1.5	Apply vacuum (600 -700 mm Hg) for 40-45 minutes to evaporate the extra amount of purified water and free from the lumps and air bubbles in the gelatin mass. Ensure that no air bubbles are present in gelatin mass.
10.1.6	Dissolve Colour Ponceau 4R Supra 3.205Kg in Purified Water 12.0Kg in a S.S. Vessel. Then add into Gelatin cooking vessel and rinse the container with Purified water 6.0Kg and add it to the Gelatin cooking vessel.
10.1.7	Disperse Titanium Dioxide 1.122 Kg in Glycerin 7.50 Kg and pass through colloidal mill for 15 – 20 mins and then add it into Gelatin cooking vessel. Rinse the colloidal mill with Purified water 12.00 Kg and add it into Gelatin cooking vessel.
10.1.8	Mix the colour solution with gelatin mass for 20- 25 minutes. Deaerate the gelatin mass by applying Vacuum for 25- 30 minutes.
10.1.9	Stop vacuum and collect sample of gelatin mass from bottom valve and spread on the SS plate and observe against the light for air bubble entrapment in gelatin mass. Ensure that no air bubbles are present in gelatin mass.
10.1.10	Keep aside Gelatin Holding Tank for 4 – 6 hrs at 65ºC + 5ºC for maturation of gelatin.
Note : If gelatin mass is not going to use after 6 hrs of maturation, switch off the heater. Switch on heater 6 hrs before starting Encapsulation.	
10.2	**Medicament Manufacturing**

10.2.1	Filter Medium Chain Triglyceride 73.20 Kg and Refined soya oil 24.00 Kg through # 100 S.S. sieve and collect in medicament holding vessel, start nitrogen purging. Keep aside Medium Chain Triglycerides 10.50 Kg and Refined soya oil 21.00 Kg for further process.
10.2.2	Add Refined soya oil 6.00 Kg into Soya lecithin container, heat to 50ºC – 60ºC, add into medicament holding vessel and mix for 5 – 10 minutes.
10.2.3	Collect Refined soya oil 15.00 Kg in a S.S. vessel. Add Hydrogenated vegetable oil 0.150 kg , White bees wax 0.150 kg, Butylated Hydroxyanisole 0.090 kg , Butylated Hydroxytoluene 0.090 kg, Methyl paraben 0.300 kg, Propyl paraben 0 .300 kg and dissolve with continuous heating to 55º-75ºC. Transfer the bulk solution to medicament holding vessel with continuous mix for 5 – 10 minutes.
10.2.4	Add Calcium Carbonate 375.00 Kg to medicament holding vessel with continuous stirring for 10 – 15 minutes
10.2.5	Add Magnesium oxide heavy 24.879 Kg to medicament holding vessel with continuous stirring for 15 – 20 minutes
10.2.6	Sift Zinc Sulpahate monohrdrate 6.174 Kg, Citric Acid 4.500 Kg & Disodium Edetate 0.300 kg through # 80 S.S. sieve, then add to Medicament holding Vessel and mix with continuous stirring for 15 – 20 mins.
10.2.7	Pass the medicament through inline homogenizer for 30-50 minutes.
10.2.8	Add Natural Vit-E 3.00 Kg to Medicament holding Vessel and mix for 15 – 20 mins
10.2.9	Add Vitamin K2 -7, 8.805 Kg to medicament holding vessel and mix for 15 – 20 minutes.
10.2.10	Collect Medium Chain Triglycerides 6.00 Kg in a S.S. vessel, disperse Methylcobalamin 0.783 kg and L-Methyl Folate 0.549 kg and pass through # 100 S.S sieve. Then add to Medicament holding Vessel. Rinse the S.S. vessel with Medium Chain Triglycerides 1.500 Kg and add into Medicament holding Vessel with continuous stirring for 20-30 mins
10.2.11	Pass the Medicament through # 60 S.S sieve with the help of vibro sifter or manually and collect in Medicament holding vessel and mix with continuous stirring for 15 – 20 mins
10.2.12	Collect Medium Chain Triglycerides 1.500 Kg in a S.S vessel, dissolve Calcitriol 105.00 mg by using Sonicator, then add to Medicament holding vessel. Rinse the S.S. vessel with

	Medium Chain Triglycerides 1.500 Kg and add into Medicament holding vessel with continuous stirring for 90-120 mins
10.2.13	Carry out deaeration of medicament by applying vacuum 600 to 700 mm of Hg for 35 – 45 minutes.
10.2.14	Description: Pale brown to pink colour viscous oily paste.

Note: Entire manufacturing process to be carried out under Nitrogen purging & under sodium vapour lamp**.**

10.3	**Encapsulation process**
10.3.1	Maintain the encapsulation area temperature at $18^0C \pm 3^0C$ and Humidity 35% ± 5 %RH.
10.3.2	Check all gaskets & change parts, assemble 20SK minim oval die roll to encapsulation machine with respective segment. Connect medicament pipe from hopper to segment.
10.3.3	Transfer the gelatin holding tank to encapsulation area and connect the feed pipe from gelatin holding tank to spreader box. Maintain gelatin holding tank temperature at 60°c + 5°c, spreader box temperature at 55°c + 5°c, Segment temperature at 40°c + 5°c & cool drum temperature at 10°c + 3°c.
10.3.4	Fill approximately 9.99 kg of Refined soya oil in the hopper and run the machine and adjust the ribbon thickness and fill weight of capsules as per In-process specification. Check and adjust the fill weight of capsules entire length of die roll. Discard the Refined soya oil capsules and remove the Refined soya oil from the hopper.
10.4.5	Transfer the medicament tank to feeding area and fill the medicament in the hopper and Encapsulate as per standard procedure and set the parameters as per In process specifications.
10.3.6	Transfer capsules to tumble drier and tumble the capsules for 30-45 minutes and unload into degreasing pan
10.3.7	Target fill weight :1875.00 mg
10.4	**Capsule degreasing**
10.4.1	Load the capsules into degreasing pan and add 6-8 numbers of MBPP Wipes. Run the machine for 15 Minutes.

10.5	**Drying**
10.5.1	Spread capsule on trays put tray in trolley & transfer to drying area (Temperature at 22°c + 3°c and relative humidity 18 + 5%). Shuffle the capsule every 30 min for 2 hours & followed by every 6 hours. Dry the capsule for 40-48 hours to achieve the LOD of capsule shell 6-10 %. (LOD at 105°c for 3 hours).Unload the dried capsules NMT 6.000 kg in poly bag & transfer to quarantines area.
10.6	**Inspection**
10.6.1	Spread the capsule on inspection table & reject the under size and over size capsules, empty capsule shell, capsule having air bubbles , twin capsules, deshaped capsules & defected capsules.
10.6.2	Collect good capsules in double line polybag & transfer to quarantine area.
10.7	**Finished product analysis**
10.7.1	Intimate the in process quality control department for sampling & send the sample to Q.C. for analysis for analysis of finished product as per current finished product specification.

11.0 CALIBRATION / QUALIFICATION:

All equipment utilized in conducting the Validation activity shall be with in calibration.

Calibration shall be conducted in-house in accordance with approved SOP's or by an external body. All standards used in calibration shall be traceable to a national standard and shall remain within calibration for the duration of the Validation exercise.

12.0 METHODOLOGY FOR VALIDATION OF PROCESS:

Details of the testing to be carried out are

a. Raw materials

b. Gelatin mass manufacturing

c. Medicament preparation

d. Encapsulation process

e. Drying

ACCEPTANCE CRITERIA:

The overall criteria by which the efficiency of the manufacturing procedure shall be judged is based on the following:

A Validation batch shall be considered acceptable if all In-process results, Finished product results and additional validation testing meets the acceptance criteria as outlined in Section Sample Summary.

PREPARATION OF VALIDATION REPORT:

1. The Validation Team shall prepare a Validation report, which compiles and reports the Finished Product Results for scale down batch. The batch will be released for stability studies based on the Finished Product testing.
2. The report shall be submitted to the same discipline responsible for review of the Validation protocol and approved by those same disciplines before the product is considered validated.

13.0 SAMPLE SUMMARY:

Stage	Location	Sample Qty.	Sample Type	Frequency	Tests	Acceptance Criteria	Responsibility
Raw Material Testing	Raw Material Drums	As per Specification	Sample of Raw Materials	Prior to Dispensing	As per RM Specification	As per RM Specifications	Q.C.
Manufacturing process							
Medicament preparation	Medicament mixing unit	40 g Each© location (α) Composite 40.0 gm	(Top (T1, T2, T3), Middle(M1, M2, M3), Bottom (B1,B2,B3,B4) & composite)	At the end of medicament preparation	Assay & Description	As per specification	IPQA & Q.C
Encapsulation *	In-process Testing	6 capsules	Individual capsule	Maximum speed	Description Ribbon Thickness	Red coloured, oval shaped Soft gelatin capsules containing pale brown to pink coloured viscous oily paste. 0.90 + 0.05 mm	IPQA/ Production
		6 capsules	Individual capsule	Minimum speed			
		6 capsules	Individual capsule	Optimum Speed			

The medicament sample will be collected from all three locations [Top (T1, T2, T3), Middle (M1, M2, M3) & Bottom (B1,B2,B3,B4)] along with Composite sample.

Stage	Location	Sample Qty.	Sample Type	Frequency	Tests	Acceptance Criteria	Responsibility
Encapsulation *	In-process Testing	6 capsules	Individual capsule	Full Hopper	Gelatin Shell weight Average net weight of capsules Gross weight of Individual Capsule Segment Temperature Spreader Box Temperature Duct Temperature Gelatin Feed tank Temperature	600.0 + 60 mg 1875.0mg + 3.0 % 2475.0mg + 5.0 % 40 + 5ºC 55 + 5ºC 10 + 3ºC 60 + 5ºC	IPQA/ Production
		6 capsules	Individual capsule	Half hopper			
		6 capsules	Individual capsule	End Hopper			
		6 capsules	Individual capsule	At initial stage			
		6 capsules	Individual capsule	At middle stage			
		6 capsules	Individual capsule	At end stage			
		6 capsules	Individual capsule	At Regular interval			
Drying	Capsule drying ©	20 capsules©	Composite sample	After 32 hr of drying	Appearance & LOD	Red coloured, oval shaped Soft gelatin capsules containing pale brown to pink coloured viscous oily paste.	IPQA & Q.C.
	Capsule drying ©	20 capsules©	Composite sample	After 37 hr of drying			

Stage	Location	Sample Qty.	Sample Type	Frequency	Tests	Acceptance Criteria	Responsibility
Drying	Capsule drying	20 capsules©	Composite sample	After 42 hr. of drying	Appearance & LOD	6.0 %-10.0 %	IPQA & Q.C.
Finished	Pooled Capsules Container	100 capsules©	Composite sample	After Inspection	As per Finish Product Specification	As per Finish Product Specification	IPQA & Q.C.

* To be performed by IPQA / Production

© To be performed by Q C

(α) Sample to be collected in triplicate from different locations as specified in protocol out of which one set to be send to QC and rest of two set to be retained by IPQA

The medicament sample will be collected from all three locations {Top (T1,T2,T3), Middle(M1,M2,M3) & Bottom(B1,B2,B3,B4)} along with Composite sample.

14.0 RAW MATERIALS:

RATIONALE:

The raw materials shall be tested to ensure that the materials are of the acceptable quality prior to their use in the manufacturing. All the API and excipients shall be tested as per the respective pharmacopoeial monograph. The details of reference monographs, vendor and analytical reference number are to be written in validation report.

15.0 ENCAPSULATION:

1 RATIONALE:

On release of the medicament by QC, the medicament is taken up for encapsulation. During encapsulation stage, the homogeneous medicament must be encapsulated on the encapsulation machine. To validate the encapsulation process for Calcitriol & Multivitamins Softgelatin capsules, the encapsulation machine is run at a speed that will be challenged to study the effect of different machine RPM, the different hopper fill levels. At the regular speed, samples from run with minimum speed and the run with maximum speed samples are collected for analysis which is defined in the sample summary. The in-process testing shall be carried out at regular intervals during the machine run. These samples shall be tested as per the sample summary to meet the acceptance criteria specified there in.

2 PROCEDURE:

2.1 Appropriately label the sample containers and collect samples as follows:

2.2 Set the machine, and adjust the encapsulation parameters. After stabilization of the encapsulation machine, the parameters mentioned below are checked and recorded in the respective BMR

Parameters of Evaluation

1.	Description	5.	Gross weight of Individual capsule
2.	Ribbon thickness	6.	Spreader Box Temperature
3.	Gelatin feed tank Temp.	7.	Segment temperature
4	Average net Weight of 6 capsules	8.	Duct temperature

2.3 After the start encapsulation operation, collect Capsules at regular intervals till the end of the Encapsulation cycle as per the sample summary.

2.4 From the sample collected at regular interval, 6 Capsules shall be used for In-Process testing like –

1.	Description	5.	Gross weight of Individual capsule
2.	Ribbon thickness	6.	Spreader Box Temperature
3.	Gelatin feed tank Temp.	7.	Segment temperature
4	Average net Weight of capsules	8.	Duct temperature

2.5 At following speed, samples shall be collected for checking physical parameters and to record it in BMR

- Maximum speed
- Minimum speed
- Optimum Speed

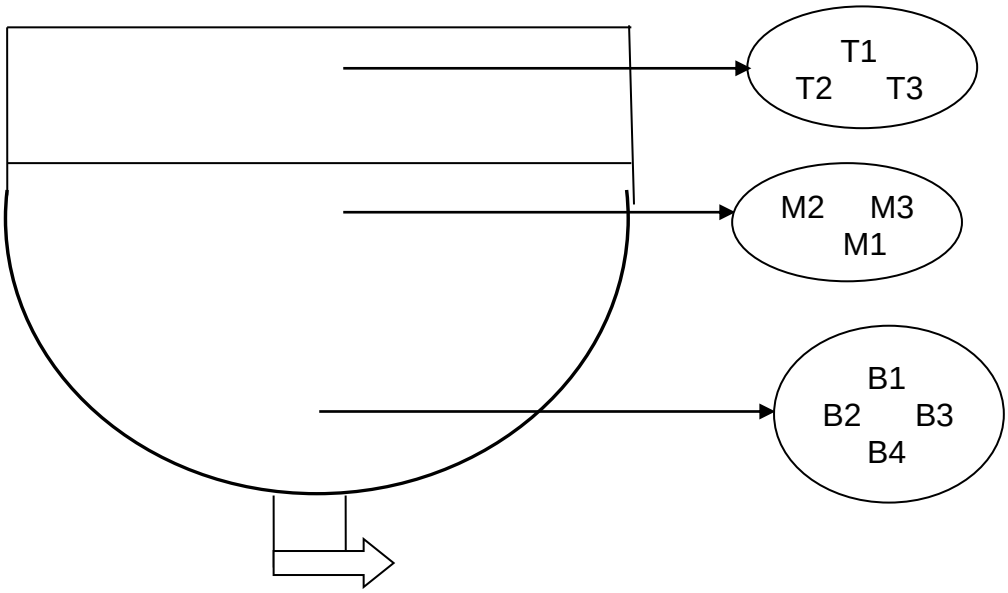
2.6 At different level of Hopper, samples shall be collected for checking physical parameters and to record it in BMR

- Full Hopper
- Half Hopper
- End Hopper

2.7 At different stages of encapsulation, samples shall be collected for checking physical parameters and to record it in BMR

- Initial stage
- Middle stage
- End stage

16.0 SAMPLING PLAN FOR MEDICAMENT PREPARATION VESSEL :



Sampling location:

Top		**Middle**		**Bottom**	
T1	Rear side of tank.	M1	Front side of tank.	B1	Rear side of tank.
T2	Left side of tank.	M2	Left side of tank.	B2	Left side of tank.
T3	Right side of tank.	M3	Right side of tank.	B3	Right side of tank.
C--------- Composite Sample				B4	Front side of tank.

17.0 SPECIFICATIONS:

17.1 **In process Specifications of capsule : (As per MMF*)**

S.No.	Parameters	Specifications
1.	Description	Red coloured, oval shaped Soft gelatin capsules containing pale brown to pink coloured viscous oily paste.
2.	Average fill weight	1875.00 mg + 3.0%
3.	Uniformity of fill weight	+ 5% of average fill weight
4.	Ribbon thickness	0.90 + 0.05 mm
5.	Gelatin Shell weight	600.0 mg + 60.0 mg
6.	Gross weight of capsule	2475.00 mg + 5 %

17.2 Uncontrolled Copy of Raw material specification attached:_____

17.3 Uncontrolled Copy of Inprocess specification for Lubricated blend and core tablets attached:_____

17.4 Uncontrolled Copy of Finished product specification attached:_____

18.0 YIELD DETAILS:

Yield obtained at each stage during validation shall be recorded in validation report.

19.0 DESTRUCTION OF REMAINING VALIDATION SAMPLES:

All remaining samples of the validation batch shall be destroyed as per respective SOP, details to be recorded in validation report.

20.0 SUMMARY, CONCLUSION AND APPROVAL:

Record the summary of the validation study with special emphasis on physical parameter, chemical parameter and evaluation of data obtained in validation report. Details of out of specification / deviation if any should be recorded in validation report. Record the recommendations or suggestions based on the implementations of the results in validation report. It should include the approval of quality assurance, quality control and production head.

21.0 ABBREVIATIONS:

QA	: Quality Assurance
QC	: Quality Control
OOS	: Out of Specification
SOP	: Standard Operating Procedure
LOD	: Loss on Drying
BMR	: Batch Manufacturing Record
MMF	: Master Manufacturing Formula
A.R. No.	: Analytical Report Number
NLT	: Not Less Than
NMT	: Not More Than
PVR	: Process validation report
IRMB	: Infra Red Moisture Balance
API	: Active Pharmaceutical Ingredient

REVISION CARD

S.No.	PPV No.	Reason for Revision	Change Control No.
1		New	---------