PROCESS VALIDATION REPORT OF CALCITRIOL & MULTIVITAMINS SOFTGEL CAPSULES

Batch Size:	**BMR No.:**
Protocol No.:	**Page No.:** 1 of 53

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1.0 REPORT 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*:

Department	Name	Designation	Signature	Date

BATCHES UNDER VALIDATION

Sr. No	Batch No.	Manufacturing Date	Expiry Date
1			
2			
3			

* The validation team includes production. QA, QC, and engineering as applicable

Reference Validation Protocol No.: ……..

3.0 INTRODUCTION:

Calcitriol & Multivitamins Softgelatin Capsules has been developed using the Soft Gel Encapsulation Technology. The batch conducted during the Validation exercise shall be setup for stability study, and other parameters monitored periodically and shall reviewed by the validation task force.

OBJECTIVE:

The objective of this exercise is to develop a **PROCESS VALIDATION REPORT** to demonstrate that the critical operation involved in the manufacturing process of product are capable of consistently producing batches which meet the limits of acceptance criteriaa.

JUSTIFICATION FOR VALIDATION:

MONITORING:

All the critical unit operation, process parameter specified in the Batch Manufacturing Record monitored and results are recorded in the validation.

TYPE OF VALIDATION:

4.0 EQUIPMENT CALIBRATION / QUALIFICATION RECORD

BATCH NO.:

Equipment	Location	Equipment No.	In Calibration / Qualification	Calibration / Qualification Due	Recorded By/Date	Checked By/Date
Reverse Laminar Air Flow	Dispensing Area					
Balance						
Balance						
Balance						
Balance	Production Area					
Balance						
Balance						
Balance						
Balance						
Gelatin Cooking Vessel	Gelatin mass manufacturing area					
Gelatin Feeding Tank						

PROCESS VALIDATION REPORT OF CALCITRIOL & MULTIVITAMINS SOFTGEL CAPSULES

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Equipment	Location	Equipment No.	In Calibration / Qualification	Calibration / Qualification Due	Recorded By/Date	Checked By/Date
Gelatin Feeding Tank						
Hotplate						
Colloidal Mill						
Sieves 60#, 100#,80#	Medicament preparation area					
Medicament mixing unit.						
Medicament Holding Vessel						
Hot Plate						
Colloidal Mill						
Vibro Sifter						
Ultrasonic Sonicator						
Encapsulation M/C	Encapsulation area					
Tumbler Dryer						
Degreasing Pan						
Capsule Inspection Table	Inspection area					
Capsule shorting Machine						

Reviewed by : _____ Date: _____

Validation

BATCH NO.:

Equipment	**Location**	**Equipment No.**	**In Calibration / Qualification**	**Calibration / Qualification Due**	**Recorded By/Date**	**Checked By/Date**
Reverse Laminar Air Flow	Dispensing Area					
Balance						
Balance						
Balance						
Balance	Production Area					
Balance						
Balance						
Balance						
Balance						
Gelatin Cooking Vessel	Gelatin mass manufacturing area					
Gelatin Feeding Tank						

Equipment	Location	Equipment No.	In Calibration / Qualification	Calibration / Qualification Due	Recorded By/Date	Checked By/Date
Gelatin Feeding Tank						
Hotplate						
Colloidal Mill						
Sieves 60#, 100#,80#	Medicament preparation area					
Medicament mixing unit.						
Medicament Holding Vessel						
Hot Plate						
Colloidal Mill						
Vibro Sifter						
Ultrasonic Sonicator						
Encapsulation M/C	Encapsulation area					
Tumbler Dryer						
Degreasing Pan						
Capsule Inspection Table	Inspection area					
Capsule shorting Machine						

Reviewed by : _____ Date: _____

Validation

BATCH NO.:

Equipment	**Location**	**Equipment No.**	**In Calibration / Qualification**	**Calibration / Qualification Due**	**Recorded By/Date**	**Checked By/Date**
Reverse Laminar Air Flow	Dispensing Area					
Balance						
Balance						
Balance						
Balance	Production Area					
Balance						
Balance						
Balance						
Balance						
Gelatin Cooking Vessel	Gelatin mass manufacturing area					
Gelatin Feeding Tank						

PROCESS VALIDATION REPORT OF CALCITRIOL & MULTIVITAMINS SOFTGEL CAPSULES

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Equipment	Location	Equipment No.	In Calibration / Qualification	Calibration / Qualification Due	Recorded By/Date	Checked By/Date
Gelatin Feeding Tank						
Hotplate						
Colloidal Mill						
Sieves 100#,80#	Medicament preparation area					
Medicament mixing unit.						
Medicament Holding Vessel						
Hot Plate						
Colloidal Mill						
Vibro Sifter						
Ultrasonic Sonicator						
Encapsulation M/C	Encapsulation area					
Tumbler Dryer						
Degreasing Pan						
Capsule Inspection Table	Inspection area					
Capsule shorting Machine						

Reviewed by : _____ Date: _____

Validation

5.0 RAW MATERIAL 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 excipients shall be tested as per the Pharmacopoeial monograph of respective excipients. The details of reference monographs, vendor and analytical reference number are given below:

Raw Material	**Reference Monograph**	**Name of vendor**	**A. R. No.**		
			B. No.:	**B. No.:**	**B. No.:**
Gelatin IP (200 Bloom)					
Glycerin IP					
Sorbitol Solution (70 %) (Non-Crystallising) IP					
Methyl Paraben IP					
Propyl Paraben IP					
Fumaric Acid IP					
Colour Ponceau 4R Supra IHS					
Titanium Dioxide IP					
Purified Water IHS*					
Calcitriol IP @					
Calcium Carbonate IP (BD-NLT 1g/ml)					
Vitamin K2-7 IHS #					
Mecobalamin JP £					
Magnesium oxide heavy IP					
Zinc Sulphate Monohydrate BP					
L-Methyl Folate Calcium IHS $					

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Raw Material	**Reference Monograph**	**Name of vendor**	**A. R. No.**		
			B. No.:	**B. No.:**	**B. No.:**
Natural Vitamin E IHS					
Methyl Paraben IP					
Propyl Paraben IP					
White Bees Wax IP					
Hydrogenated Vegetable Oil BP (Lubritab)					
Butylated Hydroxytoluene IP					
Butylated Hydroxyanisole BP					
Lecithin USP-NF					
Disodium Edetate IP					
Citric Acid IP (Anhydrous)					
Refined Soya Oil BP					
Medium Chain Triglycerides BP (Hariol-538)					
Refined Soya Oil BP (For Fill Weight Setting & Machine Flush)					
Light Liquid Paraffin IP (For Machine Lubrication & Ribbon Lubrication)					

Reviewed by : _____ Date: _____

Validation

6.0 USAGE OF RAW MATERIAL (ACTIVE)

Active Material	B.No.	A. R. No.	API B.No.	Assay (%)
Calcitriol				
				Limit: NLT 97.0 & NMT 103.0

Active Material	B.No.	A. R. No.	API B.No.	Assay (%)	LOD (%,w/w)
Calcium Carbonate					
				Limit: Between 98.0 to 100.5	Limit: NMT 2.0 % (w/w)

Active Material	B.No.	A. R. No.	API B.No.	Assay	LOD (%,w/w)
Vitamin K2-7					
				Limit: NLT 2500	Limit: NMT 8.0 % (w/w)

Active Material	B.No.	A. R. No.	API B.No.	Assay (%)	Water (%,w/w)
Mecobalamin					
				Limit: NLT 98.0	Limit: NMT 12.0 % (w/w)

Active Material	B.No.	A. R. No.	API B.No.	Assay (%)
Zinc Sulphate Monohydrate				
				Limit: NLT 99.0 to NMT 101.0

Active Material	B.No.	A. R. No.	API B.No.	Assay (%)
Heavy Magnesium oxide				
				Limit: NLT 98.0 to NMT 100.5

Active Material	**B.No.**	**A. R. No.**	**API B.No.**	**Assay (%)**	**Water (%,w/w)**
L-Methyl folate					
				Limit: NLT 95.0	**Limit: NMT 25.0 % (w/w)**

Reviewed by : _____ Date: _____

Validation

7.0 GELATIN MANUFACTURING PROCESS PARAMETERS & RESULTS:

7.1 Gelatin mass manufacturing parameter and results

Hot water circulation Temp.						
Batch No.	**Date**	**Gelatin Preparation**	**Process Time**		**Observed Temp.**	**Recorded By (Sign & Date)**
			Start	**End**		

Reviewed by : _____ Date: _____

Validation

FREQUENCY FOR EVERY 60 MIN

Sr. No.	**Date**	**Time**	**Observation**					**Recorded By (Sign & Date)**
			Vacuum Applied in mm Hg	**Gelatin Cooking Vessel Temp.**	**Gelatin Mass Temp.**	**Stirrer Speed**	**Appearance of gelatin**	
Batch No.:								
Gelatin Mass manufacturing :								
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								

Reviewed by : _____ Date: _____

Validation

FREQUENCY FOR EVERY 60 MIN

S.No.	**Date**	**Time**	**Observation**					**Recorded By (Sign & Date)**
			Vacuum Applied in mm Hg	**Gelatin Cooking Vessel Temp**	**Gelatin Mass Temp.**	**Stirrer Speed**	**Appearance of gelatin**	
Batch No.:								
Gelatin Mass manufacturing :								
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								

PROCESS VALIDATION REPORT OF CALCITRIOL & MULTIVITAMINS SOFTGEL CAPSULES

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Validation

FREQUENCY FOR EVERY 60 MIN

Sr. No.	**Date**	**Time**	**Observation**					**Recorded By (Sign & Date)**
			Vacuum Applied in mm Hg	**Gelatin Cooking Vessel Temp**	**Gelatin Mass Temp.**	**Stirrer Speed**	**Appearance of gelatin**	
Batch No.:								
Gelatin Mass manufacturing :								
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								

Reviewed by : _____ Date: _____

Validation

8.0 MATURATION OF GELATIN MASS IN GELATIN HOLDING TANK (FREQUENCY AT 1 HR)

Sr. No.	Date	Time	Set Temp.	Observed Temp.	Air Bubble	Uniformity of mass	Recorded By (Sign & Date)
Batch No.:							
Gelatin Mass holding tank ID :							
1							
2							
3							
4							
5							
6							
7							
Gelatin Mass holding tank ID :							
1							
2							

3							
4							
5							
6							
7							

Reviewed by : _____ Date: _____

Validation

S.No.	**Date**	**Time**	**Set Temp.**	**Observed Temp.**	**Air Bubble**	**Uniformity of mass**	**Recorded By (Sign & Date)**
Batch No.:							
Gelatin Mass holding tank ID :							
1							
2							
3							
4							
5							
6							
7							
Gelatin Mass holding tank ID :							
1							
2							

3							
4							
5							
6							
7							

Reviewed by : _____ Date: _____

Validation

Sr. No.	**Date**	**Time**	**Set Temp.**	**Observed Temp.**	**Air Bubble**	**Uniformity of mass**	**Recorded By (Sign & Date)**
Batch No.:							
Gelatin Mass holding tank ID :							
1							
2							
3							
4							
5							
6							
7							
Gelatin Mass holding tank ID :							
1							

2							
3							
4							
5							
6							
7							

Reviewed by : _____ Date: _____

Validation

Sr. No.	**Date**	**Time**	**Set Temp.**	**Observed Temp.**	**Air Bubble**	**Uniformity of mass**	**Recorded By (Sign & Date)**
Batch No.:							
Gelatin Mass holding tank ID :							
1							
2							
3							
4							
5							
6							
7							

PROCESS VALIDATION REPORT OF CALCITRIOL & MULTIVITAMINS SOFTGEL CAPSULES

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Gelatin Mass holding tank ID :							
1							
2							
3							
4							
5							
6							
7							

Reviewed by : _____ Date: _____

Validation

Sr. No.	**Date**	**Time**	**Set Temp.**	**Observed Temp.**	**Air Bubble**	**Uniformity of mass**	**Recorded By (Sign & Date)**
Batch No.:							
Gelatin Mass holding tank ID :							
1							
2							
3							
4							
5							
6							

7							
Gelatin Mass holding tank ID :							
1							
2							
3							
4							
5							
6							
7							

Reviewed by : _____ Date: _____

Validation

Sr. No.	**Date**	**Time**	**Set Temp.**	**Observed Temp.**	**Air Bubble**	**Uniformity of mass**	**Recorded By (Sign & Date)**
Batch No.:							
Gelatin Mass holding tank ID :							
1							
2							
3							
4							
5							

6							
7							
Gelatin Mass holding tank ID :							
1							
2							
3							
4							
5							
6							
7							

Reviewed by : _____ Date: _____

Validation

9.0 MEDICAMENT MANUFACTURING PROCESS PARAMETER

9.1 MEDICAMENT PREPARATION

Sr. No.	**Batch No.**	**Parameter**				
		Stirring Start (Time/Date)	**Stirring Stop (Time/Date)**	**Mesh No. Used**	**Vacuum Applied in mm Hg**	**Recorded By (Sign & Date)**

Reviewed by : _____ Date: _____

Validation

10.0 SAMPLE COLLECTION SUMMARY

Product	**Calcitriol & Multivitamins**		
Sample Location↓	**Sample quantity (in gm)**		
	Batch No.	**Batch No.**	**Batch No.**
T1			
T2			
T3			

M1			
M2			
M3			
B1			
B2			
B3			
B4			
Sampled by/date			

Reviewed by: _____ Date:_____
Validation

Product	**Calcitriol & Multivitamins**		
Sample Location↓	**Sample quantity in gm**		
	Batch No.	**Batch No.**	**Batch No.**
Composite Sample			
Sampled by/date			

Reviewed by: _____ Date:_____
Validation

11.0 RESULTS OF ASSAY FOR MEDICAMENT
Batch No.

Sampling location	**% Assay**				
	Calcitriol	**Calcium carbonate**	**Mecobalamin**	**Vitamin K2-7**	**L-Methyl Folate**
T1					

T2					
T3					
M1					
M2					
M3					
B1					
B2					
B3					
B4					
Mean					
Minimum					
Maximum					
Checked By/ Date					

Reviewed by: _____ Date:_____

Validation

Result for composite sample

Batch No.

PROCESS VALIDATION REPORT OF CALCITRIOL & MULTIVITAMINS SOFTGEL CAPSULES

Batch Size:	**BMR No.:**
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% of Assay & Description				
Calcitriol	**Calcium carbonate**	**Mecobalamin**	**Vitamin K2-7**	**L-Methyl Folate**
Description				
Checked By/ Date				

Reviewed by: _____ Date:_____
Validation

Batch No.

PROCESS VALIDATION REPORT OF CALCITRIOL & MULTIVITAMINS SOFTGEL CAPSULES

Batch Size:	**BMR No.:**
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Sampling location	**% Assay**				
	Calcitriol	**Calcium carbonate**	**Mecobalamin**	**Vitamin K2-7**	**L-Methyl Folate**
T1					
T2					
T3					
M1					
M2					
M3					
B1					
B2					
B3					
B4					
Mean					
Minimum					
Maximum					
Checked By/ Date					

Reviewed by: _____ Date:_____

Validation

Result for composite sample

Batch No.

% of Assay & Description				
Calcitriol	**Calcium carbonate**	**Mecobalamin**	**Vitamin K2-7**	**L-Methyl Folate**
Description				
Checked By/ Date				

Reviewed by: _____ Date:_____

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PROCESS VALIDATION REPORT OF CALCITRIOL & MULTIVITAMINS SOFTGEL CAPSULES

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Batch No.

Sampling location	% Assay				
	Calcitriol	**Calcium carbonate**	**Mecobalamin**	**Vitamin K2-7**	**L-Methyl Folate**
T1					
T2					
T3					
M1					
M2					
M3					
B1					
B2					
B3					
B4					
Mean					
Minimum					
Maximum					
Checked By/ Date					

Reviewed by: _____ Date:_____

Validation

Result for composite sample

Batch No.

% of Assay & Description				
Calcitriol	**Calcium carbonate**	**Mecobalamin**	**Vitamin K2-7**	**L-Methyl Folate**
Description				
Checked By/ Date				

Reviewed by: _____ Date:_____

Validation

12.0 SAMPLES COLLECTED DURING ENCAPSULATION FOR IN-PROCESS PARAMETERS

Batch No.	Sample Stage	Sample Quantity	Sampled By/Date
	Minimum Speed		
	Maximum Speed		
	Optimum Speed		
	Full Hopper		
	Half Hopper		
	End Hopper		
	Initial stage		
	Middle Stage		
	End stage		
	Minimum Speed		
	Maximum Speed		
	Optimum Speed		
	Full Hopper		
	Half Hopper		
	End Hopper		
	Initial stage		
	Middle Stage		
	End stage		
	Minimum Speed		
	Maximum Speed		
	Optimum Speed		
	Full Hopper		
	Half Hopper		
	End Hopper		
	Initial stage		
	Middle Stage		
	End stage		

NOTE: In-process testing shall be carried out as per frequency in BMR and the recordings shall be done in the BMR and the results shall be evaluated.

13.0 INDIVIDUAL IN-PROCESS TEST DATA AND EVALUATION OF IN PROCESS DATA:

INDIVIDUAL IN-PROCESS TEST DATA (SPEED)						
Batch Number:	Date:					
TESTS	RESULTS					
	Minimum Speed ( )		Maximum Speed ( )		Optimum speed( )	
Description						
Gelatin Feed Tank temperature (°C)						
Duct temperature (°C)						
Segment temperature (°C)						
Spreader Box temperature (°C)	Left	Right	Left	Right	Left	Right
Ribbon Thickness (From ribbon continuously formed) (mm)						

Cavity No	1	2	3	4	5	6	Avg. Net Wt.
Minimum Speed ( )							
Gross Wt.							
Shell Wt.							
Net Wt.							
Maximum Speed ( )							
Gross Wt.							
Shell Wt.							
Net Wt.							
Optimum Speed ( )							

Gross Wt.							
Shell Wt.							
Net Wt.							

Reviewed by: _____ Date:_____

Validation

INDIVIDUAL IN-PROCESS TEST DATA (HOPPER)							
Batch Number:			Date:				
TESTS	RESULTS						
	Full Hopper		**Half Hopper**		**End Hopper**		
Description							
Gelatin Feed Tank temperature (°C)							
Duct temperature (ºC)							
Segment temperature (ºC)							
Spreader Box temperature (ºC)	Left	Right	Left	Right	Left	Right	
Ribbon Thickness (From ribbon continuously formed) (mm)							

Cavity No	1	2	3	4	5	6	Avg. Net Wt.
Full Hopper							
Gross Wt.							
Shell Wt.							
Net Wt.							
Half Hopper							
Gross Wt.							
Shell Wt.							
Net Wt.							
End Hopper							

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Gross Wt.							
Shell Wt.							
Net Wt.							

Reviewed by: _____ Date:_____
Validation

INDIVIDUAL IN-PROCESS TEST DATA (STAGE)							
Batch Number:	Date:						
TESTS	RESULTS						
	Initial Stage		**Middle Stage**		**End Stage**		
Description							
Gelatin Feed Tank temperature (°C)							
Duct temperature (°C)							
Segment temperature (°C)							
Spreader Box temperature (°C)	Left	Right	Left	Right	Left	Right	
Ribbon Thickness (From ribbon continuously formed) (mm)							
Cavity No	1	2	3	4	5	6	Avg. Net Wt.
Initial Stage							
Gross Wt.							
Shell Wt.							
Net Wt.							
Middle Stage							
Gross Wt.							
Shell Wt.							
Net Wt.							

End Stage							
Gross Wt.							
Shell Wt.							
Net Wt.							

Reviewed by: _____ Date:_____

Validation

EVALUATION:

Reviewed by: _____ Date:_____

Validation

INDIVIDUAL IN-PROCESS TEST DATA (SPEED)							
Batch Number:		Date:					
TESTS		RESULTS					
		Minimum Speed ( )		Maximum Speed ( )		Optimum speed( )	
Description							
Gelatin Feed Tank temperature (°C)							
Duct temperature (°C)							
Segment temperature (°C)							
Spreader Box temperature (°C)		Left	Right	Left	Right	Left	Right
Ribbon Thickness (From ribbon continuously formed) (mm)							

Cavity No	1	2	3	4	5	6	Avg. Net Wt.
Minimum Speed ( )							
Gross Wt.							
Shell Wt.							
Net Wt.							
Maximum Speed ( )							

Gross Wt.							
Shell Wt.							
Net Wt.							
Optimum Speed ( )							
Gross Wt.							
Shell Wt.							
Net Wt.							

Reviewed by: _____ Date:_____

Validation

INDIVIDUAL IN-PROCESS TEST DATA (HOPPER)						
Batch Number:	Date:					
TESTS	RESULTS					
	Full Hopper		**Half Hopper**		**End Hopper**	
Description						
Gelatin Feed Tank temperature (°C)						
Duct temperature (°C)						
Segment temperature (°C)						
Spreader Box temperature (°C)	Left	Right	Left	Right	Left	Right
Ribbon Thickness (From ribbon continuously formed) (mm)						

Cavity No	1	2	3	4	5	6	Avg. Net Wt.
Full Hopper							
Gross Wt.							
Shell Wt.							
Net Wt.							

Half Hopper							
Gross Wt.							
Shell Wt.							
Net Wt.							
End Hopper							
Gross Wt.							
Shell Wt.							
Net Wt.							

Reviewed by: _____ Date:_____

Validation

INDIVIDUAL IN-PROCESS TEST DATA (STAGE)							
Batch Number:	Date:						
TESTS	RESULTS						
	Initial Stage		**Middle Stage**		**End Stage**		
Description							
Gelatin Feed Tank temperature (°C)							
Duct temperature (°C)							
Segment temperature (°C)							
Spreader Box temperature (°C)	Left	Right	Left	Right	Left	Right	
Ribbon Thickness (From ribbon continuously formed) (mm)							
Cavity No	1	2	3	4	5	6	Avg. Net Wt.
Initial Stage							
Gross Wt.							
Shell Wt.							

Net Wt.							
Middle Stage							
Gross Wt.							
Shell Wt.							
Net Wt.							
End Stage							
Gross Wt.							
Shell Wt.							
Net Wt.							

Reviewed by: _____ Date:_____
Validation

EVALUATION:

Reviewed by: _____ Date:_____

Validation

INDIVIDUAL IN-PROCESS TEST DATA (SPEED)							
Batch Number:	Date:						
TESTS	RESULTS						
	Minimum Speed ( )		Maximum Speed ( )		Optimum speed( )		
Description							
Gelatin Feed Tank temperature (°C)							
Duct temperature (°C)							
Segment temperature (°C)							
Spreader Box temperature (°C)	Left	Right	Left	Right	Left	Right	
Ribbon Thickness (From ribbon continuously formed) (mm)							

Cavity No	1	2	3	4	5	6	Avg.

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							Net Wt.
Minimum Speed ( )							
Gross Wt.							
Shell Wt.							
Net Wt.							
Maximum Speed ( )							
Gross Wt.							
Shell Wt.							
Net Wt.							
Optimum Speed ( )							
Gross Wt.							
Shell Wt.							
Net Wt.							

Reviewed by: _____ Date:_____

Validation

INDIVIDUAL IN-PROCESS TEST DATA (HOPPER)						
Batch Number:	Date:					
TESTS	RESULTS					
	Full Hopper		**Half Hopper**		**End Hopper**	
Description						
Gelatin Feed Tank temperature (°C)						
Duct temperature (°C)						
Segment temperature (°C)						
Spreader Box temperature (°C)	Left	Right	Left	Right	Left	Right

PROCESS VALIDATION REPORT OF CALCITRIOL & MULTIVITAMINS SOFTGEL CAPSULES

Batch Size:	**BMR No.:**
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Ribbon Thickness (From ribbon continuously formed) (mm)							
Cavity No	1	2	3	4	5	6	Avg. Net Wt.
Full Hopper							
Gross Wt.							
Shell Wt.							
Net Wt.							
Half Hopper							
Gross Wt.							
Shell Wt.							
Net Wt.							
End Hopper							
Gross Wt.							
Shell Wt.							
Net Wt.							

Reviewed by: _____ Date:_____

Validation

INDIVIDUAL IN-PROCESS TEST DATA (STAGE)						
Batch Number:	Date:					
TESTS	RESULTS					
	Initial Stage		**Middle Stage**		**End Stage**	
Description						
Gelatin Feed Tank temperature (°C)						
Duct temperature (°C)						
Segment temperature (°C)						
Spreader Box temperature (°C)	Left	Right	Left	Right	Left	Right

PROCESS VALIDATION REPORT OF CALCITRIOL & MULTIVITAMINS SOFTGEL CAPSULES

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Ribbon Thickness (From ribbon continuously formed) (mm)							
Cavity No	1	2	3	4	5	6	Avg. Net Wt.
Initial Stage							
Gross Wt.							
Shell Wt.							
Net Wt.							
Middle Stage							
Gross Wt.							
Shell Wt.							
Net Wt.							
End Stage							
Gross Wt.							
Shell Wt.							
Net Wt.							

Reviewed by: _____ Date:_____
Validation

EVALUATION:

Reviewed by: _____ Date:_____

Validation

14.0 DRYING DETAILS OF CAPSULE:

Batch No.	Drying Started At		Drying End At		Total Drying Time
	Date	Time	Date	Time	

15.0 SAMPLE COLLECTION AND LOD RESULTS:

S.N.	Batch No.	Drying Time	Sample Quantity	Description	Sampled By	LOD Result Limit 6.0-10.0%
1		After 32 hr of drying				
2		After 37 hr of drying				
3		After 42 hr of drying				
1		After 32 hr of drying				
2		After 37 hr of drying				
3		After 42 hr of drying				
1		After 32 hr of drying				
2		After 37 hr of drying				
3		After 42 hr of drying				

Reviewed by : _____ Date: _____
Validation

16.0 FINISHED PRODUCT ANALYSIS REPORT:
(As per specification No. …….)

S. No	**Test**	**Specification**	**BATCH NO:**		

PROCESS VALIDATION REPORT OF CALCITRIOL & MULTIVITAMINS SOFTGEL CAPSULES

Batch Size:	**BMR No.:**
Protocol No.:	**Page No.:** 50 of 53

S. No	**Test**	**Specification**	**BATCH NO:**		
1.	**Description**	Red coloured, oval shaped, softgelatin capsules containing pale brown to pink coloured viscous oily paste.			
2	**Identification** For Calcitriol (By HPLC) For Vitamin K2-7 (By HPLC) For Mecobalamine (By HPLC)	The retention time of the principal peak in the chromatogram of sample preparation should correspond to that of the principal peak in the chromatogram of standard preparation as obtained in the "Assay" for Calcitriol. The retention time of the principal peak in the chromatogram of sample preparation should correspond to that of the principal peak in the chromatogram of standard preparation as obtained in the "Assay" for Vitamin K2-7. The retention time of the principal peak in the chromatogram of sample preparation should correspond to that of the principal peak in the chromatogram of standard preparation as obtained in the "Assay" for mecobalamine.			

S. No	Test	Specification	BATCH NO:		
	For L-Methyl folate	The retention time of the principal peak in the chromatogram of sample preparation should correspond to that of the principal peak in the chromatogram of standard preparation as obtained in the "Assay" for L-Methyl Folate.			
3	**Average net content** (mg)	1875 + 5.0% (1781.3 - 1968.8)			
4	**Average Weight** (mg)	2250.0 + 5.0 % (2137.5 - 2362.5)			
5	**Uniformity of weight** (mg)	Not more than two of individual weights deviate from the average weight by more than 7.5 % and none deviates by more than 15 %.			
6	**Disintegration Time** (min)	Not more than 60			
7	**Assay** **Calcitriol** (By HPLC, as [$C_{27}H_{44}O_3$]) -mcg per capsule -% label claim	 Not less than 0.225 Not less than 90.0			

PROCESS VALIDATION REPORT OF CALCITRIOL & MULTIVITAMINS SOFTGEL CAPSULES

Batch Size:	**BMR No.:**
Protocol No.:	**Page No.:** 52 of 53

S. No	**Test**	**Specification**	**BATCH NO:**		
	Calcium Carbonate (By Titrimetry, as $CACO_3$)				
	-mg per capsule	Not less than 1125.0			
	-% label claim	Not less than 90.0			
	Mecobalamin (By HPLC)				
	-mcg per capsule	Not less than 1350.0			
	-% label claim	Not less than 90.0			
	Vitamin K2-7 (By HPLC)				
	-mcg per capsule	Not less than 40.5			
	-% label claim	Not less than 90.0			
	L-Methyl Folate (By HPLC)				
	-mcg per capsule	Not less than 720.0			
	-% label claim	Not less than 90.0			
	Zinc (By AAS)				
	-mg per capsule	Not less than 6.75			
	-% label claim	Not less than 90.0			
	Magnesium (By AAS)				
	-mg per capsule	Not less than 45.0			
	-% label claim	Not less than 90.0			

Reviewed by: _____ Date:_____

Validation

17.0 PERCENTAGE YIELD AT THE END OF INSPECTION:

Batch No.	% yield	Limit*

* Yield Limit is tentative and will be finalised after 10 or more production batches.

Reviewed by: _____ Date:_____
Validation

18.0 DESTRUCTION OF REMAINING SAMPLES:

Batch No.:	Destruction done by / Date	Checked by / Date

All remaining samples of the batch are destroyed as per SOP No. ----------

Reviewed by: _____ Date:_____
Validation

19.0 SUMMARY, CONCLUSION AND APPROVAL REPORT:

Reviewed by: _____ Date:_____

CONCLUSION:

Calcitriol & Multivitamins Batch Nos.:_____ , _____and _____ manufactured in the facility as the validation batch meet the specification of Softgel. The process of manufacturing was carried as per the approved Batch Manufacturing records and process of Manufacturing is validated. The all process Validation batches has been manufactured and validated in full compliance with cGMP requirement.

Batch No.	**A.R.No. of Finished Product**

APPROVAL

	HEAD – PRODUCTION	**HEAD – QC**	**HEAD – QA**
SIGN & DATE			

REVISION CARD

S. No.	**RPV No.**	**Reason for Revision**	**Change Control No.**
1		New	-------