PROCESS VALIDATION REPORT

FOR

PYRIDOXINE SUSTAINED RELEASE TABLETS

PROCESS VALIDATION REPORT OF PYRIDOXINE SUSTAINED RELEASE TABLETS	
Batch Size: 1000000 Tablets	**BMR No.:** ……
Report No.: ……..	**Page No.:** 2 of 26

TABLE OF CONTENTS

PROCESS VALIDATION REPORT OF PYRIDOXINE SUSTAINED RELEASE TABLETS	
Batch Size: 1000000 Tablets	**BMR No.:** ……
Report No.: ……..	**Page No.:** 3 of 26

1.0 APPROVAL

Prepared By	Signature	Date
(Quality Assurance)		

Checked By	Signature	Date
(Production)		
(Quality Control)		
(Quality Assurance)		

Approved By	Signature	Date
(Quality Assurance)		

2.0 ABSTRACT

The report documents are the evidence that the manufacturing process of the batch will result in a product complying with the designed specifications. Quality of the subsequent batch can be predicted with a high degree of assurance to meet desired specifications.

3.0 PRODUCT DETAILS

3.1 Product Name

……..

3.2 Generic Name

Pyridoxine Sustained Release Tablets.

3.3 Batch Details

S.No.	BATCH No.	MFG DATE	SHELF LIFE*	BATCH SIZE	
				Kg	No. of Tablets
1					
2					
3					

*** Shelf life is tentative and to be ascertained based on the results of stability studies.**

3.4 Location of Manufacturing

…….

3.5 Product Packaging

Packaging Style: **Sale Pack –** Blister of 30 Tablets.

P.S Pack - Blister of 04 Tablets.

4.0 DOCUMENTATION

Following documents were reviewed during compilation of report:

- Batch Manufacturing Record and Batch Packaging Record.
- Raw Material Analysis data.
- Analysis report of In process, Bulk and Finished product.
- Analysis report of validation samples.
- In-process tests during manufacturing.

5.0 PROCESS MONITORING

The process parameters / variables of the unit operations were studied / monitored and documented in the report as per the details given in protocol. The details are documented as:

Table- I - Details of input materials with vendor details

Table- II - Details of input packaging material

Table- III - Equipment details

Table- IV - Environmental conditions of manufacturing area

Table- V - Batch fabrication

1. Sifting
2. Dry Mixing
3. Granulation
4. Drying
5. Sifting and Milling
6. Mixing and lubrication
7. Blend uniformity analysis
8. Compression stage
9. Inprocess details during compression
10. Primary packaging

Table-VI - Analytical results of finished product

Table- VII - % Yeilds

PROCESS VALIDATION REPORT OF PYRIDOXINE SUSTAINED RELEASE TABLETS	
Batch Size: 1000000 Tablets	**BMR No.:** ……
Report No.: ……..	**Page No.:** 7 of 26

TABLE- I - DETAILS OF INPUT MATERIALS WITH VENDOR DETAILS:

RM Code	Ingredients	Batch Details (A.R. No./ Manufacturer Name)		
	Pyridoxine Hydrochloride IP/BP			
	Talc IP/BP			
	Ethyl Cellulose (50 Cps) IP/USP			
	Isopropyl Alcohol IP/BP			
	Magnesium Stearate IP/BP			

TABLE- II- DETAILS OF INPUT PACKAGING MATERIAL:

PM Code	Packaging Material	Specification No.	Batch Details (A. R. No. / Manufacturer Name)		
	Ptd. Alu. Blister Foil Foil Width: 206 mm Foil Gauge: 0.025mm				
	PVC foil with Metallic Lusture (Bilcare – Patina) Foil Width: 210 mm Foil Gauge: 0.25mm Colour : Peach	PMS/B014/05-02			

TABLE- III - EQUIPMENT DETAILS:

S. No.	Equipment Name	Make	Equipment Used (ID. No.)		
			Batch No.		
1.	Weighing Balance*				
2.	Weighing Balance*				
3.	Dispensing Booth				
4.	Weighing Balance^{+}				
5.	Vibratory Sifter				
6.	Rapid Mixer Granulator				
7.	Fluid Bed Drier				
8.	Multimill				
9.	Conta Blender				
10.	Tablet Compression Machine				
11.	Blister packaging machine				

***Used in Dispensing Area.** $^{+}$**Used in Granulation Area.**

PROCESS VALIDATION REPORT OF PYRIDOXINE SUSTAINED RELEASE TABLETS

Batch Size: 1000000 Tablets	**BMR No.:** ……
Report No.: ……..	**Page No.:** 10 of 26

TABLE- IV - ENVIRONMENTAL CONDITIONS OF MANUFACTURING AREA:

S. No.	**Manufacturing Steps**	**Observation**		
		Batch No.		
1.	**Dispensing of Raw materials**			
	% RH			
	Temperature (°C)			
2.	**Granulation**			
	% RH			
	Temperature (°C)			
3.	**Compression**			
	% RH			
	Temperature (°C)			
4.	**Inspection**			
	% RH			
	Temperature (°C)			
5.	**Packaging Cubicle**			
	% RH			
	Temperature (°C)			

TABLE- V - BATCH FABRICATION:

1.0 Sifting

S. No.	**Parameter**	**Ingredients Name**	**Observations**		
			Batch Number		
1	Sieve used for sifting (Mesh)	Pyridoxine Hydrochloride IP/BP			
2		Talc IP/BP			
3		Ethyl Cellulose (50 Cps) IP/USP			
4		Magnesium Stearate IP/BP			

2.0 Dry Mixing

Parameters	Observations											
	Batch Number											
	A	B	C	D	A	B	C	D	A	B	C	D
Mixing time (Min.)												

2.1 Blend Homogeneity

Sampling Location	Limits	% ASSAY											
		After 10 Minutes.											
		Batch Number											
		A	B	C	D	A	B	C	D	A	B	C	D
Top Left (T1)	**Assay:** 95 % to 105% , **RSD:** NMT 2.0 %												
Top Centre (T2)													
Top Right (T3)													
Middle Left (M1)													
Middle Centre (M2)													
Middle Right (M3)													
Bottom Left (B1)													
Bottom Centre (B2)													

Bottom Right (B3)													
Discharge (D)													
Minimum													
Maximum													
Mean %													
RSD %													

3.0 Granulation

Parameters	**Observations**											
	Batch Number											
	A	**B**	**C**	**D**	**A**	**B**	**C**	**D**	**A**	**B**	**C**	**D**
Total time taken												

4.0 Drying

4.1 Semi drying

Parameters	**Observations**											
	Batch Number											
	A	**B**	**C**	**D**	**A**	**B**	**C**	**D**	**A**	**B**	**C**	**D**
Inlet air temperature												
Total drying time												

4.2 Total drying

Parameters	Observations											
	Batch Number											
	A	B	C	D	A	B	C	D	A	B	C	D
Inlet air temperature												
Total drying time												

4.3 Results of Moisture Content

B.No.	Sub Lot	Location of Sampling	Result (NMT 1.0%)
	A	Top (Left + Centre + Right)	
		Middle (Left+Centre+Right)	
		Bottom (Left+Centre+Right)	
	B	Top (Left+Centre+Right)	
		Middle (Left+Centre+Right)	
		Bottom (Left+Centre+Right)	
	C	Top (Left+Centre+Right)	
		Middle (Left+Centre+Right)	
		Bottom (Left+Centre+Right)	
	D	Top (Left+Centre+Right)	
		Middle (Left+Centre+Right)	
		Bottom (Left+Centre+Right)	
	A	Top (Left+Centre+Right)	
		Middle (Left+Centre+Right)	
		Bottom (Left+Centre+Right)	
	B	Top (Left+Centre+Right)	
		Middle (Left+Centre+Right)	
		Bottom (Left+Centre+Right)	
	C	Top (Left+Centre+Right)	
		Middle (Left+Centre+Right)	
		Bottom (Left+Centre+Right)	
	D	Top (Left+Centre+Right)	
		Middle (Left+Centre+Right)	
		Bottom (Left+Centre+Right)	

	A	Top (Left+Centre+Right)	
		Middle (Left+Centre+Right)	
		Bottom (Left+Centre+Right)	
	B	Top (Left+Centre+Right)	
		Middle (Left+Centre+Right)	
		Bottom (Left+Centre+Right)	
	C	Top (Left+Centre+Right)	
		Middle (Left+Centre+Right)	
		Bottom (Left+Centre+Right)	
	D	Top (Left+Centre+Right)	
		Middle (Left+Centre+Right)	
		Bottom (Left+Centre+Right)	

5.0 Sifting and Milling

Parameters	Observations											
	Batch Number											
	A	B	C	D	A	B	C	D	A	B	C	D
Sifter Sieve No.												
Integrity of Sieve												
Multimill Screen size												

6.0 Mixing and Lubrication

Parameters	Observations		
	Batch Number		
Blender speed (rpm)			
Mixing Time (minutes)			
Blender Occupancy (%)			

7.0 Physical characteristics and Blend uniformity of lubricated granules

7.1 Physical characteristics

Parameters	Observations		
	Batch Number		
Pour Density			
Tap Density			
Compressibility Index			

7.2 Blend uniformity of lubricated granules

S.No.	Sampling Location	Limits	% Assay		
			After 10 Minutes.		
			Batch Number		
1.	Top Left (T1)	**Assay : 95** % to **105%** , **RSD NMT 2.0 %**			
2.	Top Centre (T2)				
3.	Top Right (T3)				
4.	Middle Left (M1)				
5.	Middle Centre (M2)				
6.	Middle Right (M3)				
7.	Bottom Left (B1)				
8.	Bottom Centre (B2)				
9.	Bottom Right (B3)				
10.	Discharge (D)				
	Minimum				
	Maximum				
	Mean %				
	RSD %				

8.0 Compression

Parameters	**Observations**								
	Batch Number								
M/C Speed (rpm)									
Compaction Force									
Yield (%)									
Assay	**Initial**	**Middle**	**End**	**Initial**	**Middle**	**End**	**Initial**	**Middle**	**End**
90 % to 110%									
RSD NMT 2.0 %									

PROCESS VALIDATION REPORT OF PYRIDOXINE SUSTAINED RELEASE TABLETS

Batch Size: 1000000 Tablets	**BMR No.:** ……
Report No.: ……..	**Page No.:** 20 of 26

Parameter	**Batch Number**								
Dissolution (Minimum value)	**Initial**	**Middle**	**End**	**Initial**	**Middle**	**End**	**Initial**	**Middle**	**End**
2 Hrs: 50%-70% of Active Input									
RSD NMT 5.0 %									
4 Hrs: 70%-90% of Active Input									
RSD NMT 5.0 %									
6 Hrs: 90%-110% of Active Input									
RSD NMT 5.0 %									

9.0 In process details during Compression

Parameters	**Limit**	**Observation**		
		Batch Number		
Weight of 20 Tablets (gm)				
Individual Weight Variation				
Hardness ($Kg/cm^{2)}$				
Thickness				
Friability				

10.0 Primary Packaging

Attribute	Limit	Observations		
		Batch Number		
Sealing Roller Temp	180 - 210^{0}C			
Forming Roller Temp	110-135^{0}C			
Leak Test	Pass			
Batch over Printing	Complies			

PROCESS VALIDATION REPORT OF PYRIDOXINE SUSTAINED RELEASE TABLETS	
Batch Size: 1000000 Tablets	**BMR No.:** ……
Report No.: ……..	**Page No.:** 23 of 26

TABLE-VI - ANALYTICAL RESULTS OF FINISHED PRODUCT

S.No.	Tests	Observations			Specification	
1.	Appearance				White, circular, biconvex, uncoated tablet.	
2.	Average weight				253.4mg ± 5% (240.73 mg to 266.07 mg)	
3.	Dissolution				2 Hrs	50%-70% of Labelled amount.
					4 Hrs	70%-90% of Labelled amount.
					6 Hrs	90%-110% of Labelled amount.
4.	Assay				90% to 110% of the Labelled amount. 90mg to 110mg of the Labelled amount	

* COA attached with the validation report.

PROCESS VALIDATION REPORT OF PYRIDOXINE SUSTAINED RELEASE TABLETS	
Batch Size: 1000000 Tablets	**BMR No.:** ……
Report No.: ……..	**Page No.:** 24 of 26

TABLE- VII - % YEILDS

S.No.	Stage	% Yield observed		
		Batch No.		
1.	Lubrication			
2.	Compression			
3.	Packaging			

6.0 EVALUATION OF RESULTS

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7.0 CONCLUSION

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Prepared By: **Checked By:**

8.0 ATTACHMENTS

s S.No.	Attachments
8.1	Reports of Moisture Content.
8.2	Pour, Tap Density and Compressibility Index Reports.
8.3	Certificate of Analysis of all validation batches.
8.4	Reports of all validation samples (Including raw data and chromatograms etc.)

9.0 REFERENCE

S.No.	Documents
9.1	Batch manufacturing record and Batch packaging record.
9.2	Process validation protocol.
9.3	Validation master plan.