ANALYTICAL METHOD

VALIDATION REPORT

FOR

PRE & PROBIOTIC CAPSULES

SUPERSEDE REPORT No.	
DATE OF VALIDATION	
VALIDATION BATCH No.	
VALIDATION BATCH SIZE	

REPORT CONTENTS

1.0 REPORT PRE APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY CONTROL)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY CONTROL)			
MANAGER (QUALITY ASSURANCE)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

To compile the data of Analytical Method Validation carried out as per Analytical Method Validation Protocol (Protocol No. …….) the **Assay test of Pre & Probiotic Capsules** is validated and suitable for testing samples of commercial batches.

3.0 SCOPE:

This Analytical Method Validation Report provides information after compilation of Analytical Method Validation Data that the applicable for **Assay Test of Pre & Probiotic Capsules** for Accuracy, Precision, Specificity, Linearity & Range, Robustness test methods is suitable for testing of samples of commercial batches.

4.0 RESPONSIBILITY:

The validation group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this report:

DEPARTMENTS	RESPONSIBILITIES
Quality Control	• Preparation and Review of Analytical Method Validation Report. • Execution of Analytical Method Validation Activity as per Protocol and to compile the data in Analytical Method Validation Report. • Preparation of Analysis Report and submission to Quality Assurance.
Quality Assurance	• Preparation, Review and Approval of Analytical Method Validation Report based on Analytical Method Validation Protocol and Analytical Method Validation Data. • Co-ordination with QC to carryout Analytical Method Validation. • Monitoring of Analytical Method Validation Activity.

ANNEXURE-I

5.0 TRAINING RECORDS:

S.No.	Name of Trainee	Department	Designation	Acceptance Criteria	Signature of Trainee
				All personnel involved in execution of the protocol shall be trained in the required procedure and shall be documented	

Name of the Trainer: …….

Sign & Date:

Inference:

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Reviewed By:
Sign & Date……

ANNEXURE-II

6.0 INSTRUMENT CALIBRATION VERIFICATION:

S.No.	Instrument Name	Instrument ID No.	Calibration Status	Calibration Date	Calibration Due Date	Checked By (Sign & Date) QC

Inference:

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Reviewed By:
Sign & Date……

ANNEXURE-III

7.0 MATERIALS AND INSTRUMENTS DETAILS:

7.1 PRODUCT DETAILS:

- **Product Name :**
- **Batch No. :**
- **Batch Size :**
- **Mfg. Date :**
- **STP No. :**

DETAILS OF MATERIALS USED:

S.No.	Name of Media/ Chemical	Manufacturer	Lot No./Batch No.	Grade

PHARMA DEVILS	ANALYTICAL METHOD VALIDATION REPORT FOR PRE & PROBIOTIC CAPSULES	PROTOCOL No.:

DETAILS OF INSTRUMENTS/EQUIPMENT USED:

S.No.	Instrument Name	Make	Model	Functional & Performance requirements	Identification No.	Condition

DETAILS OF FILTER/CENTIRFUGE USED FOR VALIDATION:

S.No.	Name	Size	B. No./Lot No.	Make

Checked By:
Officer/Executive-QC
Sign & Date……..

Verified By:
Manager-QC
Sign & Date…….

Inference:

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Reviewed By:
Sign & Date……

ANNEXURE-IV

8.0 SPECIFICITY:

Plate No.	Content of *Streptococcus faecalis* (In millions)	Content of *Clostridia butyricum* (In millions)	Content of *Bacillus mesentricus* (In millions)	Content of *Lactic acid bacillus* (In millions)
1.				
2.				
3.				

Acceptance Criteria: There should be no interference by the blank and placebo in the determination of the analyte

Analyzed By:
Officer/Executive-QC
Sign & Date……..

Verified By:
Manager-QC
Sign & Date…….

Inference:

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Reviewed By:
Sign & Date……

ANNEXURE-V

9.0 METHOD PRECISION:

S.No.	Content of *Streptococcus faecalis* (in millions)	Content of *Clostridia butyricum* (in millions)	Content of *Bacillus mesentricus* (in millions)	Content of *Lactic acid bacillus* (in millions)
1.				
2.				
3.				
4.				
5.				
6.				
Mean				
STD. DEV.				
%RSD				

Acceptance Criteria: RSD should not be more than 10.0%

Analyzed By:
Officer/Executive-QC
Sign & Date……

Verified By:
Manager-QC
Sign & Date……

Inference:

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Reviewed By:
Sign & Date……

ANNEXURE VI

10.0 INTERMEDIATE PRECISION:

PARTICULARS	RESULTS							
	ANALYST-I				ANALYST-II			
Date of Analysis								
Analyst Name								
Contents (in millions)	*Streptococcus faecalis*	*Clostridia butyricum*	*Bacillus mesentricus*	*Lactic acid bacillus*	*Streptococcus faecalis*	*Clostridia butyricum*	*Bacillus mesentricus*	*Lactic acid bacillus*
1.								
2.								
3.								
4.								
5.								
6.								
Average								
STD								
RSD								
Relative difference								

Acceptance Criteria: RSD of assay results obtained for six preparations by second analyst should NMT 10%. The relative difference between the average results obtained by both analysts should NMT 10%.

Analyzed By:
Officer/Executive-QC
Sign & Date……

Verified By:
Manager-QC
Sign & Date……

Inference:

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Reviewed By:
Sign & Date……

ANNEXURE-VII

11.0 LINEARITY & RANGE:

S.No.	Concentration	Contents (in millions)				Contents (in millions)			
		Streptococcus faecalis	***Clostridia butyricum***	***Bacillus mesentricus***	***Lactic acid bacillus***	***Streptococcus faecalis***	***Clostridia butyricum***	***Bacillus mesentricus***	***Lactic acid bacillus***
1.	60%								
2.	80%								
3.	100%								
4.	120%								
5.	140%								
Slope									
Intercept									
Coefficient of Variance									

Acceptance Criteria: Plot of concentration vs No. of colony forming units shall be linear coefficient of variance shall be close to 1.0

Analyzed By:
Officer/Executive-QC
Sign & Date…….

Verified By:
Manager-QC
Sign & Date…….

Inference:

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Reviewed By:
Sign & Date……

ANNEXURE-VIII

12.0 ACCURACY/RECOVERY:

12.1 Content of *Streptococcus faecalis* (in millions)

S.No.	S. No.	Known amount added in placebo (wt.in mg)		Recovery		% Recovery
				Individual Value	Average Value	
1.	1	80 % added of Label Claim				
	2					
	3					
2.	1	100 % added of Label Claim				
	2					
	3					
3.	1	120 % added of Label Claim				
	2					
	3					

Acceptance Criteria: Should be between 90.0% and 110.0%

Analyzed By:
Officer/Executive-QC
Sign & Date…….

Verified By:
Manager-QC
Sign & Date……..

Inference:

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Reviewed By:
Sign & Date……..…

12.2 Content of *Clostridia butyricum* (in millions)

S. No.	S. No.	Known amount added in placebo (wt.in mg)		Recovery		% Recovery
				Individual Value	Average Value	
1.	1	80 % added of Label Claim				
	2					
	3					
2.	1	100 % added of Label Claim				
	2					
	3					
3.	1	120 % added of Label Claim				
	2					
	3					

Acceptance Criteria: Should be between 90.0% and 110.0%

Analyzed By:
Officer/Executive-QC
Sign & Date……..

Verified By:
Manager-QC
Sign & Date……

Inference:

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Reviewed By:
Sign & Date……

12.3 Content of *Bacillus mesentricus* (in millions)

S.No.	S.No.	Known amount added in placebo (wt.in mg)		Recovery		% Recovery
				Individual Value	Average Value	
1.	1	80 % added of Label Claim				
	2					
	3					
2.	1	100 % added of Label Claim				
	2					
	3					
3.	1	120 % added of Label Claim				
	2					
	3					

Acceptance Criteria: Should be between 90.0% and 110.0%

Checked By:
Officer/Executive-QC
Sign & Date……..

Verified By:
Manager-QC
Sign & Date…….

Inference:

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Reviewed By:
Sign & Date…….

12.4 Content of *Lactic acid bacillus* (in millions):

S.No.	S.No.	Known amount added in placebo (wt.in mg)		Recovery		% Recovery
				Individual Value	Average Value	
1.	1	80 % added of Label Claim				
	2					
	3					
2.	1	100 % added of Label Claim				
	2					
	3					
3.	1	120 % added of Label Claim				
	2					
	3					

Acceptance Criteria: Should be between 90.0% and 110.0%

Analyzed By:
Officer/Executive-QC
Sign & Date…….

Verified By:
Manager-QC
Sign & Date…….

Inference:

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Reviewed By:
Sign & Date……

ANNEXURE-IX

13.0 SUMMARIZED VALIDATION REPORT:

S.No.	Validation Parameters		Acceptance criteria	Observation
1.	**Specificity**		There should be no growth observed in Placebo	
2.	**Precision**			
	Method Precision		RSD: Not more than 10.0%	
	Intermediate precision **Analyst I** **Analysis II** **Relative difference**		RSD: Not more than 10.0%	
3.	**Linearity**		Plot of concentration vs. No. of colony forming units shall be linear coefficient of variance shall be close to 1.0	
4.	**Accuracy (Recovery)**	**80%**	Recovery: Between 90.0% and 110.0%	
		100%		
		120%		

Checked By:
Officer/Executive-QC
Sign & Date…….

Verified By:
Manager-QC
Sign & Date…….

Inference:

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Reviewed By:
Sign & Date……

14.0 ATTACHMENTS:

1. Records for all critical parameters with graphical representation where applicable.
2. Raw data generated during the execution of this protocol.

15.0 DEVIATION (IF ANY):

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16.0 CONCLUSION:

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17.0 RECOMMENDATION:

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18.0 ABBREVIATIONS:

OD	:	Oral Dosage
Sr.	:	Senior
Pvt.	:	Private
Ltd.	:	Limited
QA	:	Quality Assurance
cGMP	:	Current Good Manufacturing Practices
FDA	:	Food & Drug Administration
LAF	:	Laminar Air Flow
pH	:	Potential of Hydrogen
ml	:	Milliliter
NaCl	:	Sodium Chloride
AR	:	Analytical Grade
Gm	:	Gram
°C	:	Degree Centigrade
lbs	:	Pound
cfu	:	Colony Forming Unit
Wt.	:	Weight
CO_2	:	Carbon Dioxide
RSD	:	Relative Standard Deviation
ICH	:	International Conference On Harmonization

19.0 REPORT POST APPROVAL:

Signing of this report indicates that the Analytical Method Validation for **Assay Test of Pre & Probiotic capsules** has been completed as per approved Protocol.

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY CONTROL)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY CONTROL)			
MANAGER (QUALITY ASSURANCE)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			