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Generic name	GENSET	Effective Date	01/01/2024
Protocol No.	PVP-G13	Ref. SOP No.	QAGN/017

PROCESS VALIDATION PROTOCOL

Generic Name	GENSET
Label claim	Each film coated tablet contains: Cetirizine Hydrochloride BP10 mg Excipients q.s. Colour: Approved colour used
Dosage Form	Tablets
Reference BMR No	BMRT/195-00
Batch Size	3000000
Shelf Life	36 Months
MFG. LIC. NO.	PON/DRUGS/19 13 4323

PROTOCOL APPROVAL

	Department	Name	Designation	Sign & date
Prepared by	Quality Assurance	R. VASANTHI	Jr. Executive	R. Vasanthi 01/01/2024
	Production	BALAJI BROMANIAN, R	MANAGER	B. Balaji 01/01/2024
Reviewed by	Quality Control	A. VALLABHAN	MANAGER	A. Vallabhan 01/01/2024
	Quality Assurance	R. S. Balamurugan	Manager	R. S. Balamurugan 01/01/2024
Approved by	Quality Assurance	R. S. Balamurugan	Manager	R. S. Balamurugan 01/01/2024

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2.0 OBJECTIVE

To monitor the process for establishing documented evidence to ensure that the process variables including the critical process parameters are under control and to demonstrate that the process consistently produces a product meeting its predetermined specification and quality attributes.

3.0 SCOPE

The validation activity shall be carried out to ensure that this product, meets predetermined specification and quality attributes when manufactured in stages from Dispensing, Granulation, Compression and Packing.

4.0 RESPONSIBILITY

Department	Responsibilities
Quality Assurance	To prepare, review, approved and authorized the protocol. Execution these protocol samplings during validation as per sampling plan.
Production	To review and approve the protocol and to co-ordinate and support for process validation.
Quality Control	To review and approve the protocol and responsible to analysis of collected samples.

5.0 IDENTIFICATION OF VALIDATION TEAM AND TRAINING

Personnel shall be identified from QA, QC, PD department and trained for executing this validation activity.

S. No.	Name	Department	Designation	Sign/Date
1.	Vasanthi. R	QA	Jr. Executive	01/01/24
2.	Janakiraman	Prod'n	Jr. Exe	01/01/2024
3.	S. Sudha	QA	Officer	01/01/24
4.	Anbaraman	QA	Jr. Executive	01/01/24
5.	P. Arul Krishnan	Prod'n.	Asst. manager	P. Arul Krishnan
6.				
7.				
8.				
9.				

Training details

Name of the trainer: Stephen R.

Duration: 30 min

Signature Of trainer: [Signature] 01/01/2024

Training details shall be attached in training attendance sheet.

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PROCESS VALIDATION PROTOCOL

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Protocol No.	PVP-G13	Ref. SOP No.	QAGN/017

6.0 ABBREVIATIONS

Acronym	Definition	Acronym	Definition
P	Protocol	NMT	Not more than
QA	Quality Assurance	°C	Degree Celsius
QC	Quality Control	%	Percentage
PV	Process validation	mg.	Milligram
BMR	Batch manufacturing record	RPM	Rotation per minute
TABS	Tablets	RSD	Relative standard deviation
IP	Indian pharmacopeia	OOS	Out of Specification
BP	British pharmacopeia	g.	Gram
USP	United states pharmacopeia	Kg.	Kilogram
ICH	International conference on harmonization	lt.	Litre
GMP	Current Good Manufacturing practices	mm.	Millimetre
IH	In house	ml.	Millilitre
API	Active pharmaceutical ingredient	NLT	Not less then
PD	Production	FG	Finished goods
ID	Identification	RH	Relative humidity
S.	Serial	R-LAF	Reverse laminar Air flow
No.	Number	LOD	Loss on drying
CPP	Critical process parameter	DT	Disintegration time
CQA	Critical quality attributes	Qty.	Quantity
CPC	Critical process control	IPC	In process container
UV	Ultra violet	NA	Not applicable
HPLC	High performance liquid chromatography	MLT	Microbial limit test
Max.	Maximum	HMI	Human Machine Interface
Min.	Minimum		

7.0 TYPE OF VALIDATION

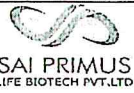
Prospective validation	-
Concurrent validation	√
Re-validation	-

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8.0 REASON FOR VALIDATION

Reasons	Tick in the appropriate row	Reasons	Tick in the appropriate row
New formulation	√	Significant changes in process	-
Change in formulation	-	Change/modification in equipment	-
Change in location	-	Any other reasons (specify)	Concurrent validation
Critical change in some of materials	-		

9.0 PRE REQUISITES OF PROCESS VALIDATION

1. The batches will be manufactured as per the respective batch manufacturing record.
2. The equipments utilized for manufacturing as per list of equipments and BMR.
3. The raw material used for manufacturing will be from approved manufacturer and shall be released by quality control.
4. The critical process parameters of the process will be evaluated with respect to quality attributes of the products
5. Sampling of in-process samples will be carried as per established sampling procedure and plan.
6. Critical in-process will be evaluated with respect to the laid down specification.
7. Finished drug product of these batches will be analysed as per laid down test procedures and comply with respect to the specifications.

10.0 PRODUCT DETAILS

Product Name	GENSET		
Dosage Form	Oral Tablet		
Label Claim	Each film coated tablet contains: Cetirizine Hydrochloride BP10 mg Excipients q.s. Colour: Approved colour used		
Average weight of Coated tablet	120.8 mg		
Batch number	1	2	3
	GF210101	GF210216	GF210301
Batch size	30.0L	30.0L	30.0L
Manufacturing date	01/2024	02/2024	03/2024
Expiry date	12/2023	01/2024	02/2024
Started on	02/01/2024	25/02/2024	21/03/2024
Completed on	05/01/2024	01/03/2024	03/03/2024

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11.0 BILL OF MATERIALS

Sr. No.	Name of the Ingredient	Spec.	Item Code	Quantity/ Tablets (mg)	Std. quantity per 30,00,000 tablets (kg)	OA/ PL (%)	Req. quantity per 30,00,000 tablets (kg)
Dry mixing material:							
1	Cetirizine Hydrochloride*	BP	RAI/SP/C018	10.000	30.000	-	30.000
2	Dried Maize Starch**	BP	IRM/SP/M001	59.900	179.700	-	179.700
3	Lactose Monohydrate	BP	REX/SP/L003	32.800	98.400	-	98.400
Binder Material:							
4	Dried Maize Starch	BP	IRM/SP/M001	4.270	12.810	-	12.810
5	Purified Water	BP	NA	q.s.	40.000	-	40.000
Theoretical Weight of Dried Granules				106.970	320.910	-	320.910
Lubrication Material:							
6	Colloidal Silicon Dioxide	BP	REX/GH/C001	0.470	1.410	-	1.410
7	Sodium Starch Glycollate	BP	REX/GH/S001	5.880	17.640	-	17.640
8	Purified Talc	BP	REX/SP/P011	2.340	7.020	-	7.020
9	Magnesium Stearate	BP	REX/GH/M001	2.340	7.020	-	7.020
Theoretical Weight of the Lubricated granules				118.000	354.000	-	354.000
Theoretical weight of Compressed tablet				118.000	354.000	-	354.000
Coating Material:							
10	Instacoat White (IC-U-3849)	IHS	REX/SP/I006	3.500	10.500	-	10.500
11	Purified Water	BP	NA	q.s	25.000	-	25.000
Theoretical weight of Coated tablet				121.500	364.500	-	364.500
Actual weight of Coated tablet				120.800@	362.400@	-	362.400@

12.0 RAW MATERIAL ANALYTICAL REPORT NUMBERS USED FOR BATCHES

All raw material analytical report numbers refer BMR.

13.0 PROCESS EQUIPMENT DESCRIPTION

S. No.	Equipment name	Equipment ID No	Calibration/qualification status
			Next calibration due
1.	Dispensing Booth	ST/DSB/001	Qualified
2.	Vibratory sifter	PD/VBS/001	Qualified
3.	Octagonal blender	PD/OAB/002	Qualified
4.	Compression machine	PD/COM/001	Qualified
5.	Packing machine (Alu Alu Packing)	PD/ALU/001	Qualified
6.	Weighing balance (IPQA)	IPQA/WB/001	Qualified
7.	Vernier caliper	IPQA/VB/001	Qualified
8.	Friability apparatus	IPQA/FBA/001	Qualified
9.	Hardness tester	QA/HPT/001	Qualified

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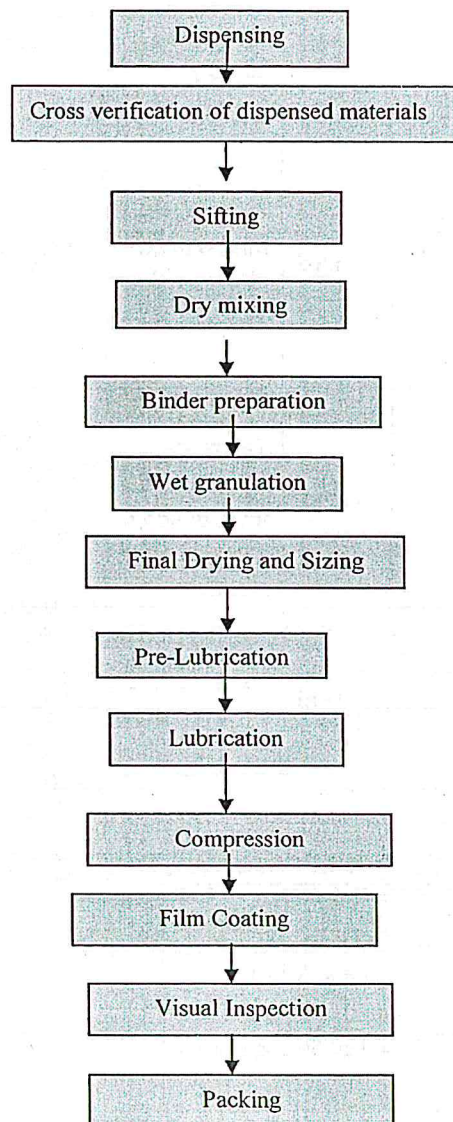
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10.	Disintegration tester	QA/DTM/001	Qualified
11.	Dissolution test apparatus	NA	NA
12.	Sieve Shaker	QC/SVS/001	Calibrated
13.	HPLC	QC/HPLC/002	Calibrated
14.	UV	QC/UV/001	Calibrated
15.	Bulk Density/Tap Density	-	Calibrated

14.0 PROCESS FLOWCHART



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Generic name **GENSET**

Effective Date

01/01/2024

Protocol No. **PVP-G13**

Ref. SOP No.

QAGN/017

15.0 CRITICAL PROCESS PARAMETERS AND CRITICAL PROCESS ATTRIBUTES

S. No	Process stage	CPP	CQA	CPC	Rational for selection	Process verification
1.	Dispensing	Weighing balance	Weight variation	Manual	Critical process leads to affect product quality	Monthly calibration status and daily verification status will be verified before the use.
2.	Vibratory sifter	Sieve size	Size reduction	Manual	Size of the partial may leads to product quality	Sieve size selection done based on BMR. Sieve integrity shall be verified before and after use.
3.	Blending	RPM & Time	Assay and blend uniformity.	Manual	RPM and mixing time will affect the affect product quality.	- Set RPM & time intervals samples shall be collected. - Sampling locations shall be identified based on the occupancy of blender. - Blending/ lubrication time shall be concluded after execution of batches.
4.	Compression	Turret RPM Compression pressure Hopper level	Physical, chemical properties of tablets.	Manual	Turret speed, pressure, granule level in hopper will affect product quality.	- Sample shall be collect at thickness, various speed, hopper level - Turret RPM & pressure shall be verified.
5.	Packing	Machine speed	Description of tablets, leak test.	Manual	- Forming and sealing quality - Speed of the machine	Check the forming temperature, sealing temperature and machine speed, Leak test.

16.0 STAGE WISE SAMPLING LOCATION AND SAMPLE QUANTITY

Stage	Sample Location	Sample size	Test
At Lubrication (withdraw sample at 2, 3 and 4Mins)	10Location Sample	Unit dose 1x to 3x, where x = 120.80 mg (120.8 mg to 362.4 mg).	Blend uniformity
Lubricated Blend	Composite sample	75 gm	Complete analysis as per in-process lubricated granules specification

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Generic name	GENSET	Effective Date	01/01/2024
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Compression	Hardness Challenge	LHS	50 tablets	Description, average weight, Uniformity of weight, thickness, hardness, friability, disintegration time and Dissolution.
		RHS		
Compression	Speed challenge (RPM)	LHS	50 tablets	Description, average weight, Uniformity of weight, thickness, hardness, friability, disintegration time and Assay
		RHS		
Compression	Hopper level challenge	LHS	75 tablets	Description, average weight, Uniformity of weight, thickness, hardness, friability, disintegration time and Content Uniformity
		RHS		
Compression	Composite sample	100 tablets		Description, average weight, Uniformity of weight, thickness, hardness, friability, disintegration time and Assay
Finished Product	120tabs			Complete analysis as per in-process compressed tablets specification
				Microbial tests as per finished product specification
Packing (withdraw sample at High Temp & Low RPM)	temperature challenge	10 blisters or entire sealing drum		Appearance, Leak test and Assay
	Speed challenge.			

17.0 ACCEPTANCE CRITERIA FOR ALL STAGES

18.1 In process specification for Lubricated blend

S. No.	Test	Specification
1.	Appearance	Light Orange colour granular powder
2.	Blend uniformity (Ramipril)	NLT 90% and NMT 110.0%
3.	%RSD	NMT 5 %
4.	Bulk density	For information only
5.	Tap density	For information only
6.	Particle size	For information only
7.	LOD	For information only
8.	Assay (Ramipril)	NLT 90% and NMT 110.0%

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18.2 In process product specification (Core Tablets Specification)

S. No.	Test	Specification
1.	Description	White coloured, caplet shaped, film coated tablet with break line on one side and plain on other side
2.	Identification by IR	The infrared absorption spectrum of the residue is concordant with the reference spectrum of Cetirizine Hydrochloride
3.	Average Weight of Tablets	120.0 mg $\pm$ 5.0% (Limit: 114.0mg to 126.0 mg)
4.	Uniformity of weight Tablets	Not More Than 2 of the Individual weights deviate from the average by more than $\pm$ 7.5% and more deviate by more than $\pm$ 15.0%
5.	Hardness	NLT 3.0 Kg
6.	Thickness (mm)	2.8 mm $\pm$ 0.3 mm
7.	Friability	NMT 1 % w/w
8.	Disintegration Time	NMT 30 Minutes
9.	Assay Each Uncoated Tablet Contains:	NLT 95.0% NMT 105.0%
10.	Content Uniformity	NLT 85.0% and NMT 115.0%
11.	Dissolution:	NLT 80.0% (Q) of the stated amount
12.	Related Substance	Impurity A, B, and G Each impurity Not more than 0.3 % Single maximum unknown impurity Not more than 0.2 % Total impurity Not more than 1.0 %
13.	Microbiological Limits Total Aerobic Microbial counts Fungi E.coli Salmonella S.Aureus P. aeruginosa	NMT 1000 cfu/g NMT 100 cfu/g Should Be absent Should Be absent Should Be absent Should Be absent

18.0 PRODUCT ASSESSMENT CRITERIA

The data will be collected, summarized and a conclusion will be drawn. Any out of specification/Deviation should be investigated. The results should meet limits of acceptance specifications.

19.0 NON COMPLIANCE

Details of deviation (including justification of acceptance if any) done to successfully carryout the validation exercise and any OOS results obtained should be recorded.

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Generic name GENSET

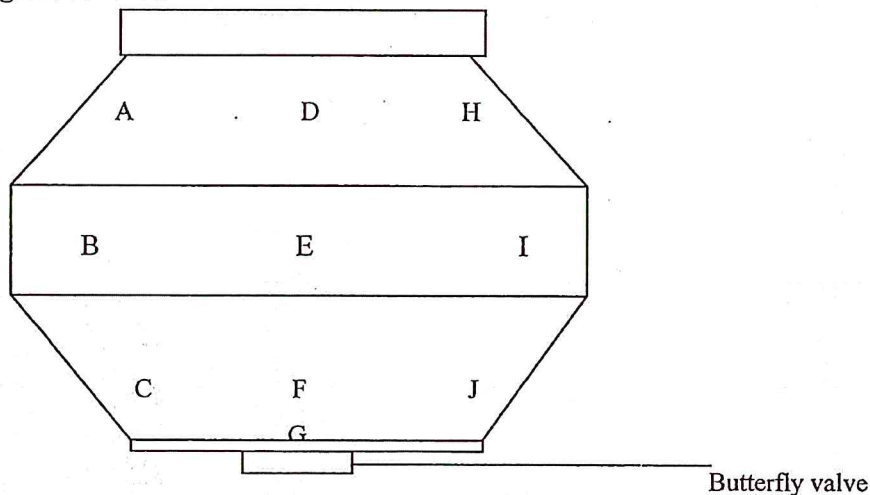
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20.0 SAMPLING LOCATIONS DIAGRAMS.

1. Octagonal blender:



SYMBOL	Location	SAMPLING LOCATION DETAILS
A	Left- Top	From the left side corner near wall side of the blender approx. 2 inch below the top surface of the powder bed.
B	Left- Middle	From the left middle corner near wall side of the blender approx. 5 inch below the top surface of the powder bed.
C	Left- Bottom	From the left side bottom wall side of the blender approx. 2 inch away from the left side of the wall.
D	Center- Top	From the center of the blender approx. 2 inch below the top surface of the powder bed.
E	Center- Middle	From the center of the blender middle surface of the powder bed.
F	Center- Bottom	From the center bottom of the blender bottom layer of the powder bed.
G	Discharge- Port	Approx. center of the discharge port of the blender.
H	Right- Middle	From the right middle corner near side of the blender approx. 2 inch below the top surface of the powder bed.
I	Right- Bottom	From the right-side bottom wall of the blender approx. 2 inch away from the right side of wall.

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J	Right-Top	From the right side, corner near wall of the blender approx. 2 inch below the top surface of the powder bed.
Composite Sample		Composite sample from all location.

21.0 REFERENCE DOCUMENTS

To prepare the validation protocol current version of below mentioned documents are referred, which provide Adequate information of manufacturing & packing process.

Sl No	Documents	Ref. No.
1	Master Formula Record (MFR)	MFR/T/106-00
2	Batch Manufacturing Record (BMR)	BMR/T/195-00
3	Batch Packing Record (BPR)	BPR/T/195-00
4	Finished Product Specification (FPS)	FPS: G13
5	Process Validation SOP	QAGN/017

22.0 REVISION HISTORY

S. No.	Effective date	Version No.	Reason for changes
01	01/01/2021	00	New document

23.0 ATTACHMENTS

Analytical reports shall be attached in process validation report.

24.0 REPORT

After execution of protocol, report will be prepared and final conclusion will be drawn.

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PROCESS VALIDATION REPORT

Generic Name	GENSET
Label claim	Each film coated tablet contains: Cetirizine Hydrochloride BP10 mg Excipients q.s. Colour: Approved colour used
Dosage Form	Tablets
BMR No	BMR/T/195-00
Batch Size	3000000
Shelf Life	36 Months
MFG. LIC. NO.	PON/DRUGS/19 13 4323
Product Code	G13

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PROCESS VALIDATION REPORT

Batch Size: 3000000

Generic name **GENSET**

Protocol No. **PVR-G13**

2.0 OBJECTIVE

To ensure that the critical process variables are checked during validation and to demonstrate the process capability on equipment and utility ensuring that the product meets its predetermined specifications and quality attributes.

The Process validation is being taken for generation of sufficient data and establishing of standard manufacturing process.

Three consecutive batches of **GENSET** have taken up for Process Validation. If any problem is observed during manufacturing, the Process Validation shall be extended to other three consecutive batches.

3.0 SCOPE

The scope of this report is limited to the Process Validation of **GENSET**, which defines the procedural aspects to be followed while carrying out process validation activity that includes prerequisites before commencing the actual work.

This report is applicable for the process validation of **GENSET** to be manufactured at Sai Primus Life Biotech Pvt Ltd.

Based on the Validation data and summary report, if required BMR will be revised.

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:

Functional Area	Responsibility
Production	- Execution of Process Validation Batch. - Review of Process Validation Report. - Review of Technology Transfer cum Process Validation Report.
Quality Assurance	- Co-ordination with Production and QC to carryout process validation batch. - Monitoring and sampling at the different stages. - Checking and approval of Process Validation Report.
Quality Control	- Analysis of validation batch samples. - Preparation of analytical report and submit to Quality Assurance Department. - Review of Process Validation Report.
Maintenance	To provide necessary utility and environmental condition in process equipment and area

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Generic name	GENSET	
Protocol No.	PVR-G13	

5.0 ABBREVIATIONS

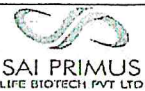
Acronym	Definition	Acronym	Definition
P	Protocol	NMT	Not more than
QA	Quality Assurance	°C	Degree Celsius
QC	Quality Control	%	Percentage
PV	Process validation	mg.	Milligram
BMR	Batch manufacturing record	RPM	Rotation per minute
TABS	Tablets	RSD	Relative standard deviation
IP	Indian pharmacopeia	OOS	Out of Specification
BP	British pharmacopeia	g.	Gram
USP	United states pharmacopeia	Kg.	Kilogram
ICH	International conference on harmonization	lt.	Litre
cGMP	Current Good Manufacturing practices	mm.	Millimeter
IH	In house	ml.	Milliliter
API	Active pharmaceutical ingredient	NLT	Not less then
PD	Production	FG	Finished goods
ID	Identification	RH	Relative humidity
S.	Serial	R-LAF	Reverse laminar Air flow
No.	Number	LOD	Loss on drying
CPP	Critical process parameter	DT	Disintegration time
CQA	Critical quality attributes	Qty.	Quantity
CPC	Critical process control	IPC	In process container
UV	Ultra violet	NA	Not applicable
HPLC	High performance liquid chromatography	MLT	Microbial limit test
Max.	Maximum	HMI	Human Machine Interface
Min.	Minimum		

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PROCESS VALIDATION REPORT		Batch Size: 3000000
Generic name	GENSET	
Protocol No.	PVR-G13	

6.0 PRODUCT DETAILS

Generic Name	GENSET		
Dosage Form	Oral Tablet		
Label Claim	Each film coated tablet contains: Cetirizine Hydrochloride BP10 mg Excipients q.s. Colour: Approved colour used		
Average weight of coated tablet	120.8 mg		
Batch number	GF210101	GF210216	GF210301
Batch size	30.0 L	30.0 L	30.0 L
Manufacturing date	01/2021	02/2021	03/2021
Expiry date	12/2023	01/2024	02/2024
Started on	02.01.2021	25.02.2021	31.03.2021
Completed on	05.01.2021	01.03.2021	03.05.2021

7.0 PROCESS EQUIPMENT DESCRIPTION

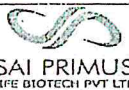
S. No.	Equipment name	Equipment ID No	Calibration/qualification status
1.	Dispensing Booth	ST/DPB/001	Qualified
2.	Vibratory sifter	PDVBS/001	Qualified
3.	Octagonal blender	PD/OCB/001	Qualified
4.	Compression machine	PD/COM/002	Qualified
5.	Packing machine (Alu Alu Packing)	PD/ALU/001	Qualified
6.	Weighing balance (IPQA)	QA/BAL/002	Calibrated
7.	Vernier caliper	QAVEC/001	Calibrated
8.	Friability apparatus	QA/FRT/001	Calibrated
9.	Hardness tester	QA/HRD/001	Calibrated
10.	Disintegration tester	QA/DTA/002	Calibrated
11.	Dissolution test apparatus	QC/DIS/001	Calibrated
12.	Sieve Shaker	QC/SSH/001	Qualified
13.	HPLC	QC/HPL/001	Calibrated
14.	UV	QC/UVS/001	Calibrated

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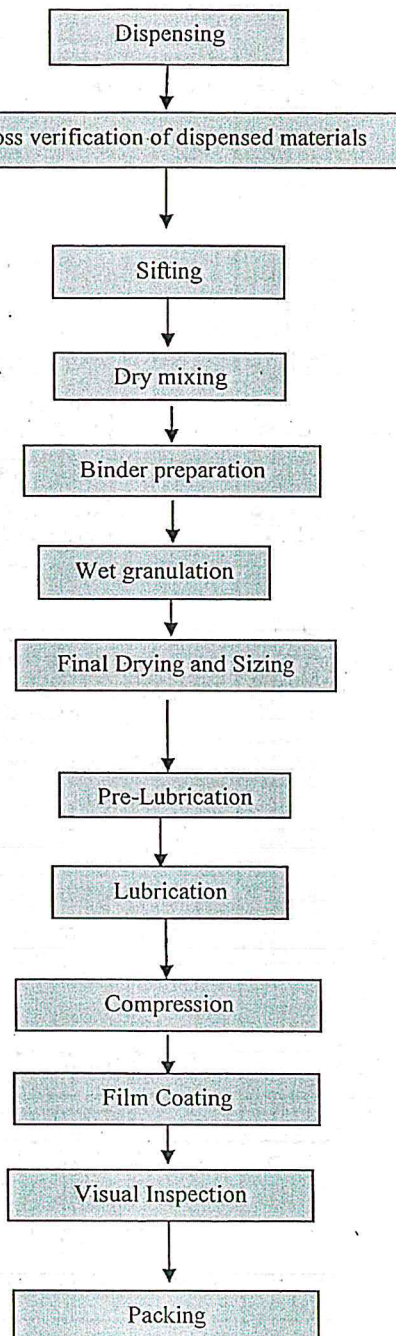
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Generic name	GENSET	
Protocol No.	PVR-G13	

8.0 PROCESS FLOWCHART



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	PROCESS VALIDATION REPORT	
Generic name	GENSET	
Protocol No.	PVR-G13	

9.0 BILL OF MATERIALS :

Sr. No.	Name of the Ingredient	Spec.	Item Code	Quantity / Tablets (mg)	Std. quantity per 30,00,000 tablets (kg)	OA/ PL (%)	Req. quantity per 30,00,000 tablets (kg)
Dry mixing material:							
1	Cetirizine Hydrochloride*	BP	RAI/SP/C018	10.000	30.000	-	30.000
2	Dried Maize Starch**	BP	IRM/SP/M001	59.900	179.700	-	179.700
3	Lactose Monohydrate	BP	REX/SP/L003	32.800	98.400	-	98.400
Binder Material:							
4	Dried Maize Starch	BP	IRM/SP/M001	4.270	12.810	-	12.810
5	Purified Water	BP	NA	q.s.	40.000	-	40.000
Theoretical Weight of Dried Granules				106.970	320.910	-	320.910
Lubrication Material:							
6	Colloidal Silicon Dioxide	BP	REX/GH/C001	0.470	1.410	-	1.410
7	Sodium Starch Glycollate	BP	REX/GH/S001	5.880	17.640	-	17.640
8	Purified Talc	BP	REX/SP/P011	2.340	7.020	-	7.020
9	Magnesium Stearate	BP	REX/GH/M001	2.340	7.020	-	7.020
Theoretical Weight of the Lubricated granules				118.000	354.000	-	354.000
Theoretical weight of Compressed tablet				118.000	354.000	-	354.000
Coating Material:							
10	Instacoat White (IC-U-3849)	IHS	REX/SP/I006	3.500	10.500	-	10.500
11	Purified Water	BP	NA	q.s	25.000	-	25.000
Theoretical weight of Coated tablet				121.500	364.500	-	364.500
Actual weight of Coated tablet				120.800 @	362.400@	-	362.400@

10.0 MANUFACTURING PROCESS DETAILS:

SIFTING:

Step No.	Name of Ingredient	Specified in Approved BMR	Observation		
			Batch No.:		
			GF210101	GF210216	GF210301
1.	Sift cetirizine HCl and Purified Talc, through 40#	Mesh size of sieve (40 #)	40#		
		Sieve Integrity Check before use	OK		
		Sieve Integrity Check after use	OK		
2	Dried Maize starch, colloidal silicon dioxide sodium starch Glycolate and Lactose through 30#	Mesh size of sieve (30 #)	30#		
		Sieve Integrity Check Before use	OK		
		Sieve Integrity Check after use	OK		
3	Magnesium Stearate through 60#	Mesh size of sieve (60 #)	60#		
		Sieve Integrity Check Before use	OK		
		Sieve Integrity Check after use	OK		

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	PROCESS VALIDATION REPORT	
Generic name	GENSET	
Protocol No.	PVR-G13	
Batch Size: 3000000		

DRY MIXING:

Specified in approved BMR	Setting Time	Observations		
		Batch No.:		
		GF210101	GF210216	GF210301
Transfer the sifted material into the RMG. Mix for 10 minutes with impeller at slow speed and	10 Min.	Transferred the sifted material into the RMG. Mix for 10 minutes with impeller at slow speed and chopper 'off'		

BINDER PREPARATION:

Specified in approved BMR	Setting Time	Observations		
		Batch No.:		
		GF210101	GF210216	GF210301
Take purified water and disperse Dried Maize Starch to form slurry. Take Purified Water in Paste Kettle and heat till reaches 90°C - 95°C. Add the slurry to the purified water in the paste kettle and cool the paste till 40 - 45°C.	----	Take purified water and disperse Dried Maize Starch to form slurry. Take Purified Water in Paste Kettle and heat till reaches 90°C - 95°C. Add the slurry to the purified water in the paste kettle and cool the paste till 40 - 45°C.		

WET GRANULATION:

Specified in approved BMR	Setting Time	Observations		
		Batch No.:		
		GF210101	GF210216	GF210301
Add binder solution into RMG/Mass mixer take 1 min for binder addition with impeller slow speed and Chopper OFF.	1 min	Added binder solution into RMG/Mass mixer take 1 min for binder addition with impeller slow speed and Chopper OFF.		
After binder addition allow mixing to form a coherent mass. If required allow mixing till required consistency of granules obtained with impeller at slow speed and chopper at slow speed.	1 min	After binder addition allowed to mixing for 1 minutes with impeller at slow speed and chopper at slow speed and got the granules at desirable level.		

DRYING AND SIFTING:

Specified in approved BMR	Setting Time	Observations		
		Batch No.:		
		GF210101	GF210216	GF210301
Load the wet mass into the FBD bowl and air dry the wet mass	----	Load the wet mass into the FBD bowl and air dry the wet mass		
Load the wet mass into the cleaned FBD bowl Dry at inlet temperature 45-55°C till the LOD reached up to 1.5 - 2.0% w/w.	1 min	Load the wet mass into the cleaned FBD bowl Dry at inlet temperature 45-55°C till the LOD reached up to 1.5 - 2.0% w/w.		
Sift the dried granules through 30 # sieve.	--	Sift the dried granules through 30 # sieve.		
Mill the oversized granules through 1.0 mm multi mill screen fitted with (knives forward medium speed) followed by sifting through 30# sieve on vibrating sifter and collect the sifted granules in double polythene lined cleaned	---	Milled the oversized granules through 1.0 mm multi mill screen fitted with (knives forward medium speed) followed by sifting through 30# sieve on vibrating sifter and collected the sifted granules in double polythene lined cleaned HDPE containers, record the		

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Generic name	GENSET	
Protocol No.	PVR-G13	

BLENDING & LUBRICATION:

Specified in approved BMR	Setting Time	Observations		
		Batch No.:		
		GF210101	GF210216	GF210301
Blending				
Load the dried and sifted granules, sifted Colloidal Silicon Dioxide, Sodium starch Glycolate, Purified talc in to the blender and mix at 10 rpm for 15 minutes.	15 Min. At 8 RPM	Load the dried and sifted granules, sifted Colloidal Silicon Dioxide, Croscarmellose Sodium, Purified talc and Magnesium Stearate in to the blender and mix at 10 rpm for 15 minutes.		
Lubrication				
Load the Sifted Magnesium Stearate into the above Pre-lubricated blend and mix for further 5 minutes at 10 RPM.	5 min. at 10 RPM	Load the Sifted Magnesium Stearate into the above Pre-lubricated blend and mix for further 5 minutes at 10 RPM.		

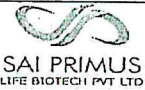
COMPRESSION: (Machine Setting)

Machine Description		Setting as per Approved BMR	Batch No.:		
			GF210101	GF210216	GF210301
Compression machine type		27 Station Double Rotary	27 Station Double Rotary		
Punch Description	Upper punch	10.00 x 4.00 mm caplet shaped with Breakline punches.	10.00 x 4.00 mm caplet shaped with Breakline punches.		
	Lower punch	10.00 x 4.00 mm caplet shaped plain punches.	19.75 mm x 8.75 mm caplet shaped plain punches.		
	Dies	10.00 x 4.00 mm suitable for above punches.	10.00 x 4.00 mm suitable for above punches.		
Tooling Type		D-Tooling	D-Tooling		

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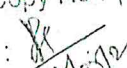
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	PROCESS VALIDATION REPORT	
Generic name	GENSET	
Protocol No.	PVR-G13	

COMPRESSION (Speed Challenge Test):

Sr. No.	Parameters	Parameters as per approved BMR	Observation					
			B. No.: GF210101					
			Low speed (10RPM)			High Speed (25RPM)		
			LHS	RHS	LHS	RHS		
1	Description	White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.	Ok	OK	OK	OK		
2	Weight of 20 Tablets	2.36 g $\pm$ 3.0 % (2.289 g to 2.431 g)	2.354 gm	2.340 gm	2.360 gm	2.351 gm		
3	Average weight (mg)	118.000 mg $\pm$ 2.0 % (115.640 mg – 120.360 mg)	117.6 mg	117.8 mg	117.1 mg	117.9 mg		
4	Uniformity of weight Tablets	118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)	116	117	120	119	117	119
5	Hardness (KP)	NLT 3.0 Kg (To be established)	3.0 kg	3.5 kg	3.5 kg	3.0 kg		
6	Thickness (mm)	2.70 mm $\pm$ 0.3 mm (2.40 mm – 3.00 mm)	2.78 mm	2.76 mm	2.67 mm	2.74 mm		
7	Friability	NMT 1% w/w	0.01 %	0.03 %	0.12%	0.16%		
8	Disintegration Time	NMT 15 Minutes	02 Min 46 Sec	02 Min 36 Sec	02 Min 43 Sec	02 Min 44 Sec		

Sr. No.	Parameters	Parameters as per approved BMR	Observation					
			B. No.: GF210216					
			Low speed (10RPM)			High Speed (25RPM)		
			LHS	RHS	LHS	RHS		
1	Description	White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.	Ok	OK	OK	OK		
2	Weight of 20 Tablets	2.36 g $\pm$ 3.0 % (2.289 g to 2.431 g)	2.329 gm	2.295 gm	2.335 gm	2.342gm		
3	Average weight (mg)	118.000 mg $\pm$ 2.0 % (115.640 mg – 120.360 mg)	117.5 mg	117.6 mg	117.1mg	116.9 mg		
4	Uniformity of weight Tablets	118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)	115	120	118	116	117	120
5	Hardness (KP)	NLT 3.0 Kg (To be established)	3.5 kg	3.0 kg	3.5 kg	3.5 kg		
6	Thickness (mm)	2.70 mm $\pm$ 0.3 mm (2.40 mm – 3.00 mm)	2.68 mm	2.74 mm	2.75 mm	2.77 mm		
7	Friability	NMT 1% w/w	0.02 %	0.01 %	0.13%	0.11%		
8	Disintegration Time	NMT 15 Minutes	01 Min 54 Sec	02 Min 21 Sec	01 Min 23 Sec	01 Min 45 Sec		

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PROCESS VALIDATION REPORT		Batch Size: 3000000
Generic name	GENSET	
Protocol No.	PVR-G13	

Sr. No.	Parameters	Parameters as per approved BMR	Observation							
			B. No.: GF210301							
			Low speed (10RPM)				High Speed (25RPM)			
			LHS		RHS		LHS		RHS	
1	Description	White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.	Ok		OK		OK		OK	
2	Weight of 20 Tablets	2.36 g ± 3.0 % (2.289 g to 2.431 g)	2.41 gm		2.32gm		2.34 gm		2.425gm	
3	Average weight (mg)	118.000 mg ± 2.0 % (115.640 mg – 120.360 mg)	118.2 mg		117.2 mg		118.7 mg		118.4 mg	
4	Uniformity of weight Tablets	118.000 mg ± 7.5 % (109.150 mg – 126.850 mg)	117	121	116	118	115	121	122	116
5	Hardness (KP)	NLT 3.0 Kg (To be established)	3.0 kg		3.0 kg		3.0 kg		3.5 kg	
6	Thickness (mm)	2.70 mm ± 0.3 mm (2.40 mm – 3.00 mm)	2.77mm		2.70 mm		2.69 mm		2.74 mm	
7	Friability	NMT 1% w/w	0.04 %		0.13 %		0.15%		0.14%	
8	Disintegration Time	NMT 15 Minutes	01 Min 36 Sec		02 Min 44 Sec		01 Min 26 Sec		02 Min 38 Sec	

COMPRESSION (At optimum Speed Low Hardness & High Hardness):

Sr. No.	Parameters	Parameters as per approved BMR	Observation							
			B. No.: GF210101							
			Low Hardness				High Hardness			
			RPM:20				RPM:20			
1	Description	White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.	OK		OK		OK		OK	
2	Weight of 20 Tablets	2.36 g ± 3.0 % (2.289 g to 2.431 g)	2.354 g		2.355 g		2.355 g		2.550 g	
3	Average weight (mg)	118.000 mg ± 2.0 % (115.640 mg – 120.360 mg)	115.2 mg		116.3 mg		115.5 mg		116.7 mg	
4	Uniformity of weight Tablets	118.000 mg ± 7.5 % (109.150 mg – 126.850 mg)	117	116	120	123	116	118	121	124
5	Hardness (KP)	NLT 3.0 Kg (To be established)	3.0 kg		3.0 kg		3.5 kg		4.0 kg	
6	Thickness (mm)	2.70 mm ± 0.3 mm (2.40 mm – 3.00 mm)	2.72 mm		2.74 mm		2.64 mm		2.62 mm	
7	Friability	NMT 1% w/w	0.19 %		0.21 %		0.05 %		0.06 %	
8	Disintegration Time	NMT 15 Minutes	01 Min 58 Sec		01 Min 55 Sec		03 Min 40 Sec		03 Min 27 Sec	

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Generic name	GENSET	
Protocol No.	PVR-G13	

Sr. No.	Parameters	Parameters as per approved BMR	Observation			
			B. No.: GF210216			
			Low Hardness		High Hardness	
			RPM:20		RPM:20	
1	Description	White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.	OK	OK	OK	OK
2	Weight of 20 Tablets	2.36 g $\pm$ 3.0 % (2.289 g to 2.431 g)	2.336 g	2.310 g	2.345 g	2.570 g
3	Average weight (mg)	118.000 mg $\pm$ 2.0 % (115.640 mg – 120.360 mg)	115.9 mg	115.7 mg	116.3 mg	116.4 mg
4	Uniformity of weight Tablets	118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)	115	121	124	121
5	Hardness (KP)	NLT 3.0 Kg (To be established)	4.0 kg	3.5 kg	3.5 kg	4.0 kg
6	Thickness (mm)	2.70 mm $\pm$ 0.3 mm (2.40 mm – 3.00 mm)	2.69 mm	2.71 mm	2.65 mm	2.60 mm
7	Friability	NMT 1% w/w	0.05 %	0.13 %	0.07 %	0.04 %
8	Disintegration Time	NMT 15 Minutes	01 Min 21 Sec	01 Min 35 Sec	01 Min 50 Sec	02 Min 02 Sec

Sr. No.	Parameters	Parameters as per approved BMR	Observation			
			B. No.: GF210301			
			Low Hardness		High Hardness	
			RPM:20		RPM:20	
1	Description	White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.	OK	OK	OK	OK
2	Weight of 20 Tablets	2.36 g $\pm$ 3.0 % (2.289 g to 2.431 g)	2.36 g	2.42 g	2.41 g	2.36 g
3	Average weight (mg)	118.000 mg $\pm$ 2.0 % (115.640 mg – 120.360 mg)	116.3 mg	1159 mg	116.5 mg	117.2 mg
4	Uniformity of weight Tablets	118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)	120	123	120	122
5	Hardness (KP)	NLT 3.0 Kg (To be established)	4.0 kg	4.0 kg	3.5 kg	3.0 kg
6	Thickness (mm)	2.70 mm $\pm$ 0.3 mm (2.40 mm – 3.00 mm)	2.54 mm	2.53 mm	2.69 mm	2.67 mm
7	Friability	NMT 1% w/w	0.12 %	0.11 %	0.09 %	0.04 %
8	Disintegration Time	NMT 15 Minutes	01 Min 23 Sec	02 Min 06 Sec	01 Min 41 Sec	02 Min 14 Sec

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	PROCESS VALIDATION REPORT	
Generic name	GENSET	
Protocol No.	PVR-G13	

COMPRESSION (At Optimum Speed Hopper Challenge Test):

Sr. No.	Parameters	Parameters as per approved BMR	Observation					
			B. No.: GF210101					
			RPM: 20					
			Full Hopper		Middle Hopper		Low Hopper	
1	Description	White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.	OK		OK		OK	
2	Weight of 20 Tablets	2.36 g $\pm$ 3.0 % (2.289 g to 2.431 g)	2.32 g	2.36 g	2.31 g	2.36 g	2.34 g	2.35 g
3	Average weight (mg)	118.000 mg $\pm$ 2.0 % (115.640 mg – 120.360 mg)	116.4 mg		117.0 mg		117.2 mg	
4	Uniformity of weight Tablets	118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)	121	122	120	121	122	120
5	Hardness (KP)	NLT 3.0 Kg (To be established)	4.0 kg		4.0 kg		4.0 kg	
6	Thickness (mm)	2.70 mm $\pm$ 0.3 mm (2.40 mm – 3.00 mm)	2.52 mm		2.49 mm		2.52 mm	
7	Friability	NMT 1% w/w	0.10 %		0.11 %		0.10 %	
8	Disintegration Test	NMT 15 Minutes	01 Min 11 Sec		01 Min 43 Sec		01 Min 23 Sec	

Sr. No.	Parameters	Parameters as per approved BMR	Observation					
			B. No.: GF210216					
			RPM: 24					
			Full Hopper		Middle Hopper		Low Hopper	
1	Description	White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.	OK		OK		OK	
2	Weight of 20 Tablets	2.36 g $\pm$ 3.0 % (2.289 g to 2.431 g)	2.33 g	2.31 g	2.32 g	2.34 g	2.30 g	2.34 g
3	Average weight (mg)	118.000 mg $\pm$ 2.0 % (115.640 mg – 120.360 mg)	116.9 mg		116.5 mg		117.9 mg	
4	Uniformity of weight Tablets	118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)	120	122	123	121	124	122
5	Hardness (KP)	NLT 3.0 Kg (To be established)	4.0 kg		4.0 kg		4.0 kg	
6	Thickness (mm)	2.70 mm $\pm$ 0.3 mm (2.40 mm – 3.00 mm)	2.56 mm		2.59 mm		2.58 mm	
7	Friability	NMT 1% w/w	0.09 %		0.12 %		0.11 %	
8	Disintegration Test	NMT 15 Minutes	01 Min 41 Sec		01 Min 24 Sec		01 Min 52 Sec	

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	PROCESS VALIDATION REPORT	
Generic name	GENSET	
Protocol No.	PVR-G13	

Sr. No.	Parameters	Parameters as per approved BMR	Observation					
			B. No.: GF210301					
			RPM: 24					
			Full Hopper		Middle Hopper		Low Hopper	
1	Description	White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.	OK		OK		OK	
2	Weight of 20 Tablets	2.36 g $\pm$ 3.0 % (2.289 g to 2.431 g)	2.30 g	2.32 g	2.36 g	2.35 g	2.34 g	2.32 g
3	Average weight (mg)	118.000 mg $\pm$ 2.0 % (115.640 mg – 120.360 mg)	117.2 mg		117.04 mg		117.9 mg	
4	Uniformity of weight Tablets	118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)	123	120	1232	121	124	120
5	Hardness (KP)	NLT 3.0 Kg (To be established)	4.0 kg		3.5 kg		4.2 kg	
6	Thickness (mm)	2.70 mm $\pm$ 0.3 mm (2.40 mm – 3.00 mm)	2.57 mm		2.59 mm		2.53 mm	
7	Friability	NMT 1% w/w	0.12 %		0.13 %		0.14 %	
8	Disintegration Test	NMT 15 Minutes	01 Min 22 Sec		01 Min 32 Sec		01 Min 42 Sec	

COATING

Coating Solution Preparation:

Specified in approved BMR	Observations		
	Batch No.:		
	GF210101	GF210216	GF210301
Charge Purified water and Instacoat White (IC-U-3849) in a ss container slowly under continuous stirring. Continue stirring until uniform solution is obtained. If required mill the solution in colloidal mill until uniform solution is obtained. If required filter the solution through 100 nylon mesh if necessary.	Charge Purified water and Instacoat White (IC-U-3849) in a ss container slowly under continuous stirring. Continue stirring until uniform solution is obtained. If required mill the solution in colloidal mill until uniform solution is obtained. If required filter the solution through 100 nylon mesh if necessary.		

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	PROCESS VALIDATION REPORT	
Generic name	GENSET	
Protocol No.	PVR-G13	

Procedure for Film Coating:

Specified in Approved BMR				
Charge dedusted cores about 364.2 Kg to coating pan. Transfer the coating solution into SS tank. Set and monitor the parameters like PAN RPM, DOSING RATE, INLET AIR TEMP, EXHAUST AIR TEMP, BED TEMP, as per the specification. Start spraying and continue till solution is getting over.				
Parameter	Limits	Observation		
		GF210101	GF210216	GF210301
Avg Weight Gained	2.0 ± 0.5 % w/w	2.12%	2.14%	2.10%

FINAL COATING PARAMETERS

Parameters	Limits	Observed		
		GF210101	GF210216	GF210301
Description	White coloured capsule shaped film coated tablets with breakline on one side and plain on other side	OK		
Theoretical weight per tablet	120.800 mg ± 3 % (117.176 mg – 124.424 mg)	120 mg	121 mg	120 mg
Weight of 20 tablets	2.416 g ± 3 % (2.344 g – 2.488 g)	2.389 g	2.386 g	2.401 g
Uniformity of weight	120.800 mg ± 5 % (114.760 mg – 126.840 mg)	117 mg	119 mg	120 mg
Length (mm)	10.20 mm ± 0.1 mm (10.10 mm – 10.30 mm)	10.11 mm	10.12 mm	10.11 mm
Width (mm)	4.10 mm ± 0.1 mm (4.00 mm – 4.20 mm)	4.08 mm	4.05 mm	4.09 mm
Thickness	(2.50 mm – 3.10 mm)	2.81 mm	2.85 mm	2.88 mm
Disintegration test	NMT 30 min	03 Min 12 Sec	03 min 16 Sec	04 Min 12 Sec

10.5 INSPECTION

Parameter	Specified	Observation		
		Batch No.:		
		GF210101	GF210216	GF210301
Equipment Name	Inspection Machine	Inspection Machine		
Equipment ID No.	PD/INB/001	PD/INB/001		
No. of Rejected Tablets	To be recorded	500 No's	7167 No's	6080 No's

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		Revision No: 00
PROCESS VALIDATION REPORT		Batch Size: 3000000
Generic name	GENSET	
Protocol No.	PVR-G13	

PACKING PROCESS:

BILL OF PACKING MATERIALS:

Material Name	Item code	UOM	Req. Qty. for 30.0 Lac	Issued Qty.	Approved vendor
144mm Genset double side printed foil 0.025mm	PPF/SP/G013	Kg	45.900	45.900	Atarva Foil
148 mm PVC Film Clear (60 GSM)	PBF/SP/P002	Kg	153.000	153.000	Atarva Foil
3x10's Genset printed carton	PHC/SP/G001	No	102000	102000	Anup Printers
Genset Insert	PHL/SP/G001	No	102000	102000	Anup Printers
Shrink Sleeves (PVC)	PPS/SP/P001	No	5100	5100	NA
5 PLY 390X390X260 MM C/BOXES	PUS/GH/C001	No	209	209	True Carton
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	15	15	Sams packaging
3' Plain BOPP Tape	PUB/SP/B001	No	3	3	Sams packaging
Strapping role.	PPR/SP/S001	Mtrs	500	500	Sams packaging

PACKING VALIDATION:

Parameters	Specified	Observation			
		Batch No.:			
		GF210101		GF210216	
		Low speed/ Low temp.	Low speed/ High temp.	High speed/ High temp.	High speed/ Low temp.
Machine Speed	To be established	10	10	35	35
Forming / Sealing Temperature	To be established	170°C	220°C	220°C	170°C
Pack Quality	Should be proper	It is Proper	It is Proper	It is Proper	It is Proper
Leak Test	Should be absent	Absent	Absent	Absent	Absent
Printing Details	Should be legible and clear	Legible and Clear	Legible and Clear	Legible and Clear	Legible and Clear
Proper Sealing	Should be proper	It is Proper	It is Proper	It is Proper	It is Proper
Horizontal cutting	Should be OK	Ok	Ok	Ok	Ok
Vertical cutting	Should be OK	Ok	Ok	Ok	Ok
Comments/ Remarks	Complies/does not comply with respected to standards of specification	Complies	Complies	Complies	Complies

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	PROCESS VALIDATION REPORT	
Generic name	GENSET	
Protocol No.	PVR-G13	

11.0 ANALYTICAL RESULTS:

Analytical Result of Dry Mixing (For 08Min)

Test	Limit	Observation			
UNIFORMITY OF BLEND	90.0% to 110.0% of the label claim. (RSD NMT 5.0%)	B. No→	GF210101	GF210216	GF210301
		Sample No.	Cetirizine Hydrochloride		
		1	102.13	100.97	101.23
		2	99.59	97.30	98.50
		3	97.81	101.31	99.80
		4	101.25	101.93	101.32
		5	102.67	95.36	96.38
		6	101.97	103.16	102.08
		7	99.54	96.62	97.56
		8	102.18	101.90	99.80
		9	98.31	97.84	101.23
		10	100.39	102.09	99.90
		Min.	97.81	95.36	96.38
		Max.	102.67	103.16	102.08
		Mean	100.584	99.848	99.78
		% RSD	1.710	2.773	1.830
Comments/Remarks	Complies/does not comply with respected to standards of				
	Complies				

Analytical Result of Dry Mixing (For 10Min)

Test	Limit	Observation			
UNIFORMITY OF BLEND	90.0% to 110.0% of the label claim. (RSD NMT 5.0%)	B. No→	GF210101	GF210216	GF210301
		Sample No.	Cetirizine Hydrochloride		
		1	100.89	101.97	100.50
		2	102.46	102.24	102.30
		3	98.23	97.30	99.20
		4	101.46	103.09	102.50
		5	102.55	102.52	102.41
		6	99.13	97.43	98.80
		7	99.27	101.83	100.52
		8	103.19	101.93	102.35
		9	98.48	96.50	97.45
		10	103.35	100.64	101.50
		Min.	98.23	96.50	97.45
		Max.	103.35	103.09	102.50
		Mean	100.901	100.545	100.75
		% RSD	1.968	2.468	1.767
Comments/Remarks	Complies/does not comply with respected to standards of				
	Complies				

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PROCESS VALIDATION REPORT		Batch Size: 3000000
Generic name	GENSET	
Protocol No.	PVR-G13	

Analytical Result of Dry Mixing (For 12 Min)

Test	Limit	Observation			
UNIFORMITY OF BLEND	90.0% to 110.0% of the label claim. (RSD NMT 5.0%)	B. No-→	GF210101	GF210216	GF210301
		Sample No.	Cetirizine Hydrochloride		
		1	99.27	98.32	99.50
		2	102.04	100.15	101.20
		3	98.65	101.31	99.80
		4	102.40	101.86	101.50
		5	103.93	101.33	102.30
		6	99.23	98.90	99.60
		7	99.29	100.16	99.86
		8	101.55	99.92	100.30
		9	101.82	100.59	101.45
		10	99.72	98.33	99.89
		Min.	98.65	98.32	99.50
		Max.	103.93	101.86	102.30
		Mean	100.79	100.087	
		% RSD	1.761	1.250	
Comments/ Remarks	Complies/does not comply with respected to standards of				
	Complies				

Analytical Result of Lubricated Blend (For 04Min)

Test	Limit	Observation			
UNIFORMITY OF BLEND	90.0% to 110.0% of the label claim. (RSD NMT 5.0%)	B. No-→	GF210101	GF210216	GF210301
		Sample No.	Cetirizine Hydrochloride		
		1	101.44	101.14	101.44
		2	101.24	97.98	103.50
		3	102.71	99.45	102.33
		4	99.39	99.00	100.45
		5	99.25	101.65	101.19
		6	99.73	99.05	103.54
		7	101.03	96.17	103.53
		8	99.99	98.71	102.35
		9	99.49	99.72	102.33
		10	99.58	101.61	102.06
		Min.	99.25	96.17	100.45
		Max.	102.71	101.65	103.54
		Mean	100.385	99.448	102.272
		% RSD	1.149	1.717	1.027
Comments/ Remarks	Complies/does not comply with respected to standards of				
	Complies				

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Generic name	GENSET	
Protocol No.	PVR-G13	

Analytical Result of Lubricated Blend (For 05Min)

Test	Limit	Observation			
UNIFORMITY OF BLEND	90.0% to 110.0% of the label claim. (RSD NMT 5.0%)	B. No-->	GF210101	GF210216	GF210301
		Sample No.	Cetirizine Hydrochloride		
		1	101.16	98.25	102.09
		2	99.26	101.52	103.96
		3	101.47	100.99	102.22
		4	99.11	98.71	103.02
		5	99.50	100.00	101.56
		6	99.44	99.49	103.32
		7	98.61	97.45	101.88
		8	100.65	101.36	102.39
		9	99.24	98.13	102.00
		10	99.52	101.36	103.98
		Min.	98.61	97.45	101.56
		Max.	101.47	101.52	103.98
		Mean	99.796	99.726	102.642
		% RSD	0.953	1.539	0.849
Comments/Remarks	Complies/does not comply with respected to standards of				
	Complies				

Analytical Result of Lubricated Blend (For 06Min)

Test	Limit	Observation			
UNIFORMITY OF BLEND	90.0% to 110.0% of the label claim. (RSD NMT 5.0%)	B. No-->	GF210101	GF210216	GF210301
		Sample No.	Cetirizine Hydrochloride		
		1	100.06	102.25	103.53
		2	97.21	98.40	101.96
		3	96.99	99.06	101.04
		4	100.40	98.49	98.71
		5	102.24	98.33	101.77
		6	97.42	100.20	100.99
		7	100.29	100.63	101.67
		8	99.89	99.81	102.81
		9	99.49	99.19	103.50
		10	101.08	100.43	102.44
		Min.	96.99	98.33	98.71
		Max.	102.24	102.25	103.53
		Mean	99.509	99.679	101.842
		% RSD	1.765	1.244	1.393
Comments/Remarks	Complies/does not comply with respected to standards of				
	Complies				

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PROCESS VALIDATION REPORT

Batch Size: 3000000

Generic name GENSET

Protocol No. PVR-G13

Sr. No.	Parameters		Acceptance Criteria	Observation	
				Batch No. GF210101	
1	Description		White coloured granules	White coloured granules	
2	LOD		Informative	1.74%	
3	Bulk Density (gm/ml)		Informative	0.81 gm/l	
4	Tapped Density (gm/ml)		Informative	0.94 gm/l	
5	Assay (%)		90.0% to 110.0 %	99.85%	
6	Sieve Analysis	30#	Informative	99.56	0.44
		40#		99.02	0.98
		60#		96.98	3.02
Comments/ Remarks	Complies/does not comply with respected to standards of specification			complies	

Sr. No.	Parameters		Acceptance Criteria	Observation	
				Batch No. GF210216	
1	Description		White coloured granules	White coloured granules	
2	LOD		Informative	1.85%	
3	Bulk Density (gm/ml)		Informative	0.83 gm/l	
4	Tapped Density (gm/ml)		Informative	0.74 gm/l	
5	Assay (%)		90.0% to 110.0 %	99.92%	
6	Sieve	30#	Informative	99.73	0.27
	Analysis	40#		98.98	1.02
		60#		96.23	3.77
Comments/ Remarks		Complies/does not comply with respected to standards of specification		complies	

Sr. No.	Parameters		Acceptance Criteria	Observation	
				Batch No. GF210301	
1	Description		White coloured granules	White coloured granules	
2	LOD		Informative	1.88%	
3	Bulk Density (gm/ml)		Informative	0.85 gm/l	
4	Tapped Density (gm/ml)		Informative	0.74 gm/l	
5	Assay (%)		90.0% to 110.0 %	99.94%	
6	Sieve Analysis	30#	Informative	99.31	0.69
		40#		98.72	1.28
		60#		97.6	2.40
Comments/ Remarks	Complies/does not comply with respected to standards of specification			complies	

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PROCESS VALIDATION REPORT		Batch Size: 3000000
Generic name	GENSET	
Protocol No.	PVR-G13	

Analytical Result of Compression at Different Speed:

Test		Limit	Observation	
			Batch No.: GF210101	
			Low Speed	High Speed
			RPM:10	RPM: 30
Assay	Cetirizine Hydrochloride	90.0% to 110.0 %	100.26	101.34
Comments/ Remarks	Complies/does not comply with respected to standards of specification		Complies	Complies

Test		Limit	Observation	
			Batch No.: GF210216	
			Low Speed	High Speed
			RPM:10	RPM: 30
Assay	Cetirizine Hydrochloride	90.0% to 110.0 %	99.80	100.88
Comments/ Remarks	Complies/does not comply with respected to standards of specification		Complies	Complies

Test		Limit	Observation	
			Batch No.: GF210301	
			Low Speed	High Speed
			RPM:10	RPM: 30
Assay	Cetirizine Hydrochloride	90.0% to 110.0 %	99.84	99.88
Comments/ Remarks	Complies/does not comply with respected to standards of specification		Complies	Complies

Analytical Result of Compression at Different Compression Pressure:

Test		Limit	Observation					
			Batch No.: GF210101					
			Low Hardness			High Hardness		
			RPM:20			RPM: 20		
Dissolution	Cetirizine Hydrochloride	NLT 80.0 %	97.70	95.11	98.04	100.75	97.29	96.77
			96.95	101.66	99.43	99.71	100.72	98.00
Comments / Remarks	Complies/does not comply with respected to standards of specification		Complies			Complies		

Test		Limit	Observation					
			Batch No.: GF210216					
			Low Hardness			High Hardness		
			RPM:20			RPM: 20		
Dissolution	Cetirizine Hydrochloride	NLT 80.0 %	100.32	98.72	100.85	97.65	98.18	96.58
			98.72	97.65	97.12	100.85	98.18	100.32
Comments / Remarks	Complies/does not comply with respected to standards of specification		Complies			Complies		

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Generic name	GENSET	
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Test		Limit	Observation					
			Batch No.: GF210301					
			Low Hardness			High Hardness		
			RPM:20			RPM: 20		
Dissolution	Cetirizine Hydrochloride	NLT 80.0 %	99.82	99.66	100.01	97.85	99.84	99.25
			99.94	99.27	99.32	99.41	98.98	98.58
Comments / Remarks	Complies/does not comply with respected to standards of specification		Complies			Complies		

Analytical Result of Compression at Optimum Speed(Hopper Challenge):

Test	Limit	Observation (Composite Sample)						
UNIFORMITY OF CONTENT	85.0% to 115.0% of the label claim.	Sample No.	BatchNo.: GF210101		BatchNo.: GF210216		Batch No.: GF210301	
			Low Hopper	Full Hopper	Low Hopper	Full Hopper	Low Hopper	Full Hopper
		Content->	Cetirizine Hydrochloride					
		1	100.64	100.24	101.57	99.20	100.01	102.09
		2	99.30	98.49	99.20	100.12	99.85	103.96
		3	99.04	100.12	100.17	97.12	99.65	102.22
		4	101.08	101.79	98.52	100.12	100.05	103.02
		5	101.88	101.53	97.65	98.95	98.63	101.56
		6	101.66	98.40	100.25	97.90	99.85	103.32
		7	102.39	102.37	98.52	98.81	98.63	101.88
		8	100.32	103.77	99.20	99.82	100.05	102.39
		9	103.71	101.53	102.74	100.78	98.62	102.00
		10	102.28	103.37	98.43	101.43	100.05	103.98
		Min.	99.04	98.40	97.65	97.12	98.62	101.56
		Max.	103.71	103.77	102.74	101.43	100.05	103.98
Mean	101.23	101.16	99.62	99.43	99.54	102.642		
% RSD	1.432	1.819	1.580	1.310	0.644	0.849		
Comments/ Remarks		Complies / does not comply with respected to standards of specification		Complies				

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PROCESS VALIDATION REPORT		Batch Size: 3000000
Generic name	GENSET	
Protocol No.	PVR-G13	

FINISHED PRODUCT REPORT:

Parameter	Specified	Observation
		Batch No: GF210101
		Composite Sample
Appearance	White coloured, caplet shaped, film coated tablet with break line on one side and plain on other side	White coloured, caplet shaped, film coated tablet with break line on one side and plain on other side
Identification By IR		
Cetirizine hydrochloride BP	The infrared absorption spectrum of the residue is concordant with the <i>reference spectrum</i> of cetirizine hydrochloride.	Complies
Average weight	120.00 mg $\pm$ 5.0 % (114.00 mg to 126.00 mg)	119.60 mg
Uniformity of weight	Not more than 2 of the individual weights deviate from the average weight by more than $\pm$ 7.5 % and none deviate by more than $\pm$ 15 %.	+1.17 % to -1.33 %
Dimensions:		
Thickness	2.50 mm to 3.10 mm	Min 2.80 mm Max 2.84 mm Avg. 2.82 mm
Length	9.90 mm to 10.30 mm	Min 10.13 mm Max 10.15 mm Avg. 10.14 mm
Breadth	3.90 mm to 4.30 mm	Min 4.11 mm Max 4.14 mm Avg. 4.12 mm
Hardness	NLT 3.0 kg/cm ²	3.96 kg/cm ²
Disintegration Time	NMT 30 mins	04 minutes 05 seconds
Dissolution Cetirizine Hydrochloride BP -10 mg	Not less than 85.0 % and Not more than 115.0 % of labelled claim.	Min 93.82 % Max 103.94 % Avg. 98.79 %
Assay		
Each Film coated tablet contains:		
Cetirizine Hydrochloride BP 10 mg	Not less than 95.0 % and Not more than 105.0 %	100.89 %
Related Substance Single Maximum unknown Impurity	NMT 0.2%	Not Detected
Total Impurities	NMT 1%	Not Detected
Microbiological Limits Total Aerobic Microbial counts Fungi E.coli Salmonella S.Aureus P. aeruginosa	NMT 1000 cfu/g NMT 100 cfu/g Should Be absent Should Be absent Should Be absent Should Be absent	10 cfu/g <10cfu/g Absent Absent Absent Absent

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Generic name	GENSET	
Protocol No.	PVR-G13	

Parameter	Specified	Observation		
		Batch No: GF210216		
		Composite Sample		
Appearance	White coloured, caplet shaped, film coated tablet with break line on one side and plain on other side	White coloured, caplet shaped, film coated tablet with break line on one side and plain on other side		
Identification By IR				
Cetirizine hydrochloride BP	The infrared absorption spectrum of the residue is concordant with the <i>reference spectrum</i> of cetirizine hydrochloride.	Complies		
Average weight	120.00 mg $\pm$ 5.0 % (114.00 mg to 126.00 mg)	120.70 mg		
Uniformity of weight	Not more than 2 of the individual weights deviate from the average weight by more than $\pm$ 7.5 % and none deviate by more than $\pm$ 15 % .	+2.73 % to -2.23 %		
Dimensions:				
Thickness	2.50 mm to 3.10 mm	Min 2.78 mm	Max 2.82 mm	Avg. 2.79 mm
Length	9.90 mm to 10.30 mm	Min 10.16 mm	Max 10.18 mm	Avg. 10.16 mm
Breadth	3.90 mm to 4.30 mm	Min 4.11 mm	Max 4.14 mm	Avg. 4.12 mm
Hardness	NLT 3.0 kg/cm ²	3.78 kg/cm ²		
Disintegration Time	NMT 30 mins	05 minutes 12 seconds		
Dissolution Cetirizine Hydrochloride BP -10 mg	Not less than 85.0 % and Not more than 115.0 % of labelled claim.	Min 95.56 %	Max 101.86 %	Avg. 98.88 %
Assay Each Film coated tablet contains:				
Cetirizine Hydrochloride BP 10 mg	Not less than 95.0 % and Not more than 105.0 %	101.03 %		
Related Substance Single Maximum unknown Impurity	NMT 0.2%	Not Detected		
Total Impurities	NMT 1%	Not Detected		
Microbiological Limits Total Aerobic Microbial counts Fungi E.coli Salmonella S.Aureus P. aeruginosa	NMT 1000 cfu/g NMT 100 cfu/g Should Be absent Should Be absent Should Be absent Should Be absent	10 cfu/g <10cfu/g Absent Absent Absent Absent		

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	Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Revision No: 00
PROCESS VALIDATION REPORT		Batch Size: 3000000
Generic name	GENSET	
Protocol No.	PVR-G13	

Parameter	Specified	Observation		
		Batch No: GF210301		
		Composite Sample		
Appearance	White coloured, caplet shaped, film coated tablet with break line on one side and plain on other side	White coloured, caplet shaped, film coated tablet with break line on one side and plain on other side		
Identification By IR				
Cetirizine hydrochloride BP	The infrared absorption spectrum of the residue is concordant with the <i>reference spectrum</i> of cetirizine hydrochloride.	Complies		
Average weight	120.00 mg $\pm$ 5.0 % (114.00 mg to 126.00 mg)	119.60 mg		
Uniformity of weight	Not more than 2 of the individual weights deviate from the average weight by more than $\pm$ 7.5 % and none deviate by more than $\pm$ 15 % .	+1.17 % to -1.33 %		
Dimensions:				
Thickness	2.50 mm to 3.10 mm	Min 2.80 mm	Max 2.84 mm	Avg. 2.82 mm
Length	9.90 mm to 10.30 mm	Min 10.13 mm	Max 10.15 mm	Avg. 10.14 mm
Breadth	3.90 mm to 4.30 mm	Min 4.11 mm	Max 4.14 mm	Avg. 4.12 mm
Hardness	NLT 3.0 kg/cm ²	3.96 kg/cm ²		
Disintegration Time	NMT 30 mins	04 minutes 05 seconds		
Dissolution Cetirizine Hydrochloride BP -10 mg	Not less than 85.0 % and Not more than 115.0 % of labelled claim.	Min 93.82 %	Max 103.94 %	Avg. 98.79 %
Assay Each Film coated tablet contains:				
Cetirizine Hydrochloride BP 10 mg	Not less than 95.0 % and Not more than 105.0 %	100.89 %		
Related Substance Single Maximum unknown Impurity	NMT 0.2%	Not Detected		
Total Impurities	NMT 1%	Not Detected		
Microbiological Limits Total Aerobic Microbial counts Fungi E.coli Salmonella S.Aureus P. aeruginosa	NMT 1000 cfu/g NMT 100 cfu/g Should Be absent Should Be absent Should Be absent Should Be absent	10 cfu/g <10cfu/g Absent Absent Absent Absent		

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	PROCESS VALIDATION REPORT	
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11.0 PROCESS YIELD STATEMENT:

Sr. No.	Stage	Observation (%)		
		Batch No.:		
		GF210101	GF210216	GF210301
1.	Blending & Lubrication	99.57%	99.85%	99.88%
2.	Compression	99.25%	99.72%	99.80%
3.	Inspection	99.15%	99.28%	97.16%
4.	Packing	96.28%	98.02%	96.58%

12.0 Deviation and Justification/Corrective Action:

Sr. No.	Deviation details	Justification(s) / Corrective Action(s)	Remarks Acceptable / Not acceptable
1.			
2.			
3.			
4.			

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	PROCESS VALIDATION REPORT	Batch Size: 3000000
Generic name	GENSET	
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13.0 SUMMARY:

The Process Validation of Genset has been carried out and the results found satisfactory

14.0 CONCLUSION:

Process Validation of Genset batch No. GF210101, GF210216 and GF210301 has been carried out to establish the consistency of the process of all the results obtained at blending, compression, coating and Packaging stage are found within the limit.

Hence the process stands validated and documented to follow the same process for manufacturing of future batches

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	PROCESS VALIDATION REPORT	
Generic name	GENSET	
Protocol No.	PVR-G13	

15.0 REPORT APPROVAL:

The process Validation Report of batch "GENSET" having batch size of 30,00,000 Tablets has been reviewed and complies with requirements.

Prepared By:	
Name: <u>R. VASANTHI</u>	
Sign / Date: <u>R. Vasanthi 12/05/2021</u> (Quality Assurance)	
Checked and Reviewed By:	
Name: <u>A. VALLABHARAJAN</u>	Name: <u>BALAJI BRAMBHANIAN R.</u>
Sign/Date: <u>A. Vallabharajan 12/05/2021</u> (Quality Control)	Sign/Date: <u>Balaji Brambhanian R. 12/05/2021</u> (Production)

Comments: We certify that the process Validation report for "GENSET" having batch size of 30,00,000 Tablets has been accepted.

Report Approved By:
Name: <u>K. S. Balamurugan</u>
Sign / Date: <u>K. S. Balamurugan 12/05/2021</u> (Head QA)

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