SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT Factory: R.S. No. 4/3, Plot No.33, Kurumbapet I Villianur Commune, Puducherry-605009.		Page 1 of 14  Revision No: 00
	PROCESS VALIDATION PROTOCOL		Batch Size:600000
Generic name	RAMITHIAZIDE 5/12.5	Effective Date	24/10/2020
Protocol No.	PVP-R09	Ref. SOP No.	QAGN/017

# PROCESS VALIDATION PROTOCOL

Generic Name	RAMITHIAZIDE 5/12.5		i taran o
Label claim	Each Uncoated tablet contains: Ramipril BP	12.5 mg	
Dosage Form	Tablets		
Reference BMR No	BMR/T/134-00	en en en en	
Batch Size	600000		i Lygraphy the system of
Shelf Life	36Months	wer with the second section of the second	
MFG. LIC. NO.	PON/DRUGS/19 13 4323		the second two forces are a figure

# PROTOCOL APPROVAL

	Department	Name	Designation	Sign & date
Prepared by	Quality Assurance	Ramkumar	Executive	المدراها المراجعة
Reviewed by	Production	7. ARULKRISHNAN	Asst-Managa	7. Anoul 9. 7. 23/10/2020
Keylened by	Quality Control	A-VALLARAJAY	Managar	22/10/202
Approved by	Quality Assurance	R. STEPHEN.	Dy NANAUER	- toplials



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	SAI PRIMUS LIFE BIOTECH PV		Page 2 of 14
SAI PRIMUS	Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Villianur Commune, Puducherry-605009.	Industrial Estate,	Revision No: 00
	PROCESS VALIDATION PROTOCOL		Batch Size: 600000
Generic name	RAMITHIAZIDE 5/12.5	Effective Date	24/10/2020
Protocol No.	PVP-R09	Ref. SOP No.	QAGN/017

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Generic name	RAMITHIAZIDE 5/12.5	Effective Date	24/10/2020
Protocol No.	PVP-R09	Ref. SOP No.	QAGN/017

#### 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 American	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
<b>5</b> (	RAMAUMAR	Q A	Executive	
02	S. Anborasan	QA.	Trainer	A
ივ	San thiya	Packing	Chemist	84
θη	N. Balabasker	Production	Traine domit	N. Brl
05	M. Sadishkumar	Stow	Eleutive	7.80
06	C. Prabalakuran	U A	Traine	4
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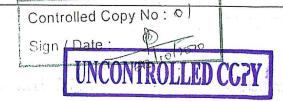
Training details

Name of the trainer: 3 teplen - R

Duration: 45 www. Signature Of trainer:

Training details shall be attached in training attendance sheet.





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SAI PRIMUS	Factory: R.S. No. 4/3, Plot No.33, Kurumbape Villianur Commune, Puducherry-605009.		Revision No: 00	
	PROCESS VALIDATION PROTOCOL		Batch Size:600000	
Generic name	RAMITHIAZIDE 5/12.5	Effective Date	24/10/2020	
Protocol No.	PVP-R09	Ref. SOP No.	QAGN/017	

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41.47	ADDIN			

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.	Millimetre
IH	In house	ml.	Millilitre
API	Active pharmaceutical ingredient	NLT	Not less then
PD	Production	FG	Finished goods
ID	Identification The Asset Contact Inc.	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	1
Re-validation	

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SAI PRIMUS	Revision No: 00		
Treservative	PROCESS VALIDATION PROTOCOL	10 EVE AVE 400	Batch Size:600000
Generic name	RAMITHIAZIDE 5/12.5	Effective Date	24/10/2020
Protocol No.	PVP-R09	Ref. SOP No.	QAGN/017

Reasons	Fick in the appropriate row	Reasons	Tick in the appropriate row
New formulation	THE REPORT OF THE PARTY OF	Significant changes in process	क्ष्मित १९४५ - वं १ <u>५</u> १००५ वटि । वर्षे ह
Change in formulation		Change/modification in equipment	The bank graphs of
Change in location	1	Any other reasons (specify)	Concurrent validation
Critical change in some of materials			

#### 9.0 PRE REQUISITES OF PROCESS VALIDATION

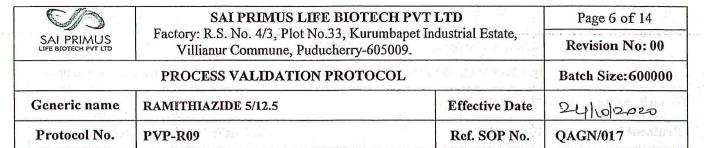
- 1. The batches will be manufactured as per the respective batch manufacturing record.
- 2. The equipments utilized for manufacturing as per list of equipments and BMR.
- The raw material used for manufacturing will be from approved manufacturer and shall be released by quality control.
- 4. The critical 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	RAMITHIAZIDE 5/12.5		ment maint language t
Dosage Form	Oral Tablet		as would applicate the F
Label Claim	Each Uncoated tablet contain Ramipril BP Hydrochlorothiazide BP Excipients Colour: Erythrosine Supra	5 mg 12.5 mg	ylkony AT.
Average weight of Coated tablet	200.00 mg		
Batch number	13. 195.	2	3
Dacin number	GF 201004	GF 201207	6F210317
Batch size	6.0L	6.0L	6.0L
Manufacturing date	10/2020	12/2020	03/2021
Expiry date	09/2023	11/2023	02/2021
Started on	26/10/2020	24/12/2020	31/03/2021
Completed on	07/11/2020	05/01/2021	24/04/2021



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Sr. No	Name of the Ingredient	Spec.	Item Code	Quantity/ Tablets (mg)	Std. quantity per 6,00,000 tablets (kg)	OA/ PL (%)	Req. quantit per 6,00,000 tablets (kg)
Dry	mixing material:	il, e k e	The state of the s		- M2		er i heitensen
1	Ramipril*	BP	RAI/SP/R006	5.000	3.000	2	3.060
2	Hydrochlorothiazide^	BP	RAI/SP/H001	12.500	7.500	2	7.650
3	Maize Starch**^^	BP	REX/SP/M013	61.400	36.840	·	36.840
4	Lactose Monohydrate	IP.	REX/SP/L003	74.000	44.400	-	44.400
5	Microcrystalline Cellulose PH 102	IP	REX/SP/M014	30.000	18.000		18.000
Bind	ler Material:	r un Kelk	ry that they b	- 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1	The second of the last	31-20	www.att
6	Gelatin	IP	REX/SP/G001	2.000	1.200		1.200
7	Maize Starch	BP	REX/SP/M013	5.000	3.000	-1. Try	3.000
8	Erythrosine Supra	IHS	REX/SP/E005	0.100	0.060	-	0.060
9	Purified Water	BP	NA	q.s.	30.000	ar erry	30.000
i ga	Theoretical V	Weight o	f Dried Granules	190.000	114.000	1 2-151	114.210
Lub	rication Material:			×	and the second second	rja i Straj	र अस्तिकात ।
10	Sodium Starch Glycollate	BP	REX/SP/S004	5.000	3.000	4 - 4	3.000
11	Colloidal Silicon Dioxide	BP	REX/SP/C001	1.000	0.600	-	0.600
12	Magnesium Stearate	IP	REX/SP/M011	4.000	2.400		2.400
Ì	Theoretical Weight of	f the Lu	bricated granules	200.000	120.000	-	120.210
}	Theoretical we	ight of C	compressed tablet	200.000	120.000	_	120.210





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Generic name	RAMITHIAZIDE 5/12.5	Effective Date	24/10/2020
Protocol No.	PVP-R09	Ref. SOP No.	OAGN/017

12.0	RAW	MA	<b>TERIALS</b>	MANUF	ACTURE	R - API

1.0 RAMIPRIL:	Manufactur	The partners	s na casacha vari	
A.R. No	Batch No	Mfg. date	Exp. date	Qty.
			ū.	
* "				
		taling to the	= 8	

A.R. No	Batch No	Mfg. date	Exp. date	Qty.
				A A A A A A A A A A A A A A A A A A A
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# 13.0 RAW MATERIAL ANALYTICAL REPORT NUMBERS USED FOR BATCHES

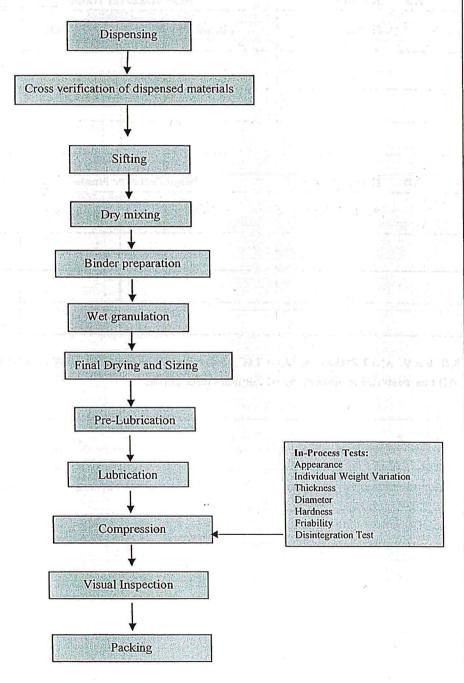
All raw material analytical report numbers refer BMR.

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Generic name	RAMITHIAZIDE 5/12.5	Effective Date	24/10/2020
Protocol No.	PVP-R09	Ref. SOP No.	QAGN/017

### 14.0 PROCESS FLOWCHART









Generic name

Protocol No.

PVP-R09

# SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.

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Batch Size:600000

# PROCESS VALIDATION PROTOCOL

RAMITHIAZIDE 5/12.5 Effective Date 24/10/2020

Ref. SOP No. | QAGN/017

15.0 CRITICAL PROCESS PARAMETERS AND CRITICAL PROCESS ATTRIBUTES

Š. No	Process stage	СРР	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.	Dry Mixing	Mixing Time and Speed	Uniformity	Auto/ manual	RPM and mixing time will affect the affect product quality	Mixing time and speed shall be concluded after execution of batches.
4.	Drying	Inlet, bed temperature and Drying Time	Loss on drying	Auto/ manual	LOD will affect the affect product quality	Sampling locations shall be identified based on the occupancy of Drier.
5.	Size reduction	Screen size	Size reduction	Manual	Size of the partial may leads to product quality	Screen size selection done based on BMR.
6.	Blending	RPM & Time	Assay and blend uniformity.	Manual	RPM and mixing time will affect the affect product quality.	<ul> <li>Set RPM &amp; time intervals samples shall be collected.</li> <li>Sampling locations shall be identified based on the occupancy of blender.</li> <li>Blending/ lubrication time shall be concluded after execution of batches.</li> </ul>
7.	Compression	Turret RPM Compression pressure Hopper level	Physical, chemical properties of tablets.	Manual	Turret speed, pressure, granule level in hopper will affect product quality.	<ul> <li>Sample shall be collect at thickness, various speed, hopper level</li> <li>Turret RPM &amp; pressure shall be verified.</li> </ul>
8	Packing	Machine speed	Description of tablets, leak test.	Manual	<ul> <li>Forming and sealing quality</li> <li>Speed of the machine</li> </ul>	Check the forming temperature, sealing temperature and machine speed, Leak test.



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· Whe sails	PROCESS VALIDATION PROTOCOL	the state of the	Batch Size: 600000
Generic name	RAMITHIAZIDE 5/12.5	Effective Date	24/10/2020
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# 16.0 STAGE WISE SAMPLING LOCATION AND SAMPLE QUANTITY

Stage	Sample Location	Sample s	size	Test
At Dry Mixing stage (withdraw sample at 9, 10 and 11Min)	10Location Sample and Composite	Unit dose 1x to 3x, where x = 182.9 mg (182.9 mg to 548.7 mg).		Blend uniformity and Assay
At Lubrication stage(withdraw sample at 2, 3 and 4Mins)	10Location Sample	Unit dose 1x to 3x, where x = 150 mg (200 mg to 600 mg).		Blend uniformity
Lubricated Blend	Composite sample	75 gm		Complete analysis as per in-process lubricated granules specification
Compression	Hardness Challenge	LHS	50 tablets	Description, average weight, Uniformity of weight, thickness, hardness, friability, disintegration time and Dissolution.
Compression	Speed challenge (RPM)	LHS 50 tablets		Description, average weight, Uniformity of weight, thickness, hardness, friability, disintegration time and Assay
Compression	Hopper level challenge	LHS	75 tablets	Description, average weight, Uniformity of weight, thickness, hardness, friability, disintegration time and Content Uniformity
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 Speed challenge.	entire	isters or sealing rum	Appearance, Leak test and Assay





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Generic name	RAMITHIAZIDE 5/12.5	Effective Date	24/10/2020
Protocol No	PVP_R09	Ref. SOP No.	OAGN/017

# 17.0 ACCEPTANCE CRITERIA FOR ALL STAGES

# 17.1 In process specification for Dry Mixing:

S. No.	Test	Specification
1.	Appearance	white colour granular powder
2.	Blend uniformity (Ramipril BP and Hydrochlorothiazide BP)	NLT 90% and NMT 110.0%
3.	Assay (Ramipril BP and Hydrochlorothiazide BP)	NLT 90% and NMT 110.0%

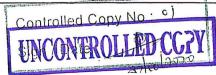
# 17.2 In process specification for Dry Mixing:

S. No.	Test	Specification
1.	Appearance	Pink 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%

# 17.3 In process product specification (Core Tablets Specification)

S. No.	Test	Specification		
1.	Description	Pink coloured, circular shaped, uncoated tablet with breakline 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 Ramipril & Hydrochlorthiazide		
3.	Group Weight	4.000 g± 3.0 % (3.880 gm to 4.120 gm)		
4.	Average Weight of Tablets	200.000 mg ± 3.0 % (194.000 mg – 206.000 mg)		
5.	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%		
6.	Diameter	$7.93 \text{ mm} \pm 0.2 \text{mm}$		
7.	Hardness	NLT 3.0 Kg		
8.	Thickness (mm)	3.20 mm ±0.3 (2.90 mm - 3.50 mm)		
9.	Friability	NMT 1 % w/w		
10.	Disintegration Time	NMT 15 Minutes		
11.	Assay Each Uncoated Tablet Contains:	NLT 90.0% NMT 110.0%		
12.	Content Uniformity	NLT 85.0% and NMT 115.0%		
13.	Dissolution:	NLT 85.0% of the label claim		





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Generic name	RAMITHIAZIDE 5/12.5	Effective Date	24/10/2020	
Protocol No.	PVP-R09	Ref. SOP No.	QAGN/017	

14.	Related Substance	Impurity A NMT 2.0% Impurity D NMT 6.0% Impurity E NMT 2.0% Single Maximum unknown impurity NMT0.5% Total Impurities NMT 6.0%
15.	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

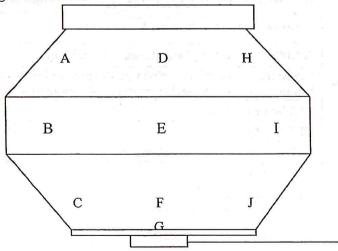
The data will be collected, summarized and a conclusion will be drawn. Any out of specification/Deviation should be investigated. The results should meet limits of acceptance specifications.

#### 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.

# 20.0 SAMPLING LOCATIONS DIAGRAMS.

1. Octagonal blender:



Butterfly valve



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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.

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#### PROCESS VALIDATION PROTOCOL

Batch Size:600000

Generic nameRAMITHIAZIDE 5/12.5Effective DateDelical 200Protocol No.PVP-R09Ref. SOP No.QAGN/017

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.
В	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.
<b>D</b>	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.
н	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 right side of wall.	
J	Right-Top	From the right side, corner near wall of the blender approx.  2 inch below the top surface of the powder bed.
Compo	site 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.

SI No	Documents	Ref. No.
1	Master Formula Record (MFR)	MFR/T/058-00
2	Batch Manufacturing Record (BMR)	BMR/T/134-00
3	Batch Packing Record (BPR)	BPR/T/134-00
4	Finished Product Specification (FPS)	FPS: R09
5	Process Validation SOP	QAGN/017





CID	SAI PRIMUS LIFE BIOTECH PVT LTD  Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 14 of 14
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Protocol No.	PVP-R09	Ref. SOP No.	QAGN/017

#### 22.0 REVISION HISTORY

S. No.	Effective date	Version No.	Reason for changes
01	24/10/2020.	00 1 1 2 2	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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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.

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PROCESS VALIDATION REPORT

Generic name

**RAMITHIAZIDE 5/12.5** 

Protocol No.

PVR-R09

# **PROCESS VALIDATION REPORT**

Generic Name	RAMITHIAZIDE 5/12.5	
Label claim	Each Uncoated tablet contains: Ramipril BP	
Dosage Form	Tablets	
BMR No	BMR/T/134-00	
Batch Size	600000	
Shelf Life	36 Months	-2
MFG. LIC. NO.	PON/DRUGS/19 13 4323	= 7
Product Code	R09	- 14







Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.

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PROCESS VALIDATION REPORT

Generic name

**RAMITHIAZIDE 5/12.5** 

Protocol No.

PVR-R09

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#### PROCESS VALIDATION REPORT

Generic name	RAMITHIAZIDE 5/12.5		\$ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	
Protocol No.	PVR-R09	= ±		in the second second

#### 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 it 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 RAMITHIAZIDE 5/12.5 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 RAMITHIAZIDE 5/12.5, 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 **RAMITHIAZIDE 5/12.5** to be manufactured at Generic Health Care Private Limited, Puducherry.

#### 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.				
Quality Assurance	<ul> <li>Co-ordination with Production and QC to carryout process validation batch.</li> <li>Monitoring and sampling at the different stages.</li> <li>Checking and approval of Process Validation Report.</li> </ul>				
Quality Control	<ul> <li>Analysis of validation batch samples.</li> <li>Preparation of analytical report and submit to Quality Assurance Department.</li> <li>Review of Process Validation Report.</li> </ul>				
Maintenance	To provide necessary utility and environmental condition in process equipment and area				







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Generic name

**RAMITHIAZIDE 5/12.5** 

Protocol No.

PVR-R09

# 5.0 ABBREVIATIONS

Acronym	Definition	Acronym	Definition
P	Protocol	NMT	Not more than
QA	Quality Assurance	°C	Degree Celsius
QC 1	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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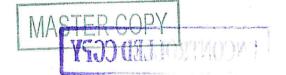
Protocol No. PVR-R09

# 6.0 PRODUCT DETAILS

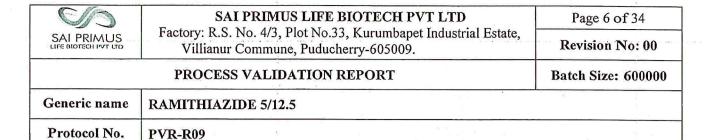
Generic Name	RAMITHIAZIDE 5/12.5						
Dosage Form	Oral Tablet	Oral Tablet					
Each Uncoated tablet contains: Ramipril BP							
Average weight of coated tablet	200.00mg						
Batch number	GF201004	GF201207	GF210317				
Batch size	6.0L	6.0L	6.0L				
Manufacturing date	10/2020	12/2020	03/2021				
Expiry date	09/2023 11/2023		02/2024				
Started on	26/10/2020	31/03/2021					
Completed on	07/11/2020	05/01/2021	27/04/2021				

# 7.0 PROCESS EQUIPMENT DESCRIPTION

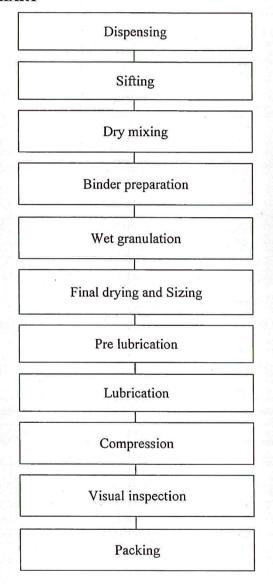
C No	Equipment name	Favinment ID No.	Calibration/qualification status
S. No.	Equipment name	Equipment ID No	Next calibration due
1.	Dispensing Booth	ST/DPB/001	Qualified
2.	Vibratory sifter	PDVBS/001	Qualified
3.	Octagonal blender	PD/OCB/001	Qualified
4.	Compression machine	PD/COM/002	Qualified
5.	Packing 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

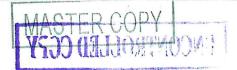


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#### 8.0 PROCESS FLOWCHART









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#### 9.0 BILL OF MATERIALS:

S. No	Name of the Ingredient	Spec .	Item Code	Quantity/ Tablets (mg)	Std. quantity per 6,00,000 tablets (kg)	OA/ PL (%)	Req. quantity per 6,00,000 tablets (kg)
Dry	mixing material:						
1	Ramipril*	BP	RAI/SP/R006	5.100 <sup>#</sup>	3.000	2	3.060#
2	Hydrochlorothiazide^	ВР	RAI/SP/H005	12.750 <sup>#</sup>	7.500	2	7.650#
3	Dried Maize Starch**^^	BP	IRM/SP/M001	56.450	33.870	-	33.870
4	Lactose Monohydrate	BP	REX/SP/L003	77.900	46.740		46.740
5	Microcrystalline Cellulose PH 102	BP	REX/SP/M010	30.000	18.000	-	18.000
Bind	ler Material:			*. : *:			
6	Gelatin	BP	REX/SP/G001	2.000	1.200	-	1.200
7	Butylated Hydroxy Anisole (BHA)	BP	REX/SP/B002	0.200	0.120	-	0.120
8	Citric Acid Anhydrous	BP	RAI/SP/C016	1.000	0.600	1-	0.600
9	Magnesium Oxide Heavy	BP	REX/SP/M021	1.500	0.900	-	0.900
10	Maize Starch	BP	REX/SP/M020	5.000	3.000	-	3.000
11	Erythrosine Supra	IHS	REX/SP/E005	0.100	0.060	=	0.060
12	Purified Water	BP	NA	q.s.	30.000	- 1	30.000
	Theoretical Wo	eight of	Dried Granules	192.000	114.990	- 2"	115.200
Lub	rication Material:				41		A A
13	Sodium Starch Glycollate	BP	REX/SP/S004	5.000	3.000	-	3.000
14	Colloidal Silicon Dioxide	BP	REX/SP/C001	1.000	0.600	-	0.600
15	Stearic Acid	BP	REX/SP/S003	2.000	1.200	-	1.200
	Theoretical Weight of t	he Lub	ricated granules	200.000	119.790	-	120.000
	Theoretical weigh	nt of Co	mpressed tablet	200.000	119.790	-	120.000







Generic name

# SAI PRIMUS LIFE BIOTECH PVT LTD

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**RAMITHIAZIDE 5/12.5** 

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# 10.0 MANUFACTURING PROCESS DETAILS:

# **10.1. SIFTING:**

C4			Observation	Observation			
Step No.	Name of Ingredient	Specified in Approved BMR	Batch No.:				
				GF201207	GF210317		
1.	Sift Ramipril, Hydrochlorthiazide,	Mesh size of sieve (40 #)	40#				
	Dried Maize starch, Lactose monohydrate,	Sieve Integrity Check before use	#	OK			
Microcrystalline Cellulose PH102 through 40#.		Sieve Integrity Check after use		OK			
2	Sift Sodium Starch Glycollate and	Mesh size of sieve (60 #)	2 4 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	60#	telople i		
	Magnesium Stearate	Sieve Integrity Check Before use	- # # - # =	OK			
in the	through 60#	Sieve Integrity Check after use		OK			
3	Sift Colloidal Silicon Dioxide through 30#	Mesh size of sieve (30 #))	y === ====	30#			
\	_ ising smought som	Sieve Integrity Check Before use	7 L	OK			
	*	Sieve Integrity Check after use		OK	AN THE STATE OF TH		

# 10.2 DRY MIXING:

Specified in approved BMR	Setting	Observations  Batch No.:			
	Time				
		GF201004	GF201207	GF210317	
Transfer the sifted Dried maize starch followed by Ramipril, Hydrochlorothiazide, Microcrystalline Cellulose PH 102 and finally lactose into the RMG/Mass mixer. Mix for 10 minute with impeller at slow speed and chopper 'off'.	10 Min.	Transfered the sifted Dried maize starch followed Ramipril, Hydrochlorothiazide, Microcrystalline			







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# 10.2 BINDER PREPARATION:

	Setting		Observations	S
Specified in approved BMR	Time	Batch No.:		
	111110	GF201004	GF201207	GF210317
0.900 Kg of Magnesium Oxide Heavy and mix with 3.000 Kg of Purified Water to form a homogeneous suspension with continuous mixing.		0.900 Kg of Magnesium Oxide Heavy and mix will 3.000 Kg of Purified Water to form a homogeneous suspension with continuous mixing.		
Take 18.000 Kg of Purified Water in Paste Kettle and heat till reaches 95°C and dissolve Butylated Hydroxy anisole (BHA), Citric Acid Anhydrous and Erythrosine Supra followed by Gelatin and Maize starch to form a Homogeneous paste with continuous mixing.	95ºC	Take 18.000 Kg of Purified Water in Paste Ket and heat till reaches 95°C and dissolve Butylat Hydroxy anisole (BHA), Citric Acid Anhydrous a Erythrosine Supra followed by Gelatin and Mai starch to form a Homogeneous paste we continuous mixing.		

#### 10.2 WET GRANULATION:

	Setting	Observations  Batch No.:		
Specified in approved BMR	Time			
		GF201004	GF201207	GF210317
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 min for binder addition with impeller slow speed Chopper OFF.		
After binder addition allow mixing for 5 minutes. If required allow mixing for 5 min or till required consistency of granules obtained with impeller at slow speed and chopper at slow speed.	1 min	minutes with imp	Idition allowed to peller at slow speed of the granules at o	d and chopper at

# 10.2 DRYING AND SIFTING:

	Setting	Observations		
Specified in approved BMR	Time		Batch No.:	
		GF201004	GF201207	GF210317
Load the wet mass into the FBD bowl/ Tray drier tray and air dry the wet mass till solvent smell vanishes.		Load the wet mass into the FBD bowl/ Tray drier tray and air dry the wet mass till solvent smell vanishes.		
Load the wet mass into the cleaned FBD bowl Dry at inlet temperature 50-55°c till the LOD reached up to 2.2% w/w.	1 min	Load the wet mass into the cleaned FBD bowl Dry at inlet temperature 50-55°c. LOD Limit: 1.5-2.2% w/w.		







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and the second s		The No. of the Control of the Contro
Sift the dried granules through 20 # sieve. Record the observation.		Sifted the dried granules through 20 # sieve.
Mill the oversized granules through 1.5 mm multi mill screen fitted with (knives forward medium speed) followed by sifting through 20# sieve on vibrating sifter and collect the sifted granules in double polythene lined cleaned HDPE containers, record the weights.	<u></u>	Milled the oversized granules through 1.5 mm multi mill screen fitted with (knives forward medium speed) followed by sifting through 20# sieve on vibrating sifter and collected the sifted granules in double polythene lined cleaned HDPE containers, record the weights.

#### 10.2 BLENDING & LUBRICATION:

	Setting							
Specified in approved BMR	Time	Batch No.:						
		GF201004	GF201207	GF210317				
Blending								
Load the dried and sifted granules, sifted Sodium Starch Glycollate and Colloidal Silicon Dioxide in to the blender and mix at 8 rpm for 15 minutes	20 Min. at 10 RPM	Loaded the dried and sifted granules, sifted Sodi Starch Glycollate and Colloidal Silicon Dioxide to the blender and mixed at 8 rpm for 15 minutes.						
Lubrication								
Take 5.000 Kg of Pre-Lubricated blend and mix sifted Magnesium Stearate into it then Load into above Pre-lubricated blend and mix for further 2 minutes at 8 RPM	5 min. at 10 RPM	with sifted Magnesium Stearate and loaded in						

# 11.0 COMPRESSION: (Machine Setting)

Machin	e Description	Setting as per Approved BMR	Batch No.:					
			GF201004	GF201207	GF210317			
Compre	ssion machine type	27 Station Double Rotary	27 Station Double Rotary					
ion	Upper punch	7.93 mm Circular shaped flat faced beveled edge punches.	7.93 mm Circular shaped flat faced beveled edge punches.					
Punch Description	Lower punch	7.93 mm Circular shaped flat faced plain punches.	7.93 mm Cir plain punche	cular shaped fles.	at faced			
Ď	Dies	7.93 mm suitable for above punches	7.93 mm suitable for above punches					
Tooling Type D-Tooling D-Tooling				a				







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# 11.1 PRE-COMPRESSION:

Note: As per the protocol Pre-compressed tablets analyzed 1st batch only.

# 11.2 COMPRESSION (Speed Challenge Test):

				Ol	serva	tion				
Sr.		Parameters as per approved	B. No.	: GF2	01004					
No.	Parameters	BMR	Low s	peed			High Speed			
			RPM:	10			RPM		į.	
			- 3	LH	S			RI	IS	
1	Description	Pink coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side	O	K	C	ΣK	OK OF		ΣK	
2	Weight of 27 Tablets	5.400 g ± 3.0 % (5.238 g to 5.562 g)	5.40 gn		5.403 gm		- 200		106 m	
3	Average weight (mg)	200.000 mg ± 3.0 % (194.000 mg – 206.000 mg)	200	mg	200mg		200mg		200	)mg
4	Uniformity of weight Tablets	200.000 mg ± 5.0 % (190.000 mg – 210.000 mg)	193	207	196	208	194	207	193	208
5	Hardness (Kg)	NLT 3.0 Kg (To be established)	6.0	kg	6.	6.0kg		)kg	4.0kg	
6	Thickness (mm)	3.20 mm ± 0.3 mm (2.90 mm – 3.50 mm)	3.12	mm	3.14mm		3.13	3mm	3.23	Bmm
7	Friability	NMT 1% w/w	0.0	3%	0.0	)4%	0.0	2%	% 0.02%	
8	Disintegration Time	NMT 15 Minutes		Min Sec		Min Sec		Min Sec		







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				Ob	servat	ion																
Sr.		Parameters as per approved	B. No.:	GF20	1207																	
No.	Parameters	BMR	Low sp		High Speed																	
			RPM:	10			RPM:25															
			LHS				RHS															
1	Description	Pink coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side	ок ок				OK		OK													
2	Weight of 27 Tablets	5.400 g ± 3.0 % (5.238 g to 5.562 g)	5.41 gm		5.423 gm				5.403 gm		5.412 gm											
3	Average weight (mg)	200.000 mg ± 3.0 % (194.000 mg – 206.000 mg)	201	mg	202mg		201mg		201mg													
4	Uniformity of weight Tablets	200.000 mg ± 5.0 % (190.000 mg – 210.000 mg)	193	208	195	206	193	206	195	207												
5	Hardness (Kg)	NLT 3.0 Kg (To be established)	3.8	kg	4.5	4.5kg		4.5kg		4.5kg		4.5kg		4.5kg		4.5kg		4.5kg		Bkg	4.0	kg
6	Thickness (mm)	$3.20 \text{ mm} \pm 0.3 \text{ mm}$ (2.90 mm - 3.50 mm)	3.12	2mm 3.13mm		3mm	am 3.23mm 3.2		3.28	8mm												
7	Friability	NMT 1% w/w	0.03% 0.04		4%	0.0	2%	0.02	2%													
8	Disintegration Time	NMT 15 Minutes	227.784.55274.5			parameter personages     Description			02Min 12Sec													

			Observation B. No.: GF210317									
Sr. No.	Parameters	Parameters as per approved BMR	RPM: 10  LHS				High Speed RPM: 25					
1	Description	Pink coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side	O	K	OK		OK OK		OK OF			
2	Weight of 27 Tablets	5.400 g ± 3.0 % (5.238 g to 5.562 g)	5.4 gn		5.386 gm				5.4 gi			126 m
3	Average weight (mg)	200.000 mg ± 3.0 % (194.000 mg – 206.000 mg)	201mg		199mg		199mg		200mg		0mg 201	
4	Uniformity of weight Tablets	200.000 mg ± 5.0 % (190.000 mg – 210.000 mg)	198	204	197	210	189	209	188	210		







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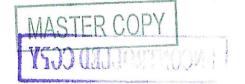
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5	Hardness (KP)	NLT 3.0 Kg (To be established)	3.8kg	3.6kg	4.0kg	4.3kg
6	Thickness (mm)	3.20 mm ± 0.3 mm (2.90 mm – 3.50 mm)	3.19mm	3.18mm	3.24mm	3.26mm
7	Friability	NMT 1% w/w	0.04%	0.02%	0.02%	0.03%
8	Disintegration Time	NMT 15 Minutes	02Min 34Sec	02Min 26Sec	02Min 14Sec	02Min 26Sec

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

Sr.		Parameters as per approved	B. N	o.: GF	bserva 20100	THE RESERVE AND						
No.	Parameters	BMR	Low	Low Hardness RPM:20			High Hardness RPM:20					
1	Description	Pink coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side	OK OK				OK					
2	Weight of 27 Tablets	5.400 g ± 3.0 % (5.238 g to 5.562 g)	5.414 gm		5.423 gm		100000000000000000000000000000000000000			5.403 gm		412 gm
3	Average weight (mg)	200.000 mg ± 3.0 % (194.000 mg – 206.000 mg)	20	01mg 202mg		2mg	201mg		2011			
4	Uniformity of weight Tablets	200.000 mg ± 5.0 % (190.000 mg – 210.000 mg)	193	208	195	206	193	206	195	207		
5	Hardness (KP)	NLT 3.0 Kg (To be established)	3.:	5kg	3.	3.2kg		3kg	3.1	kg		
6	Thickness (mm)	3.20 mm ± 0.3 mm (2.90 mm – 3.50 mm)	3.20	Smm	3.29	9mm	3.33	3.32mm 3.29		9mm		
7	Friability	NMT 1% w/w	0.03%		0.0	)4%	0.0	)2%	0.02	2%		
8	Disintegration Time	NMT 15 Minutes				Min Sec						







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					Observ	vation				
Sr.	Parameters	Parameters as per approved	B. N	lo.: G	F2012	07				- F
No.		BMR	Low	Hard	ness		High	Hard	dness	
		and the property of the property of the party of	RPM	I: 20			RPM	[: 20	_	
1	Description	Pink coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side	С	K	C	K	С	K	C	K
2	Weight of 27 Tablets	5.400 g ± 3.0 %		14		123	5.4	4		412
		(5.238 g to 5.562 g)	gm gm		gm		gm			
3	Average weight (mg)	200.000 mg ± 3.0 % (194.000 mg – 206.000 mg)	201mg 20		202mg		201mg		201mg	
4	Uniformity of weight Tablets	200.000 mg ± 5.0 % (190.000 mg – 210.000 mg)	193	208	195	206	193	206	195	207
5	Hardness (KP)	NLT 3.0 Kg (To be established)	3.8	8kg	4.5	5kg	4.3	Bkg	4.0kg	
6	Thickness (mm)	$3.20 \text{ mm} \pm 0.3 \text{ mm}$ (2.90 mm – 3.50 mm)	3.12	3.12mm 3.13mm		3mm	3.23mm 3.28n		8mm	
7	Friability	NMT 1% w/w	0.03%		0.0	14%	0.0	2%	0.02%	
8	Disintegration Time	NMT 15 Minutes	- 115.5.0	Min Sec	0.000	Min Sec	TO MERCE ESSENCES AND A		02Min 14Sec	

					bserv	ation				
Sr.	Parameters	Parameters as per approved	B. N	lo.: G	F <b>2103</b>	17				
No.		BMR		Hard	ness			Hard	ness	11.2
			RPM	I: 20			RPM	[: 20		
1	Description	Pink coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side	ок ок		ОК		(	OK		
2	Weight of 27 Tablets	5.400 g ± 3.0 % (5.238 g to 5.562 g)	5.405 gm		5.413 gm		5.4 gi		5.410 gm	
3	Average weight (mg)	200.000 mg ± 3.0 % (194.000 mg – 206.000 mg)	200mg		201mg		200mg		20	00mg
4	Uniformity of weight Tablets	200.000 mg ± 5.0 % (190.000 mg – 210.000 mg)	194	207	193	207	195	206	194	206
5	Hardness (KP)	NLT 3.0 Kg (To be established)	3.0	6kg	3.:	5kg	3.3kg		4.0kg	
6	Thickness (mm)	3.20 mm ± 0.3 mm (2.90 mm – 3.50 mm)	3.10	6mm	3.1	3.14mm 3.17		3.17mm 3.18		.8mm
7	Friability	NMT 1% w/w	0.0	)2%	0.0	)3%	0.0	)1%	0.02%	
8	Disintegration Time	NMT 15 Minutes	200.00	02Min         02Min         02M           29Sec         23Sec         24Se		2000				



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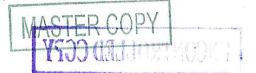
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# 10.3.4 COMPRESSION (At Optimum Speed Hopper Challenge Test):

				Observ	ation				
Sr.	Parameters	Parameters as per	B. No.:	GF2010	)4				
No.		approved BMR	RPM: 2	4		14.			
		自然国际国际基本等产品。 18	Full H	lopper	Middle I	Hopper	Low Hopper		
1	Description	Pink coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side	OK OK				OK		
2	Weight of 27 Tablets	5.400 g ± 3.0 % (5.238 g to 5.562 g)	5.402	gm gm	5.395 gm		5.395 gm 5.384		
3	Average weight (mg)	200.000 mg ± 3.0 % (194.000 mg – 206.000 mg)	200	)mg	200	200mg		Omg	
4	Uniformity of weight Tablets	200.000 mg ± 5.0 % (190.000 mg – 210.000 mg)	194	206	193	205	194	206	
5	Hardness (KP)	NLT 3.0 Kg (To be established)	3.8	Bkg	4.5	5kg	4.1	3kg	
6	Thickness (mm)	3.20 mm ± 0.3 mm (2.90 mm – 3.50 mm)	3.12	3.12mm 3.13mm		3.12mm 3.13mm		3.23	3mm
7	Friability	NMT 1% w/w	0.03%		0.0	)4%	0.0	2%	
8	Disintegration Test	NMT 15 Minutes	02Mir	39Sec	02Mir	ı 22Sec	02Mir	ı 12Sec	

				Observ	ation					
Sr.	Parameters	Parameters as per	B. No.:	GF20120	)7					
No.		approved BMR	RPM: 2	4						
			Full F	lopper	Middle I	<b>Hopper</b>	Low Hopper			
1	Description	Pink coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side	C	OK.	C	K	C	ÞΚ		
2	Weight of 27 Tablets	5.400 g ± 3.0 % (5.238 g to 5.562 g)	5.413	gm	5.42	5.428 gm		5.428 gm 5.423		gm /
3	Average weight (mg)	200.000 mg ± 3.0 % (194.000 mg – 206.000 mg)	20	201mg 201mg		201mg				
4	Uniformity of weight Tablets	200.000 mg ± 5.0 % (190.000 mg – 210.000 mg)	193	205	194	206	196	205		
5	Hardness (KP)	NLT 3.0 Kg (To be established)	3.8kg 3.5kg		5kg	3.9	9kg			
6	Thickness (mm)	3.20 mm ± 0.3 mm (2.90 mm – 3.50 mm)	3.10	6mm	3.13	8mm	3.24	4mm		







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7	Friability	NMT 1% w/w	0.03%	0.04%	0.02%
8	Disintegration Test	NMT 15 Minutes	02Min 42Sec	02Min 26Sec	02Min 36Sec

	Sr. Parameters as per			Obser	vation			
Sr.	Parameters	· 电影影响 化多性性 化邻苯基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲	B. No.: GF210317					
No.		approved BMR	RPM:	24				
			Full 1	Hopper	Middle H	Iopper	Low H	opper
1	Description	Pink coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side.	(	OK	ОК		OK	
2	Weight of 27 Tablets	5.400 g ± 3.0 % (5.238 g to 5.562 g)			5.385 gm		5.387 gm	
3	Average weight (mg)	200.000 mg ± 3.0 % (194.000 mg – 206.000 mg)			199mg		199mg	
4	Uniformity of weight Tablets	200.000 mg ± 5.0 % (190.000 mg – 210.000 mg)	194	206	193	205	194	206
5	Hardness (KP)	NLT 3.0 Kg (To be established)	3.	.6kg	3.8	8kg	3.9	Okg
6	Thickness (mm)	3.20 mm ± 0.3 mm (2.90 mm – 3.50 mm)	3.19mm		3.23	3mm	3.2	7mm
7	Friability	NMT 1% w/w	0.	02%	0.0	0.04% 0.03%		3%
8	Disintegration Test	NMT 15 Minutes	02Mi	n 29Sec	02Mir	i 33Sec	02Mir	26Sec

#### 12.0 INSPECTION

			Observation			
Parameter	Specified	Batch No.:				
		GF201004	GF210317			
Equipment Name Inspection Machine		Inspection Machine				
Equipment ID No.	PD/INB/001		PD/INB/001	1		
No. of Rejected Tablets	To be recorded	1300 Nos	2200 Nos	900 Nos		







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#### PROCESS VALIDATION REPORT

Generic name | RAMITHIAZIDE 5/12.5

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# 13.0 PACKING PROCESS:

#### 13.1 BILL OF PACKING MATERIALS:

Material Name	Item code	UOM	Req. Qty. for 6.0 Lac	Issued Qty.
252 mm Ramithiazide 5/12.5 Printed foil	PPF/SP/R009	Kg	45.000	45.000
252 mm Alu Alu Base foil	PPF/SP/A019	Kg	150.000	150.000
3x10'S Ramithiazide 5/12.5mg Carton	PPC/SP/R010	No	20000	20000
Ramithiazide Printed Leaflet	PPL/SP/R002	No	20000	20000
Shrink Sleeves (PVC)	PPS/SP/P001	No	2000	2000
5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	No	75	75
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	3	3
3' Plain BOPP Tape	PPR/SP/S001	Mtrs	300	300
Strapping role.	NA	No	91	91

#### 13.2 PACKING VALIDATION:

		Observation Batch No.:					
Parameters	Specified	GF201004	GF20	01207	GF210317		
		Low speed/	Low speed/	High speed/	High speed/		
# # # # # # # # # # # # # # # # # # #		Low temp.	High temp.	High temp.	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		





Protocol No.

#### SAI PRIMUS LIFE BIOTECH PVT LTD

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PROCESS VALIDATION REPORT

Generic name RAMITHIAZIDE 5/12.5

PVR-R09

#### 14.0 ANALYTICAL RESULTS:

# 14.1.1 Analytical Result of Lubricated Blend (For 03 Min)

Test	Limit	Observation									
	CONTRACTOR OF CONTRACTOR	Sample No.	Batch No.:	Batch No.:							
			GF20	1004	GF20	1207	GF21	0317			
			F	Ramipril BP		Hydro	chlorothiaz	ide BP			
	=	1	101.88%	101.21%	102.64%	99.75%	100.95%	97.90%			
		2	98.39%	97.22%	101.51%	99.51%	98.01%	99.53%			
		3	92.23%	98.47%	97.62%	98.41%	99.72%	98.12%			
LEND	90.0% to	4	101.87%	102.34%	98.44%	100.40%	100.91%	97.80%			
)F BL	110.0% of the label claim.	5	94.07%	101.22%	93.81%	97.72%	98.24%	97.45%			
UNIFORMITY OF BLEND		6	102.96%	96.74%	99.30%	97.39%	99.90%	99.22%			
ORM	RSD NMT	7 .	99.77%	100.89%	97.62%	96.54%	97.62%	96.48%			
UNIF	5.0%	8	102.55%	103.72%	98.74%	94.62%	97.49%	99.92%			
		9	92.93%	98.38%	100.23%	96.22%	96.82%	101.03%			
		10	93.84%	100.41%	102.01%	101.29%	99.96%	101.21%			
		Min.	92.23%	96.74%	93.81%	94.62%	96.82%	96.48%			
		Max.	102.96%	103.72%	102.64%	101.29%	100.95%	101.21%			
		Mean	98.05%	100.06%	99.19%	98.19%	98.96%	98.87%			
		% RSD	4.43	2.27	2.62	2.11	1.51	1.58			
Comme nts/ Remark	Complies comply respected	does not with to standards			Comp	olies					







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# PROCESS VALIDATION REPORT

Generic name | RAMITHIAZIDE 5/12.5

Protocol No. PVR-R09

# 14.1.2 Analytical Result of Lubricated Blend (For 04 Min)

Test	Limit	Observation								
og 2000-pui 20 200-915-24-220		Sample No.	Batch No.:							
	7 5 5		GF20	1004	GF20	1207	GF21	10317		
	) (a) (b) (c) (c) (c) (c) (c) (c) (c) (c) (c) (c		I	Ramipril BI		Hydro	chlorothiaz	ide BP		
		1	98.43%	96.95%	101.38%	97.84%	99.36%	98.13%		
		2	97.18%	98.67%	101.15%	97.70%	97.45%	97.92%		
		3	94.71%	94.22%	98.89%	97.69%	98.54%	98.22%		
END		4	99.37%	98.60%	101.23%	98.13%	101.81%	98.10%		
F BL	90.0% to 110.0% of	5	98.20%	97.90%	97.87%	97.14%	101.65%	97.54%		
ITY O	the label	6	104.47%	103.10%	100.71%	101.11%	100.54%	100.07%		
UNIFORMITY OF BLEND	NMT 5.0%	7	95.52%	100.96%	98.02%	98.18%	97.75%	99.88%		
UNIR		8	98.86%	94.09%	98.15%	94.79%	97.20%	100.15%		
	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	9	94.69%	102.97%	100.81%	99.79%	102.09%	99.67%		
	- <u> </u>	10	98.57%	95.20%	97.05%	96.34%	102.46%	96.71%		
		Min.	94.69%	94.09%	97.05%	94.79%	97.20%	96.71%		
		Max.	104.47%	103.10%	101.45	101.11%	102.46%	100.15%		
		Mean	98.00%	98.27%	99.53%	97.87%	99.89%	98.64%		
	I	% RSD	2.91	3.35	1.69	1.76	2.07	1.22		
Comments / Remarks	Complies/d comply with re standard specifica	spected to s of			Con	nplies				



UNCONTROLLED CC?Y



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#### PROCESS VALIDATION REPORT

Generic name RAMI

**RAMITHIAZIDE 5/12.5** 

Protocol No.

PVR-R09

# 14.1.2 Analytical Result of Lubricated Blend (For 05Min)

Test	Limit				Observation			
	SARCESONE SETTENBER SETTENBER	Sample No.	Batch No.:					
-			GF20	1004	GF20	1207	GF21	0317
		[[] [] [] [] [] [] [] [] [] [] [] [] []		Ramipril BP		Hydro	chlorothiazi	de BP
		1	93.86%	102.05%	97.40%	96.80%	100.34%	97.34%
7 y		2	92.69%	93.88%	98.25%	98.62%	101.65%	98.76%
	7.	3	91.79%	94.10%	104.12%	100.22%	97.45%	100.43%
e e	10 E	4	102.43%	95.09%	98.56%	100.67%	98.94%	101.35%
UNIFORMITY OF BLEND	90.0% to 110.0% of	5	102.18%	105.38%	98.35%	103.09%	100.52%	100.95%
Y OF	the label claim.	6	101.53%	101.56%	97.78%	99.58%	101.52%	97.21%
RMIT	RSD NMT	7	98.73%	97.95%	98.41%	103.76%	100.69%	99.55%
NIFO	5.0%	8	96.24%	99.78%	98.53%	98.37%	99.33%	99.44%
Ď	, , ,	9	102.02%	102.53%	98.31%	96.98%	98.35%	97.03%
		10	91.56%	92.99%	100.39%	96.65%	98.99%	98.38%
32 Ta		Min.	91.56%	92.99%	97.40%	96.65%	97.45%	97.03%
		Max.	102.43%	105.38%	104.12%	103.76%	101.69%	101.35%
	¥.=2	Mean	97.30%	98.53%	99.01%	99.47%	99.78%	99.04%
	1 00 12	% RSD	4.72	4.41	1.97	2.52	1.38	1.58
Comme nts/ Remark	Complies/do comply wit to stand	h respected			Com	plies		







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# PROCESS VALIDATION REPORT

Generic name RAMITHIAZIDE 5/12.5

Protocol No. PVR-R09

Sr. No.			Parameters	Acceptance Criteria	Observ Batch No. GF2		
1	Descri	ptio	n	Pink colour granules.	Pink colour		
2	LOD			Informative	2.11%		
3	Bulk I	Dens	sity (gm/ml)	Informative	0.3942	2gm/l	
4	Tapped Density (gm/ml)			Informative	0.471	lgm/l	
			Ramipril BP		100.2		
5	Assay (%) Hydrochlorothiazide BP		Hydrochlorothiazide	90.0% to 110.0 %	99.7	2%	
			60#		94.26%	5.74%	
	Siev		80#		84.12%	15.88%	
6	Analysis		100#	Informative	81.04%	18.96%	
	2	120#		61.44%	3856%		
Comr	nents iarks		nplies/does not comply cification	with respected to standards of	complies		
Sr.			Parameters	Acceptance Criteria	Observation		
No.			rarameters	Acceptance Criteria	Batch No. GF201207		
1	Descr	iptic	on	Pink colour granules.	Pink colour granules.		
2	LOD.	-9 000		Informative	2.06%		
3	Bulk l	Den	sity (gm/ml)	Informative	0.3716gm/l		
4	Тарре	ed D	ensity (gm/ml)	Informative	0.4926gm/l		
	Assa	11/	Ramipril BP		99.53%		
5	(%)		Hydrochlorothiazide BP	90.0% to 110.0 %	99.56%		
			60#		95.92%	4.08%	
6	Siev		80#	Informative	85.26%	14.74%	
U	Analy	100#	Intormative	81.45%	18.55%		
			120#	9	60.23%	39.77%	
	ments narks		mplies/does not comply ecification	with respected to standards of	Com	plies	
Sr.				Acceptance Criteria	Obser	vation	







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PROCESS VALIDATION REPORT Batch Size: 600000

Generic name	RAMITHIAZIDE 5/12.5
Protocol No.	PVR-R09

1	Description	n	Pink colour granules.	Pink colour granules.	
2	LOD		Informative	2.09	9%
3	Bulk Dens	sity (gm/ml)	Informative	0.373	69g/l
4	4 Tapped Density (gm/ml)		Informative	0.502	26g/l
	Assay Ramipril BP			98.74%	
5	5 (%)	Hydrochlorothiazide BP	90.0% to 110.0 %	99.70%	
		60#		94.23%	5.77%
6	Sieve	80#	]	86.26%	13.74%
0	Analysis	100#	Informative	80.73%	19.27%
		120#		60.66%	39.34%
Comments   Complies/does not comply with respected to standards of   Remarks   specification			Com	plies	

# 14.1.3 Analytical Result of Compression at Different Speed:

				Obse	rvation	
	π	`est	Limit	Batch No.: GF201004	The state of the s	
	4	CSI .	Limit	Low Speed	High Speed	
				RPM:10	RPM: 30	
Assay	Ramip		90.0% to 110.0 %	99.70%	100.14%	
%	Hydrod BP	chlorothiazide	90.0% to 110.0 %	99.76%	99.37%	
	nents/ arks	Complies/does no to standards of sp	ot comply with respected ecification	Complies	Complies	
				Observation		
	n	Cest	Limit	Batch No.: GF201207		
		est		Low Speed	High Speed	
				RPM:	RPM:	
Assay	Ramip	ril BP	90.0% to 110.0 %	99.92%	99.64%	
%	Hydro BP	chlorothiazide	90.0% to 110.0 %	99.93%	99.64%	
11	Comments/ Complies/does no to standards of sp		ot comply with respected pecification	Complies	Complies	







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#### PROCESS VALIDATION REPORT

Generic name | RAMITHIAZIDE 5/12.5

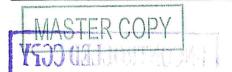
Protocol No. PVR-R09

				Observation  Batch No.: GF210317		
			Limit			
	Test		Low		High Speed	
				RPM:	RPM:	
	Assay Ramipril BP Hydrochlorothiazide BP		00.00/ 110.00/	99.67%	99.54%	
Assay			90.0% to 110.0 %	99.62%	99.39%	
Comments/ Complies/does n Remarks to standards of s			ot comply with respected pecification	Complies	Complies	

# 14.1.4 Analytical Result of Compression at Different Compression Pressure:

	Test				Obser	vation		
			Batch No.: GF201004					
	est		Low Ha	rdness		I	High Hardne	SS
			RPM:24			RPM: 24		
	Ramipril BP	NLT	93.46 %	99.63%	96.29%	93.19%	100.26%	97.79%
Dissolution	Hydrochlorot hiazide BP	75.0 %	93.77 %	98.23%	96.47%	93.63%	97.50%	95.94%
Comments / Remarks	Complies/does of comply with restandards of specification			Complies			Complies	

			Observation						
			Batch No.: GF201207						
	Test	Limit	Low Ha	rdness		High Hardness			
			RPM: 2	4	HAMP O	RPM: 24			
	Ramipril BP	NLT	91.63%	100.93%	95.72%	93.46%	100.02%	97.07%	
Dissolution	Hydrochlorothiazide BP	75.0 %	91.84%	96.96%	94.15%	94.00%	96.99%	95.13%	
Comments / Remarks	Complies/does not comply with respected to standards of specification				Com	plies			





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Protocol No. PVR-R09

	The state of the s		Observation						
	Tost	Limit	Batch No.: GF210317						
	Test		Low Hardness			High Hardness			
			RPM: 2	4		RPM: 24			
D: 1.	Ramipril BP	NLT	98.34%	103.09%	100.37%	97.21%	101.90%	99.65%	
Dissolution	Hydrochlorothiazide BP	75.0 %	96.03%	99.84%	98.06%	96.93%	100.11%	98.23%	
Comments / Remarks  Complies/does not comprespected to standards of specification		y with			Com	plies			

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

Test	Limit				Observation	Adams.			
		Sample	Batch No.: GF201004						
		No.	Full H	lopper	Middle	Hopper	Low H	lopper	
2		1	94.07%	100.44%	103.19%	102.09%	97.76%	100.39%	
		2	90.84%	98.74%	99.13%	96.63%	103.50%	98.81%	
LY	lain	3	99.04%	97.55%	91.61%	96.39%	91.81%	102.45%	
YTE	pel c	4	93.60%	98.38%	95.10%	102.08%	103.43%	96.26%	
CONTENT	ie la	5	99.60%	97.56%	102.08%	97.53%	91.79%	102.27%	
OF	of th	6	10208%	102.03%	93.03%	103.01%	98.94%	100.11%	
TY	%(	7.	99.42%	102.23	102.71%	101.69%	100.61%	98.47%	
UNIFORMITY OF	85.0% to 115.0% of the label claim.	8	102.71%	100.03%	103.27%	98.07%	99.18%	95.82%	
FOI	to ]	9	102.27%	97.33%	93.91%	98.95%	95.36%	97.66%	
	%0"	10	98.25%	96.29%	105.52%	102.09%	97.55%	98.11%	
,	85	Min.	90.84%	96.29%	91.61%	96.39%	91.79%	95.82%	
	9 1	Max.	102.71%	102.23%	105.52%	103.01%	103.50%	102.45%	
		Mean	98.19%	99.06%	98.96%	99.85%	97.99%	99.04%	
	V.	% RSD	4.13	2.05	4.14	2.58	4.20	2.28	
Comm Rema			mplies / does not comply with respected to ndards of specification  Complies						







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# PROCESS VALIDATION REPORT

Generic name | RAMITHIAZIDE 5/12.5

Protocol No. | PVR-R09

Test	Limit	<b>为新的表现</b>			Observation				
,		Sample Batch No.: GF201207							
	,	No.	Full H	lopper	Middle	Hopper	Low Hopper		
	\$1.00 \$1.00		Comp	posite	Comp	posite	Com	posite	
	, ° , -°	1	100.82%	98.24%	96.03%	98.51%	98.78%	102.26%	
	ij	2	93.75%	101.88%	95.66%	96.39%	102.67%	100.88%	
ENJ	clai	3	98.09%	101.75%	93.11%	97.23%	97.95%	98.83%	
INC	abel	.4	94.39%	98.12%	98.87%	102.02%	101.31%	98.19%	
CC	ihe l	5	94.88%	102.08%	98.82%	99.33%	98.55%	102.00%	
(O	of 1	6	102.79%	98.42%	93.19%	100.99%	98.94%	98.49%	
UNIFORMITY OF CONTENT	85.0% to 115.0% of the label claim.	7	100.83%	100.79%	103.72%	97.26%	99.01%	98.47%	
)RIV	116	8	94.06%	98.03%	98.55%	97.87%	103.90%	97.93%	
IIFC	% to	9	95.18%	97.33%	93.91%	99.86%	100.86%	97.54%	
5	35.0	10	101.63%	100.79%	99.15%	100.36%	98.72%	98.18%	
	<b>w</b>	Min.	93.75%	97.33%	93.11%	96.39%	97.95%	97.54%	
		Max.	102.79%	102.08%	103.72%	102.02%	103.90%	102.26%	
		Mean	97.64%	99.74%	97.10%	99.27%	100.07%	99.28%	
-		% RSD	3.66	1.88	3.44	1.70	2.00	1.76	
Comm Rema	St. Carrier		does not con tandards of s		pected to		Complies		

Test	Limit		Observation						
		Sample	Batch No.:	Batch No.: GF210317					
		No.	Full H	opper	Middle	Hopper	Low H	lopper	
L	claim.		Comp	oosite	Comp	oosite	Comp	oosite	
EN		1	101.44%	100.19%	99.45%	99.32%	97.89%	100.14%	
LNC	label	2	100.52%	99.95%	99.32%	96.64%	98.96%	99.84%	
OF CONTENT	of the l	3	98.41%	97.53%	100.51%	96.40%	103.18%	96.81%	
	THE RESIDENCE OF THE PROPERTY OF THE PARTY O	4	99.30%	99.78%	96.76%	98.42%	99.71%	97.70%	
	115.0%	5	95.71%	99.33%	98.30%	97.51%	99.87%	100.03%	
UNIFORMITY		6	98.30%	98.36%	97.56%	98.25%	98.30%	101.12%	
E E	% tc	7	103.73%	98.21%	99.78%	100.53%	98.41%	99.51%	
l b	85.0% to	8	98.96%	96.40%	99.54%	101.62%	104.96%	95.83%	
		9	97.67%	100.0%	101.27%	99.62%	98.51%	99.43%	
		10	98.41%	100.05%	101.89%	98.42%	100.39%	101.66%	





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# PROCESS VALIDATION REPORT

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Generic name	RAMITHIAZIDE 5/12.5

Protocol No. PVR-R09

	Min.	95.71%	96.40%	96.79%	96.40%	97.89%	95.83%
	Max.	103.73%	100.19%	101.89%	101.62%	104.96%	101.66%
	Mean	99.25%	98.98%	99.44%	98.67%	100.02%	99.21%
Text M	% RSD	2.22	1.30	1.59	1.66	2.31	1.87
Comments/ Remarks		does not con andards of s		pected to		Complies	

# 14.1.6 Analytical Result of Composite Tablets:

Parameters	Specified	Observation Batch No.: GF201004	
		Composite Sample	
Description	Pink coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side side	Pink coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side on other	
Weight of 20 tablets	2.800 g± 3.0 % (2.716 gm to 2.884 gm)	2.788gm	
Average weight(mg)	140.000 mg ± 3.0 % (133.000 mg – 147.000 mg	139.4mg	
Uniformity of weight	140.00 mg ± 5.0 % (133.000 mg – 147.000 mg)	Min: -1.52% and Max: 2.05%	
Thickness	3.40 mm ± 0.2 mm (3.20 mm – 3.60 mm)	Min: 3.35mm to Max: 3.45mm	
Hardness (N)	NLT 4.0 Kg (To be established)	4.0kg	
Friability	NMT 1% w/w	0.26%	
Disintegration Time	NMT 15 Minutes	02Min 16Sec	
Average Diameter	6.80 mm ± 0.2mm	6.80mm	

Parameters	Specified	Observation Batch No.: GF201207 Composite Sample
Description	Pink coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side side	Pink coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side on other
Weight of 20 tablets	2.800 g± 3.0 % (2.716 gm to 2.884 gm)	2.812gm
Average weight(mg)	140.000 mg ± 3.0 % (133.000 mg – 147.000 mg	140.6mg







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# PROCESS VALIDATION REPORT

Generic name | RAMITHIAZIDE 5/12.5

Uniformity of weight	140.00 mg ± 5.0 % (133.000 mg – 147.000 mg)	Min: -2.03mm; Max: 1.55mm
Thickness	3.40 mm ± 0.2 mm (3.20 mm – 3.60 mm)	Min: 3.36mm and Max: 3.40mm
Hardness (N)	NLT 4.0 Kg (To be established)	4.5Kg
Friability	NMT 1% w/w	0.30%
Disintegration Time	NMT 15 Minutes	02Min and 25Sec
Average Diameter	6.80 mm ± 0.2mm	Min: 6.80mm and Max: 6.82mm

		Observation	
Parameters	Specified	Batch No.: GF210317	
Description	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side	
Weight of 20 tablets	2.800 g± 3.0 % (2.716 gm to 2.884 gm)	2.822gm	
Average weight(mg)	140.000 mg ± 3.0 % (133.000 mg – 147.000 mg	141.1mg	
Uniformity of weight	140.00 mg ± 5.0 % (133.000 mg – 147.000 mg)	Min: -1.04: Max: 2.05mm	
Thickness	3.40 mm ± 0.2 mm (3.20 mm – 3.60 mm)	Min: 3.29mm: Max: 3.40mm	
Hardness (N)	NLT 4.0 Kg (To be established)	4.5Kg	
Friability	NMT 1% w/w	0.25%	
Disintegration Time	NMT 15 Minutes	2min and 30Sec	
Average Diameter	6.80 mm ± 0.2mm	Min: 6.80mm to Max: 6.83mm	





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PROCESS VALIDATION REPORT

Generic name RAMITHIAZIDE 5/12.5

Protocol No. PVR-R09

# 15.0 FINISHED PRODUCT REPORT:

		Observation  Batch No: GF201004			
Parameter	Specified				
		Composite	Sampl	e	
Appearance	Pink coloured, flat, round, beveled edged uncoated tablet with break line on one side and plain on other side.	Pink coloured, flat, round, beveled edged uncoated tablet with break lir on one side and plain on other side.			
Identification			. 7 .		
Ramipril BP	The retention time of one of the major peak in the chromatogram of sample preparation corresponds to the peak due to Ramipril in standard preparation as obtained in assay.	Complies			7
Hydrochlorothiazide BP	The retention time of one of the major peak in the chromatogram of sample preparation corresponds to the peak due to Hydrochlorothiazide in standard preparation as obtained in assay.	Complies			
Average weight	200.0 mg ± 5.0 % (Limit:190.0 mg to 210.0 mg)	202.95mg			
Uniformity of weight	200.0 mg ± 5.0 % (Limit: 190.0 mg to 210.0 mg)	-1.50% +0.90%			
Dimensions:					
Thickness	3.20 mm ± 0.3 mm (2.90 mm – 3.50 mm)	3.10mm	3.15mm. 3.12mm		
Hardness	NLT 3.0 kg	3.9Kg/cm <sup>2</sup>	m = 1.0 i		
Diameter	7.90 mm ± 0.2mm	8.02 mm	8.05	mm	8.04 mm
Friability	NMT 1.0 %	0.14%			
Disintegration Time	NMT 15mins	02Min 16Sec			
Dissolution		94.43 %	101.6	8 %	97.94 %
Ramipril BP and Hydrochlorothiazide BP	Not less than 75 % of labeled amount	97.40 %	100.64 % 99.49		99.49 %
Uniformity of content Ramipril BP 5 mg and	85.0 % to 115.0 % of average value.	102.23%	104.2	24%	103.26%
Hydrochlorothiazide BP 12.5 mg	85.0 % to 115.0 % of average value.	100.93%	103.8	33%	99.49%
Assay			***************************************		
Each uncoated tablet contains: Ramipril BP 5 mg and	Not less than 90.0 % and Not more than 110.0 %	99.01%			1
Hydrochlorothiazide BP 12.5 mg	99.05%				





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#### PROCESS VALIDATION REPORT

Generic name RAMITHIAZIDE 5/12.5

Protocol No. PVR-R09

Related Substance		
Impurity A	NMT 2.00%	Not Detected(ND)
Impurity D	NMT 6.00%	Not Detected(ND)
Impurity E	NMT 2.00%	Not Detected(ND)
Single Maximum	NMT 0.5%	Below Detection Limit(BDL)
unknown Impurity		
Total Impurities	NMT 6.0%	Below Detection Limit(BDL)
Microbiological Limits	a y	
Total Aerobic Microbial	NMT 1000 cfu/g	20cfu/g
counts		
Total Yeasts and Mould	NMT 100 cfu/g	<10cfu/g
Counts		
E.coli	Should Be absent	Absent
Salmonella	Should Be absent	Absent
S.Aureus	Should Be absent	Absent
P. aeruginosa	Should Be absent	Absent

		Observation			
Parameter	Specified	Batch No: GF201207 Composite Sample			
Appearance	Pink coloured, flat, round, beveled edged uncoated tablet with break line on one side and plain on other side.	Pink coloured, flat, round, beveled edged uncoated tablet with break line on one side and plain on other side.			
Identification		2 1	* .	-	William N. E.
Ramipril BP	The retention time of one of the major peak in the chromatogram of sample preparation corresponds to the peak due to Ramipril in standard preparation as obtained in assay.	Complies		_ W	
Hydrochlorothiazide BP	The retention time of one of the major peak in the chromatogram of sample preparation corresponds to the peak due to Hydrochlorothiazide in standard preparation as obtained in assay.	Complies			
Average weight	200.0 mg ± 5.0 % (Limit:190.0 mg to 210.0 mg)	201.40mg			
Uniformity of weight	200.0 mg ± 5.0 % (Limit:190.0 mg to 210.0 mg)	-1.79% +1.19%		9%	
Dimensions:					
Thickness	3.20 mm ± 0.3 mm (2.90 mm – 3.50 mm)	3.10mm 3.14mm. 3.12		3.12mm	
Hardness	NLT 3.0 kg	3.2Kg/cm <sup>2</sup>			
Diameter	7.90 mm ± 0.2mm	8.02mm	8.06r	nın	8.04mm
Friability	NMT 1.0 %	0.18%			





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# PROCESS VALIDATION REPORT

Generic name | RAMITHIAZIDE 5/12.5

Not less than 75 % of labeled amount	96.12 %	101.97 %	98.85 %
	96.67%	99.52%	98.13%
85.0 % to 115.0 % of average value.	101.61%	103.33%	102.30%
85.0 % to 115.0 % of average value.	98.66%	102.12%	99.69%
- 3 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2			
Not less than 90.0 % and Not more than	101.54%		
110.0 %	98.59%		
NMT 2.00% NMT 6.00% NMT 2.00% NMT 0.5%	Not Detected(ND) Not Detected(ND) Not Detected(ND) Below Detection Limit(BDL)		
NM1 6.0%	Below Dete	ection Limit(E	BDL)
NMT 1000 cfu/g	20cfu/g		
NMT 100 cfu/g	<10cfu/g		
Should Be absent	Absent		
Should Be absent	Absent		
	Absent		
	85.0 % to 115.0 % of average value.  85.0 % to 115.0 % of average value.  Not less than 90.0 % and Not more than 110.0 %  NMT 2.00% NMT 6.00% NMT 0.5%  NMT 1000 cfu/g  NMT 1000 cfu/g  Should Be absent	85.0 % to 115.0 % of average value.   101.61%	96.67%   99.52%





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Batch Size: 600000

# PROCESS VALIDATION REPORT

Generic name | RAMITHIAZIDE 5/12.5

		Observation  Batch No: GF210317  Composite Sample		
Parameter	Specified			
	(1) (1) (1) (1) (1) (1) (1) (1) (1) (1)			
Appearance	Pink coloured, flat, round, beveled edged uncoated tablet with break line on one side and plain on other side.	Pink coloured, flat, round, beveled edged uncoated tablet with break lin on one side and plain on other side.		
Identification				_
Ramipril BP	The retention time of one of the major peak in the chromatogram of sample preparation corresponds to the peak due to Ramipril in standard preparation as obtained in assay.	Complies		
Hydrochlorothiazide BP	The retention time of one of the major peak in the chromatogram of sample preparation corresponds to the peak due to Hydrochlorothiazide in standard preparation as obtained in assay.	Complies	)	
Average weight	200.0 mg ± 5.0 % (Limit: 190.0 mg to 210.0 mg)	201.85mg		
Uniformity of weight	200.0 mg ± 5.0 % (Limit: 190.0 mg to 210.0 mg)	-1.56% +1.90%		
Dimensions:		2		
Thickness	3.20 mm ± 0.3 mm (2.90 mm – 3.50 mm)	3.10mm	3.15mm. 3.12mm	
Hardness	NLT 3.0 kg	3.8Kg/cm <sup>2</sup>		. ragini.
Diameter	$7.90 \text{ mm} \pm 0.2 \text{mm}$	7.98mm	8.02mm	8.00mm
Friability	NMT 1.0 %	0.15%		2.5
Disintegration Time	NMT 15mins	02Min 25S	lec	
Dissolution Ramipril BP and	Not less than 75 % of labeled amount	101.54%	01.54% 104.66% 102.	
Hydrochlorothiazide BP	Not less than 75 70 or labeled unlouit	96.67%	99.52%	98.13%
Uniformity of content Ramipril BP 5 mg and	85.0 % to 115.0 % of average value.	101.61%	103.339	6 102.30%
Hydrochlorothiazide BP 12.5 mg	85.0 % to 115.0 % of average value.	98.66%	102.129	% 99.69%
Assay				
Each uncoated tablet contains:	Not less than 90.0 % and Not more than 110.0 %	101.52%	a	







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Batch Size: 600000

# PROCESS VALIDATION REPORT

Generic name RAMITHIAZIDE 5/12.5

Ramipril BP 5 mg and Hydrochlorothiazide BP 12.5 mg		100.83%
Related Substance		
Impurity A	NMT 2.00%	Not Detected(ND)
Impurity D	NMT 6.00%	Not Detected(ND)
Impurity E	NMT 2.00%	Not Detected(ND)
Single Maximum	NMT 0.5%	Below Detection Limit(BDL)
unknown Impurity	· · · · · · · · · · · · · · · · · · ·	1 2
Total Impurities	NMT 6.0%	Below Detection Limit(BDL)
Microbiological Limits		
Total Aerobic Microbial	NMT 1000 cfu/g	20cfu/g
counts		1 A 1 A 1 A 1 A 1 A 1 A 1 A 1 A 1 A 1 A
Total Yeasts and Mould	NMT 100 cfu/g	<10cfu/g
Counts		
E.coli	Should Be absent	Absent
Salmonella	Should Be absent	Absent
S.Aureus	Should Be absent	Absent
P. aeruginosa	Should Be absent	Absent





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SAI PRIMUS		Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		
	PROCESS VALIDATION REPORT			
Generic name	RAMITHIAZIDE 5/1	12.5	-	
Protocol No.	PVR-R09	2 ·		
6.0 Deviation	n and Justification/Correc	ctive Action:		
Sr. No.	Deviation details	Justification(s) / Corrective Action(s)	Remarks Acceptable / Not acceptable	
1.			10 to	
2.		wt/		
3.				
7.0 SUMMA		mon of Romitmasid	i 5/12,5 hm	
	CATALIA GET			
	STALL ST	U		
	CAIMIN GAT	0	1	
	CAIMIN GAT			
	CAIMIN GAT			
18.0 CONC	LUSION:			
18.0 CONC	LUSION:	Ramitmartde 5/215		
18.0 CONC	LUSION: Provess of	- and QF 2/09/8 h	aux hem	
18.0 CONC The Octaor	LUSION:  Provess of  DOY, GF201207	tu overula obrained	Joon blinding	
18.0 CONC The Octaor	LUSION:  Provess of  DOY, GF201207	tu overula obrained	aux bem	
18.0 CONC The CLF 2010	LUSION:  Provess of  DOY, GF201207	- and QF 2/09/8 h	Joon blinding	

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# SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009. PROCESS VALIDATION REPORT Batch Size: 600000 Generic name RAMITHIAZIDE 5/12.5 Protocol No. PVR-R09

#### 19.0 REPORT APPROVAL:

The process Validation Report of batch "RAMITHIAZIDE 5/12.5" having batch size of 6,00,000 Tablets has been reviewed and complies with requirements.

Prepare	ed By:
Name: Crc	then
Sign / Date: Qua	hity Assurance
Checked and I	Reviewed By:
Name: A. VALLARAJAN	Name: BAUA SUBILAM ANDON. A
Sign/Date:Quality Control	Sign/Date: Dalaluman Production 19/09/2011
Comments: We certify that the process Validation report, 00,000 Tablets has been accepted.	rt for "RAMITHIAZIDE 5/12.5" having batch size o

Name: Name:



