SAI PRIMUS LIFE	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S.No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Page 1 of 3
		No.RMS: RAI/SP/R006
	RAW MATERIAL SPECIFICATION	Revision No.: 01
Title:	RAMIPRIL BP	Review Period: 3 Years
	Item Code: RAI/SP/R006	Effective Date: 18/11/2024

GENERAL INFORMATION	
Molecular formula	$C_{23}H_{32}N_2O_5$
Molecular weight	416.5
Pack details	15 kg packed in PVC Drum.
Storage conditions	Product from light.
Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
Quantity of sample required for chemical analysis	10 g
Quantity of reserve sample	20 g
Sampling Instructions	SOP No.: QCGN/018
Retest period	12 months

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
Date	18/11/2024	18/11/2024	18/11/2024
Department: Quality Control		Date of Issue: 18/11/2024	

SAI PRIMUS LIFE	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S.No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Page 2 of 3
		No.RMS: RAI/SP/R006
	RAW MATERIAL SPECIFICATION	Revision No.: 01
Title:	RAMIPRIL BP	Review Period: 3 Years
	Item Code: RAI/SP/R006	Effective Date: 18/11/2024

S.No.	TEST	LIMITS	METHOD
1	DESCRIPTION	White or almost white, crystalline powder	Follow section I of method of analysis
2	SOLUBILITY	Sparingly soluble in water, freely soluble in methanol.	Follow section II of method of analysis
3	IDENTIFICATION A. SPECIFIC OPTICAL ROTATION (on dried basis) B. By IR	 + 32.0° to + 38.0° The IR absorption spectrum of sample should be concordant with the spectrum obtained with Ramipril working standard.	Follow section III of method of analysis
4	APPEARANCE OF SOLUTION	The solution should be clear and colourless	Follow section IV of method of analysis
5	SPECIFIC OPTICAL ROTATION (on dried basis)	+ 32.0° and + 38.0°	Follow section V of method of analysis
6	RELATED SUBSTANCES (By HPLC) IMPURITY A IMPURITY B IMPURITY C IMPURITY D UNSPECIFIED IMPURITY TOTAL IMPURITIES	 NMT 0.5 % NMT 0.5 % NMT 0.5 % NMT 0.5 % NMT 0.10 % NMT 1.0 %	Follow Section VI of method of Analysis
7	SULPHATED ASH	NMT 0.1 %	Follow section VII of method of analysis
8	LOSS ON DRYING (1.0 g/60°C under vacuum/4 h)	NMT 0.2 %	Follow section VIII of method of analysis

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
Date	18/11/2024	18/11/2024	18/11/2024
Department: Quality Control		Date of Issue:	18/11/2024

SAI PRIMUS LIFE	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S.No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Page 3 of 3
		No.RMS: RAI/SP/R006
	RAW MATERIAL SPECIFICATION	Revision No.: 01
Title:	RAMIPRIL BP	Review Period: 3 Years
	Item Code: RAI/SP/R006	Effective Date: 18\11\2024

S.No.	TEST	LIMITS	METHOD
9	ASSAY (By Potentiometry) (on dried basis)	98.0 % - 101.0 %	Follow section IX of method of analysis

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No.RMS: RAI/SP/R006
2	Revision No.: 01	Periodic Revision

END OF DOCUMENT

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
Date	18/11/2024	18/11/2024	18/11/2024
Department: Quality Control		Date of Issue: 18/11/2024	

SAI PRIMUS LIFE	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S.No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Page 1 of 9
		No. RMSTP: RAI/SP/R006
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 01
Title:	RAMIPRIL BP	Review Period: 3 Years
	Item Code: RAI/SP/R006	Effective Date: 18/11/2024

METHOD OF ANALYSIS

SECTION I

DESCRIPTION

By physical observation.

Take the sample in a clean dry glass petri-dish and record its appearance.

White or almost white, crystalline powder.

SECTION II

SOLUBILITY

Weigh the quantity specified below in each test tube and check the solubility with appropriate solvent given.

Qty. to be taken (g)	Solvent	Volume(mL)	Limit
1.0	Methanol	1 to 10	Freely soluble
1.0	Water	30 to 100	Sparingly soluble

SECTION III

IDENTIFICATION

A. SPECIFIC OPTICAL ROTATION

Refer section V.

B. By IR

Triturate about 1 mg of the substance with approximately of 300 mg of dry, finely powdered of potassium bromide IR. Or potassium chloride IR, as directed. Those quantities are usually suitable for disc 13 mm in diameter. Grind the mixture thoroughly, spread it uniformly in a suitable die and compress under vacuum at pressure of about 800 Mpa. Commercial dies are available and the manufacturer's instructions should be strictly followed. Mount the

resultant discs in a suitable holder in the spectrometer. Several factors, such as inadequate or excessive grinding, moisture or other impurities in the halide carrier, may give rise to unsatisfactory discs. A disc should be rejected, if visual inspection shows lack of uniformly or if the transmittance at about 2000 cm^{-1} (5 µm) in the absence of a specific absorption band is less than 75 % without compensation. If the other ingredients of tablets, injections, or other dosage forms are not completely removed from the substance being examined, they may contribute to the spectrum.

Record the background spectrum. Record and compare the spectrum from 4000-400 cm^{-1} for the working standard and the sample.

SECTION-IV

APPEARANCE OF SOLUTION

Dissolve 0.1 g in methanol and dilute to 10.0 mL with the same solvent.

Weigh accurately about 100 mg of the test sample into a 100 ml volumetric flask, add 15 ml of methanol, dissolve the contents and make up to the volume with methanol. The solution is clear and colorless.

Clarity

Take two matched, flat bottomed test tubes of colorless transparent, neutral glass. Place 20 ml of the sample solution in one test tube and 20 ml of freshly prepared opalescence standard in another test tube. After 5 minutes of reference suspension preparation, compare the contents of the tubes against a black background by viewing in diffused day light down the vertical axes of the tubes

Standard of opalescence

Dissolve 1.0 g of hydrazine sulphate in sufficient water to produce 100 ml and allow to stand for 6 hours. Add 25 ml of this solution to a solution containing 2.5 g of hexamine in 25 ml of water. Mix well and allow to stand for 24 hours. This suspension is stable for 2 months provided that it is stored in a glass container free from surface defects. The suspension must not adhere to the glass and must be well mixed before use.

To prepare the standard of opalescence, dilute 15 ml of the suspension to 1000 ml with water. This suspension must be used within 24 hours of preparation.

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		No. RMSTP: RAI/SP/R006
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Color

Take two matched, flat bottomed test tubes of colorless transparent, neutral glass. Place 20 ml of the sample solution in one test tube and 20 ml of methanol in another test tube. Examine the columns of liquid in diffused daylight by viewing down the vertical axes of the tubes against a white background.

SECTION V

SPECIFIC OPTICAL ROTATION

Preparation of solvent mixture

Mixture of 14 mL of hydrochloric acid and 86 mL of methanol.

Procedure

Accurately weigh and transfer about 250 mg of sample to a 25 ml volumetric flask. Dissolve in 10 ml of solvent. Mixture and mix well. Adjust the content of the flask by suspending the flask in a constant temperature bath. Make up the volume with solvent mixture maintained and mix well. Transfer the solution to the polarimeter tube within 30 min from the time of preparation and maintain the solution during this interval. Reserve portion of solution for the blank determination. Determine the zero point of the polarimeter and then take five readings of the sample and the blank.

Calculation

$$[\alpha]^{25}_{D} = \frac{Z \times V}{L \times W}$$

Where
Z = Corrected observed rotation, In degrees
L = length of polarimeter tube in dm
V = volume of solvent
W= weight of the sample

	Prepared by	Checked by	Approved By
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Signature			
Date	18/11/2024	18/11/2024	18/11/2024
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SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S.No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Page 4 of 9
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SECTION VI

RELATED SUBSTANCES (By HPLC)

Chromatographic system

Instrument	: HPLC equipped with UV detector
Column	: C 18, 3µm,250 mm x 4.0 mm)
Wavelength	: 210 nm
Flow rate	: 1.0 ml / minute
Injection volume	: 10 µl
Temperature	: 65°C

Preparation of mobile phase A

Dissolve 2.0 g of sodium perchlorate in a mixture of 0.5 mL of triethylamine and 800 mL of water for chromatography; adjust to pH 3.6 with phosphoric acid and add 200 mL of acetonitrile.

Preparation of mobile phase B

Dissolve 2.0 g of sodium perchlorate in a mixture of 0.5 mL of triethylamine and 300 mL of water for chromatography; adjust to pH 2.6 with phosphoric acid and add 700 mL of acetonitrile.

Gradient program: Time (min)	Mobile phase A (%)	Mobile phase B (%)
0-6	90	10
6-7	90-75	10-25
7-20	75-65	25-35
20-30	65-25	35-75
30-50	25	75

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Signature			
Date	18/11/2024	18/11/2024	18/11/2024
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		No. RMSTP: RAI/SP/R006
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Title:	RAMIPRIL BP	Review Period: 3 Years
	Item Code: RAI/SP/R006	Effective Date: 18/11/2024

Preparation of test solution

Accurately weigh and transfer about 20 mg of sample into a 20 mL volumetric flask, dissolve with and sonicate for 5 min cool and dilute to volume with mobile phase A.

Preparation of reference solution (a)

Dissolve 2 mg of ramipril impurity A, 2 mg of ramipril impurity B, 2 mg of ramipril impurity C, and 2 mg of ramipril impurity D in mobile phase A and dilute to 25 ml with mobile phase A. To 1 ml of this solution, add 5.0 ml of the test solution and dilute to 10 ml with mobile phase B.

Preparation of reference solution (b)

Dilute 5.0 mL of test solution to 100 mL with mobile phase B. Dilute 5.0 mL of this solution to 50.0 mL with mobile phase B.

Preparation of reference solution (c)

Dilute 1.0 mL of reference solution (b) solution to 10.0 mL with mobile phase B.

Equilibration with the mobile phase at the initial composition for at least 35 min; if a suitable baseline cannot to be Obtained, use another grade of triethylamine.

Idendification of impurities Use the chromatogram obtained with reference solution (a) to identify the peaks due to impurities A, B, C and D.

Relative retention With reference to ramipril (retention time = about 18 min): impurity A = about 0.8; impurity B = about 1.3; impurity C = about 1.5; impurity D = about 1.7.

System suitability:

Resolution: minimum 3.0 between the peaks due to impurity A and ramipril in the chromatogram obtained with reference solution (a)

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Signature			
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Signal-to-noise ratio: minimum 3.0 for the principal peak in the chromatogram obtained with reference solution (c).

Symmetry factor: 0.8 to 2.0 for the peak due to ramipril in the chromatogram obtained with test solution.

Limits:

— Correction factor: for the calculation of content, multiply the peak area of impurity C by 2.4.
— impurities A, B, C, D: for each impurity, not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (0.5 per cent);
— unspecified impurities: for each impurity, not more than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.10 per cent);
— total: not more than twice the area of the principal peak in the chromatogram obtained with reference solution (b) (1.0 per cent).

Disregard any peak with an area less than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.05%).

Calculation

1. any Impurity $= \frac{AT}{AS} \times \frac{WS}{20} \times \frac{5}{50} \times \frac{1}{10} \times \frac{20}{SW} \times \frac{P}{100} \times 100$

6. Total impurities = Sum of all other impurities excluding Impurity A, B, C, D

Where

AT = Area of Impurity A peak in the chromatogram for sample solution.
AS = Area of impurity A peak in the chromatogram for reference solution (a)
SW = Weight of sample (mg)
WS = Weight of Allopurinol impurity standard.
P = Percent purity of Ramipril impurity standard (on such basis).

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
Date	18/11/2024	18/11/2024	18/11/2024
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SECTION VII

SULPHATED ASH

Ignite a suitable crucible at 600±50°C for 30 minutes, allow to cool in a desiccator over silica gel or other suitable desiccant and weigh (W1). Place the 1.0 g of the substance under examination in the crucible and weigh (W2). Moisten the substance under examination with a small amount of sulfuric acid (usually 1 mL) and heat gently at a low temperature as practicable until the sample is thoroughly charred. After cooling, moisten the residue with small amount of sulfuric acid (1 mL), heat gently until white fumes are no longer evolved and ignite at 600±50°C until the residue is completely incinerated. Ensure that flames are not produced at any time during the procedure. Allow the crucible to cool in a desiccator over silica gel or other suitable desiccant (W3), weigh it again and calculate the percentage of residue.

Ignite the sample to constant weight (W_4 g).

Repeat the operation until the two successive weighing do not differ by more than 0.5 mg.

Percentage of Sulphated ash (%) $= \frac{W_4-W_1}{W_2-W_1} \times 100$

Where

W_1 = Weight of empty crucible in g.
W_2 = Weight of crucible + sample in g.
W_3 = Weight of crucible + sample in g (after Ignition-I).
W_4 = Weight of crucible + sample in g (after Ignition-II).

SECTION VIII

LOSS ON DRYING

Weigh a glass-stoppered, shallow weighing bottle that has been previously dried in vacuum at 60°C (W_1 g).The drying is carried out 0.1 kpa at a pressure. Transfer to the bottle about 1.0 g of sample and distribute the sample evenly by gentle sidewise shaking. Weigh the bottle and the sample (W_2 g). Dry the loaded weighing bottle by placing in vacuum at 60°C for 4 h, with its lid opened. After drying is completed, remove the weighing bottle from

the oven and close the bottle properly. Allow it to cool to room temperature in a desiccator. Weigh the bottle and sample (W_3 g).

Calculation

Percentage of LOD (%) = $\frac{W_2-W_3}{W_2-W_1} \times 100$

Where

W_1 = Weight of empty weighing bottle in g.
W_2 = Weight of empty weighing bottle + sample in g.
W_3 = Weight of empty weighing bottle + sample in g (after drying).

SECTION IX

ASSAY (By Potentiometry)

Accurately weigh and transfer about 300 mg of the sample was dissolve in 25ml of methanol and add 25ml of water. Titrate with 0.1M sodium hydroxide, determining the end-point potentiometrically. Carry out a blank titration.

1 ml of 0.1 M sodium hydroxide is equivalent to 41.65 mg of Ramipril.

Calculation

$$\text{Assay (\%) (on dried basis)} = \frac{(Vs - Vb) \times M \times 41.65}{W} \times \frac{100}{(100 - LOD)}$$

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Title:	RAMIPRIL BP	Review Period: 3 Years
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Where

Vs = Volume consumed for sample (mL)
Vb = Volume consumed for blank (mL)
M = Actual molarity of sodium hydroxide
LOD = Percent loss on drying of sample
W = Sample weight (mg)

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No. RMSTP: RAI/SP/R006
2	Revision No.: 01	Periodic Revision

END OF DOCUMENT

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
Date	18/11/2024	18/11/2024	18/11/2024
Department: Quality Control		Date of Issue: 18/11/2024	

SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S.No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009	Page 1 of 3
	RAW MATERIAL SPECIFICATION	No. RMS: RAI/GH/H002
Title:	HYDROCHLOROTHIAZIDE BP	Revision No.: 01
	Item Code: RAI/GH/H002	Review Period:2 Years
		Effective Date: 16/07/2022

GENERAL INFORMATION	
Molecular formula	$C_7H_8ClN_3O_4S_2$
Molecular weight	297.7
Pack details	5 kg packed in plastic container.
Storage conditions	Store protected from light and moisture.
Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
Quantity of sample required for analysis	15 g
Quantity of reserve sample	30 g
Sampling Instructions	SOP No.: QCGN/018
Retest period	12 months

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
Date	16/07/2022	16/07/2022	16/07/2022
Department: Quality Control		Date of Issue: 16/07/2022	

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		No. RMS: RAI/GH/H002
	RAW MATERIAL SPECIFICATION	Revision No.: 01
Title:	HYDROCHLOROTHIAZIDE BP	Review Period:2 Years
	Item Code: RAI/GH/H002	Effective Date: 16/07/2021

S. No.	TEST	LIMITS	METHOD
1	DESCRIPTION	White or almost white, crystalline powder.	Follow Section I of method of analysis
2	SOLUBILITY	Very slightly soluble in water, Soluble in acetone; sparingly soluble in ethanol (96 %); It dissolves in dilute solutions of alkali hydroxides.	Follow Section II of method of analysis
3	IDENTIFICATION* A. By UV B. By IR C. By TLC D. By Chemical	 Max Absorbance at about 273/323 nm is about 5.4 to 5.7. The IR absorption spectrum of sample should be concordant with the spectrum obtained with Hydrochlorothiazide working standard. The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution (a). A violet color develops.	Follow Section III of method of analysis
4	ACIDITY OR ALKALINITY	The solution is yellow and NMT 0.4 mL of 0.01 M hydrochloric acid is required to change the color of the indicator to red.	Follow Section IV of method of analysis

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature	K.Kumar	A.S	
Date	16/07/2021	16/07/2021	16/07/2021
Department: Quality Control		Date of Issue: 16/07/2021	

SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S.No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009	Page 3 of 3
		No. RMS: RAI/GH/H002
	RAW MATERIAL SPECIFICATION	Revision No.: 01
Title:	HYDROCHLOROTHIAZIDE BP	Review Period:2 Years
	Item Code: RAI/GH/H002	Effective Date: 16/07/2022

S. No.	TEST	LIMITS	METHOD
5	RELATED SUBSTANCES (By HPLC) - Impurities A, B, C - Unspecified impurities - Total impurities	 NMT 0.5 % NMT 0.1% NMT 1.0 %	Follow Section V of method of analysis
6	CHLORIDES	NMT 100 ppm	Follow Section VI of method of analysis
7	LOSS ON DRYING (1.0 g/105°C)	NMT 0.5 %	Follow Section VII of method of analysis
8	SULPHATED ASH	NMT 0.1 %	Follow Section VIII of method of analysis
9	ASSAY (on dried basis) (By HPLC)	97.5 % - 102.0 %	Follow Section IX of method of analysis

* Test A, C, D may be omitted if tests B are carried out. Tests B may be omitted if test A, C, D is carried out.

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No. RMS: RAI/GH/H002
2	Revision No.: 01	Periodic Revision

END OF DOCUMENT

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature	K.Kavitha	A.S	
Date	16/07/2022	16/07/2022	16/07/2022
Department: Quality Control		Date of Issue: 16/07/2022	

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	RAW MATERIAL STANDARD TEST PROCEDURE	No. RMS: RAI/GH/H002
Title:	HYDROCHLOROTHIAZIDE BP	Revision No.: 01
	Item Code: RAI/GH/H002	Review Period: 2 Years
		Effective Date: 16/07/2021

METHOD OF ANALYSIS

SECTION I

DESCRIPTION

By Physical observation:

Take the sample in a clean dry glass petri-dish and record its appearance.

White or almost white crystalline powder.

SECTION II

SOLUBILITY

Measure the volume specified below in each test tube and checks the solubility with appropriate solvent given

Qty. to be taken (g)	Solvent	Volume (mL)	Limit
0.01	Water	10 to 100	Very slightly soluble
1	Acetone	10 to 30	Soluble
0.1	Ethanol (96 %)	3 to 10	Sparingly soluble
1	Sodium hydroxide	10 to 30	It dissolves

SECTION III

IDENTIFICATION

A. By UV

Test solution: Dissolve 50. 0 mg in 10 mL of 0.1 M sodium hydroxide and dilute to 100.0 mL with water. Dilute 2.0 mL of this solution to 100.0 mL with 0.01 M sodium hydroxide.

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature	K.Lokesh		
Date	16/07/2021	16/07/2021	16/07/2021
Department: Quality Control		Date of Issue: 16/07/2021	

Spectral range 250-350 nm

Absorption maxima At 273 nm and 323 nm.

Absorbance ratio A_{273}/A_{323} = 5.4 to 5.7

B. By IR

Triturate about 1–2 mg of the sample with approximately 300-400 mg of fine dry powder of potassium bromide. Grind the mixture well and spread 100 mg of the powder uniformly in the die. Mount the die on the die holder in the spectrophotometer. Record the background spectrum. Record and compare the spectrum from 4000-450 cm^{-1} for the working standard and the sample.

The IR absorption spectrum of the sample should be concordant with the spectrum of the Hydrochlorothiazide working standard.

C. By TLC

Mobile phase

Ethyl acetate.

Test solution

Dissolve 50 mg of the substance to be examined in acetone and dilute to 10 mL with the same solvent.

Reference solution (a)

Dissolve 50 mg of Hydrochlorothiazide working standard in acetone and dilute to 10 mL with the same solvent.

Reference solution (b)

Dissolve 25 mg of Chlorothiazide working standard in reference solution (a) and dilute to 5 mL with the same reference solution (a).

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature	K.Kumar	A.S	
Date	16/07/2022	16/07/2022	16/07/2022
Department: Quality Control		Date of Issue: 16/07/2022	

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	RAW MATERIAL STANDARD TEST PROCEDURE	No. RMS: RAI/GH/H002
Title:	HYDROCHLOROTHIAZIDE BP	Revision No.: 01
	Item Code: RAI/GH/H002	Review Period: 2 Years
		Effective Date: 16/07/2012

Procedure

Apply separately to the plate 2 µL of each solution. Development over ½ of the plate. After development dry the plate in a current of warm air and examine in UV light at 254 nm.

System suitability: reference solution (b)

The chromatogram shows 2 clearly separated spots.

The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution (a).

D. By Chemical

Gently heat about 1 mg with 2 mL of a freshly prepared 0.5 g/L solution of chromotropic acid, sodium salt in a cooled mixture of 35 volumes of water and 65volumes of sulfuric acid.

A violet colour develops.

SECTION III

ACIDITY OR ALKALINITY

Shake 0.5 g of the powdered substance to be examined with 25 mL of water for 2 min and filter. To 10 mL of the filtrate add 0.2 mL of 0.01 M sodium hydroxide and 0.15 mL of methyl red solution.

The solution is yellow and NMT 0.4 mL of 0.01 M hydrochloric acid is required to change the color of the solution to red.

SECTION IV

RELATED SUBSTANCES
(By HPLC)

Solvent mixture (a)

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
Date	16/07/2012	16/07/2012	16/7/2012
Department: Quality Control		Date of Issue: 16/07/2012	

Mixture of acetonitrile and methanol in the ratio of 50:50.

Solvent mixture (b)

Dilute 50 mL of solvent mixture (a) to 200 mL with phosphate buffer (pH 3.2).

Mobile phase A

Add 60 mL of methanol and 10 mL of tetrahydrofuran to 940 mL of phosphate buffer (pH 3.2).

Mobile phase B

Add 50 mL of tetrahydrofuran to a mixture of 500 mL of methanol and 500 mL of phosphate buffer (pH 3.2).

Test solution (a)

Dissolve 30.0 mg of the substance to be examined in 5 mL of a mixture of equal volumes of acetonitrile and methanol using sonication if necessary, and dilute to 20 mL with phosphate buffer pH 3.2.

Test solution (b)

Dilute 1.0 mL of the test solution (a) to 20.0 mL with phosphate buffer solution pH 3.2.

Reference solution (a)

Dissolve 3 mg of Chlorthiazide (impurity A) and 3 mg of Hydrochlorothiazide working standard in 5 mL of a mixture of equal volumes of acetonitrile and methanol using sonication if necessary, and dilute to 20.0 mL with phosphate buffer solution pH 3.2. Dilute 5 mL of this solution to 100.0 mL with the solvent mixture (b).

Reference solution (b)

Dilute 1.0 mL of test solution (a) to 100 mL with solvent mixture (b). Dilute 1.0 mL of this solution to 10

mL with solvent mixture (b).

Reference solution (c)

Dissolve 30.0 mg of Hydrochlorothiazide working standard in 5 mL of a mixture of equal volumes of acetonitrile and methanol using sonication if necessary, and dilute to 20.0 mL with phosphate buffer solution pH 3.2. Dilute 1.0 mL of this solution to 20.0 mL with phosphate buffer solution pH 3.2.

Reference solution (d)

Dissolve 3.0 mg of Hydrochlorothiazide for peak identification working standard (containing impurities B and C) in 5 mL of a mixture of equal volumes of acetonitrile and methanol using sonication if necessary, and dilute to 2.0 mL with phosphate buffer solution pH 3.2.

Chromatographic conditions

Column : C18, 3 µm (100 mm x 4.6 mm)

Wavelength : 224 nm

Flow rate : 0.8 mL/min

Injection volume : 10 µL

Gradient program :

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0	100	0
17	55	45
30	55	45

Relative retention: with reference to hydrochlorothiazide (retention time = about 8 min); impurity B = about 0.7; impurity A = about 0.9; impurity C = 2.8

Evaluation of system suitability

Inject the reference solution (a) into the chromatograph and record the chromatograms.

The system is suitable for analysis, if;

The resolution between Impurity A and Hydrochlorothiazide peaks is not less than 2.5.

Procedure

Inject blank, reference solution (b) and test solution into the chromatograph and record the chromatograms. Examine the blank chromatogram for any extraneous peaks, and disregard any corresponding peaks observed in the chromatogram of the test solution.

Note: Disregard any peak with an area less than 0.1 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.05 %).

Calculation

1. Any unknown impurity $= \frac{AT}{AS} \times \frac{SW}{10} \times \frac{1}{50} \times \frac{5}{20} \times \frac{20}{SW} \times 100$

2. Total impurities = Sum of all unknown impurities

Where

AT = Area of any unknown impurity peak in the chromatogram for test solution.
AS = Area of Hydrochlorothiazide peak in the chromatogram for reference solution (b).
SW = Weight of sample (mg)

SECTION V

CHLORIDES

Sample solution

Dissolve 1 g of sample in 25 mL of acetone and dilute to 30 mL with water. Prepare the standard using 5 mL of acetone containing 15 per cent V/V of water and 10 mL of chloride standard solution (5 ppm)

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature	K. Koothan	A. S.	
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SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S.No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Page 7 of 9
		No. RMS: RAI/GH/H002
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 01
Title:	HYDROCHLOROTHIAZIDE BP	Review Period: 2 Years
	Item Code: RAI/GH/H002	Effective Date: 16/07/2011

Procedure

Transfer the sample solution to a Nessler cylinder. Add 10 mL of dilute nitric acid and dilute to 50 mL with water and add 1 mL of 0.1 M silver nitrate. Stir immediately with a glass rod and allow to stand for 5 min, protected from light. When viewed transversely against a black background, any opalescence produced is not more intense than that obtained by treating a mixture of 10 mL of chloride standard solution (25 ppm Cl) and 5 mL of water in the same manner.

SECTION VI

LOSS ON DRYING

Weigh a glass-stoppered, shallow weighing bottle that has been previously dried in an oven at 105°C for 30 min (W_1 g). Transfer to the bottle about 1 g of sample and distribute the sample evenly by gentle sidewise shaking. Weigh the bottle and the sample (W_2 g). Dry the loaded weighing bottle in an oven at 105°C, with its lid opened. After drying is completed, remove the weighing bottle from the oven and close the bottle properly. Allow it to cool to room temperature in a desiccator. Weigh the bottle and sample (W_3 g).

Calculation

Percentage of LOD (%) $= \frac{W_2-W_3}{W_2-W_1} \times 100$

SECTION VII

SULPHATED ASH

Pre ignite a silica crucible at 600 ± 25°C for 10 minutes, cool to room temperature in a desiccator. Weigh the empty crucible (W_1 g). Transfer approximately 1 g of sample to the crucible and reweigh it, (W_2 g). Ignite, gently, until the substance is thoroughly charred. Cool and moisten the sample with concentrated sulphuric acid (about 1 mL) and heat gently at as low a temperature until the sample is thoroughly charred. Cool and again moisten the residue with about 1 mL of concentrated sulphuric acid, heat gently until white fumes are no longer evolved and ignite, until the residue is completely incinerated. (No black residue should be visible). Cool the crucible in a desiccator and reweigh (W_3 g).

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Percentage of Sulphate ash (%) $= \frac{W_3-W_1}{W_2-W_1} \times 100$

Where

W_1 = Weight of empty crucible in g.
W_2 = Weight of crucible + sample in g.
W_3 = Weight of crucible + sample in g (after Ignition).

SECTION VIII

ASSAY (By HPLC)
(As deicribed in RS with following modification)

Gradient program : Time (min) | Mobile phase A (%) | Mobile phase B (%)

Time (min)	Mobile phase A (%)	Mobile phase B (%)
0	80	20
4	80	20
10	20	80

Flow rate- 1.6ml/mins

Inject test solution (b) and reference solution (a) and (c)
Relative retention: with reference to hydrochlorothiazide (retention time = about 2.2 min); impurity A = about 0.9.

Evaluation of system suitability
Inject the reference solution (a) into the chromatograph and record the chromatograms.

The system is suitable for analysis, if;

The resolution between Impurity A and Hydrochlorothiazide peaks is not less than 2.0.

Assay (%) (on as is basis) $= \frac{AT \times WS \times 1 \times 20 \times 20 \times P}{AS \times 20 \times 20 \times SW \times 1 \times 100} \times 100$

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		No. RMS: RAI/GH/H002
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$$\text{Assay (\%) (on dried basis)} = \frac{\text{Assay (\%)}}{(100 - \text{LOD})} \times 100$$

Where

AT = Average area of Hydrochlorothiazide peak in the chromatogram for test solution.
AS = Average area of Hydrochlorothiazide peak in the chromatogram for reference solution.
WS = Weight of working standard (mg).
SW = Weight of sample (mg).
P = Percent purity of Hydrochlorothiazide working standard (on as is basis).
LOD = Percent loss on drying of the sample.

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No.: RMSTP: RAI/GH/H002
2	Revision No.: 01	Periodic Revision

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		No.RMS: IRM/SP/M001
	RAW MATERIAL SPECIFICATION	Revision No.: 01
Title:	DRIED MAIZE STARCH	Review Period: 3 Years
	Item Code: IRM/SP/M001	Effective Date: 08/06/2024

GENERAL INFORMATION	
Molecular formula	NA
Molecular weight	NA
Pack details	25 kg packed in plastic container.
Storage conditions	Store in well-closed containers.
Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
Quantity of sample required for chemical analysis	30 g
Quantity of reserve sample	60 g
Sampling Instructions	SOP No.: QCGN/018
Retest period	12 months

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
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Date	08/06/2024	08/06/2024	08/06/2024
Department: Quality Control		Date of Issue: 08/06/2024	

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		No.RMS: IRM/SP/M001
	RAW MATERIAL SPECIFICATION	Revision No.: 01
Title:	DRIED MAIZE STARCH	Review Period: 3 Years
	Item Code: IRM/SP/M001	Effective Date: 08/06/2024

S.No.	TEST	LIMITS	METHOD
1	DESCRIPTION	Very fine white and slightly yellow powder, irregular white masses which are readily reducible to powder, creaks when pressed between fingers, odorless and tasteless.	Follow section I of method of analysis
2	BULK DENSITY	0.65 m/cc to 0.9 m/cc	Follow section II of method of analysis
3	LOSS ON DRYING (IR moisture balance for 15 min at 105°C)	NMT 15% w/w	Follow section III of method of analysis
4	SIEVE SIZE	100% passes through 60#	Follow section IV of method of analysis

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No.RMS: IRM/SP/M001
2	Revision No.: 01	Periodic Revision

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	RAW MATERIAL STANDARD TEST PROCEDURE	No.RMSTP: IRM/SP/M001
Title:	DRIED MAIZE STARCH	Revision No.: 01
	Item Code: IRM/SP/M001	Review Period: 3 Years
		Effective Date: 08/06/2024

METHOD OF ANALYSIS

SECTION I

DESCRIPTION

Take about 1.g of the sample in a clean dry glass Petri dish and record its appearance.

Very fine white and slightly yellow powder, irregular white masses which are readily reducible to powder, creaks when pressed between fingers, odorless and tasteless.

SECTION II

BULK DENSITY

Weighed accurately 10 g of sample in a 50 mL stoppered measuring cylinder. Fit the cylinder to Bulk Density apparatus. Note down the volume. Run the apparatus for 150 tapping. Check the volume occupied by the material. Calculate the bulk density accordingly.

SECTION III

LOSS ON DRYING

Set the I.R moisture balance temperature at 105°C. After reaching 105°C maintain the same temperature for 15 minutes.

Placed 5.0 g quantity of the substance to be examined in an I.R moisture balance. Kept the sample in an I.R moisture balance at 105 °C for 15 minutes. Turn off the infrared lamp. Rotate the scale where pointer coincides with the index & % mark. % mark where pointer coincides with the index is the % LOD of the sample.

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		No.RMSTP: IRM/SP/M001
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 01
Title:	DRIED MAIZE STARCH	Review Period: 3 Years
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SECTION III

SIEVE SIZE

Weighed accurately 10 g of sample and place it on 60 # sieve. Fit the sieve shaker apparatus. Run the apparatus. Weighed accurately the amount passed through the sieve and record this weight as W1. Calculate the accordingly.

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No.: RMSTP: IRM/SP/M001
2	Revision No.: 01	Periodic Revision

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	RAW MATERIAL SPECIFICATION	**No.RMS: REX/SP/L003**
	LACTOSE MONOHYDRATE 200 MESH BP	**Revision No.: 02**
Title:	**Item Code: REX/SP/L003**	**Review Period:3 Years**
		Effective Date: 22/11/2024

GENERAL INFORMATION	
Molecular formula	$C_{12}H_{22}O_{11}.H_2O$
Molecular weight	360.3
Pack details	25 kg packed in Poly Woven bag
Storage conditions	Store protected from moisture at a temperature not exceeding 30°C.
Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Avoid inhaling. Reseal the containers immediately after sampling.
Quantity of sample required for analysis	25 g
Quantity of reserve sample	90 g
Quantity for microbial analysis	20 g
Sampling Instructions	SOP No.: QCGN/018
Retest period	12 months

	Prepared by	**Checked by**	**Approved By**
Designation	**Executive QC**	**Sr.Executive QC**	**Manager QC**
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	RAW MATERIAL SPECIFICATION	**No.RMS: REX/SP/L003**
	LACTOSE MONOHYDRATE 200 MESH BP	**Revision No.: 02**
Title:	**Item Code: REX/SP/L003**	**Review Period:3 Years** **Effective Date:** 22/11/2024

S.No.	TEST	LIMITS	METHOD
1	DESCRIPTION	White or almost white, crystalline powder.	Follow Section I of method of Analysis
2	SOLUBILITY	Freely but slowly soluble in water, practically insoluble in ethanol (96%).	Follow Section II of method of Analysis
3	IDENTIFICATION* A. By IR B. By TLC C. By Chemical D. Water (By KF)	 The IR absorption spectrum of sample should be concordant with the spectrum obtained with Lactose working standard. The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution. A red colour develops. 4.5% to 5.5%	Follow Section III of method of Analysis
4	APPEARANCE OF SOLUTION (Method II)	The solution S is clear and not more intensely colored than reference solution BY_7.	Follow Section IV of method of Analysis
5	ACIDITY OR ALKALINITY	Not more than 0.4 mL of 0.1 M sodium hydroxide is required to change the colour of the indicator to pink or red.	Follow Section V of method of Analysis
6	SPECIFIC OPTICAL ROTATION	+ 54.4° to + 55.9°	Follow Section VI of method of Analysis

	Prepared by	Checked by	Approved By
Designation	**Executive QC**	**Sr.Executive QC**	**Manager QC**
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		No.RMS: REX/SP/L003
	RAW MATERIAL SPECIFICATION	Revision No.: 02
	LACTOSE MONOHYDRATE 200 MESH BP	Review Period:3 Years
Title:	Item Code: REX/SP/L003	Effective Date: 22/11/2024

S.No.	TEST	LIMITS	METHOD
7	ABSORBANCE At 400 nm At 210 nm to 220 nm At 270 nm to 300 nm	Maximum 0.05% (5.0 mg) NMT 0.04 for test solution (a) NMT 0.25 for test solution (b) NMT 0.07 for test solution (b)	Follow Section VII of method of Analysis
8	WATER (0.50 g)	4.5% to 5.5%	Follow Section VIII of method of Analysis
9	SULFATED ASH	NMT 0.1%	Follow Section IX of method of Analysis
10	MICROBIAL CONTAMINATION - Total aerobic microbial count (TAMC) - Escherichia coli	 NMT 10^2 CFU/g Must be absent	Follow Section X of method of Analysis

* First identification: A, D Second identification: B, C, D

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No.RMS: REX/SP/L003
2	Revision No.: 01	Periodic Revision
3	Revision No.: 02	Refer to Change control No.CC/24/123

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		No.RMSTP: REX/SP/L003
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	LACTOSE MONOHYDRATE 200 MESH BP	Review Period: 3 Years
	Item Code: REX/SP/L003	Effective Date: 22\11\2024

METHOD OF ANALYSIS

SECTION I

DESCRIPTION

By physical observation.

Take the sample in a clean dry glass petri-dish and record its appearance.

White or almost white, crystalline powder.

SECTION II

SOLUBILITY

Weigh the quantity specified below in each test tube and check the solubility with appropriate solvent given.

Qty. to be taken (g)	Solvent	Volume(ml)	Limit
1.0	Water	1-10	Freely soluble
0.01	Ethanol (96 %)	≥100	Practically insoluble

SECTION III

IDENTIFICATION

A. By IR

Triturate about 1 mg of the substance with approximately of 300 mg of dry, finely powdered of potassium bromide IR. Or potassium chloride IR, as directed. Those quantities are usually suitable for disc 13 mm in diameter. Grind the mixture thoroughly, spread it uniformly in a suitable die and compress under vacuum at pressure of about 800 Mpa. Commercial dies are available and the manufacturer's instructions should be strictly followed. Mount the resultant discs in a suitable holder in the spectrometer. Several factors, such as inadequate or excessive grinding, moisture or other impurities in the halide carrier, may give rise to unsatisfactory discs. A disc should be rejected, if visual inspection shows lack of uniformly or if the transmittance at about 2000 cm^{-1} (5 µm) in the absence of a specific absorption band is less than 75 % without compensation. If the other ingredients of tablets, injections, or other dosage forms are not completely removed from the substance being examined, they may contribute to the spectrum.

Record the background spectrum. Record and compare the spectrum from 4000-400 cm^{-1} for the working standard and the sample

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		No.RMSTP: REX/SP/L003
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B. By TLC

Solvent mixture : water, methanol (40:60 *V/V*).

Test solution : Dissolve 10 mg of the substance to be examined in the solvent mixture and dilute to 20 mL with the solvent mixture.

Reference solution : Dissolve 10 mg of lactose monohydrate CRS in the solvent mixture and dilute to 20 mL with the solvent mixture.

Plate TLC silica gel plate.

Mobile phase : water, methanol , glacial acetic acid, methylene chloride (10:15:25:50 *V/V/V/V*); measure the volumes accurately, as a slight excess of water produces cloudiness.

Application 2 µL; thoroughly dry the points of application.

Development A Over 3/4 of the plate.

Drying *A* In a current of warm air.

Development B Immediately, over 3/4 of the plate, after renewing the mobile phase.

Drying B In a current of warm air.

Detection Spray with a solution of 0.5 g of thymol in a mixture of 5 mL of sulfuric acid and 95 mL of ethanol(96 %); heat at 130 °C for 10 min.

Results The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution.

C. By Chemical

Dissolve 0.25 g of sample in 5 mL of water. Add 5 mL of ammonia and heat in a water bath at 80°C for 10 min.

A red color develops.

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D. WATER See section IX.

SECTION IV

APPEARANCE OF SOLUTION

Preparation of solution S

Dissolve 1 g of sample in boiling water and dilute to 10 mL with boiling water.

Clarity of solution

Take two matched, flat bottomed test tubes of colorless transparent, neutral glass. Place 20 mL of the sample solution in one test tube and 20 mL of water in another test tube. After 5 minutes of reference suspension preparation, compare the contents of the tubes against a black background by viewing in diffused day light down the vertical axes of the tubes.
A liquid is considered clear if its clarity is the same as that of water.

Color of solution

Take two matched, flat bottomed test tubes of colorless transparent, neutral glass. Place 20 mL of the sample solution In one test tube and 20 mL of reference solution in another test tube. Examine the colors of liquid in diffused daylight by viewing down the vertical axes of the tubes against a white background.

The solution is clear and more intensely colored than reference solution BY_7.

Preparation of reference solution BY_7

Add 2.5 mL of standard solution BY to a 100 mL volumetric flask and 97.5 ml with 1% w/v solution of hydrochloric acid make up the volume.

Preparation of standard solution BY

Mix 2.4 mL of yellow solution, 1.0 mL of red solution, 0.4 mL of blue solution and 6.2 mL of 1% w/v solution of hydrochloric acid.

Preparation of yellow solution

Dissolve 46 g of ferric chloride in a mixture of 25 mL of hydrochloric acid and 975 mL of water and dilute to 1000 mL with same mixture. Adjust the solution to contain 45 mg of $FeCl_3$, 6H2O per mL by adding the same acidic mixture. Protect the solution from light.

Preparation of red solution

Dissolve 60 g of cobalt chloride in a mixture of 25 mL of hydrochloric acid and 975 mL of water and dilute to 1000 mL with same mixture. Adjust the solution to contain 59.5 mg of $CoCl_2$, 6H2O per mL by adding the same acidic mixture.

Preparation of blue solution

Dissolve 63 g of copper sulfate in a mixture of 25 mL of hydrochloric acid and 975 mL of water and dilute to 1000 mL with same mixture. Adjust the solution to contain 62.4 mg of $CuSO_4$, 5H2O per mL by adding the same acidic mixture. Protect the solution from light.

SECTION V

ACIDITY OR ALKALINITY

Dissolve 6 g of sample by heating in 25 mL of carbon dioxide free water, cool and add 0.3 mL of phenolphthalein solution. The solution is colorless.

Not more than 0.4 mL of 0.1M sodium hydroxide is required to change the colour of the indicator to pink or red.

SECTION VI

SPECIFIC OPTICAL ROTATION (anhydrous substance).

Dissolve 10 g of sample in 80 ml carbon dioxide free water, heat to 50°C. Allow to cool and add 0.2 ml of dilute ammonia. Allow to stand for 30 min and dilute to 100 ml with water.

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		No.RMSTP: REX/SP/L003
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	LACTOSE MONOHYDRATE 200 MESH BP	Review Period: 3 Years
	Item Code: REX/SP/L003	Effective Date: 22/11/2024

Calculation

$$= \frac{Z \times V}{L \times W}$$

Where

Z = Corrected observed rotation, in degrees
L = length of polarimeter tube in dm
V = volume of solvent
W= weight of the sample

SECTION VII

ABSORBANCE (By UV) (proteins and light-absorbing impurities)

Preparation of test solution (a)

Solution S

Preparation of test solution (b)

Dilute 1 mL of test solution (a) to 10 mL with water.

Procedure

Scan test solution (a) at 400 nm and test solution (b) between 210-300 nm.

Results:

— at 400 nm: maximum 0.04 for test solution (a);
— from 210 nm to 220 nm: maximum 0.25 for test solution (b);
— from 270 nm to 300 nm: maximum 0.07 for test solution (b).

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
Date	22/11/2024	22/11/2024	22/11/2024
Department: Quality Control		Date of Issue: 22/11/2024	

SAI PRIMUS LIFE BIOTECH PVT. LTD.	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S.No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Page 6 of 7
		No.RMSTP: REX/SP/L003
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	LACTOSE MONOHYDRATE 200 MESH BP	Review Period: 3 Years
	Item Code: REX/SP/L003	Effective Date: 22/11/2024

SECTION VIII

WATER

Standardization of KF reagent

Place enough mixture of formamide and methanol in the ratio of 1:2 in the titration vessel and pre titrate with KF reagent to the end point. Quickly add 25 mg to 50 mg of distilled water. Titrate to the end point. Note down the titre value in mL.

Calculate the factor (F) of the reagent using the following formula.

$$F = \frac{\text{Weight of water taken (mg)}}{\text{Titre value in (mL)}}$$

Procedure

Place enough mixture of formamide and methanol in the ratio of 1:2 in the titration vessel and titrate with the KF reagent to the end point. Quickly add about 500 mg of sample. Note down the weight by difference, accurately in mg. Stir for 1minute or till it dissolves. Titrate to the end point with KF reagent. Note down the titre value in mL.

Calculation

$$\text{Water (\%)} = \frac{\text{Titre value x factor x 100}}{\text{Weight of sample taken (mg)}}$$

SECTION IX

SULPHATED ASH

Ignite a suitable crucible at 600±50°C for 30 minutes, allow to cool in a desiccator over silica gel or other suitable desiccant and weigh (W1). Place the 1.0 g of the substance under examination in the crucible and weigh (W2). Moisten the substance under examination with a small amount of sulfuric acid (usually 1 mL) and heat gently at a low temperature as practicable until the sample is thoroughly charred. After cooling, moisten the residue with small

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		No.RMSTP: REX/SP/L003
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	LACTOSE MONOHYDRATE 200 MESH BP	Review Period: 3 Years
	Item Code: REX/SP/L003	Effective Date: 22/11/2024

amount of sulfuric acid (1 mL), heat gently until white fumes are no longer evolved and ignite at 600±50°C until the residue is completely incinerated. Ensure that flames are not produced at any time during the procedure. Allow the crucible to cool in a desiccator over silica gel or other suitable desiccant (W3), weigh it again and calculate the percentage of residue.

Ignite the sample to constant weight (W_4 g).
Repeat the operation until the two successive weighing do not differ by more than 0.5 mg.

Percentage of Sulphated ash (%) $= \frac{W_4-W_1}{W_2-W_1} \times 100$

Where
W_1 = Weight of empty crucible in g.
W_2 = Weight of crucible + sample in g.
W_3 = Weight of crucible + sample in g (after Ignition-I).
W_4 = Weight of crucible + sample in g (after Ignition-II).

SECTION X

MICROBIAL CONTAMINATION

Refer general SOP no. QCMB/006.

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No. RMSTP: REX/SP/L003
2	Revision No.: 01	Periodic Revision
3	Revision No.: 02	Refer to Change control No.CC/24/123

END OF DOCUMENT

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Format No.: F/QCGN/041/01

SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S.No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009	Page 1 of 3 No.RMS: REX/SP/M010
	RAW MATERIAL SPECIFICATION	Revision No.: 01
Title:	MICROCRYSTALLINE CELLULOSE BP (PH 102)	Review Period: 2 Years
	Item Code: REX/SP/M010	Effective Date: 05/01/2023

GENERAL INFORMATION	
Molecular formula	$C_6H_{10+2}O_{5+1}$
Molecular weight	NA
Pack details	25 kg or 50 kg packed in poly bags in poly sac.
Storage conditions	Preserve in well-closed containers.
Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Avoid inhaling. Reseal the containers immediately after sampling.
Quantity of sample required for analysis	30 g
Quantity of sample required for microbial analysis	20 g
Quantity of reserve sample	60 g
Sampling Instructions	SOP No.: QCGN/018
Retest period	12 months

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
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Date	05/01/2023	05/01/2023	05/01/2023
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	RAW MATERIAL SPECIFICATION	Revision No.: 01
Title:	MICROCRYSTALLINE CELLULOSE BP (PH 102)	Review Period: 2 Years
	Item Code: REX/SP/M010	Effective Date: 05/01/2023

S. No.	TEST	LIMITS	METHOD
1	DESCRIPTION	A White or almost white, fine or granular powder, slightly hygroscopic powder.	Follow Section I of method of Analysis
2	SOLUBILITY	Practically insoluble in water; in acetone; in anhydrous ethanol; in toluene; in dilute acids and in a 50 g/L solution of sodium hydroxide.	Follow Section II of method of Analysis
3	IDENTIFICATION A. By IR B. By Chemical B. Degree of polymerisation	 The IR absorption spectrum of sample should be concordant with the spectrum obtained with working standard. The sustance becomes violet blue. Not more than 350	Follow Section III of method of Analysis
4	SOLUBILITY	It dissolves completely, leaving no residue.	Follow Section IV of method of Analysis
5	pH	5.0 to 7.5	Follow Section V of method of Analysis
6	CONDUCTIVITY	The conductivity of the test solution does not exceed the conductivity of the water by more than 75µS.cm^{-1}	Follow Section VI of method of Analysis
7	ETHER-SOLUBLE SUBSTANCES	Maximum 0.05%	Follow Section VII of method of Analysis
8	WATER-SOLUBLE SUBSTANCES	Maximum 0.25%	Follow Section VIII of method of Analysis
9	LOSS ON DRYING	Maximum 7.0%	Follow Section IX of method of Analysis
10	SULFATED ASH	Maximum 0.1%	Follow Section X of method of Analysis

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	RAW MATERIAL SPECIFICATION	Revision No.: 01
Title:	MICROCRYSTALLINE CELLULOSE BP (PH 102)	Review Period: 2 Years
	Item Code: REX/SP/M010	Effective Date: 05/01/2023

S. No.	TEST	LIMITS	METHOD
11	MICROBIAL CONTAMINATION		Follow Section XI of method of Analysis
	- Total aerobic microbial Count (TAMC)	NMT 10^3 CFU/g	
	- Total yeast and mould Count (TYMC)	NMT 10^2 CFU/g	
	- E. coli	Must be absent	
	- Pseudomonas aeruginosa	Must be absent	
	- Staphylococcus aureus	Must be absent	
	- Salmonella	Must be absent	

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No.RMS: REX/SP/M010
2	Revision No.: 01	Periodic Revision

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	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 01
Title:	MICROCRYSTALLINE CELLULOSE BP (PH 102)	Review Period: 2 Years
	Item Code: REX/SP/M010	Effective Date: 05/01/2023

METHOD OF ANALYSIS

SECTION I

DESCRIPTION

By Physical observation:

Take about 5 g of the sample in a clean dry glass petri-dish and record its appearance.

White or almost white, fine or granular, slightly hygroscopic powder.

SECTION II

SOLUBILITY

Measure the volume specified below in each test tube and check the solubility with appropriate solvent given

Qty. to be taken (g)	Solvent	Volume (mL)	Limit
0.01	Water	≥100	Practically insoluble
0.01	Acetone	≥100	Practically insoluble
0.01	Anhydrous ethanol	≥100	Practically insoluble
0.01	Toluene	≥100	Practically insoluble
0.01	Dilute acids	≥100	Practically insoluble
0.01	50 g/L solution of sodium hydroxide	≥100	Practically insoluble

SECTION III

IDENTIFICATION

A.By IR

Triturate about 1 mg of the substance with approximately of 300 mg of dry, finely powdered of potassium bromide IR. Or potassium chloride IR, as directed. Those quantities are usually suitable for disc 13 mm in diameter. Grind the

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mixture thoroughly, spread it uniformly in a suitable die and compress under vacuum at pressure of about 800 Mpa. Commercial dies are available and the manufacturer's instructions should be strictly followed. Mount the resultant discs in a suitable holder in the spectrometer. Several factors, such as inadequate or excessive grinding, moisture or other impurities in the halide carrier, may give rise to unsatisfactory discs. A disc should be rejected, if visual inspection shows lack of uniformly or if the transmittance at about 2000 cm^{-1} (5 µm) in the absence of a specific absorption band is less than 75 % without compensation. If the other ingredients of tablets, injections, or other dosage forms are not completely removed from the substance being examined, they may contribute to the spectrum.

Record the background spectrum. Record and compare the spectrum from 4000-400 cm^{-1} for the working standard and the sample.

B. Reaction with iodinated zinc chloride solution

Place about 10 mg on a watch glass and disperse in 2 mL of iodinated zinc chloride solution.

C. Degree of polymerisation

Transfer 1.300 g of sample in 125 mL conical flask. Add 25.0 mL of water and 25.0 mL of cupriethylenediamine hydroxide solution. Immediately purge the solution with nitrogen, insert the stopper and shake until completely dissolved. Transfer an appropriate volume of the solution to suitable capillary viscometer. Equilibrate the solution at 25 ± 0.1 °C for at least 5 min. Record the flow time (t_1) in seconds between the 2 marks on the viscometer. Calculate the kinematic viscosity (v_1) of the solution using the following expression:

where
$t_1(k_1)$
k_1 = viscometer constant.

Dilute a suitable volume of cupriethylenediamine hydroxide solution with an equal volume of water and measure the flow time (t_2) using a suitable capillary viscometer. Calculate the kinematic viscosity (v_2) of the solvent using the following expression:

where
t_2 (k_2)
k_2 = viscometer constant.

Determine the relative viscosity (η_{rel}) of the substance to be examined using the following expression:

$$v_1 / v_2$$

Determine the intrinsic viscosity ($[\eta]_c$) by interpolation, using the intrinsic viscosity table (Table 0.16-1).

Calculate the degree of polymerization (P) using the following expression:

$$\frac{95\,[\eta]_c}{m\,[(100 - b) / 100]}$$

where
m = mass in grams of the substance to be examined.
b = loss on drying as a percentage.

SECTION IV

SOLUBILITY

Dissolve 50 mg of sample in 10 mL of ammoniacal solution of copper tetrammine. It dissolves completely, leaving no residue.

SECTION V

pH

Shake 50 g with 40 mL of carbon dioxide-free water for 20 min and centrifuge.

SECTION VI

CONDUCTIVITY

The conductivity of the test solution does not exceed the conductivity of the water by more than 75 µS cm^{-1}. Use as test solution the supernatant liquid obtained in the test for pH. Measure the conductivity of the supernatant liquid after a stable reading has been obtained and measure the conductivity of water used to prepare the test solution.

Periodic Revision done: PF 04/01/2026

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	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 01
Title:	MICROCRYSTALLINE CELLULOSE BP (PH 102)	Review Period: 2 Years
	Item Code: REX/SP/M010	Effective Date: 05/01/2023

SECTION VII

ETHER-SOLUBLE SUBSTANCES

Maximum 0.05% (5 mg) for the difference between the weight of the residue and the weight obtained from a blank determination

Place 10 g of sample in chromatography column about 20 mm in internal diameter and pass 50 mL of peroxide free ether through the column. Evaporate to eluate to dryness. Dry the residue at 105 °C for 30 min, allow to cool in a desiccator and weigh. Carry out a blank determination.

SECTION VIII

WATER-SOLUBLE SUBSTANCES

Maximum 0.25% (12.5 mg) for the difference between the mass of the residue and the mass obtained from a blank determination.

Shake 5.0 g of sample with 80 mL of water for 10 min. Filter through a filter paper with the aid of vacuum into a tared flask. Evaporate to dryness on a water bath avoiding charring. Dry at 105 °C for 1 h, allow to stand in a desiccator and weigh. Carry out a blank determination.

SECTION IX

LOSS ON DRYING

Weigh a glass-stoppered, shallow weighing bottle that has been previously dried in a hot air oven at 105°C (W_1 g). Transfer to the bottle about 1 g of sample and distribute the sample evenly by gentle sidewise shaking. Weigh the bottle and the sample (W_2 g). Dry the loaded weighing bottle by placing in a hot air oven at 105°C for 3 h, with its lid opened. After drying is completed, remove the weighing bottle from the oven and close the bottle properly. Allow it to cool to room temperature in a desiccator. Weigh the bottle and sample (W_3 g).

Dry the sample to constant weight. (W_4 g).

The two consecutive weighing should not differ by more than 0.5 mg.

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Calculation

Percentage of LOD (%) = $\frac{W_2-W_3}{W_2-W_1} \times 100$

Where

W_1 = Weight of empty weighing bottle in g.
W_2 = Weight of empty weighing bottle + sample in g.
W_3 = Weight of empty weighing bottle + sample in g (after drying-I).
W_4 = Weight of empty weighing bottle + sample in g (after drying-II).

SECTION X

SULPHATED ASH

Pre ignite a silica crucible at 600±50°C for 10 minutes, cool to room temperature in a desiccator. Weigh the empty crucible (W_1 g). Transfer approximately 1.0 g of sample to the crucible and reweigh it, (W_2 g). Ignite, gently, until the substance is thoroughly charred. Cool and moisten the sample with concentrated sulphuric acid (about 1 mL) and heat gently at as low a temperature until the sample is thoroughly charred. Cool and again moisten the residue with about 1 mL of concentrated sulphuric acid, heat gently until white fumes are no longer evolved and ignite, until the residue is completely incinerated. (No black residue should be visible). Cool the crucible in a desiccator and reweigh (W_3 g).

Ignite the sample to constant weight (W_4 g).
Repeat the operation until the two successive weighing do not differ by more than 0.5 mg.

Percentage of Sulphated ash (%) = $\frac{W_4-W_1}{W_2-W_1} \times 100$

Where

W_1 = Weight of empty crucible in g.
W_2 = Weight of crucible + sample in g.
W_3 = Weight of crucible + sample in g (after Ignition-I).
W_4 = Weight of crucible + sample in g (after Ignition-II).

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	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 01
Title:	MICROCRYSTALLINE CELLULOSE BP (PH 102)	Review Period: 2 Years
	Item Code: REX/SP/M010	Effective Date: 05/01/2023

SECTION XI

MICROBIAL CONTAMINATION

Refer general SOP No.QCMB/006.

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No.RMSTP: REX/SP/M010
2	Revision No.: 01	Periodic Revision

END OF DOCUMENT

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Approved by QA: 04/01/2025

Effective Date: 04/01/2025

Next Review: 03/01/2028

Revision Number: 02

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Periodic Revision done: 19/04/2025

Format No.: F/QCGN/041/01

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		No. RMS: REX/SP/G001
	RAW MATERIAL SPECIFICATION	**Revision No.: 00**
Title:	**GELATIN BP**	**Review Period:2 Years**
	Item Code: REX/SP/G001	**Effective Date:** 19/04/2023

GENERAL INFORMATION	
Molecular formula	NA
Molecular weight	NA
Pack details	25 kg / 50 kg packed in Poly bag (inside) and Paper bag (outside).
Storage conditions	Store in tightly closed container. Protected from moisture.
Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
Quantity of sample required for chemical analysis	30 g
Quantity of sample required for microbiological analysis	20 g
Quantity of reserve sample	50 g
Sampling Instructions	SOP No.: QCGN/018
Retest period	12 months

	Prepared by	**Checked by**	**Approved By**
Designation	**Executive QC**	**Sr.Executive QC**	**Manager QC**
Signature			
Date	19/04/2023	19/04/2023	19/04/2023
Department: Quality Control		**Date of Issue:** 19/04/2023	

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		No. RMS: REX/SP/G001
	RAW MATERIAL SPECIFICATION	Revision No.: 00
Title:	GELATIN BP	Review Period:2 Years
	Item Code: REX/SP/G001	Effective Date: 19/04/2023

S. No.	TEST	LIMITS	METHOD
1	DESCRIPTION Gelling grade	Faintly yellow or light yellowish-brown solid, usually occurring as translucent sheets, shreds, granules or powder.	Follow Section I of method of analysis
2	SOLUBILITY Gelling grade	Practically insoluble in common organic solvents; gelling grades swell in cold water and give on heating a colloidal solution which on cooling forms a more or less firm gel.	Follow Section II of method of analysis
3	IDENTIFICATION a) Colour test b) Colour test	 A violet colour is produced. The content flow out immediately for non-gelling grades and do not flow out immediately for gelling grades.	Follow Section III of method of analysis
4	pH	3.8 to 7.6	Follow Section IV of method of analysis
5	CONDUCTIVITY	NMT 1 $mS\text{-}cm^{-1}$.	Follow Section V of method of analysis
6	SULFUR DIOXIDE	NMT 50 ppm	Follow Section VI of method of analysis
7	PEROXIDE	NMT 10 ppm	Follow Section VII of method of analysis
8	GEL STRENGTH	80 to 120 of nominal value	Follow Section VIII of method of analysis
9	IRON	NMT 30 ppm	Follow Section IX of method of analysis

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
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		No. RMS: REX/SP/G001
	RAW MATERIAL SPECIFICATION	Revision No.: 00
Title:	GELATIN BP	Review Period:2 Years
	Item Code: REX/SP/G001	Effective Date: 19/04/2023

S. No.	TEST	LIMITS	METHOD
10	CHROMIUM	NMT 10 ppm	Follow Section X of method of analysis
11	ZINC	NMT 30 ppm	Follow Section XI of method of analysis
12	LOSS ON DRYING (5g/105°/16h)	NMT 15.0 % w/w	Follow Section XII of method of analysis
13	MICROBIAL LIMITS A) Total aerobic microbial count B) Total yeast microbial count C) Escherichia coli D) Salmonella	 Not more than 1000 CFU/g Not more than 100 CFU/g Absent Absent	Follow Section XIII of method of analysis

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No.RMS: REX/SP/G001

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		No.RMSTP:REX/SP/G001
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 00
Title:	GELATIN BP	Review Period: 2 Years
	Item Code: REX/SP/G001	Effective Date: 19/04/2023

METHOD OF ANALYSIS

SECTION I

DESCRIPTION

Gelling grade: Faintly yellow or light yellowish-brown solid, usually occurring as translucent sheets, shreds, granules or powder.

SECTION II

SOLUBILITY

Gelling grade: Practically insoluble in common organic solvents; gelling grades swell in cold water and give on heating a colloidal solution which on cooling forms a more or less firm gel.

SECTION III

IDENTIFICATIONS

(A) To 2 ml of solution S add 0.05 ml of copper sulfate solution. Mix and add 0.5 ml of dilute sodium hydroxide solution.

(B) In a test tube about 15 mm internal diameter, place 0.5 g of the substance to be examined and add 10 ml of water. Allow to stand for 10 min, heat at 60°C for 15 minutes, keep the tube upright at 2-8 ° C for 6 hours and invert the test-tube.

SECTION IV

pH

Preparation of solution S
Dissolve 1.00 g in carbon dioxide-free water at about 55°C, dilute to 100 ml with the same solvent and keep the solution at this temperature to carry out tests.

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Procedure

Note down the pH of solution S directly by using pH meter.

SECTION V

CONDUCTIVITY

Prepare10.0 g/L solution of test substance in water and measure the conductivity at 30 ± 1.0 °C.

SECTION VI

SULPHUR DIOXIDE

Procedure

Add 150 ml of water to a 500-ml three-necked, round-bottomed flask fitted with a water-cooled reflux condenser 200 mm long the upper end of which is connected to an absorption tube. The flask is fitted with a 100-ml dropping funnel and a gas inlet tube which reaches nearly to the bottom of the flask. Pass a stream of carbon dioxide through the flask at a rate of 100 ml per minute for 15 minutes. Connect an absorption tube containing 10 ml of hydrogen peroxide solution (10 vol) previously neutralised to a 0.1% w/v solution of bromophenol blue in ethanol (20%) and without interrupting the flow of carbon dioxide, introduce through the funnel 25 g of the test substance and 80 ml of 2M hydrochloric acid. Boil for 1 hour, disconnect the absorption tube and stop the flow of carbon dioxide. Wash the contents of the absorption tube into a 250-ml conical flask, heat on a water-bath for 15 minutes and allow to cool. Titrate with 0.01M sodium hydroxide using a 0.1% w/v solution of bromophenol blue in ethanol (20%) as indicator, until the colour changes from yellow to violet-blue.

Each ml of 0.01M sodium hydroxide is equivalent to 0.0003203 g of sulphur dioxide.

Calculation

$$\text{Assay \%w/w (on dried basis)} = \frac{V \times 0.0003203 \times M \times 100}{0.01 \times W} \times \frac{100}{(100\text{-LOD})}$$

Where
W =weight of test substance in g
V = ml of 0.01M sodium hydroxide used for test.

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M = molarity of 0.01M sodium hydroxide
LOD =Loss on drying of the test substance (%w/w)

SECTION VII

PEROXIDES

Peroxidase transfers oxygen from peroxides to an organic redox indicator which is converted to a blue oxidation product. The intensity of the colour obtained is proportional to the quantity of peroxide and can be compared with a colour scale provided with the test strips, to determine the peroxide concentration.

Suitability test

Dip a test strip for 1 s into hydrogen peroxide standard solution (2 ppm H_2O_2), such that the reaction zone is properly wetted. Remove the test strip, shake off excess liquid and after 15 s compare the reaction zone with the colour scale provided. The test strips are suitable if the colour matches that of the 2 ppm concentration.

Test preparation

Weigh accurately 20±0.1 g of the test substance in a beaker and add 80.0±0.2 ml of Water. Stir to moisten all gelatin and allow the sample to stand at room temperature for 1-3 h. Cover the beaker with a watch-glass. If dissolution is not complete, place the beaker for 20 ± 5 min in a water-bath at 65 ± 2 °C to dissolve the sample. Stir the contents of the beaker with a glass rod to achieve a homogeneous solution. Dip a test strip for 1 s into the test solution, such that the reaction zone is properly wetted. Remove the test strip, shake off excess liquid and after 15 s compare the reaction zone with the colour scale provided. Multiply the concentration read from the colour scale by a factor of 5 to calculate the concentration in parts per million of peroxide in the substance to be examined.

SECTION VIII

GEL STRENGTH

The gel strength is expressed as the mass in grams necessary to produce the force which, applied to a plunger 12.7 mm in diameter, makes a depression 4 mm deep in a gel having a concentration of 6.67 per centm/m and matured at 10 °C.

Periodic Revision done: JKA 19/04/2025

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Apparatus Texture analyser or gelometer with:

— a cylindrical piston 12.7 ± 0.1 mm in diameter with a plane pressure surface with a sharp bottom edge.

— a bottle 59 ± 1 mm in internal diameter and 85 mm high.

Adjust the apparatus according to the manufacturer's manual. Settings are: distance 4 mm, test speed 0.5 mm/s.

Method:

Place 7.5 g of the substance to be examined in a bottle. Add 105 mL of water, close the bottle and allow to stand for 1-4 h. Heat in a water-bath at 65 ± 2 °C for 15 min. While heating, stir gently with a glass rod. Ensure that the solution is uniform and that any condensed water on the inner walls of the bottle is incorporated. Allow to cool at room temperature for 15 min and transfer the bottle to a thermostatically controlled bath at 10.0 ± 0.1 °C, and fitted with a device to ensure that the platform on which the bottle stands is perfectly horizontal. Close the bottle with a rubber stopper and allow to stand for 17 ± 1 h. Remove the bottle from the bath and quickly wipe the water from the exterior of the bottle. Centre the bottle on the platform of the apparatus so that the plunger contacts the sample as near to its midpoint as possible and start the measurement.

SECTION IX

IRON (By Atomic absorption spectrometry, method-II)

Test solution

To 5.00 g of the test substance to be examined, in a conical flask, add 10 ml of hydrochloric acid. Close the flask and place in a water-bath at 75–80 °C for 2 h, the gelatin may be allowed to swell after addition of the acid and before heating, the heating time may be prolonged, and a higher temperature may be used). Allow to cool and adjust the contents of the flask to 100.0 g with water.

Reference solutions

Prepare the reference solutions using iron standard solution (8 ppm Fe), diluted as necessary with water.

Wavelength: 248.3 nm.

Periodic Revision done: JA 19/04/2025

Format No.: F/QCGN/041/02

SECTION X

CHROMIUM (By Atomic absorption spectrometry, method-II)

Test solution

To 5.00 g of the test substance to be examined, in a conical flask, add 10 ml of hydrochloric acid. Close the flask and place in a water-bath at 75–80 °C for 2 h, the gelatin may be allowed to swell after addition of the acid and before heating, the heating time may be prolonged, and a higher temperature may be used). Allow to cool and adjust the contents of the flask to 100.0 g with water.

Reference solution

Prepare the reference solutions using chromium standard solution (100 ppm Cr), diluted if necessary with water.

Wavelength: 357.9 nm.

SECTION XI

ZINC (By Atomic absorption spectrometry, method-II)

Test solution

To 5.00 g of the test substance to be examined, in a conical flask, add 10 ml of hydrochloric acid. Close the flask and place in a water-bath at 75–80 °C for 2 h, the gelatin may be allowed to swell after addition of the acid and before heating, the heating time may be prolonged, and a higher temperature may be used). Allow to cool and adjust the contents of the flask to 100.0 g with water.

Reference solution

Prepare the reference solutions using zinc standard solution (10 ppm Zn), diluted if necessary with water.

Wavelength: 213.9 nm.

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		No.RMSTP:REX/SP/G001
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 00
Title:	GELATIN BP	Review Period: 2 Years
	Item Code: REX/SP/G001	Effective Date: 19/04/2023

SECTION XII

LOSS ON DRYING

Weigh a glass-stoppered, shallow weighing bottle that has been previously dried in a hot air oven at 105°C for 30 min (W_1 g). Transfer to the bottle about 5.0 g of sample and distribute the sample evenly by gentle sidewise shaking. Weigh the bottle and the sample (W_2 g). Dry the loaded weighing bottle by placing in a hot air oven at 105°C for 16 h, with its lid opened. After drying is completed, remove the weighing bottle from the oven and close the bottle properly. Allow it to cool to room temperature in a desiccator. Weigh the bottle and sample (W_3 g). Dry the sample to constant weight (W_4 g).
The two consecutive weighing should not differ by more than 0.5 mg.

Calculation

Percentage of LOD (%) = $\frac{W_2-W_4}{W_2-W_1} \times 100$

Where

W_1 = Weight of empty weighing bottle in g.
W_2 = Weight of empty weighing bottle + sample in g.
W_3 = Weight of empty weighing bottle + sample in g (after drying-I).
W_4 = Weight of empty weighing bottle + sample in g (after drying-II).

SECTION XIII

Microbial Limit Test

Refer to SOP No. QCMB/006.

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No. RMSTP: REX/SP/G001

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Approved by QA: 19/04/2025

Effective Date: 19/04/2025

Next Review: 19/04/2028

Revision Number: 01

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	RAW MATERIAL SPECIFICATION	**No. RMS: REX/SP/E005**
Title:	**ERYTHROSINE SUPRA IH**	**Revision No.: 00**
	Item Code: REX/SP/E005	**Review Period:3 Years**
		Effective Date: 28/09/2023

GENERAL INFORMATION	
Molecular formula	NA
Molecular weight	NA
Pack details	2 kg packed in plastic container.
Storage conditions	Store in cool and dry place.
Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
Quantity of sample required for analysis	10 g
Quantity of reserve sample	20 g
Sampling Instructions	SOP No.: QCGN/018
Retest period	12 months

	Prepared by	**Checked by**	**Approved By**
Designation	**Executive QC**	**Sr. Executive QC**	**Manager QC**
Signature			
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	RAW MATERIAL SPECIFICATION	**No. RMS: REX/SP/E005**
Title:	**ERYTHROSINE SUPRA IH**	**Revision No.: 00**
	Item Code: REX/SP/E005	**Review Period:3 Years**
		Effective Date: 28/09/2023

S. No.	TEST	LIMITS	METHOD
1	DESCRIPTION	Dark red-brown coloured fine powder.	Follow Section I of method of Analysis
2	SOLUBILITY	Soluble in water.	Follow Section II of method of Analysis
3	LOSS ON DRYING	NMT 13.0 %	Follow Section III of method of Analysis
4	WATER INSOLUBLE MATTER	NMT 0.2 %	Follow Section IV of method of Analysis
5	DYE CONTENT (OBD)	Between 87.0 – 100.0 % w/w	Follow Section V of method of Analysis

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No.RMS: REX/SP/E005

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		No.RMSTP: REX/SP/E005
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 00
Title:	ERYTHROSINE SUPRA IH	Review Period: 3 Years
	Item Code: REX/SP/E005	Effective Date: 28/09/2023

METHOD OF ANALYSIS

SECTION I

DESCRIPTION

By Physical observation:

Take 1 g of the sample in a clean dry glass petri-dish and record its appearance.

Dark red-brown coloured fine powder.

SECTION II

SOLUBILITY

Measure the volume specified below in each test tube and check the solubility with appropriate solvent given

Qty. to be taken (g)	Solvent	Volume (mL)	Limit
1.0	Water	10 to 30	Soluble

SECTION III

LOSS ON DRYING

Weigh a glass-stoppered, shallow weighing bottle that has been previously dried in a hot air oven at 105°C for 30 min (W_1 g). Transfer to the bottle about 1 g of sample and distribute the sample evenly by gentle sidewise shaking. Weigh the bottle and the sample (W_2 g). Dry the loaded weighing bottle by placing in a hot air oven at 105°C for 3 h, with its lid opened. After drying is completed, remove the weighing bottle from the oven and close the bottle properly. Allow it to cool to room temperature in a desiccator. Weigh the bottle and sample (W_3 g).

Dry the sample to constant weight (W_4 g).
The two consecutive weighing should not differ by more than 0.5 mg.

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	RAW MATERIAL STANDARD TEST PROCEDURE	No.RMSTP: REX/SP/E005
Title:	ERYTHROSINE SUPRA IH	Revision No.: 00
	Item Code: REX/SP/E005	Review Period: 3 Years
		Effective Date: 28/09/2023

Calculation

Percentage of LOD (%) = $\frac{W_2-W_4}{W_2-W_1} \times 100$

Where

W_1 = Weight of empty weighing bottle in g.
W_2 = Weight of empty weighing bottle + sample in g.
W_3 = Weight of empty weighing bottle + sample in g (after drying-I).
W_4 = Weight of empty weighing bottle + sample in g (after drying-II).

SECTION IV

WATER INSOLUBLE MATTER

Dissolve 2 g of the material in 200 ml of hot water and allow the solution to cool at room temperature. Filter through a previously weighed and tarred sintered glass crucible, wash with cool water until the washings are colourless and dry at 135°C for 3 hours. Cool in a desiccator and weigh.

Calculation

$$\% \text{ water insoluble matter} = \frac{M2 - M1}{M} \times 100$$

Where

M = Weight of material taken for test.
M1 = Weight of empty crucible.
M2 = Weight of crucible + residue

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	RAW MATERIAL STANDARD TEST PROCEDURE	No.RMSTP: REX/SP/E005
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	Item Code: REX/SP/E005	Review Period: 3 Years
		Effective Date: 28/09/2023

SECTION V

DYE CONTENT

Weigh 200 mg of sample and transfer in 200 mL volumetric flask. Add 120 mL of water dissolve and make up the volume with water. Pipette out 10 mL of solution in 100 mL volumetric flask and dilute up to mark with water. Further dilute 10 mL solution in 100 mL volumetric flask and make up the volume with water.

Measure the absorbance at 527 nm, taking 1080 as specific absorbance.

Calculation

$$\text{\% of Dry content (on as is basis)} = \frac{A_{spl}}{1080} \times \frac{1}{100} \times \frac{200}{\text{Sample weight (in g)}} \times \frac{100}{10} \times 1000 \times 100$$

$$\text{\% of Dry content (on dried basis)} = \frac{\text{\% Dry content (on as is basis)}}{(100 - \text{LOD})} \times 100$$

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No. RMSTP: REX/SP/E005

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		No. RMS: REX/SP/S004
	RAW MATERIAL SPECIFICATION	Revision No.: 01
Title:	SODIUM STARCH GLYCOLATE (TYPE A) BP	Review Period: 3 Years
	Item Code: REX/SP/S004	Effective Date: 15/06/2024

GENERAL INFORMATION	
Molecular formula	NA
Molecular weight	NA
Pack container details	5 kg packed in plastic container.
Storage conditions	Store in an airtight container, protected from light.
Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Avoid inhaling. Reseal the containers immediately after sampling.
Quantity of sample required for analysis	25 g
Quantity of sample required for Microbiology analysis	20 g
Quantity of reserve sample	90 g
Sampling Instructions	SOP No.: QCGN/018
Retest period	12 months

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	RAW MATERIAL SPECIFICATION	No. RMS: REX/SP/S004
Title:	SODIUM STARCH GLYCOLATE (TYPE A) BP	Revision No.: 01
	Item Code: REX/SP/S004	Review Period: 3 Years
		Effective Date: 15\06\2024

S. No.	TEST	LIMITS	METHOD
1	DESCRIPTION	White or almost white, fine, free flowing powder, very hygroscopic.	Follow Section I of method of Analysis
2	SOLUBILITY	Practically insoluble in methylene chloride. It gives a translucent suspension in water.	Follow Section II of method of Analysis
3	IDENTIFICATION A. By pH B. By Chemical C. By Chemical D. Test for sodium	 5.5 to 7.5 A suspension forms that settles after standing. The solution becomes blue or violet. A dense white precipitate is formed.	Follow Section III of method of Analysis
4	APPEARANCE OF SOLUTION S1	Solution S1 is clear and colourless.	Follow Section IV of method of Analysis
5	pH	5.5 to7.5	Follow Section V of method of Analysis
6	SODIUM GLYCOLATE	NMT 2.0 %	Follow Section VI of method of Analysis
7	SODIUM CHLORIDE	NMT 7.0 %	Follow Section VII of method of Analysis
8	IRON	NMT 20 ppm	Follow Section VIII of method of Analysis
9	LOSS ON DRYING (1.000 g/130°C/1.5 h)	NMT 10.0 %	Follow Section IX of method of Analysis

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		No. RMS: REX/SP/S004
	RAW MATERIAL SPECIFICATION	Revision No.: 01
Title:	SODIUM STARCH GLYCOLATE (TYPE A) BP	Review Period: 3 Years
	Item Code: REX/SP/S004	Effective Date: 15/06/2024

S. No.	TEST	LIMITS	METHOD
10	ASSAY (calculated on the substance washed with ethanol (80% v/v) and dried)	2.8 % - 4.2 % of sodium (Na)	Follow Section of X method of Analysis
11	MICROBIAL CONTAMINATION Escherichia coli (per g) Salmonella (per 10 g)	 Must be absent Must be absent	Follow Section of XI method of Analysis

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No. RMS: REX/SP/S004
2	Revision No.: 01	Periodic Revision

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	RAW MATERIAL STANDARD TEST PROCEDURE	No. RMSTP: REX/SP/S004
Title:	SODIUM STARCH GLYCOLATE (TYPE A) BP	Revision No.: 01
	Item Code: REX/SP/S004	Review Period: 3 Years
		Effective Date: 15/06/2024

METHOD OF ANALYSIS

SECTION I

DESCRIPTION

By Physical observation:

Take the sample in a clean dry glass petri-dish and record its appearance.

White or almost white, fine, free flowing powder, very hygroscopic.

SECTION II

SOLUBILITY

Measure the volume specified below in each test tube and check the solubility with appropriate solvent given.

Practically insoluble in Methylene chloride. It gives a translucent suspension in water.

Qty. to be taken (g)	Solvent	Volume (mL)	Limit
0.01	Methylene chloride	≥ 100	Practically insoluble

SECTION III

IDENTIFICATION

A. pH

Dissolve 1.0 g of sample in 30 mL of carbon dioxide free water. Measure the pH using a suitable pH meter.

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B. By Chemical

Dissolve 4.0 g of sample in 20 mL of carbon dioxide free water with shaking and without heating a mixture. The mixture has the appearance of a gel. Add 100 mL of carbon dioxide free water and shake.
A suspension forms that settles after standing.

C. By Chemical

To an acidified solution, add iodinated potassium iodide solution. The solution becomes blue or violet.

D. Test for sodium

In 2 mL of solution S2, add 2 mL of 15 % w/v solution of potassium carbonate. Heat to boiling. No precipitate is formed. Add 4 mL of potassium pyroantimonate solution and heat to boiling. Allow to cool in ice water.

A dense, white precipitate is formed.

SECTION IV

Preparation of solution S1

Centrifuge the suspension obtained in identification test B at 2500 g for 10 min. Collect carefully the supernatant liquid.

Preparation of solution S2

Place 2.5 g of sample in a silica or platinum crucible and add 2 mL of 50 % w/v solution of sulfuric acid. Heat on a water bath, then cautiously over a naked flame raising the temperature progressively, then incinerate in a muffle furnace at 600± 25°C. Continue heating until all black particles have disappeared. Allow to cool, add few drops of dilute sulfuric acid. Heat and incinerate as above. Allow to cool, add a few drops of ammonium carbonate solution. Evaporate to dryness and incinerate cautiously. Allow to cool and dissolve the residue in 50 mL of water.

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		No. RMSTP: REX/SP/S004
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 01
Title:	SODIUM STARCH GLYCOLATE (TYPE A) BP	Review Period: 3 Years
	Item Code: REX/SP/S004	Effective Date: 15/06/2024

APPEARANCE OF SOLUTION S1

Clarity of solution

Take two matched, flat bottomed test tubes of colorless transparent, neutral glass. Place 20 mL of the solution S1 in one test tube and 20 mL of water in another test tube. After 5 minutes, compare the contents of the tubes against a black background by viewing in diffused day light down the vertical axes of the tubes.
A solution is considered clear; if its clarity is same as that of water.

Color of solution

Take two matched, flat bottomed test tubes of colorless transparent, neutral glass. Place 20 mL of the solution S1 in one test tube and 20 mL of water in another test tube. Examine the colors of liquid in diffused daylight by viewing down the vertical axes of the tubes against a white background.

A solution is colourless; if it has the appearance of water.

SECTION V

pH

Dissolve 1.0 g of sample in 30 mL of carbon dioxide free water. Measure the pH using a suitable pH meter.

SECTION VI

SODIUM GLYCOLATE

Note: Carry out the test protected from light.

Test solution

Place 0.20 g of sample in a beaker. Add 5 mL of acetic acid and 5 mL of water. Stir until dissolution is complete (about 10 min). Add 50 mL of acetone and 1 g of sodium chloride. Filter through a fast filter paper impregnated with acetone, rinse the beaker and filter with acetone. Combine the filtrate and washings and dilute to 100 mL with acetone. Allow to stand for 24 h without shaking. Use the clear supernatant liquid.

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Reference solution

Dissolve 0.310 g of glycollic acid, previously dried in vacuum over diphosphorus pentoxide at room temperature overnight, in water and dilute to 500 mL with the same solvent. To 5 mL of this solution, add 5 mL of acetic acid and allow to stand for about 30 min. Add 50 mL of acetone and 1 g of sodium chloride. Filter through a fast filter paper impregnated with acetone, rinse the beaker and filter with acetone. Combine the filtrate and washings and dilute to 100 mL with acetone. Allow to stand for 24 h without shaking. Use the clear supernatant liquid.

Procedure

Heat 2.0 mL of the test solution on a water-bath for 20 min. Cool to room temperature and add 20.0 mL of 2,7-dihydroxynaphthalene solution. Shake and heat in a water-bath for 20 min. Cool under running water, transfer to a volumetric flask and dilute to 25 mL with sulfuric acid, maintaining the flask under running water. Within 10 min, measure the absorbance at 540 nm using water as the compensation liquid. The absorbance of the solution prepared with the test solution is not greater than that of a solution prepared at the same time and in the same manner with 2.0 mL of the reference solution.

SECTION VII

SODIUM CHLORIDE

Place 0.500 g of sample in beaker and suspend in 100 mL of water. Add 1 mL of nitric acid. Titrate with 0.1 M silver nitrate, determining the end point potentiometrically, using a silver indicator electrode.

Each ml of 0.1M silver nitrate is equivalent to 0.005844 g of NaCl.

$$= \frac{\text{Titre value x Molarity of 0.1M Silver nitrate x 0.005844 x 100}}{\text{Weight sample taken (g)}}$$

SECTION VIII

IRON

Transfer 10 mL of the solution S2 to a Nessler cylinder. Add 2 mL of a 20 % w/v solution of citric acid and 0.1 mL of

thioglycollic acid, mix and make alkaline with ammonia solution. Dilute to 20 mL with water and allow to stand for 5 minutes. Any pink colour in the test solution is not more intense than that of iron standard solution (1 ppm Fe).

SECTION IX

LOSS ON DRYING

Weigh a glass-stoppered, shallow weighing bottle that has been previously dried in an oven at 130°C for 30 min (W_1 g). Transfer to the bottle about 10.0 g of sample and distribute the sample evenly by gentle sidewise shaking. Weigh the bottle and the sample (W_2 g). Dry the loaded weighing bottle in an oven at 130°C for 1.5 h, with its lid opened. After drying is completed, remove the weighing bottle from the oven and close the bottle properly. Allow it to cool to room temperature in a desiccator. Weigh the bottle and sample (W_3 g).

Dry the sample to constant weight (W_4 g).
The two consecutive weighing should not differ by more than 0.5 mg.

Calculation

Percentage of LOD (%) = $\frac{W_2-W_4}{W_2-W_1} \times 100$

Where

W_1 = Weight of empty weighing bottle in g.
W_2 = Weight of empty weighing bottle + sample in g.
W_3 = Weight of empty weighing bottle + sample in g (after drying-I).
W_4 = Weight of empty weighing bottle + sample in g (after drying-II).

SECTION X

ASSAY (By Potentiometric)

Dissolve 1.000 g of sample in 20 ml of ethanol (80 %), stir for 10 min and filter. Repeat the operation until chloride has been completely extracted and verify the absence of chloride using silver nitrate solution. Dry the residue at 105°C to constant mass. To 0.700 g of the dried residue, add 80 ml of glacial acetic acid and heat under a reflux condenser for 2 h. Cool the solution to room temperature. Titrate with 0.1 M perchloric acid, determining the end point potentiometrically. Carry out a blank titration.

Each ml of 0.1M perchloric acid is equivalent to 0.00229 g of Na.

Calculation

$$= \frac{(Vs - Vb) \times \text{Molarity factor of 0.1M perchloric acid} \times 0.00229 \times 100}{\text{Weight sample taken in g}}$$

Where

Vs = Volume consumed for sample (mL)
Vb = Volume consumed for blank (mL)

SECTION XI

MICROBIAL CONTAMINATION

Procedure:

Refer to General SOP No. : QCMB/006.

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No. RMSTP: REX/SP/S004
2	Revision No.: 01	Periodic Revision

END OF DOCUMENT

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr. Executive QC	Manager QC
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Date	15/06/2024	15/06/2024	15/06/2024
Department: Quality Control		Date of Issue: 15/06/2024	

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		No. RMS: REX/SP/C001
	RAW MATERIAL SPECIFICATION	Revision No.: 01
Title:	COLLOIDAL SILICON DIOXIDE USP	Review Period:3 Years
	Item Code: REX/SP/C001	Effective Date: 15/09/2023

GENERAL INFORMATION	
Molecular formula	SiO_2
Molecular weight	60.1
Pack details	10 kg packed in paper bags.
Storage conditions	Preserve in well-closed containers.
Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
Quantity of sample required for analysis	20 g
Quantity of reserve sample	40 g
Sampling Instructions	SOP No.: QCGN/018
Retest period	24 months

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	RAW MATERIAL SPECIFICATION	**Revision No.: 01**
Title:	**COLLOIDAL SILICON DIOXIDE USP**	**Review Period:3 Years**
	Item Code: REX/SP/C001	**Effective Date:** 15/09/2023

S. No.	TEST	LIMITS	METHOD
1	DESCRIPTION	White or almost white, fine, nongritty powder of extremely fine with a particle size of about 15 nm.	Follow Section I of method of Analysis
2	SOLUBILITY	Practically insoluble in water and in mineral acids except hydrofluoric acid. It dissolves in hot solutions of alkali hydroxides.	Follow Section II of method of Analysis
3	IDENTIFICATION A. BY CHEMICAL B.BY CHEMICAL	 A deep yellow color is produced. A greenish blue spot is produced.	Follow Section III of method of Analysis
4	pH	3.5 – 5.5	Follow Section IV of method of Analysis
5	ARSENIC	NMT 8 ppm	Follow Section V of method of Analysis
6	LOSS ON DRYING	NMT 2.5 %	Follow Section VI of method of Analysis
7	LOSS ON IGNITION	NMT2.0 %	Follow Section VII of method of Analysis
8	ASSAY (Previously ignited basis)	99.0% to 100.5%	Follow Section VIII of method of Analysis

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No.RMS: REX/SP/C001
2	Revision No.: 01	Periodic revision

END OF DOCUMENT

	Prepared by	Checked by	Approved By
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		No. RMSTP: REX/SP/C001
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 01
Title:	COLLOIDAL SILICON DIOXIDE USP	Review Period:3 Years
	Item Code: REX/SP/C001	Effective Date: 15/09/2023

METHOD OF ANALYSIS

SECTION I

DESCRIPTION

By Physical Observation:

Take the sample in a clean dry glass petri-dish and record its appearance.

White or almost white, nongritty powder of extremely fine with a particle size of about 15 nm.

SECTION II

SOLUBILITY

Measure the volume specified below in each test tube and check the solubility with appropriate solvent given.

Qty. to be taken (g)	Solvent	Volume (mL)	Limit
0.01	Water	> 100	Practically insoluble
0.01	Mineral acids	> 100	Practically insoluble

SECTION III

IDENTIFICATION

A. BY CHEMICAL

Transfer 5 mg to a platinum crucible, and mix with 200 mg of anhydrous potassium carbonate. Heat the crucible to a red color with the aid of a Bunsen burner for 10 min, and cool. Dissolve the melt in 2 ml of freshly distilled water, warming if necessary, and slowly add 2 ml of ammonium molybdate TS to the solution.

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A deep yellow color is produced.

B. BY CHEMICAL

Place 1 drop of the yellow silicomolybdate solution from identification test A on a filter paper, and evaporate the solvent. Add 1 drop of a saturated solution of o-tolidine in glacial acetic acid to reduce the silicomolybdate to molybdate blue, and place the paper over ammonium hydroxide.

A greenish blue spot is produced.

SECTION IV

pH

Dissolve 1 g of sample in 25 ml of carbon dioxide-free water. Immerse the cleaned electrode of pH meter into the test solution. Measure the value of pH which is displayed on pH meter.

SECTION V

LOSS ON DRYING

Weigh a glass-stoppered, shallow weighing bottle that has been previously dried in oven at 105°C for 30 min (W_1 g). Transfer to the bottle about 1.000 g of sample and distribute the sample evenly by gentle sidewise shaking. Weigh the bottle and the sample (W_2 g). Dry the loaded weighing bottle in oven at 105°C for 2hrs, with its lid opened. After drying is completed, remove the weighing bottle from the oven and close the bottle properly. Allow it to cool to room temperature in a desiccator. Weigh the bottle and sample (W_3 g).
Dry the sample to constant weight (W_4 g).

The two consecutive weighing should not differ by more than 0.5 mg.

Calculation

Percentage of LOD (%) = $\frac{W_2-W_4}{W_2-W_1} \times 100$

Where

W_1 = Weight of empty weighing bottle in g.
W_2 = Weight of empty weighing bottle + sample in g.
W_3 = Weight of empty weighing bottle + sample in g (after drying-I).
W_4 = Weight of empty weighing bottle + sample in g (after drying-II).

SECTION VI

LOSS ON IGNITION

Pre ignite a silica crucible at 1000±25°C for 10 minutes, cool to room temperature in a desiccator. Weigh the empty crucible (W_1 g). Transfer approximately 1 g of sample to the crucible and reweigh it, (W_2 g). Ignite, gently for 1 h. Cool the crucible in a desiccator and reweigh (W_3 g).

Calculation

Loss on ignition (%) = $\frac{W_3-W_1}{W_2-W_1} \times 100$

Where

W_1 = Weight of empty crucible in g.
W_2 = Weight of crucible + sample in g.
W_3 = Weight of crucible + sample in g (after Ignition).

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		No. RMSTP: REX/SP/C001
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 01
Title:	COLLOIDAL SILICON DIOXIDE USP	Review Period:3 Years
	Item Code: REX/SP/C001	Effective Date: 15/09/2023

SECTION VII

ARSENIC

Sample solution

To 2.5 g add 50 ml of 3 N hydrochloric acid, and reflux for 30 min using a water condenser. Cool, filter with the aid of suction, and transfer the filtrate to a 100 ml volumetric flask. Wash the filter and flask with several portions of hot water, and add the washing to the flask. Cool, and dilute with water to volume.

PROCEDURE

A 15.0 mL portion of sample solution, to which 3 mL of hydrochloric acid has been added, meets the requirements of the test, the addition of the 7 N sulfuric acid being omitted.

SECTION VIII

ASSAY

Ignite 500 mg of sample in a tared platinum crucible at 1000±25° for 2 h, cool in a desiccator, and weigh. Add 3 drops of sulfuric acid, and add enough alcohol to just moisten the sample completely. Add 15 ml of hydrofluoric acid, and in a well-ventilated hood evaporate on a hot plate to dryness, using medium heat (95°- 105°) and taking care that the sample does not spatter as dryness is approached. Heat the crucible to a red color with the aid of a Bunsen burner. Ignite the residue at 1000±25° for 30 min, cool in a desiccator, and weigh. If a residue remains, repeat the analysis, beginning with "Add 15 ml of hydrofluoric acid". The weight lost by the assay specimen, previously ignited at 1000±25°, represents the weight of SiO_2 in the portion taken.

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No. RMSTP: REX/SP/C001
2	Revision No.: 01	Periodic revision

END OF DOCUMENT

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		No.RMS: REX/SP/M011
	RAW MATERIAL SPECIFICATION	Revision No.: 02
	MAGNESIUM STEARATE BP	Review Period:3 Years
Title:	Item Code: REX/SP/M011	Effective Date: 09/12/2024

GENERAL INFORMATION	
Molecular formula	NA
Molecular weight	NA
Pack details	25 kg packed in poly bags.
Storage conditions	Store in air tight container, protect from light.
Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
Quantity of sample required for chemical analysis	20 g
Quantity of sample required for microbial analysis	20 g
Quantity of reserve sample	80 g
Sampling Instructions	SOP No.: QCGN/018
Retest period	12 months

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Date	09/12/2024	09/12/2024	09/12/2024
Department: Quality Control		Date of Issue: 09/12/2024	

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		No.RMS: REX/SP/M011
	RAW MATERIAL SPECIFICATION	Revision No.: 02
Title:	MAGNESIUM STEARATE BP	Review Period:3 Years
	Item Code: REX/SP/M011	Effective Date:09\12\2024

S.No.	TEST	LIMIT	METHOD
1	DESCRIPTION	White or almost white, very fine, light powder, greasy to the touch.	Follow section I of Method of analysis
2	SOLUBILITY	Practically insoluble in water and in anhydrous ethanol.	Follow section II of Method of analysis
3	IDENTIFICATION* A. Freezing point B. Acid value C. Assay of stearic acid and Palmitic acid (By GC) D. Test for Magnesium	 NLT 53°C 195 to 210 The retention time of the 2 principal peaks obtained with test solution corresponds to the retention time of 2 principal peaks in reference solution. A white crystalline precipitate is formed.	Follow section III of Method of analysis
4	ACIDITY OR ALKALINITY	Not more than 0.05 mL of 0.1 M HCl or 0.1 M NaOH is required to change the colour of the indicator.	Follow section IV of Method of analysis
5	CHLORIDES	NMT 0.1 %	Follow section V of Method of analysis
6	SULFATES	NMT 1.0 %	Follow section VI of Method of analysis
7	LEAD By AAS	NMT 10 ppm	Follow section VII of Method of analysis
8	NICKEL By AAS	NMT 5 ppm	Follow section VIII of Method of analysis
9	CADMIUM By AAS	NMT 3 ppm	Follow section IX of Method of analysis

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Date	09\12\2024	09\12\2024	09\12\2024
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SAI PRIMUS LIFE BIOTECH PVT. LTD.		No.RMS: REX/SP/M011
	RAW MATERIAL SPECIFICATION	Revision No.: 02
Title:	MAGNESIUM STEARATE BP	Review Period:3 Years
	Item Code: REX/SP/M011	Effective Date:09/12/2024

S.No.	TEST	LIMIT	METHOD
10	LOSS ON DRYING (105°/1.0g)	NMT 6.0 %	Follow section X of Method of analysis
11	ASSAY Magnesium (By Titration) Stearic acid in the fatty acid fraction Sum of Stearic acid and Palmitic acid (By GC)	 4.0 % - 5.0 % (on dried basis) Minimum 40.0 % NLT 90.0 %	Follow section XI of Method of analysis
12	MICROBIAL CONTAMINATION - Total aerobic microbial count (TAMC) (CFU/g) - Total yeast and mould count (TYMC) (CFU/g) - Escherichia coli - Salmonella	 NMT 10^3 (CFU/g) NMT 10^2 (CFU/g) Must be absent Must be absent	Follow section XII of Method of analysis

* First identification: C, D
Second identification: A, B, D

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No.RMS: REX/SP/M011
2	Revision No.: 01	Periodic revision
3	Revision No.: 02	Periodic revision

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Designation	Executive QC	Sr.Executive QC	Manager QC
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Department: Quality Control		Date of Issue: 09/12/2024	

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		No. RMSTP: REX/SP/M011
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	MAGNESIUM STEARATE BP	Review Period: 3 Years
	Item Code: REX/SP/M011	Effective Date: 09/12/2024

METHOD OF ANALYSIS

SECTION I

DESCRIPTION

By Physical observation

Take the sample in a clean dry glass petri-dish and record its appearance.

White or almost white, very fine, light powder, greasy to touch.

SECTION II

SOLUBILITY

Weigh the quantity specified below in each test tube and check the solubility with appropriate solvent given.

Qty. to be taken (g)	Solvent	Volume (mL)	Limit
0.01	Water	≥ 100	Practically insoluble
0.01	Anhydrous ethanol	≥ 100	Practically insoluble

SECTION III

IDENTIFICATION

Solution "S"

To 5 g of sample, add 50 mL of peroxide free ether, 20 mL of dilute nitric acid and 20 mL of water. Heat under a reflux condenser until dissolution is complete. Allow to cool. In a separating funnel, separate the aqueous layer and shake the ether layer with two quantities, each of 4 mL of water. Combine the aqueous layers, wash with 15 mL of peroxide-free ether and dilute to 50 mL with water.

Evaporate the organic layer to dryness and dry the residue at 100°C to 105°C. Keep the residue for identification tests A and B Check the freezing point of the residue obtained in the preparation of solution S.

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		No. RMSTP: REX/SP/M011
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	MAGNESIUM STEARATE BP	Review Period: 3 Years
	Item Code: REX/SP/M011	Effective Date: 09/12/2024

A. Freezing point

Procedure

Place a test tube about 150 mm × 25 mm inside a test tube about 160 mm × 40 mm; the inner tube is closed by a stopper which carries a stirrer and a thermometer (about 175 mm long and with 0.2° graduations) fixed so that the bulb is about 15 mm above the bottom of the tube.

The stirrer is made from a glass rod or other suitable material formed at one end into a loop of about 18 mm overall diameter at right angles to the rod. The inner tube with its jacket is supported centrally in a liter beaker containing a suitable cooling liquid to within 20 mm of the top. A thermometer is supported in the cooling bath.

Place a quantity of the substance, previously melted if necessary, in the inner tube such that the thermometer bulb is well-covered and determine the approximate freezing point by cooling rapidly. Place the inner tube in a bath about 5° above the approximate freezing point until all but the last traces of crystals are melted.

Fill the beaker with water or a saturated solution of sodium chloride at a temperature about 5°C lower than the approximate freezing point, insert the inner tube into the outer tube, ensuring that some seed crystals are present, and stir thoroughly until solidification takes place. The highest temperature observed during solidification of the substance is regarded as the freezing point of the substance.

B. Acid value

Weigh accurately 0.200 g of the residue obtained in the preparation of solution "S". Dissolve in 25 mL of the mixture of equal volumes of ethanol (96%) and light petroleum that has been previously neutralised with 0.1 M potassium hydroxide solution using 0.5 mL of phenolphthalein solution as an indicator. When the substance has been completely dissolved, titrate with 0.1 M potassium hydroxide solution, shaking constantly until a pink color that persists for at least 15 seconds is produced.

Calculate the acid value as given below

$$\text{Acid value} = \frac{\text{Titer value}}{\text{Weight of the sample}} \times 5.610$$

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		No. RMSTP: REX/SP/M011
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	MAGNESIUM STEARATE BP	Review Period: 3 Years
	Item Code: REX/SP/M011	Effective Date: 09/12/2024

C. Assay of stearic acid and Palmitic acid (By GC)

The retention time of the 2 principal peaks obtained with test solution corresponds to the retention time of 2 principal peaks in reference solution.

D. Test for Magnesium

To 1 ml of solution "S" add 1 ml of dilute ammonia. A white precipitate is produced which is dissolved by adding 1 ml of ammonium chloride solution. Add 1 ml of disodium hydrogen phosphate solution (120 g/L).
A white crystalline precipitate is obtained

SECTION IV

ACIDITY OR ALKALINITY

To 1 g of sample, add 20 mL of carbon dioxide free water and boil for 1 min with continuous shaking. Cool and filter. To 10 mL of the filtrate, add 0.05 mL of bromothymol blue solution.

Not more than 0.05 mL of 0.1 M hydrochloric acid or 0.1 M sodium hydroxide is required to change the colour of the indicator.

SECTION V

CHLORIDES

Dilute 10 mL of solution S to 40 mL with water. Neutralize with nitric acid, if necessary using litmus as indicator. Add 1 mL each of nitric acid and 0.1 M silver nitrate and dilute to 50 mL with water. Mix and allow to stand for 5 min protected from light.

The turbidity is not greater than that produced in a solution containing 1.4 mL of 0.02 M hydrochloric acid.

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Designation	Executive QC	Sr.Executive QC	Manager QC
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Date	09/12/2024	09/12/2024	09/12/2024
Department: Quality Control		Date of Issue: 09/12/2024	

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		No. RMSTP: REX/SP/M011
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	MAGNESIUM STEARATE BP	Review Period: 3 Years
	Item Code: REX/SP/M011	Effective Date: 09/12/2024

SECTION VI

SULFATES

Dilute 6.0 mL of solution S to 40 mL with water. Neutralize if necessary with hydrochloric acid using litmus as indicator. Add 1 mL of 3 M hydrochloric acid and 3 mL of barium chloride solution (120 g/L) and dilute to 50 mL with water. Mix and allow to stand for 10 min.

The turbidity is not greater than that produced in a solution containing 3 mL of 0.02 M sulfuric acid.

SECTION VII

LEAD (By atomic absorption spectrometry)

Instrument conditions

Source	Lead hollow-cathode lamp
Wavelength	283.3 nm
Atomisation device	Furnace
Platform	Pyrolytically coated with integrated tube

Precautions to be taken before analysis

For the preparation of all aqueous solutions and for the rinsing of glassware before use, employ water that has been passed through a strong-acid, strong-base, mixed- bed ion-exchange resin before use. Select all reagents to have as low a content of cadmium, lead and nickel as practicable and store all reagent solutions in containers of borosilicate glass. Clean glassware before use by soaking in warm 773 g/L nitric acid for 30 min and by rinsing with deionised water.

Blank solution
Use the solution described in the test for cadmium.

Modifier solution
Use the solution described in the test for cadmium.

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Test solution
Use the solution described in the test for cadmium.

Reference solution
Prepare a solution of 0.100 µg/mL of Pb by suitable dilutions of lead standard solution (100 ppm Pb) with the blank solution.

Procedure
Prepare mixtures of the test solution, the reference solution and the blank solution in the following proportions: (1.0:0:1.0 v/v/v), (1.0:0.5:0.5 v/v/v), (1.0:1.0:0 v/v/v). To each mixture, add 50 µL of modifier solution and mix. These solutions contain respectively 0 µg, 0.025 µg and 0.05 µg of lead per milliliter from the reference solution.

Operating conditions
Use the temperature programme recommended for lead by the GFAA manufacturer. An example of temperature parameters for GFAA analysis of lead is shown below.

Stage	Final Temperature (°C)	Ramp Time (s)	Hold Time (s)
Drying	110	10	20
Ashing	450	10	30
Atomisation	2000	0	5

SECTION VIII

NICKEL (By atomic absorption spectrometry)

Instrument conditions

Source	Nickel hollow-cathode lamp
Wavelength	232.0 nm
Atomisation device	Furnace
Platform	Pyrolytically coated with integrated tube

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		No. RMSTP: REX/SP/M011
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	MAGNESIUM STEARATE BP	Review Period: 3 Years
	Item Code: REX/SP/M011	Effective Date: 09/12/2024

Precautions to be taken before analysis

For the preparation of all aqueous solutions and for the rinsing of glassware before use, employ water that has been passed through a strong-acid, strong-base, mixed- bed ion-exchange resin before use. Select all reagents to have as low a content of cadmium, lead and nickel as practicable and store all reagent solutions in containers of borosilicate glass. Clean glassware before use by soaking in warm 773 g/L nitric acid for 30 min and by rinsing with deionised water.

Blank solution

Use the solution described in the test for cadmium.

Modifier solution

Dissolve 20 g of ammonium dihydrogen phosphate in water and dilute to 100 mL with the same solvent. Alternatively, use an appropriate matrix modifier as recommended by the GFAA spectrometer manufacturer.

Test solution

Use the solution described in the test for cadmium.

Reference solution

Prepare a solution of 0.050 µg/mL of Ni by suitable dilutions of a 0.2477 µg/mL solution of nickel nitrate hexahydrate in the blank solution.

Procedure

Prepare mixtures of the test solution, the reference solution and the blank solution in the following proportions: (1.0:0:1.0 v/v/v), (1.0:0.5:0.5 v/v/v), (1.0:1.0:0 v/v/v). To each mixture add 50 µL of matrix modifier solution and mix. These reference solutions contain respectively 0 µg, 0.0125 µg and 0.025 µg of nickel per millilitre from the reference solution.

Operating conditions

Use the temperature programme recommended for nickel by the GFAA manufacturer. An example of temperature parameters for GFAA analysis of nickel is shown below.

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		No. RMSTP: REX/SP/M011
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	MAGNESIUM STEARATE BP	Review Period: 3 Years
	Item Code: REX/SP/M011	Effective Date: 09/12/2024

Stage	Final Temperature °C)	Ramp Time (s)	Hold Time (s)
Drying	110	10	20
Ashing	1000	10	30
Atomisation	2300	0	5

SECTION IX

CADMIUM (By atomic absorption spectrometry)

Instrument conditions

Source — Cadmium hollow-cathode lamp

Wavelength — 228.8 nm

Atomisation device — Furnace

Platform — Pyrolytically coated with integrated tube.

Precautions to be taken before analysis

For the preparation of all aqueous solutions and for the rinsing of glassware before use, employ water that has been passed through a strong-acid, strong-base, and mixed-bed ion-exchange resin before use. Select all reagents to have as low a content of cadmium, lead and nickel as practicable and store all reagent solutions in containers of borosilicate glass. Clean glassware before use by soaking in warm 773 g/L nitric acid for 30 min and by rinsing with deionised water.

Blank solution : Dilute 25 mL of cadmium and lead-free nitric acid to 100 mL with water.

Modifier solution
Dissolve 20 g of ammonium dihydrogen phosphate and 1 g of magnesium nitrate in water and dilute to 100 mL

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with the same solvent. Alternatively, use an appropriate matrix modifier as recommended by the graphite furnace atomic absorption (GFAA) spectrometer manufacturer.

Test solution

Place 0.100 g of sample in a polytetrafluoroethylene digestion bomb and add 2.5 mL of cadmium and lead-free nitric acid. Close and seal the bomb according to the manufacturer's operating. Heat the bomb in an oven at 170°C for 3 h. Cool the bomb slowly in air to room temperature according to the bomb manufacturer's instructions. Place the bomb in a hood and open carefully as corrosive gases may be expelled. Dissolve the residue in water and dilute to 10 mL with the same solvent.

Reference solution

Prepare a solution of 0.0030 µg/mL of Cd by suitable dilutions of a 0.00825 µg/mL solution of cadmium nitrate tetrahydrate in the blank solution.

Procedure

Dilute 1 mL of the test solution to 10 mL with the blank solution. Prepare mixtures of this solution, the reference solution and the blank solution in the following proportions: (1.0:0:1.0 v/v/v), (1.0:0.5:0.5 v/v/v), (1.0:1.0:0 v/v/v). To each mixture, add 50 µL of modifier solution and mix. These solutions contain respectively 0 µg, 0.00075 µg and 0.0015 µg of cadmium per millilitre from the reference solution (Keep the remaining test solution for use in the test for lead and nickel).

Operating conditions

Use the temperature programme recommended for cadmium by the GFAA manufacturer. An example of temperature parameters for GFAA analysis of cadmium is shown below

Stage	Final Temperature(°C)	Ramp Time (S)	Hold Time (S)
Drying	110	10	20
Ashing	600	10	30
Atomisation	1800	0	5

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SECTION X

LOSS ON DRYING

Weigh a glass-stoppered, shallow weighing bottle that has been previously dried in oven at 105°C for 30 min (W_1 g). Transfer to the bottle about 1.000 g of sample and distribute the sample evenly by gentle sidewise shaking. Weigh the bottle and the sample (W_2 g). Dry the loaded weighing bottle in oven at 105°C, with its lid opened. After drying is completed, remove the weighing bottle from the oven and close the bottle properly. Allow it to cool to room temperature in a desiccator. Weigh the bottle and sample (W_3 g).
Dry the sample to constant weight (W_4 g).

The two consecutive weighing should not differ by more than 0.5 mg.

Calculation

$$\text{Percentage of LOD (\%)} = \frac{W_2 - W_4}{W_2 - W_1} \times 100$$

Where

W_1 = Weight of empty weighing bottle in g.
W_2 = Weight of empty weighing bottle + sample in g.
W_3 = Weight of empty weighing bottle + sample in g (after drying-I).
W_4 = Weight of empty weighing bottle + sample in g (after drying-II).

SECTION XI

ASSAY

Magnesium (By Titrimetry)

Dissolve 0.500 g of sample in a 250 mL conical flask. Add 50 mL of a mixture of anhydrous ethanol and butanol (in the ratio of 1:1), 5 mL of concentrated ammonia, 3 mL of ammonium chloride buffer solution pH 10, 30 mL of

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0.1 M sodium edetate and 15 mg of mordant black 11 triturate. Heat at 45-50°C until the solution is clear. Titrate with 0.1 M Zinc sulfate until the colour changes from blue to violet. Carry out a blank titration.
1 mL of 0.1 M sodium edetate is equivalent to 2.431 mg of Mg.

Calculation

$$\text{Mg (\%) (on dried basis)} = \frac{(Vs - Vb) \times M \times 2.431}{W} \times \frac{100}{(100 - LOD)} \times 100$$

Where
Vs = Volume consumed for sample (mL).
Vb = Volume consumed for blank (mL).
M = Molarity factor of Zinc sulfate.
LOD = Percent loss on drying of sample.
W = Sample weight (mg)

Stearic acid and palmitic acid (By GC)

Chromatographic condition

Column	: Fused silica column 30 m in length and 0.32 mm in dia with stationary phase of Macrogol 20000 with film thickness of 0.5 µm.
Carrier gas	: Helium
Flow rate	: 2.4 mL/min
Detector	: Flame ionization
Injection	: 1 µL
Injection port temp	: 220°C
Detector temp	: 260°C

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Column	: Time (min)	Temperature (°C)
	0 – 2	70
	2 – 36	70 – 240
	36 – 41	240

Preparation of test solution

In a conical flask fitted with a reflux condenser, dissolve 0.10 g of the sample in 5 mL of boron trifluoride-methanol solution. Boil under a reflux condenser for 10 min. Add 4 mL of heptane through the condenser and boil again under a reflux condenser for 10 min. Allow to cool. Add 20 mL of saturated sodium chloride solution. Shake and allow the layers to separate. Dry the organic layer over 0.1 g of anhydrous sodium sulfate (previously washed with heptane). Dilute 1 mL of the solution to 10 mL with heptane.

Preparation of reference solution

In a conical flask fitted with a reflux condenser, dissolve each 50 mg of the Palmitic acid and Stearic acid in 5 mL of boron trifluoride-methanol solution. Boil under a reflux condenser for 10 min. Add 4 mL of heptane through the condenser and boil again under a reflux condenser for 10 min. Allow to cool. Add 20 mL of saturated sodium chloride solution. Shake and allow the layers to separate. Dry the organic layer over 100 mg of anhydrous sodium sulfate (previously washed with heptane). Dilute 1 mL of the solution to 10 mL with heptane.

Evaluation of system suitability

Inject the reference solution into the chromatograph and record the chromatograms.

The system is suitable for analysis, if;

The resolution between methyl palmitate and methyl stearate peak is not less than 5.

The relative standard deviation for six replicate injections for methyl palmitate and methyl stearate peaks is not more than 3.0 % and not more than 1.0 % for the ratio of the areas of the peaks due to methyl palmitate to the areas of the peaks due to methyl stearate.

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Procedure

Inject the test solution. Calculate the percentage content of stearic acid and palmitic acid from the areas of the peaks in the chromatogram obtained with the test solution by the normalisation procedure, disregarding the peak due to the solvent.

SECTION XII

MICROBIAL CONTAMINATION

Refer SOP NO. QCMB/006

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No.RMS: REX/SP/M011
2	Revision No.: 01	Periodic revision
3	Revision No.: 02	Periodic revision

END OF DOCUMENT

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