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: RAI/SP/A011
	RAW MATERIAL SPECIFICATION	Revision No.: 01
Title:	AMLODIPINE BESYLATE BP	Review Period: 3 Years
	Item Code: RAI/SP/A011	Effective Date: 04/10/2024

GENERAL INFORMATION	
Molecular formula	$C_{26}H_{31}ClN_2O_8S$
Molecular weight	567.1
Pack details	25 kg packed in PVC drum
Storage conditions	In an airtight container, protected 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	04/10/2024	04/10/2024	04/10/2024
Department: Quality Control		Date of Issue: 04/10/2024	

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S.No.	TEST	LIMITS	METHOD
1	DESCRIPTION	White or almost white powder.	Follow Section I of method of Analysis
2	SOLUBILITY	Slightly soluble in water, freely soluble in methanol, sparingly soluble in anhydrous ethanol; slightly soluble in 2-propanol.	Follow Section II of Method of Analysis
3	IDENTIFICATION By IR	The Infrared absorption spectrum of sample should be concordant with the spectrum obtained to that of standard.	Follow Section III of Method of Analysis
4	OPTICAL ROTATION	-0.10° to + 0.10°	Follow Section IV of Method of Analysis
5	RELATED SUBSTANCES - Impurity D - Impurity A - Impurity E - Impurity F - Unspecified Impurity - Total impurities	 Not more than 0.3 % Not more than 0.15 % Not more than 0.15 % Not more than 0.15 % Not more than 0.10 % Not more than 0.8%	Follow Section V of Method of Analysis
6	WATER CONTENT	Not more than 0.5 %	Follow Section VI of Method of Analysis
7	SULPHATED ASH	Not more than 0.2 %	Follow Section VII of Method of Analysis

	Prepared by	Checked by	Approved By
Designation	**Executive QC**	**Sr.Executive QC**	**Manager QC**
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S.No.	TEST	LIMITS	METHOD
8	ASSAY (on anhydrous basis)	97.0 % to 102.0 %	Follow Section VIII of Method of Analysis

HISTORY:

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No. RMS: RAI/SP/A011
2	Revision No.: 01	Periodic Revision

END OF DOCUMENT

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Title:	AMLODIPINE BESILATE BP	Review Period: 3 Years
	Item Code: RAI/SP/A011	Effective Date: 04/10/2024

METHOD OF ANALYSIS

SECTION I

DESCRIPTION

By Physical observation:

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

A white or almost white 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	1 to 10	Slightly soluble
1.0	Methanol	1 to 10	Freely soluble
1.0	Ethanol	30 to 100	Sparingly soluble
0.01	2-propanol	1 to 10	Slightly soluble

SECTION III

IDENTIFICATION 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.

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Record the background spectrum. Record and compare the spectrum from 3800-650 cm^{-1} for the working standard and the sample

SECTION IV

OPTICAL ROTATION

Accurately weigh and transfer about 0.250 g of sample to a 25 mL volumetric flask. Dissolve in methanol and mix well. Adjust the content of the flask to 25°C by suspending the flask in a constant temperature bath. Make up the volume with methanol maintained at 25°C and mix well. Transfer the solution to the Polari meter tube within 30 min from the time of preparation and maintain the solution at 25°C during this interval. Reserve portion of methanol for the blank determination. Determine the zero point of the Polari meter and then take five readings of the sample and the blank at 25°C.

Calculation

$$[\alpha]^{20}_{D} = \frac{Z \times V}{L \times W}$$

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

SECTION V

RELATED SUBSTANCES (By HPLC)

Chromatographic conditions

Column : C-18, 250 mm x 4.0 mm, 5µm, octadecylsilyl silica gel.

Column Temp : 30°

Wavelength : 237 nm

Flow rate : 1.5 mL/min

Injection volume : 20 µL

Run time : 2 times the RT of Amlodipine peak in test solution (a)

Carry out the test protected from light.

Preparation of buffer

Dissolve 2.3 gm of ammonium acetate in 1000 mL of water.

Preparation of mobile phase : Mix Buffer 30 mL with methanol 70 mL. Mix well and degas.

Preparation of test solution (a)

Weigh accurately and transfer about 50 mg of the sample to a 50mL volumetric flask. Dissolve in mobile phase and make up the volume with mobile phase.

Preparation of test solution (b)

Dilute 5 mL of test solution (a) to 100 mL with mobile phase.

Preparation of reference solution (a)

Dilute 1 mL of test solution (a) to 10 mL with mobile phase. Further dilute 1 mL to 100 mL with mobile phase.

Preparation of reference solution (b)

Weigh accurately and transfer each 2.5 mg of the Amlodipine impurity B and impurity G to a 25 mL volumetric flask. Dissolve in mobile phase and make up the volume with mobile phase. Further dilute 1 mL to 10 mL with mobile phase.

Preparation of reference solution (c)

Weigh accurately and transfer 2.5 mg of the Amlodipine peak identification (containing impurity D, E and F) to a 5 mL volumetric flask. Dissolve and make up the volume with mobile phase.

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Preparation of reference solution (d)

Weigh accurately and transfer each 5 mg of the Amlodipine impurity A in acetonitrile to a 5 mL volumetric flask made volume with same solvent. Dilute 1 mL to 100 mL with mobile phase. Further dilute 1 mL to 10 mL with mobile phase.

Preparation of reference solution (e)

Weigh accurately and transfer 50 mg of the Amlodipine besylate working standard to a 50 mL volumetric flask. Dissolve in mobile phase and make up the volume with mobile phase. Further dilute 5 mL to 100 mL with mobile phase.

Identification of impurity

Use the chromatogram supplied with amlodipine for peak identification and the chromatogram supplied with reference solution (c) to identify the peak due to impurities D, E and F. Use the chromatogram supplied with reference solution (d) to identify the peak due to impurities A.

RT of amlodipine is about 20 min

Name of impurity	RRT	Correction factor
Impurity G	0.21	-
Impurity B	0.25	-
Impurity D	0.5	1.7
Impurity F	0.8	0.7
Impurity E	1.3	-

The system is suitable for analysis, if;

The resolution between the peaks corresponding to impurity G and impurity B is not less than 2.0

Procedure

Inject blank, reference solution (b), reference solution (c) and test solution (a) into the chromatograph and record the chromatograms.

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Calculation

1. Impurity A

$$= \frac{AT}{AS} \times \frac{SW}{5} \times \frac{1}{100} \times \frac{1}{10} \times \frac{50}{SW} \times 100$$

2. Any unknown impurity

$$= \frac{AT_I}{AS} \times \frac{SW_I}{50} \times \frac{1}{100} \times \frac{1}{100} \times \frac{50}{SW} \times 100$$

3. Total unknown Impurities = Sum of all unknown impurities

Where

AT = Area of impurity D peak in the chromatogram for test solution (a).
AT_I = Area of any unknown impurity peak in the chromatogram for test solution (a).
AS = Area of Amlodipine peak in the chromatogram for reference solution (b).
SW = Weight of sample (mg).
SW_I = Weight of amlodipine impurity A (mg).

SECTION VI

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.

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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.

Calculation

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 VII

WATER (By KF)

Standardization of KF reagent

Place enough anhydrous methanol 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 anhydrous methanols in the titration vessel and titrate with the KF reagent to the end point. Quickly add about 1.0 g 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.

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Calculation

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

SECTION VIII

ASSAY (By HPLC)

For mobile phase, chromatographic conditions, reference solution (a) and test solution (a), follow as under Related substances (Test B)

Procedure

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

Calculation

$$= \frac{AT \times WS \times 5 \times 50 \times 100 \times P \times 100}{AS \times 50 \times 100 \times SW \times 5 \times 100 \times (100\text{-Water})} \times 100$$

Where

AT = Area of test solution (b)
AS = Area of reference solution (a)
WS = Weight of AmLodipine besylate working standard taken in mg
SW = Weight of sample taken in mg
P = % purity of standard (on as is basis)

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No. RMSTP: RAI/SP/A011
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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	RAW MATERIAL SPECIFICATION	**Revision No.: 01**
Title:	**PERINDOPRIL ERBUMINE BP**	**Review Period: 3 Years**
	Item Code: RAI/GH/P001	**Effective Date:** 07/10/2024

GENERAL INFORMATION	
Molecular formula	$C_{23}H_{43}N_3O_5$
Molecular weight	441.6
Pack details	10 kg packed in PVC Drum.
Storage conditions	Store in an airtight container.
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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Title:	PERINDOPRIL ERBUMINE BP	Review Period: 3 Years
	Item Code: RAI/GH/P001	Effective Date: 07/10/2024

S. No.	TEST	LIMITS	METHOD
1	DESCRIPTION	White or almost white, slightly hygroscopic, crystalline powder.	Follow Section I of method of analysis
2	SOLUBILITY	Freely soluble in water and in ethanol (96 %) soluble or sparingly soluble methylene chloride.	Follow Section II of method of analysis
3	IDENTIFICATION A. By Specific Optical Rotation(OAB) B. By IR C. By TLC	 Between -69 to -66° The infrared sprectrum of the sample is concordant with the spectrum obtained from similar determination of standard spectrum. In the chromatogram obtained with the test solution a spot is observed with the same Rf in the chromatogram obtained with reference solution (c) (tert-butylamine)	Follow Section III of method of analysis
4	IMPURITY A By TLC	NMT 0.25%	Follow Section IV of method of analysis
5	STEREOCHEMICAL PURITY By HPLC Impurity I Unspecified impurities	 NMT 0.1 % NMT 0.10 %	Follow Section V of method of analysis
6	RELATED SUBSTANCES (By HPLC) Impurity E Impurity B Impurity F Impurity H Unspecified Impurity Total Impurities	 NMT 0.4 % NMT 0.3 % NMT 0.2 % NMT 0.2 % NMT 0.10 % NMT 1.0 %	Follow Section VI of method of analysis

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S. No.	TEST	LIMITS	METHOD
7	WATER (By KF / 0.50 g)	NMT 1.0 %	Follow Section VII of method of analysis
8	SULPHATED ASH	NMT 0.1 %	Follow Section VIII of method of analysis
9	ASSAY (OAB) (By Potentiometry)	99.0 % to 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/GH/P001
2	Revision No.: 01	Periodic Revision

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METHOD OF ANALYSIS

SECTION I

DESCRIPTION

By Physical observation:

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

A white or almost white slightly hygroscopic, 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 to 10	Freely soluble
1.0	Ethanol (96%)	1 to 10	Freely soluble
1.0	Methylene chloride	30 to 100	Sparingly soluble

SECTION III

IDENTIFICATION

A. OPTICAL ROTATION

Dissolve 0.250 g in ethanol (96 per) and dilute to 25.0 mL with the same solvent.

Calculation

$$[\alpha]^{20}_{D} = \frac{Z \times V}{L \times W}$$

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Where
Z = Corrected observed rotation, in degrees, at 20°C
L = length of polarimeter tube in dm
V = volume of solvent
W= weight of the sample

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.

If the spectra obtained show differences, dissolves substance to be examined and the refernce substance separately in methylene chloride, evaporate to dryness and record the new spectra using the residues.

C. THINLAYER CHROMATOGRAPHY

Examine the chromatogram obtained in the test for impurity-A

In the chromatogram obtained with the test solution a spot is observed with the same R_F as the spot with the higher R_F in the chromatogram obtained with reference solution (c) (tert-butylamine).

SECTION IV

IMPURITY A (BY THIN LAYER CHROMATOGRAPHY)

Chromatographic conditions

Plate : TLC silica gel plate

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Development : Over 2/3 of the plate

Drying : In a current of warm air

Detection : Expose to iodine vapor for at least 20 h

Application : 10 µL of the test solution and reference solutions (b) and (c)

Preparation of mobile phase

Mix 1 ml glacial acetic acid and 40 ml of Toluene and 60 ml of methanol. Mix well and degas.

Preparation of test solution

Dissolve 0.20 g of the substance to be examined in methanol and dilute to 10.0 mL with the same solvent.

Preparation of Reference solution (a)

Dissolve 5 mg of perindopril impurity A CRS in methanol and dilute to 25.0 mL with the same solvent.

Preparation of Reference solution (b)

Dilute 5.0 mL of reference solution (a) to 20.0 mL with methanol.

Preparation of Reference solution (c)

To 5 mL of reference solution (a) add 5 mL of a 20 g/L solution of l, l-dimethylethylamine in methanol.

System suitability

In the chromatogram of reference solution (C) two separately spots to be observed.

Limit. Impurity A: any spot due to impurity A is not more intense than in the chromatogram obtained with reference solution (b) 0.25 %

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SECTION V

STEREOCHEMICAL PURITY (By HPLC)

Chromatographic conditions

Column : 0.25 m x 4.6 mm, stationary phase: base-deactivated end-capped octadecylsilyl silica gel for chromotagraphy R (5 um).

Temperature : 50°C for the column and the tubing preceding the column (the method has been developed with a temperature of 50 °C for at least 30 cm of the tubing preceding the column).

Wavelength : 215 nm

Equilibration : Minimum 4 h.

Flow rate : 0.8 mL/min

Injection volume : 10 µL

Run time : 1.5 times the retention time.

Preparation of mobile phase

Mix, in the following order, 21.7 volumes of acetonitrile, 0.3 volumes of pentanol, and 78 volumes of a 1.50 g/L solution of sodium heptanesulfonate previously adjusted to pH 2.0 with a mixture of equal volumes of perchloric add and water for chromarography.

Preparation of sample solution

Dissolve 20 mg of the substance to be examined in ethanol (96 %) and dilute to 10.0 mL with the same solvent.

Preparation of Reference solution (a)

Dilute 1.0 mL of the test solution to 100.0 mL with ethanol (96 %). Dilute 1.0 mL of this solution to 10.0 mL with ethanol (96 %).

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Preparation of Reference solution (b)

Dissolve 10 mg of perindopril for stereochemical purity CRS (containing impurity l) in ethanol (96 %) and dilute to 5 mL with the same solvent.

Identification of impurities

Use the chromatogram supplied with perindopril for stereo chemical purity CRS and the chromatogram obtained with reference solution (b) to identify the peak due to impurity I.

Relative retention:

With reference to perindopril (retention time =about 100 min): impurity I =about 0.9.

System suitabl1ity:

The chromatogram obtained with reference solution (b) is similar to the chromatogram supplied with perindopril for Stereo chemical purity CRS.

- signal-to-noise ratio: minimum 3 for the principal peak in the chromatogram obtained with reference solution (a).

- peak-to-valley ratio: minimum 3, where Hp = height above the baseline of the peak due to impurity I and H, = height above the baseline of the lowest point of the curve separating this peak from the peak due to perindopril in the chromatogram obtained with reference solution (b).

Limits:
— impurity I: not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (0.1 per cent)

— unspecified impurities: for each impurity, not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (0.10 per cent)

— disregard limit: disregard any peak with a relative retention with reference to perindopril of less than 0.6 or more than 1.4.

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		No. RMSTP: RAI/GH/P001
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 01
Title:	PERINDOPRIL ERBUMINE BP	Review Period: 3 Years
	Item Code: RAI/GH/P001	Effective Date: 07/10/2024

SECTION VI

RELATED SUBSTANCES (By HPLC)

Note: Prepare the solutions immediately before use or maintain them at a temperature not exceeding 10°C.

Chromatographic conditions

Column : 150 mm x 4.0 mm, octylsilyl silica gel, 5 µm

Wavelength : 215 nm

Flow rate : 1 mL/min

Injection volume : 20 µL

Temperature : 60°C for the column and the tubing preceding the column.

Preparation of mobile phase A

Water adjust to pH (pH 2.5) with a mixture of equal volumes of perchloric acid and water.

Preparation of mobile phase B

0.03 % v/v solution of perchloric acid in acetonitrile.

Preparation of sample solution

Dissolve 60.0 mg of the substances to be examined in mobile phase A and dilute 20.0 mL with mobile phase A.

Preparation of reference solution (a)

Dissolve 3.0 mg of perindopril for peak identification CRS (containing Glimepiride Impurity B, E, F, H and K) in 1.0 mL of mobile phase A.

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Preparation of reference solution (b)

Dilute 1.0 mL of sample solution to 200.0 mL with mobile phase A.

Preparation of reference solution (c)

Dilute 1.0 mL of Reference solution (b) to 10.0 mL with mobile phase A.

Gradient program:

Time (min)	Mobile phase A (% v/v)	Mobile phase B (% v/v)
0	95	5
5	95	5
60	40	60

Identification of impurities
Use the chromatogram supplied with perindopril for peak identification CRS and the chromatogram obtained with reference solution (a) to identify the peaks due to impurities B, E, F, H and K.

Relative retention With reference to perindopril (retention time = about 25 min): impurity B = about 0.68; impurity K = about 0.72; impurity E = about 1.2; impurity F = about 1.6; impurity H = about 1.8 (impurity H may be eluted as 1 or 2 peaks).

System suitability Reference solution (a)

peak-to-valley ratio: minimum 3, where H_p = height above the baseline of the peak due to impurity B and H_v = height above the baseline of the lowest point of the curve separating this peak from the peak due to impurity K.

Limits:

Impurity E: NMT 0.8 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.4 per cent).
Impurity B: NMT 0.6 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.3 per cent).
Impurities F, H: for each impurity, NMT 0.4 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.2 per cent).

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Unspecified impurities: for each impurity, NMT 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.10 per cent).

Total: NMT twice the area of the principal peak in the chromatogram obtained with reference solution (b) (1.0 %).

Disregard limit: the area of the principal peak in the chromatogram obtained with reference solution (c) (0.05 %).

SECTION VII

WATER (By KF)

Standardization of KF reagent

Place enough anhydrous methanol 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 anhydrous methanol in the titration vessel and titrate with the KF reagent to the end point. Quickly add about 0.50 g 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

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

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		No. RMSTP: RAI/GH/P001
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Title:	PERINDOPRIL ERBUMINE BP	Review Period: 3 Years
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SECTION VIII

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.

Calculation

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 IX

ASSAY (By potentiometric)

Dissolve 0.160 g of sample in 50 mL of anhydrous acetic acid. Titrate with 0.1 N perchloric acid determining the end-point potentiometrically.

1 mL of 0.1 M perchloric acid is equivalent to 22.08 mg of perindopril Erbumine.

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Calculation

$$\text{Assay (\%) (on anhydrous basis)} = \frac{(Vs - Vb) \times N \times 22.08}{WS \times M} \times \frac{100}{(100 - \text{water})} \times 100$$

Where

Vs = Volume consumed for sample (mL)
Vb = Volume consumed for blank (mL)
M = Molarity factor of perchloric acid
N = Normality factor of perchloric acid
W = Sample weight (g)

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No. RMSTP: RAI/GH/P001
2	Revision No.: 01	Periodic Revision

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Date	07/10/2024	07/10/2024	07/10/2024
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Periodic Revision done: PF 04/01/2025

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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

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

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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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Date	05/01/2023	05/01/2023	05/01/2023
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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.

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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.

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Department: Quality Control		Date of Issue: 05/01/2023	

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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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Department: Quality Control		Date of Issue: 05/01/2023	

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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

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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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	RAW MATERIAL SPECIFICATION	Revision No.: 02
Title:	MICROCRYSTALLINE CELLULOSE BP (PH 200)	Review Period: 3 Years
	Item Code: REX/SP/M018	Effective Date: 30/05/2024

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	Store 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	100 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	30/05/2024	30/05/2024	30/05/2024
Department: Quality Control		Date of Issue: 30/05/2024	

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	RAW MATERIAL SPECIFICATION	Revision No.: 02
Title:	MICROCRYSTALLINE CELLULOSE BP (PH 200)	Review Period: 3 Years
	Item Code: REX/SP/M018	Effective Date: 30/05/2024

S. No.	TEST	LIMITS	METHOD
1	DESCRIPTION	A White or almost white, fine or granular 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 75$\mu S.cm^{-1}$	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

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
Date	30/05/2024	30/05/2024	30/05/2024
Department: Quality Control		Date of Issue: 30/05/2024	

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	RAW MATERIAL SPECIFICATION	Revision No.: 02
Title:	MICROCRYSTALLINE CELLULOSE BP (PH 200)	Review Period: 3 Years
	Item Code: REX/SP/M018	Effective Date: 30/05/2024

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

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No.RMS: REX/SP/M018
2	Revision No.: 01	Periodic Revision.
3	Revision No.: 02	Periodic Revision.

END OF DOCUMENT

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Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
Date	30/05/2024	30/05/2024	30/05/2024
Department: Quality Control		Date of Issue: 30/05/2024	

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	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	MICROCRYSTALLINE CELLULOSE BP (PH 200)	Review Period: 3 Years
	Item Code: REX/SP/M018	Effective Date: 30/05/2024

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.

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.

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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.

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.

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 5 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.

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.

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 X

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.

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

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Department: Quality Control		Date of Issue: 30/05/2024	

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 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/M018
2	Revision No.: 01	Periodic Revision
3	Revision No.: 02	Periodic Revision

END OF DOCUMENT

	Prepared by	Checked by	Approved By
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Department: Quality Control		Date of Issue: 30/05/2024	

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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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Date	15/09/2023	15/09/2023	15/09/2023
Department: Quality Control		Date of Issue: 15/09/2023	

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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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Date	15/09/2023	15/09/2023	16/09/2023
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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

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
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		No. RMS: REX/GH/C001
	RAW MATERIAL SPECIFICATION	Revision No.: 02
Title:	COLLOIDAL SILICON DIOXIDE BP	Review Period:3 Years
	Item Code: REX/GH/C001	Effective Date: 16/03/2024

GENERAL INFORMATION	
Molecular formula	SiO_2
Molecular weight	60.1
Pack details	10 kg packed in poly bags in fiber/HDPE drums or poly bags.
Storage conditions	Store in air tight container.
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	24 months

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr. Executive QC	Manager QC
Signature			
Date	16/03/2024	16/03/2024	16/03/2024
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	RAW MATERIAL SPECIFICATION	Revision No.: 02
Title:	COLLOIDAL SILICON DIOXIDE BP	Review Period:3 Years
	Item Code: REX/GH/C001	Effective Date: 16/03/2024

S.No.	TEST	LIMITS	METHOD
1.	DESCRIPTION	White or almost white, light, fine, amorphous powder, not wettable by water 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 (Test for silicates)	A white ring is formed around the drop of water.	Follow section III of Method of analysis
4.	pH	3.5 to 5.5	Follow section IV of Method of analysis
5.	CHLORIDES	NMT 250 ppm	Follow section V of Method of analysis
6.	LOSS ON IGNITION	NMT 5.0 %	Follow section VI of Method of analysis
7..	ASSAY (on ignited basis)	99.0 % to 100.5 %	Follow section VII of Method of analysis

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No.RMS: REX/GH/C001
2	Revision No.: 01	Periodic Revision
3	Revision No.: 02	Periodic Revision

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Date	16/03/2024	16/03/2024	16/03/2024
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		No. RMSTP:REX/GH/C001
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	COLLOIDAL SILICON DIOXIDE BP	Review Period: 3 Years
	Item Code: REX/GH/C001	Effective Date: 16/03/2024

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, light, fine, amorphous powder, not wettable by water 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 except hydrofluoric acid	≥ 100	Practically insoluble
1.0	Hot solutions of alkali hydroxides	10-30	Dissolves

SECTION III

IDENTIFICATION (Test for Silicates)

Weigh about 20 mg of sample and mix with 10 mg of sodium fluoride in a platinum crucible by means of a copper wire to obtain a thin slurry and add a few drops of sulphuric acid. Cover the crucible with a thin transparent plate of plastic under which a drop of water is suspended and warm gently.

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Within a short time a white ring is formed around the drop of water

SECTION IV

pH

Dissolve 1 g of sample in 30 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

CHLORIDES

To 1 g of sample, add a mixture of 20 ml of dilute nitric acid and 30 ml of water. Heat on a water bath for 15 min, shaking frequently. Dilute to 50 ml with water, filter and cool. Dilute 10 mL of the filtrate to 15 mL with water. Add 1 mL of dilute nitric acid and pour the mixture into test tube containing silver nitrate solution. Prepare the standard in a manner using 10 mL of chloride standard solution (5 ppm Cl) and 5 mL of water.

Examine the tubes laterally against a black background. After standing for 5 min, protected from light, any opalescence in the test solution is not more intense than that in the standard.

SECTION VI

LOSS ON IGNITION

Ignite a suitable crucible at 800±25°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) and ignite. 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.

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		No. RMSTP:REX/GH/C001
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
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Calculation

Dry the sample to constant weight (W_4 g).

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

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 VII

ASSAY

To the residue obtained in the test for loss on ignition, add 0.2 ml of sulphuric acid and sufficient ethanol (96 %) to moisten the residue completely. Add 6 ml of hydrofluoric acid and evaporate to dryness on a hot plate at 95°C-105°C, avoiding loss from sputtering. Wash the sides of the dish with 6 ml of hydrofluoric acid, evaporate to dryness in a well-ventilated hood. Ignite at 900±50°C. Allow the final residue to cool in a desiccator and weigh (W_4)

Calculation

$$\frac{\text{Difference between the residues (R1 - R2)}}{\text{Weight taken}} \times 100$$

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Designation	Executive QC	Sr. Executive QC	Manager QC
Signature			
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		No. RMSTP:REX/GH/C001
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	COLLOIDAL SILICON DIOXIDE BP	Review Period: 3 Years
	Item Code: REX/GH/C001	Effective Date: 16/03/2024

Where

W = Weight after ignition
R1 = Residue obtained in the test for loss on ignition
R2 = $W_4 - W_1$

The difference between the weight of the final residue **(R2)** and that of the residue obtained in the test for Loss on ignition **(R1)** represents the amount of SiO_2 in the amount of the substance taken for the test for Loss on ignition.

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No. RMSTP: REX/GH/C001
2	Revision No.: 01	Periodic Revision
3	Revision No.: 02	Periodic Revision

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		No. RMS: REX/GH/C002
	RAW MATERIAL SPECIFICATION	Revision No.: 02
Title:	CROSCARMELLOSE SODIUM BP	Review Period:3 Years
	Item Code: REX/GH/C002	Effective Date: 20/03/2024

GENERAL INFORMATION	
Molecular formula	NA
Molecular weight	NA
Pack details	10 kg packed in poly bags in fiber/HDPE drums or poly bags.
Storage conditions	Store in air tight container.
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

	Prepared by	Checked by	Approved By
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		No. RMS: REX/GH/C002
	RAW MATERIAL SPECIFICATION	Revision No.: 02
Title:	CROSCARMELLOSE SODIUM BP	Review Period:3 Years
	Item Code: REX/GH/C002	Effective Date: 20/03/2024

S.No.	TEST	LIMITS	METHOD
1	DESCRIPTION	White or greyish-white, hygroscopic powder.	Follow section I of Method of analysis
2	SOLUBILITY	Practically insoluble in acetone, in anhydrous ethanol and in toluene.	Follow section II of Method of analysis
3	IDENTIFICATION A. By Chemical B. By Chemical C. Test for sodium	 The sample absorbs methylene blue and settles as a blue, fibrous mass. A reddish-violet colour develops at the interface. A dense white precipitate is formed.	Follow section III of Method of analysis
4	pH	5.0 to 7.0	Follow section IV of Method of analysis
5	SODIUM CHLORIDE AND SODIUM GLYCOLLLATE Sum of percentage contents of sodium chloride and sodium glycollate.	NMT 0.5 %	Follow section V of Method of analysis
6	WATER SOLUBLE SUBSTANCES	NMT 10.0 %	Follow section VI of Method of analysis

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		No. RMS: REX/GH/C002
	RAW MATERIAL SPECIFICATION	Revision No.: 02
Title:	CROSCARMELLOSE SODIUM BP	Review Period:3 Years
	Item Code: REX/GH/C002	Effective Date: 20/03/2024

S.No.	TEST	LIMITS	METHOD
7	LOSS ON DRYING	NMT 10.0 % w/w	Follow section VIII of Method of analysis
8	SULFATED ASH	14.0 % - 28.0 %	Follow section IX of Method of analysis
9	MICROBIAL CONTAMINATION Total aerobic microbial count (TAMC) Total yeast and mold count (TYMC) Escherichia coli	 NMT 10^3 CFU/g NMT 10^2 CFU/g Must be absent	Follow section X of Method of analysis

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No.RMS: REX/GH/C002
2	Revision No.: 01	Periodic Revision
3	Revision No.: 02	Periodic Revision

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		No. RMSTP: REX/GH/C002
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	CROSCARMELLOSE SODIUM BP	Review Period:3 Years
	Item Code: REX/GH/C002	Effective Date: 20/03/2024

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 greyish-white, 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	Acetone	≥ 100	Practically insoluble
0.01	Anhydrous ethanol	≥ 100	Practically insoluble
0.01	Toluene	≥ 100	Practically insoluble

SECTION III

IDENTIFICATION

A. By Chemical

Mix 1 g of sample with 100 mL of methylene blue solution (4 ppm). Mix well and allow to stand. The sample absorbs methylene blue and settles as a blue, fibrous mass.

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B. By Chemical

Mix 1 g of sample with 50 mL of water. Transfer 1 mL to a test-tube and add 1 mL of water and 0.05 mL of a freshly prepared solution of 80 mg of α-napthol in 2 mL of methanol. Carefully add 2 mL of sulfuric acid down the side so that it forms a lower layer.

A reddish-violet colour develops at the interface.

C. Test for sodium

To the residue obtained in the test for sulfated ash, add 1 mL of hydrochloric acid and evaporate on a water bath. Dissolve the residue in 20 mL of water. To 2 mL of this solution, add 2 mL of 150 g/L solution of potassium carbonate and heat to boiling. No precipitate is formed. Add 4 mL of potassium pyroantimonate solution and heat to boiling. Allow the solution to attain room temperature and rub the inside of test-tube with a glass rod.

A dense white precipitate is formed.

SECTION IV

pH

Dissolve 1 g of sample in 100 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

SODIUM CHLORIDE AND SODIUM GLYCOLLATE

Sodium chloride

Weigh accurately about 5 g of sample in a 250 mL conical flask. Add 50 mL of water and 5 mL of strong hydrogen peroxide solution and heat on a water-bath for 20 min, stirring occasionally to ensure total hydration. Cool, add 100 ml of water and 10 mL of nitric acid. Titrate with 0.05 M silver nitrate determining the end-point potentiometrically using

a silver indicator electrode and a double-junction reference electrode containing a 100 g/L solution of potassium nitrate *R* in the outer jacket and a standard filling solution in the inner jacket, and stirring constantly.

1 mL of 0.05 M silver nitrate is equivalent to 2.922 mg of NaCl.

Sodium glycollate

Add 500 mg of the dried substance in a 100 mL beaker. Add 5 ml of glacial acetic acid and 5 mL of water and stir to ensure total hydration (about 15 min). Add 50 mL of acetone and 1 g of sodium chloride. Stir for several min to ensure complete precipitation of the carboxymethylcellulose. Filter through a fast filter paper impregnated with acetone into a volumetric flask, rinse the beaker and filter with 30 ml of acetone and dilute the filtrate to 100 mL with the same solvent. Allow to stand for 24 h without shaking. Use the clear supernatant to prepare the test solution.

Procedure

Preparation of reference solution

Dissolve 100 mg of glycolic acid previously dried in desiccator over diphosphorus pentoxide at room temperature in water and dilute to 100 mL with the same solvent. Use the solution within 30 days. Transfer 1 mL, 2 mL, 3 mL and 4 mL of the solution to four separate 100 mL volumetric flasks. To each flask, add 5 mL each of water and glacial acetic acid and dilute to 100 mL with acetone and mix.

Transfer 2 mL of the test solution and 2 mL of each reference solutions to separate 25 mL volumetric flasks. Heat the uncovered flasks for 20 min on a water- bath to eliminate acetone. Allow to cool and add 5 mL of 2, 7-dihydroxynaphthalene solution to each flask. Mix, add a further 15 mL of 2, 7-dihydroxynaphthalene solution and mix again. Close the flasks with aluminium foil and heat on a water- bath for 20 min. Cool and dilute to 25 mL with sulphuric acid.

Measure the absorbance of each solution at 540 nm. Prepare a blank using 2 mL of a solution containing 5 mL each of glacial acetic acid and water in 100 mL of acetone. Prepare a standard curve using the absorbances obtained with the reference solutions. From the standard curve and the absorbance of the test solution, determine the weight (a), in mg, of glycollic acid in the sample, and calculate the content of sodium glycollate from the expression:

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		No. RMSTP: REX/GH/C002
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	CROSCARMELLOSE SODIUM BP	Review Period:3 Years
	Item Code: REX/GH/C002	Effective Date: 20/03/2024

$$\frac{10 \times 1.29 \times a}{(100 - b)\, m}$$

Where

1.29 = the factor converting glycolic acid to sodium glycollate.
b = loss on drying as a percentage.
m = weight of the sample, in g.

SECTION VI

WATER SOLUBLE SUBSTANCES

Disperse 10 g of sample in 800 mL of water and stir for 1 min, every 10 min during the first 30 min. Allow to stand for 1 h and centrifuge, if necessary. Decant 200 mL of the supernatant liquid onto a fast filter paper in a vacuum filtration funnel. Apply vacuum and collect 150 mL of the filtrate. Evaporate to dryness and dry the residue at 100°C-105°C for 4 h.

SECTION VII

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 1.000 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 by placing in a hot air oven at 105°C for 6 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 (%) = $\frac{W_2-W_4}{W_2-W_1} \times 100$

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 VIII

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.

Calculation

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

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Date	20/03/2024	20/03/2024	20/03/2024
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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 IX

MICROBIAL CONTAMINATION

Refer SOP no. QCMB/006

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No. RMSTP: REX/GH/C002
2	Revision No.: 01	Periodic Revision
3	Revision No.: 02	Periodic Revision

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	RAW MATERIAL SPECIFICATION	No. RMS: REX/GH/S001
Title:	SODIUM STARCH GLYCOLATE BP	Revision No.: 01
	Item Code: REX/GH/S001	Review Period:3 Years
		Effective Date: 16\03\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	15 g
Quantity of reserve sample	70 g
Quantity of sample required 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
Signature			
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		No. RMS: REX/GH/S001
	RAW MATERIAL SPECIFICATION	Revision No.: 01
Title:	SODIUM STARCH GLYCOLATE BP	Review Period:3 Years
	Item Code: REX/GH/S001	Effective Date: 16/03/2024

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
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

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		No. RMS: REX/GH/S001
	RAW MATERIAL SPECIFICATION	Revision No.: 01
Title:	SODIUM STARCH GLYCOLATE BP	Review Period:3 Years
	Item Code: REX/GH/S001	Effective Date: 16/03/2024

S. No.	TEST	LIMITS	METHOD
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/GH/S001

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	RAW MATERIAL STANDARD TEST PROCEDURE	No.RMSTP:REX/GH/S001
Title:	SODIUM STARCH GLYCOLATE BP	Revision No.: 01
	Item Code: REX/GH/S001	Review Period: 3 Years
		Effective Date: 16/03/2024

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.
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.

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.

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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 500 g/l 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.

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.

Reference solution

Dissolve 0.310 g of glycollic acid, previously dried in desiccator 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 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 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).

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).
W4 = Weight of empty weighing bottle + sample in g (after drying-II).

SECTION X

ASSAY (By Potentiometry)

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 2.299 g of Na.

Calculation

$$= \frac{(Vs - Vb) \times \text{Molarity factor of 0.1M perchloric acid} \times 2.299 \times 100}{\text{Weight sample taken in mg}}$$

Where

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

SECTION XI

MICROBIAL CONTAMINATION

Refer to SOP No. QCMB/006.

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No. RMSTP: REX/GH/S001
2	Revision No.: 01	Periodic revision

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Designation	Executive QC	Sr. Executive QC	Manager QC
Signature			
Date	16/03/2024	16/03/2024	16/03/2024
Department: Quality Control		Date of Issue: 16/03/2024	

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		No.RMS: REX/GH/M001
	RAW MATERIAL SPECIFICATION	Revision No.: 01
Title:	MAGNESIUM STEARATE BP	Review Period:2 Years
	Item Code: REX/GH/M001	Effective Date: 25/07/2022

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	40 g
Sampling Instructions	SOP No.: QCGN/018
Retest period	12 months

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Signature	M. Bhy.		
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Title:	MAGNESIUM STEARATE BP	Review Period:2 Years
	Item Code: REX/GH/M001	Effective Date: 25/07/2022

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	NMT 10 ppm	Follow section VII of Method of analysis
8	NICKEL	NMT 5 ppm	Follow section VIII of Method of analysis
9	CADMIUM	NMT 3 ppm	Follow section IX of Method of analysis

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S.No.	TEST	LIMIT	METHOD
10	LOSS ON DRYING	NMT 6.0 %	Follow section X of Method of analysis
11	ASSAY - Magnesium - Stearic acid and Palmitic acid	 4.0 % - 5.0 % (on dried basis) 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

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Title:	MAGNESIUM STEARATE BP	Review Period:2 Years
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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

A. Freezing point

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 (Solution S).

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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.

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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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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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)

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 8 M 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.

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.

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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.

Instrument conditions

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

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)
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 8 M nitric acid for 30 min and by rinsing with deionised water.

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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.

Instrument conditions

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

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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SECTION IX

CADMIUM
(By atomic absorption spectrometry)

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

Test solution

Place 100 mg 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

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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).

Instrument conditions

Source	Cadmium hollow-cathode lamp
Wavelength	228.8 nm
Atomisation device	Furnace
Platform	Pyrolytically coated with integrated tube.

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 500 mg 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 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.

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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)

Preparation of test solution

In a conical flask fitted with a reflux condenser, dissolve 100 mg 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 100 mg 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.

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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

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

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. QCGN/006

HISTORY

S. No.	Revision Number	Reason for Revision
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