Periodic Revision done: Rf 04/01/2025

Format No.: F/QCGN/041/01

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

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

	Prepared by	**Checked by**	**Approved By**
Designation	**Executive QC**	**Sr.Executive QC**	**Manager QC**
Signature			Rf
Date	05/01/2023	05/01/2023	05/01/2023
Department: Quality Control		**Date of Issue:** 05/01/2023	

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

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

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

S. No.	TEST	LIMITS	METHOD
11	MICROBIAL CONTAMINATION - 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 Must be absent Must be absent Must be absent Must be 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/M010
2	Revision No.: 01	Periodic Revision

END OF DOCUMENT

	Prepared by	Checked by	Approved By
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Periodic Revision done: | 05/01/2023

Format No.: F/QCGN/041/02

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 6 No.: RMSTP: REX/SP/M010
	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

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

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

B. Reaction with iodinated zinc chloride solution

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

C. Degree of polymerisation

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

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

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

where
t_2 (k_2)
k_2 = viscometer constant.

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

$$v_1 / v_2$$

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

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

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

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

SECTION IV

SOLUBILITY

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

SECTION V

pH

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

SECTION VI

CONDUCTIVITY

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

Periodic Revision done: 04/01/2026

Format No.: F/QCGN/041/02

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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Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
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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).

Periodic Revision done: 04/01/2023

Format No.: F/QCGN/041/02

SECTION XI

MICROBIAL CONTAMINATION

Refer general SOP No.QCMB/006.

HISTORY

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

END OF DOCUMENT

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
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Periodic Revision done by: 04/01/2026

Approved by QA: 04/01/2025

Effective Date: 04/01/2025

Next Review: 03/01/2028

Revision Number: 02

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SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S.No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009	Page 1 of 3
		No. RMS: RAI/SP/C005
	RAW MATERIAL SPECIFICATION	Revision No.: 02
Title:	CALCIUM CARBONATE IP	Review Period: 3 Years
	Item Code: RAI/SP/C005	Effective Date: 12/09/2024

GENERAL INFORMATION	
Molecular formula	$CaCO_3$
Molecular weight	100.1
Pack container requirement	50 kg in HDPE bag.
Storage conditions	Store in a cool and dry place.
Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
Quantity of sample required for analysis	15 g
Quantity of reserve sample	30 g
Sampling Instructions	SOP No.: QCGN/018
Retest period	12 months

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature	K.D	M.M.F	BJ
Date	12/09/2024	12/09/2024	12/09/2024
Department: Quality Control		Date of Issue: 12/09/2024	

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		No. RMS: RAI/SP/C005
	RAW MATERIAL SPECIFICATION	Revision No.: 02
Title:	CALCIUM CARBONATE IP	Review Period: 3 Years
	Item Code: RAI/SP/C005	Effective Date: 12/09/2024

S. No.	TEST	LIMITS	METHOD
1	DESCRIPTION	A fine, white, microcrystalline powder.	Follow Section I of method of analysis
2	SOLUBILITY	Slightly soluble in water containing carbon dioxide or any ammonium salt; practically insoluble in water and in ethanol (95%). It is soluble with effervescence in dilute acids.	Follow Section II of method of analysis
3	IDENTIFICATION A. Test for calcium salts B. Test for carbonates	 a) A white crystalline precipitate is formed. b) A white precipitate is obtained. A white precipitate is formed that dissolves on addition of an excess of dilute hydrochloric acid.	Follow Section III of method of analysis
4	SUBSTANCES INSOLUBLE IN ACETIC ACID	NMT 0.2 %	Follow Section IV of method of analysis
5	ARSENIC	NMT 4 ppm	Follow Section V of method of analysis
6	HEAVY METALS (Method A)	NMT 20 ppm	Follow Section VI of method of analysis
7	BARIUM	The solution remains clear for NLT 15 min.	Follow Section VII of method of analysis
8	IRON	NMT 200 ppm	Follow Section VIII of method of analysis

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature	K.S	M.M	RS
Date	12/09/2024	12/09/2024	12/09/2024
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		No. RMS: RAI/SP/C005
	RAW MATERIAL SPECIFICATION	Revision No.: 02
Title:	CALCIUM CARBONATE IP	Review Period: 3 Years
	Item Code: RAI/SP/C005	Effective Date: 12/09/2024

S. No.	TEST	LIMITS	METHOD
9	MAGNESIUM AND ALKALI METALS	NMT 1.0 %	Follow Section IX of method of analysis
10	CHLORIDES	NMT 250 ppm	Follow Section X of method of analysis
11	SULPHATES	NMT 0.3 %	Follow Section XI of method of analysis
12	LOSS ON DRYING (1.0 g/200°C)	NMT 2.0 %	Follow Section XII of method of analysis
13	ASSAY(on dried basis) (By Titrimetry)	98.0% - 100.5%	Follow Section XIII of method of analysis

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No.RMS: RAI/SP/C005
2	Revision No.: 01	Periodic revision
3	Revision No.: 02	Periodic revision

END OF DOCUMENT

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature	K.S	M.M	RS
Date	12/09/2024	12/09/2024	12/09/2024
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		No. RMSTP: RAI/SP/C005
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	CALCIUM CARBONATE IP	Review Period: 3 Years
	Item Code: RAI/SP/C005	Effective Date: 12/09/2024

METHOD OF ANALYSIS

SECTION I

DESCRIPTION

By Physical observation:

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

A fine, white, microcrystalline 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	≥ 100	Practically insoluble
0.01	Ethanol (95%)	≥ 100	Practically insoluble
0.01	Any ammonium salts	1 to 10	Slightly soluble
1.0	Dilute acids	10 to 30	Soluble

SECTION III

IDENTIFICATION

A. Test for calcium salts

Preparation of solution A
Accurately weigh and transfer about 5 g of the sample to a 100 mL volumetric flask. Add 80 mL of 2M acetic acid. When effervescence ceases, boil the solution for 2 min, allow to cool. Make up to the volume with 2M acetic acid and filter. If necessary, through a sintered-glass filter reserving any residue for the test for substances insoluble in acetic acid.

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Signature	K.S	M.M	RJ
Date	12/09/2024	12/09/2024	12/09/2024
Department: Quality Control		Date of Issue: 12/09/2024	

a). To 0.2 mL of filtrate, add i mL of glacial acetic acid and 0.5 mL of potassium ferrocyanide solution, the solution remains clear. Add about 50 mg of ammonium chloride.

A white crystalline precipitate is formed.

b) To 0.2 mL of filtrate, add 0.2 mL of a 2 % w/v solution of ammonium oxalate.

A white precipitate is obtained that is only sparingly soluble in dilute acetic acid but is soluble in hydrochloric acid.

B. Test for carbonates

Suspend 0.1 g of sample in a test tube in 2 mL of water. Add 2 mL of 2M acetic acid and close the tube immediately using a stopper fitted with a glass tube bent at two right-angles, heat gently and collect the gas in 5 mL of 0.1 M barium hydroxide.

A white precipitate is formed that dissolves on addition of an excess of dilute hydrochloric acid.

SECTION IV

SUBSTANCES INSOLUBLE IN ACETIC ACID

Wash any residue obtained in Identification test A with four quantities, each of 5 mL of hot water and dry at 100°C for 1 h. The residue weighs not more than 10 mg.

SECTION V

ARSENIC

Dissolve 2.5 g of sample in 15 mL of brominated hydrochloric acid and 45 mL of water. Remove the excess of bromine with few drops of stannous chloride AsT. Introduce this solution into the bottle or conical flask. Add 5 mL of 1M potassium iodide and 10 g of zinc AsT. Immediately assemble the apparatus (refer current IP) and immerse the flask in a water bath at a temperature such that the uniform evolution of gas is maintained. After 40 min any stain produced on the mercuric chloride paper is not more intense than that obtained by treating in the same manner 1 mL of arsenic standard solution (10 ppm As) diluted to 50 mL with water.

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		No. RMSTP: RAI/SP/C005
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	CALCIUM CARBONATE IP	Review Period: 3 Years
	Item Code: RAI/SP/C005	Effective Date: 12/09/2024

SECTION VI

HEAVY METALS (Method A)

Preparation of standard solution
Into a 50 mL Nessler cylinder, pipette 1 mL of standard lead solution (20ppm of Pb) and dilute with water to 25 mL. Adjust the pH between 3.0 to 4.0 with dilute acetic acid or dilute ammonia solution and dilute the solution with water to 35 mL and mix.

Preparation of test solution
To 1 g of the sample, add 5 ml of water, and 8 mL of dilute hydrochloric acid, the latter being added slowly, shake and evaporate to dryness on a water-bath. Dissolve the residue in 20 mL of water, filter, and add to the filtrate 3 mL of dilute acetic acid and water to make 25 mL. Transfer to a 50 mL Nessler cylinder. Adjust the pH between 3.0 to 4.0 with dilute acetic acid or dilute ammonia solution and dilute the solution with water to 35 mL and mix.

Procedure
To each of the cylinders containing the standard solution and the test solution respectively, add 10 mL of freshly prepared hydrogen sulphide solution, dilute with water to 50 mL, mix, allow to stand for 5 min and view downwards over a white surface.

The color of the test solution is not more intense than that of the standard solution.

SECTION VII

BARIUM

Dissolve 0.6 g of the sample in 10 mL of 2Macetic acid by boiling, cool and add 10 mL of calcium sulphate solution. The solution remains clear for not less than 15 minutes.

SECTION VIII

IRON

Dissolve 0.2 g of the sample in 5 mL of water and 0.5 mL of iron free hydrochloric acid, boil and dilute to 40 mL

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

with water. Transfer the solution to a Nessler cylinder. Add 2 mL of a 20% w/v solution of iron-free citric acid and 0.1 mL of thioglycollic acid. Mix well and make alkaline with iron free ammonia solution, dilute to 50 mL with water and allow to stand for 5 min.

Any colour produced is not more than that obtained by treating in the same manner 2.0 mL of iron standard solution (20 ppm Fe) in place of the sample solution

SECTION IX

MAGNESIUM AND ALKALI METALS

Dissolve 1.0 g of sample in 10 mL of dilute hydrochloric acid, neutralize the solution by adding dilute ammonia solution, heat the solution to boiling and add 50 mL of hot ammonium oxalate solution. Cool, dilute to 100 mL with water and filter. To 50 mL of the filtrate add 1.5 mL of dilute sulphuric acid, evaporate to dryness on a water-bath, heat the residue to redness, allow to cool and weigh. The residue weighs not more than 5mg.

SECTION X

CHLORIDES

Weigh accurately about 1.0 g of the sample, dissolve it in water by the addition of 3 mL of nitric acid and transfer to a Nessler cylinder, dilute to 50 mL with water. Add 1 mL of 0.1M silver nitrate. Stir immediately with a glass rod and allow to stand for 5 min protected from light.

When viewed transversely against a black background any opalescence produced is not more intense than that obtained by treating a mixture of 10.0 mL of chloride standard solution (25 ppm Cl) and 5 mL of water in the same manner.

SECTION XI

SULPHATES

Note: Solutions should be prepared with distilled water.

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature	K. D	M.M	PP
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		No. RMSTP: RAI/SP/C005
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	CALCIUM CARBONATE IP	Review Period: 3 Years
	Item Code: RAI/SP/C005	Effective Date: 12|09|2024

Preparation of sample solution
Suspend 50 mg of the sample in 5 mL of water and add dropwise sufficient dilute hydrochloric acid to effect solution. Add 2 mL of dilute hydrochloric acid.

Procedure
To 1 mL of a 25 % w/v solution of barium chloride in a Nessler cylinder, add 1.5 mL of ethanolic sulphate standard solution (10 ppm SO_4), mix and allow to stand for 1 min. Add 15 mL of the sample solution in 15 mL of water and 0.15 mL of 5 Macetic acid. Add sufficient water to produce 50 mL, stir immediately with a glass rod and allow to stand for 5 min. When viewed transversely against a black background any opalescence produced is not more intense than that obtained by treating in the same manner, 15 mL of sulphate standard solution (10 ppm SO_4) in place of the solution under examination.

SECTION XII

LOSS ON DRYING

Weigh a glass-stoppered, shallow weighing bottle that has been previously dried in a hot air oven at 200°C for 30 min (W_1 g). Transfer to the bottle about 1 g of sample and distribute the sample evenly by gentle sidewise shaking. Weigh the bottle and the sample (W_2 g). Dry the loaded weighing bottle by placing in a hot air oven at 200°C, with its lid opened. After drying is completed, remove the weighing bottle from the oven and close the bottle properly. Allow it to cool to room temperature in a desiccator. Weigh the bottle and sample (W_3 g).

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

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

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).

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature	K.D	M.M	PJ
Date	12|09|2024	12|09|2024	12|09|2024
Department: Quality Control		Date of Issue: 12|09|2024	

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	RAW MATERIAL STANDARD TEST PROCEDURE	No. RMSTP: RAI/SP/C005
Title:	CALCIUM CARBONATE IP	Revision No.: 02
	Item Code: RAI/SP/C005	Review Period: 3 Years
		Effective Date: 12/09/2024

SECTION XIII

ASSAY

Weigh accurately about 0.1 g of the sample. Dissolve in 3 mL of dilute hydrochloric acid and 10 mL of water. Boil for 10 min, cool, dilute to 50 mL with water. Titrate with 0.05 M disodium edetate to within a few mL of the expected end-point, add 8 mL of sodium hydroxide solution and 0.1 g of calcon mixture and continue the titration until the colour of the solution changes from pink to a full blue colour.

1 mL of 0.05M disodium edetate is equivalent to 0.005004 g of $CaCO_3$.

Calculation

$$\text{Assay (\%) (on dried basis)} = \frac{(Vs - Vb) \times M \times 0.005004}{W} \times \frac{100}{(100 - LOD)} \times 100$$

Where

Vs = Volume consumed for sample (mL)
Vb = Volume consumed for blank (mL)
M = Molarity factor of disodium edetate
LOD = Percent loss on drying of sample
W = Sample weight (g)

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No. RMSTP: RAI/SP/C005
2	Revision No.: 01	Periodic Revision
3	Revision No.: 02	Periodic Revision

END OF DOCUMENT

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature	K.Ø	M.M.T	Rf
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		No.RMS: REX/SP/L004
	RAW MATERIAL SPECIFICATION	**Revision No.: 02**
	LACTOSE DCL-11 BP	**Review Period:3 Years**
Title:	**Item Code: REX/SP/L004**	**Effective Date:** 22/11/2024

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

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		No.RMS: REX/SP/L004
	RAW MATERIAL SPECIFICATION	Revision No.: 02
Title:	LACTOSE DCL-11 BP	Review Period:3 Years
	Item Code: REX/SP/L004	Effective Date: 22/11/2024

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

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	RAW MATERIAL SPECIFICATION	Revision No.: 02
	LACTOSE DCL-11 BP	Review Period:3 Years
Title:	Item Code: REX/SP/L004	Effective Date: 22/11/2024

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

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

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No.RMS: REX/SP/L004
2	Revision No.: 01	Periodic Revision
3	Revision No.: 02	Refer to Change control No.CC/24/123

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		No.RMSTP: REX/SP/L004
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	LACTOSE DCL-11 BP	Review Period: 3 Years
	Item Code: REX/SP/L004	Effective Date: 22/11/2024

METHOD OF ANALYSIS

SECTION I

DESCRIPTION

By physical observation.

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

White or almost white, crystalline powder.

SECTION II

SOLUBILITY

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

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

SECTION III

IDENTIFICATION

A. By IR

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

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

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		No.RMSTP: REX/SP/L004
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Title:	LACTOSE DCL-11 BP	Review Period: 3 Years
	Item Code: REX/SP/L004	Effective Date: 22/11/2024

B. By TLC

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

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

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

Plate TLC silica gel plate.

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

Application 2 µL; thoroughly dry the points of application.

Development A Over 3/4 of the plate.

Drying *A* In a current of warm air.

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

Drying B In a current of warm air.

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

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

C. By Chemical

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

A red color develops.

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D. WATER See section IX.

SECTION IV

APPEARANCE OF SOLUTION

Preparation of solution S

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

Clarity of solution

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

Color of solution

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

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

Preparation of reference solution BY_7

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

Preparation of standard solution BY

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

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	RAW MATERIAL STANDARD TEST PROCEDURE	No.RMSTP: REX/SP/L004
Title:	LACTOSE DCL-11 BP	Revision No.: 02
	Item Code: REX/SP/L004	Review Period: 3 Years
		Effective Date: 22/11/2024

Preparation of yellow solution

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

Preparation of red solution

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

Preparation of blue solution

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

SECTION V

ACIDITY OR ALKALINITY

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

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

SECTION VI

SPECIFIC OPTICAL ROTATION (anhydrous substance).

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

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	RAW MATERIAL STANDARD TEST PROCEDURE	No.RMSTP: REX/SP/L004
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	Item Code: REX/SP/L004	Review Period: 3 Years
		Effective Date: 22/11/2024

Calculation

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

Where

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

SECTION VII

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

Preparation of test solution (a)

Solution S

Preparation of test solution (b)

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

Procedure

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

Results:

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

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Signature			
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Department: Quality Control		Date of Issue: 22/11/2024	

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		No.RMSTP: REX/SP/L004
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	LACTOSE DCL-11 BP	Review Period: 3 Years
	Item Code: REX/SP/L004	Effective Date: 22/11/2024

SECTION VIII

WATER

Standardization of KF reagent

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

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

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

Procedure

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

Calculation

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

SECTION IX

SULPHATED ASH

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

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

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

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

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

SECTION X

MICROBIAL CONTAMINATION

Refer general SOP no. QCMB/006.

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No. RMSTP: REX/SP/L004
2	Revision No.: 01	Periodic Revision
3	Revision No.: 02	Refer to Change control No.CC/24/123

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	RAW MATERIAL SPECIFICATION	No. RMS: REX/SP/C008
Title:	CROSCARMELLOSE SODIUM BP	Revision No.: 03
	Item Code: REX/SP/C008	Review Period: 3 Years
		Effective Date: 22/11/2024

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

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	RAW MATERIAL SPECIFICATION	No. RMS: REX/SP/C008
Title:	CROSCARMELLOSE SODIUM BP	Revision No.: 03
	Item Code: REX/SP/C008	Review Period: 3 Years
		Effective Date: 22/11/2024

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 IR B. By Chemical C. Test for sodium	 The IR absorption spectrum of sample should be concordant with the spectrum obtained with Croscarmellose sodium working standard. The sample absorbs methylene blue and settles as a blue, fibrous mass. 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	SETTLING VOLUME	10.0 mL to 30.0 mL	Follow section V of Method of analysis
6	SODIUM CHLORIDE AND SODIUM GLYCOLLLATE (dried substance)	NMT 0.5 %	Follow section VI of Method of analysis
7	WATER SOLUBLE SUBSTANCES (dried substance)	NMT 10.0 %	Follow section VII of Method of analysis

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	RAW MATERIAL SPECIFICATION	No. RMS: REX/SP/C008
Title:	CROSCARMELLOSE SODIUM BP	Revision No.: 03
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S.No.	TEST	LIMITS	METHOD
8	LOSS ON DRYING (1.0g/105°/6h)	NMT 10.0 % w/w	Follow section VIII of Method of analysis
9	SULFATED ASH	14.0 % - 28.0 %	Follow section IX of Method of analysis
10	ASSAY - DEGREE OF SUSTITUTION (A+S) (Dried substance) By Titration	0.60-0.85	Follow section X of Method of analysis
11	MICROBIAL CONTAMINATION - Total aerobic microbial count (TAMC) - Total yeast and mould count (TYMC) - Escherichia coli	 NMT 10^3 CFU/g NMT 10^2 CFU/g Must be 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/C008
2	Revision No.: 01	Periodic Revision
3	Revision No.: 02	Periodic Revision
4	Revision No.: 03	Refer to Change control No.CC/24/123

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	RAW MATERIAL STANDARD TEST PROCEDURE	No. RMSTP: REX/SP/C008
Title:	CROSCARMELLOSE SODIUM BP	Revision No.: 03
	Item Code: REX/SP/C008	Review Period: 3 Years
		Effective Date: 22/11/2024

METHOD OF ANALYSIS

SECTION I

DESCRIPTION

By Physical Observation

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

White or 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. IR

Depending on the degree of substitution, the intensity of the absorption band at about 1750 cm^{-1} may vary.

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. 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.

C. Test for sodium

To the residue obtained in the test for sulfated ash, in 2 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 for 5 min. Immerse the cleaned electrode of pH meter into the test solution. Measure the value of pH which is displayed on pH meter.

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	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 03
Title:	CROSCARMELLOSE SODIUM BP	Review Period: 3 Years
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SECTION V

SETTLING VOLUME

Place 75 mL of water in a 100 mL graduated cylinder and add 1.5 g of the substance to be examined in 0.5 g portions, shaking vigorously after each addition. Dilute to 100 mL with water and shake again until the substance is homogeneously distributed. Allow to stand for 4 h.

SECTION VI

SODIUM CHLORIDE AND SODIUM GLYCOLLATE (Dried substance)

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.

Preparation of reference solution

Dissolve 100 mg of glycolic acid previously dried in vacuum over diphosphorus pentoxide in water and dilute to

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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:

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

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 VII

WATER SOLUBLE SUBSTANCES (Dried substance)

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.

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SECTION VIII

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).

Calculation

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

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

SECTION IX

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 X

ASSAY – DEGREE OF SUBSTITUTION

Place 1.000 g in a 500 mL conical flask, add 300 mL of a 100 g/L solution of sodium chloride and 25.0 mL of 0.1 M sodium hydroxide, stopper the flask and allow to stand for 5 min, shaking occasionally. Add 0.25 mL of m-cresol purple solution and about 15 mL of 0.1 M hydrochloric acid from a burette. Insert the stopper and shake. If the solution is violet, add 0.1 M hydrochloric acid in 1 mL portions until the solution becomes yellow, shaking after each addition. Titrate with 0.1 M sodium hydroxide until the colour turns to violet.

Calculate the number of mill equivalents (M) of base required to neutralise the equivalent of 1 g of dried substance.

Calculate the degree of acid carboxymethyl substitution (A) using the following expression:

1150M / (7102-412M-80C)

C= Sulphated ash as a percentage.

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Calculate the degree of sodium carboxymethyl substitution (S) using the following expression:

(162+58A)C / (7102-80C)

The degree of substitution is the sum of A and S.

SECTION XI

MICROBIAL CONTAMINATION

Refer QC SOP: QCMB/006

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No. RMSTP: REX/SP/C008
2	Revision No.: 01	Periodic Revision
3	Revision No.: 02	Periodic Revision
4	Revision No.: 03	Refer to Change control No.CC/24/123

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		No. RMS: REX/SP/C022
	RAW MATERIAL SPECIFICATION	**Revision No.: 01**
Title:	**COLLOIDAL SILICON DIOXIDE BP**	**Review Period: 3 Years**
	Item Code: REX/SP/C022	**Effective Date:** 21/11/2023

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	30 g
Quantity of reserve sample	60 g
Sampling Instructions	SOP No.: QCGN/018
Retest period	24 months

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		No. RMS: REX/SP/C022
	RAW MATERIAL SPECIFICATION	**Revision No.: 01**
Title:	**COLLOIDAL SILICON DIOXIDE BP**	**Review Period: 3 Years**
	Item Code: REX/SP/C022	**Effective Date:** 21/11/2023

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/SP/C022
2	Revision No.: 01	Periodic Revision

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Title:	COLLOIDAL SILICON DIOXIDE BP	Review Period: 3 Years
	Item Code: REX/SP/C022	Effective Date: 21/11/2023

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, 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	≥ 100	Practically insoluble
1.0	Alkali hydroxides.	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.

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

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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

Pre ignite a silica crucible at 900±50°C for 10 minutes, cool to room temperature in a desiccator. Weigh the empty crucible (W_1 g). Transfer approximately 200 mg of sample to the crucible and reweigh it, (W_2 g). Ignite, gently for 2 h. Cool the crucible in a desiccator and reweigh (W_3 g).

Calculation

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

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

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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, weigh (W_4)

Calculation

W_4 = 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.

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

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No. RMSTP: REX/SP/C022
2	Revision No.: 01	Periodic Revision

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		No. RMS: REX/SP/P017
	RAW MATERIAL SPECIFICATION	Revision No.: 00
Title:	PURIIFIED TALC BP	Review Period: 2 Years
	Item Code: REX/SP/P017	Effective Date: 24/08/2023

GENERAL INFORMATION	
Molecular formula	$Mg_3Si_4O_{10}(OH)_2$
Molecular weight	379.3
Pack details	25kg or 50 kg packed in poly bags in poly sac
Storage conditions	Store protected from moisture.
Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
Quantity of sample required for chemical analysis	30 g
Quantity of sample required for microbiological analysis	20 g
Quantity of reserve sample	40 g
Sampling Instructions	SOP No. QCGN/018
Retest period	12 months

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		No. RMS: REX/SP/P017
	RAW MATERIAL SPECIFICATION	Revision No.: 00
Title:	PURIIFIED TALC BP	Review Period: 2 Years
	Item Code: REX/SP/P017	Effective Date: 24/08/2023

S.No.	TEST	LIMITS	METHOD
1.	APPEARANCE	Light, homogeneous, white or almost white powder, greasy to the touch (non-abrasive).	Follow section I of method of analysis
2.	SOLUBILITY	Practically insoluble in water, in ethanol (96%) and in dilute solutions of acids and alkali hydroxides.	Follow section II of method of analysis
3.	IDENTIFICATION* A. By IR B. By Chemical C. Test for Silicates	 The IR absorption spectrum of the sample shows absorption bands at 3677±2 cm^{-1}, 1018±2cm^{-1} and 669±2cm^{-1}. A white crystalline precipitate is formed. Within a short time, a white ring is rapidly formed around the drop of the water.	Follow section III of method of analysis
4.	ACIDITY OR ALKALINITY	Not more than 0.4 mL of 0.01 M hydrochloric acid is required to change the color of the indicator to green. Not more than 0.3 mL of 0.01 M sodium hydroxide is required to change the color of the indicator to pink.	Follow section IV of method of analysis
5.	WATER SOLUBLE SUBSTANCES	Maximum 0.2 %	Follow section V of method of analysis
6.	ALUMINIUM	Maximum 2.0 %	Follow section VI of method of analysis
7.	CALCIUM	Maximum 0.9 %	Follow section VII of method of analysis
8.	IRON	Maximum 0.25 %	Follow section VIII of method of analysis
9.	LEAD	Maximum 10 ppm	Follow section IX of method of analysis
10.	MAGNESIUM	17.0 % - 19.5 %	Follow section X of method of analysis

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S.No.	TEST	LIMITS	METHOD
11.	LOSS ON IGNITION	Maximum 7.0 %	Follow section XI of method of analysis
12.	MICROBIAL CONTAMINATION If intended for oral administration - Total aerobic microbial count (TAMC) - Total yeast and mould count (TYMC)	 NMT 10^3 CFU/g NMT 10^2 CFU/g	Follow section XII of method of analysis

*First identification: A
Second identification: B,C

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No.RMS: REX/SP/P017

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		No.RMSTP: REX/SP/P017
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 00
Title:	PURIFIED TALC BP	Review Period: 2 Years
	Item Code: REX/SP/P017	Effective Date: 24/08/2023

METHOD OF ANALYSIS

SECTION I

DESCRIPTION

By physical observation.

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

Light, homogeneous, white or almost white powder, greasy to the touch (non-abrasive).

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	Ethanol (96%)	≥ 100	Practically insoluble
0.01	Dilute solution of acids	≥ 100	Practically insoluble
0.01	Dilute solution of Alkali hydroxides	≥ 100	Practically insoluble

SECTION III

IDENTIFICATION

A. By IR

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

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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. By Chemical

In a platinum crucible, melt a mixture of 0.2 g of anhydrous sodium carbonate and 2.0 g of potassium carbonate. To the melted mass, add 0.1 g of the substance to be examined and heat until the mixture is completely melted. Allow to cool and transfer the melted mass into an evaporating dish with 50 ml of hot water. Add hydrochloric acid until effervescence ceases. Add 10 ml of hydrochloric acid and evaporate to dryness on a water-bath. Allow to cool. Add 20 ml of water, heat to boiling and filter. (The residue is used for identification test C). To 5 ml of the filtrate add 1 ml of ammonia and 1 ml of ammonium chloride solution and filter. To the filtrate add 1 ml of disodium hydrogen phosphate solution.

A white, crystalline precipitate is formed.

C. Test for Silicates

Mix the residue obtained in Identification test B in a lead or platinum crucible by means of a copper wire with about 10 mg of sodium fluoride and a few drops of sulfuric acid to give a thin slurry. Cover the crucible with a thin, transparent plate of plastic under which a drop of water is suspended and warm gently.

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

SECTION IV

ACIDITY OR ALKALINITY

Boil 2.5 g of sample with 50 ml of carbon dioxide free water under reflux. Filter in vacuum. To 10 ml of the filtrate, add 0.1 ml of bromothymol blue solution.

Not more than 0.4 mL of 0.01 M hydrochloric acid is required to change the color of the indicator to green.

To 10 mL of the filtrate, add 0.1 mL of phenolphthalein solution.

Not more than 0.3 mL of 0.01 M sodium hydroxide is required to change the color of the indicator to pink.

SECTION V

WATER SOLUBLE SUBSTANCES

Add 50 mL of carbon dioxide free water to 10 g of sample. Heat to boiling and maintain boiling under a reflux condenser for 30 min. Allow the solution to attain room temperature. Filter and dilute to 50 mL with carbon dioxide free water. Take 25 mL of the filtrate, evaporate to dryness and heat at 105°C with carbon dioxide free water. Take 25 mL of the filtrate, evaporate to dryness and heat at 105°C for 1 h. The residue weighs a maximum of 10 mg.

Calculation

$$\frac{\text{Weight of the residue}}{\text{Weight of the sample}} \times 100$$

SECTION VI

ALUMINIUM (By Atomic Absorption Spectrometry)

Instrument conditions

Source	Aluminium hollow-cathode lamp
Wavelength	309.3 nm
Atomization device	Nitrous oxide-acetylene flame

Preparation of solution S1

Weigh 10 g of sample into a conical flask fitted with a reflux condenser, gradually add 50 mL of 0.5 M hydrochloric acid while stirring and heat on a water-bath for 30 min. Allow to cool. Transfer the mixture to a beaker and allow the undissolved material to settle. Filter the supernatant through medium-speed filter paper into a 100 mL volumetric flask, retaining as much as possible of the insoluble material in the beaker. Wash the residue and the beaker with 3

quantities, each of 10 mL of hot water. Wash the filter with 15 mL of hot water, allow the filtrate to cool and dilute to 100.0 mL with the same solvent.

Preparation of solution S2

Perchlorates mixed with heavy metals are known to be explosive. Take proper precautions while performing this procedure. Weigh 500 mg of sample in a 100 mL polytetrafluoroethylene dish. Add 5 mL of hydrochloric acid, 5 mL of lead-free nitric acid and 5 mL of perchloric acid. Stir gently then add 35 mL of hydrofluoric acid and evaporate slowly to dryness on a hot plate. To the residue, add 5 mL of hydrochloric acid, cover with a watch-glass, heat to boiling and allow to cool. Rinse the watch-glass and the dish with water. Transfer into a volumetric flask, rinse the dish with water and dilute to 50 mL with the same solvent.

Test solution

Add 10 mL of 25.34 g/L caesium solution to 5 mL of solution S2. Add 10 mL of hydrochloric acid and dilute to 100 mL with water.

Reference solution

Into 4 identical volumetric flasks, each containing 10 mL of hydrochloric acid, add 10 mL of 25.34 g/L solution of caesium chloride. Introduce 5 mL, 10 mL, 15 mL and 20 mL of aluminium standard solution (100 ppm Al) respectively and dilute to 100 mL with water.

SECTION VII

CALCIUM (By Atomic Absorption Spectrometry)

Instrument conditions

Source	Calcium hollow-cathode lamp
Wavelength	422.7 nm
Atomization device	Nitrous oxide-acetylene flame
Correction	Deuterium lamp

Test solution

To 5 mL of solution S2, add 10 mL each of hydrochloric acid and lanthanum chloride solution and dilute to 100 mL with water.

Reference solutions

Into 4 identical volumetric flasks, each containing 10 mL of hydrochloric acid and 10 mL of lanthanum chloride solution, introduce 1 mL, 2 mL, 3 mL, 4 mL and 5 mL of calcium standard solution (100 ppm Ca) respectively and dilute to 100 mL with water.

SECTION VIII

IRON (By Atomic Absorption Spectrometry)

Instrument conditions

Source	Iron hollow-cathode lamp
Wavelength	248.3 nm
Atomization device	Air-acetylene flame
Correction	Deuterium lamp

Test solution

To 2.5 mL of solution S1, add 50 mL of 0.5 M hydrochloric acid and dilute to 100 mL with water.

Reference solutions

Into 4 identical volumetric flasks, each containing 50 mL of 0.5 M hydrochloric acid, introduce 2 mL, 2.5 mL, 3 mL and 4 mL of iron standard solution (250 ppm Fe) respectively and dilute to 100 mL with water.

SECTION IX

LEAD (By Atomic Absorption Spectrometry)

Instrument conditions

Source	Lead hollow-cathode lamp
Wavelength	217.0 nm
Atomization device	Air-acetylene flame

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		No.RMSTP: REX/SP/P017
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 00
Title:	PURIFIED TALC BP	Review Period: 2 Years
	Item Code: REX/SP/P017	Effective Date: 24/08/2023

Test solution

Use solution S1.

Reference solutions

Into 4 identical volumetric flasks, each containing 50 mL of 0.5 M hydrochloric acid, introduce 5 mL, 7.5 mL, 10 mL and 12.5 mL of lead standard solution (10 ppm Pb) respectively and dilute to 100 mL with water.

SECTION X

MAGNESIUM (By Atomic Absorption Spectrometry)

Instrument conditions

Source	Magnesium hollow-cathode lamp
Wavelength	285.2 nm
Atomization device	Air-acetylene flame

Test solution

Dilute 0.5 mL of solution S2 to 100 mL with water. To 4 mL of the solution, add 10 mL each of hydrochloric acid and lanthanum chloride solution and dilute to 100 mL with water R.

Reference solutions

Into 4 identical volumetric flasks, each containing 10 mL of hydrochloric acid and 10 mL of lanthanum chloride solution, introduce 2.5 mL, 3 mL, 4 mL and 5 mL of magnesium standard solution (10 ppm Mg) respectively and dilute to 100 mL with water R.

SECTION XI

LOSS ON IGNITION

Pre ignite a silica crucible at 1050-1100°C for 30 minutes, cool to room temperature in a desiccator. Weigh the empty crucible (W_1). Transfer approximately 1.00 g of sample to the crucible and reweigh it, (W_2 g). ignite gently. Cool the crucible in a desiccator and reweigh (W_3 g).

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Ignite the sample to constant weight (W_4 g).

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

Calculation

$$\text{Loss on Ignition (\%)} = \frac{W_4 - W_1}{W_2 - W_1} \times 100$$

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 XII

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/SP/P017

END OF DOCUMENT

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

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

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

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

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

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

HISTORY

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

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Title:	MAGNESIUM STEARATE BP	Review Period: 3 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

Solution "S"

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

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

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A. Freezing point

Procedure

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

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

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

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

B. Acid value

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

Calculate the acid value as given below

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

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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)

Instrument conditions

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

Precautions to be taken before analysis

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

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

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

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

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

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

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

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

SECTION VIII

NICKEL (By atomic absorption spectrometry)

Instrument conditions

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

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Precautions to be taken before analysis

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

Blank solution

Use the solution described in the test for cadmium.

Modifier solution

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

Test solution

Use the solution described in the test for cadmium.

Reference solution

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

Procedure

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

Operating conditions

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

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

SECTION IX

CADMIUM (By atomic absorption spectrometry)

Instrument conditions

Source — Cadmium hollow-cathode lamp

Wavelength — 228.8 nm

Atomisation device — Furnace

Platform — Pyrolytically coated with integrated tube.

Precautions to be taken before analysis

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

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

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

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

Test solution

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

Reference solution

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

Procedure

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

Operating conditions

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

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

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SECTION X

LOSS ON DRYING

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

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

Calculation

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

Where

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

SECTION XI

ASSAY

Magnesium (By Titrimetry)

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

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

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

Calculation

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

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

Stearic acid and palmitic acid (By GC)

Chromatographic condition

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

	Prepared by	Checked by	Approved By
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Column	: Time (min)	Temperature (°C)
	0 – 2	70
	2 – 36	70 – 240
	36 – 41	240

Preparation of test solution

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

Preparation of reference solution

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

Evaluation of system suitability

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

The system is suitable for analysis, if;

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

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

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Procedure

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

SECTION XII

MICROBIAL CONTAMINATION

Refer SOP NO. QCMB/006

HISTORY

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

END OF DOCUMENT

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		No. RMS: REX/SP/W001
	RAW MATERIAL SPECIFICATION	Revision No.: 01
Title:	WINCOAT WT – 2022, WHITE IH	Review Period: 3 Years
	Item Code: REX/SP/W001	Effective Date: 02/12/2023

Molecular formula	NA
Molecular weight	NA
Pack details	25 kg packed in fibre container.
Storage conditions	Store in a cool and dry place.
Instructions & Precautions 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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		No. RMS: REX/SP/W001
	RAW MATERIAL SPECIFICATION	Revision No.: 01
Title:	WINCOAT WT – 2022, WHITE IH	Review Period: 3 Years
	Item Code: REX/SP/W001	Effective Date: 02/12/2023

S. No.	TEST	LIMITS	METHOD
1	DESCRIPTION	White powder.	Follow section I of method of analysis
2	SOLUBILITY	Partly soluble in water and in most of the organic solvents forming homogeneous suspension.	Follow section II of method of analysis
3	IDENTIFICATION BY IR	The sample spectrum should match with the standard control spectrum	Follow section III of method of analysis
4	pH	3.0 – 7.5	Follow section IV of method of analysis
5	ASH	46 % to 52 % w/w	Follow section V of method of analysis
6	ARSENIC	NMT 3 ppm	Follow section VI of method of analysis
7	HEAVY METALS	NMT 20 ppm	Follow section VII of method of analysis
8	LOSS ON DRYING	NMT 10 % w/w	Follow section VIII of method of analysis
9	TAPPED DENSITY	0.4 to 0.8 g/mL	Follow section IX of method of analysis
10	SIEVE SIZE	NLT 98 %	Follow section X of method of analysis
11	COLOUR DIFFERENCE	Should match with standard sample / previous approved lot.	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/W001
2	Revision No.: 01	Periodic Revision

END OF DOCUMENT

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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 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	Partly soluble
0.01	Most of the organic solvents	100	Partly 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 4000-625 cm^{-1} for the working standard and the sample.

SECTION IV

pH

Dissolve 2 g of sample in 100 mL of carbon dioxide free water. Measure the pH using a suitable pH meter.

SECTION V

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

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

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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SECTION VI

ARSENIC

Apparatus The apparatus consists of an arsine generator fitted with a scrubber unit and an absorber tube with standard taper or ground glass ball and socket joint between the units. However, any other suitable apparatus, embodying the principle of the assembly described and illustrated may be used

Arsenic trioxide Stock Solution

Dissolve 0.132 g of arsenic trioxide in 5 ml of 2M sodium hydroxide solution in a 1000 ml volumetric flask Neutralize the solution with 2N sulphuric acid, then add recently boiled and cooled water to volume and mix.

Standard arsenic Solution

To 10.0 ml of arsenic trioxide stock solution add 2 ml of sulphuric acid, then add recently boiled and cooled water to volume and mix. Each ml of standard Arsenic solution contains the equivalent of 1µg of Arsenic.

Sample preparation

Pipette 3.0 ml of standard arsenic solution into a generator flask, add 2 ml of sulphuric acid, mix and add the total amount of 30% hydrogen peroxide used in preparing the test preparation. Heat the mixture to strong fuming cool add cautiously 10 ml of water and again heat to strong fumes. Repeat this procedure with another 10 ml water to remove any traces of hydrogen peroxide. Cool and dilute with water to 35 ml.

Test preparation

Transfer 1.0 g of substance and add 5 ml of sulphuric acid and a few glass beads and digest in a fume hood, preferably on a hot plate and at a temperature not exceeding 120°C, until charring begins. Cautiously add dropwise 30 % hydrogen peroxide, allowing the reaction to subside and again heating between drops. Add the first few drops very slowly with sufficient mixing, in order to prevent a rapid reaction. Discontinue heating if foaming becomes excessive. When the reaction has abated, heat cautionsly, rotating the flask occasionally to prevent the specimen from caking on glass exposed to heating unit. Maintain oxidizing conditions at all times during the digestion by adding small quantities of the hydrogen peroxide solution whenever the mixture turns brown or darkens. Continue the digestion until the organic matter is destroyed, gradually raising the temperature

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of the hot plate until fumes of Sulphur trioxide are copiously evolved and the solution becomes colourless or retains only a light straw color. Cool, add cautiously 10 ml water mix and again evaporate to strong fuming, repeating this procedure to remove an ytrace of hydrogen peroxide. Cool add cautiously 10 ml water wash the sides of the flask with few ml of water and dilute with water to 35 ml.

Procedure

Treat the standard preparation and the test preparation similarly as follows. Add 20 ml of 7N sulphuric acid, 2 ml of potassium iodide TS, 0.5 ml of stronger acid stannous chloride TS, and 1 ml of isoprophylalcohol and mix. Allow to stand at room temperature for 30 minutes. Pack the scrubber tube with two pledges of cotton that have been soaked in saturated lead acetate solution, freed from excess solution by expression and dried in vacuum at room temperature leaving a 2mm space between the two pledges. Lubricate the joint with suitable stopcock grease designed for use with organic solvents and connect the scrubber unit to the absorber tube. Transfer 3.0 ml of silver diethyldithiocarbamate TS to the absorber tube. Add 3.0 g of granular zinc to the mixture in the flask, immediately connect the assembled scrubber unit, and allow the evaluation of hydrogen and the color development to proceed at room temperature for 45 minutes, siring the flask gently at 10 minutes intervals. Disconnect the absorber tube from the generator and scrubber units and transfer the absorbing solution to 1 cm absorption cell. Any red colour produced by the preparation does not exceed that produced by the standard preparation. If necessary or desirable determine the absorbance at the wavelength of maximum absorbance between 535 and 540 nm, with a suitable spectrometer or colorimeter using silver diethyldithiocarbamate TS as the blank.

SECTION VII

HEAVY METALS

Preparation of Lead Nitrate stock solution

Weigh 159.8 mg of lead nitrate and transfer it into a clean dry 1000 ml volumetric flask. Add 300 ml of water and 1.0 ml of Nitric acid. Dissolve and make up the volume with water.

Preparation of standard Lead solution

Pipette out 10.0 ml of the lead nitrate stock solution to a 100 ml volumetric flask and dilute up to the mark with water.

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pH 3.5 Acetate buffer preparation

Weigh and transfer accurately 25 g of Ammonium acetate into 25 ml of water and 38 ml of 6N Hydrochloric acid adjust the pH of the above prepared solution to 3.5 with either 6N Hydrochloric acid or 6N Ammonium hydroxide. Dilute the above solution with water to 100 ml and mix.

Preparation of standard solution

In to a 50 Ml of color comparison tube pipette 2 ml of lead standard solution (20 µg) and dilute with water to 25 mL. Adjust with 1 N acetic acid or 6N ammonium hydroxide solution to a pH between 3.0 and 4.0, dilute with water to about 40 mL and mix.

Preparation of test solution

Weigh 0.5 g of sample in a crucible, add sulphuric acid to wet the sample ignite carefully at a low temperature until charred. Add 2 mL of nitric acid add 5 drops of sulphuric acid and heat continuously until white fumes are no longer evolved. Ignite at 500° to 600°C, until the carbon is completely burnt off. Cool, add 4 mL of hydrochloric acid. Cover, digest on a water bath for 15 minutes, uncover and slowly evaporate to dryness on a water bath. Moisten the residue with 1 drop of hydrochloric acid. Add 10 mL of hot water and digest for 2 minutes. Add ammonia solution drop wise until the solution is just alkaline to litmus paper, dilute to 25 mL with water and adjust with dilute acetic acid to a pH between 3.0 and 4.0. Filter if necessary. Rinse the crucible and filter with 10 mL of water. Combine the filtrate and washing in a 50 mL Nessler cylinder. Dilute with water to about 40 mL and mix.

Preparation of Thioacetamide-Glycerin base TS

Mix 0.2 ml thioacetamide TS and 1 ml of glycerin TS and heat in a boiling water bath for 20 seconds and use mixture immediately.

Glycerin base TS

To 200 g of glycerin and water to bring the total weight to 235 g. add 140 ml of 1 N sodium hydroxide and 50 ml of water.

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Procedure

To each of the cylinders containing the standard solution and test preparation add 2 ml of pH 3.5 acetate buffer, then add 1.2 ml of thioacetamide-glycerin base TS, dilute with water tube 50 ml mix, allow to stand for 2 minutes and view downward over a white surface.

The colour produced with the test solution is not more intense than that produced with the standard solution.

Specification: NMT 10 ppm.

SECTION VIII

LOSS ON DRYING

Weigh a glass-stoppered, shallow weighing bottle that has been previously dried in a hot air oven at 100 to 105°C for 30 min (W_1 g). Transfer to the bottle about 1 g of sample and distribute the sample evenly by gentle sidewise shaking. Weigh the bottle and the sample (W_2 g). Dry the loaded weighing bottle by placing in a hot air oven at 100 to 105°C for 2 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).

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SECTION IX

TAPPED DENSITY

Weigh 10 g of the substance and transfer the quantity of the substance into a clean Dry measuring cylinder of Bulk Density apparatus. Note down the volume. Adjust the 100 taps on instrument. After 100 strokes measure the volume. Calculate the Bulk Density as follows:

$$\text{Tapped Density} = \frac{\text{Weight of the sample in g}}{\text{Volume after tapping in ml}}$$

SECTION X

SIEVE SIZE

Sieve test done on wet slurry.

Prepare wet slurry by dispersing 5 g of the substance in 100 ml of water and pass through 100#. Not less than 98.0 % w/w passes.

SECTION XI

COLOUR DIFFERENCE

Take two watch glass. On one watch glass place the substance and on other place the previously approved raw material. Compare the both visually under light.

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No.RMSTP: REX/SP/W001
2	Revision No.: 01	Periodic Revision

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		No. RMS: REX/SP/I004
	RAW MATERIAL SPECIFICATION	Revision No.: 02
Title:	IRON OXIDE YELLOW IH	Review Period: 3 Years
	Item Code: REX/SP/I004	Effective Date: 30/05/2024

GENERAL INFORMATION	
Molecular formula	NA
Molecular weight	NA
Pack details	5 kg packed in plastic container.
Storage conditions	Store in a tightly closed 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

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	RAW MATERIAL SPECIFICATION	No. RMS: REX/SP/I004
Title:	IRON OXIDE YELLOW IH	Revision No.: 02
	Item Code: REX/SP/I004	Review Period: 3 Years
		Effective Date: 30/05/2024

S.No.	TEST	SPECIFICATION	METHOD
1	DESCRIPTION	A yellow coloured powder	Follow Section I of Method of Analysis
2	WATER SOLUBLE MATTER	NMT 1.0 % w/w	Follow Section II of Method of Analysis
3	ASSAY (By Titrimetric)	NLT 97 % w/w	Follow Section III of Method of Analysis

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No.RMS: REX/SP/I004
2	Revision No.: 01	Periodic Revision
3	Revision No.: 02	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 yellow coloured powder.

SECTION II

WATER SOLUBLE MATTER

Transfer 5 g of sample to a 250 mL beaker. Add 200 ml of water and boil for 5 min. Stir well to avoid bumping. Cool the mixture and transfer the contents to a 250 mL volumetric flask. Rinse the beaker with 25 ml of water, adding the rinsing to the flask and make up the volume with water. Allow the mixture to stand for 10 min and filter the solution. Transfer 100 ml of the filtrate to a clean, dry, tared beaker and carefully evaporate the solution to dryness on a boiling water bath. Dry the residue between 105^{0}C and 110^{0}C for 2 h. Cool the beaker with residue in a desiccator. Weigh the beaker and calculate the % of water soluble matter using the formula:

Calculation

$$= \frac{250 \times 100 \times W_R}{W_S \times 100}$$

Where

W_R = Weight of the residue (g).
W_S = Weight of the sample (g).

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SECTION III

ASSAY (By Titrimetric)

Weigh accurately 200 mg of sample and transfer to a 200 ml conical flask. Add 10 ml of 5N hydrochloric acid to the flask and heat cautiously to boiling until the sample has dissolved. Allow to cool, add 6-7 drops of 30 % hydrogen peroxide and again heat cautiously to boiling until all the excess hydrogen peroxide has decomposed (for about 2-3 min). Allow to cool, add 30 ml of water and 2 g of potassium iodide. Allow to stand for 5 min. Add 30 ml of water, and titrate with 0.1 N sodium thiosulphate adding starch solution as indicator, towards the end of the titration.

Each ml of 0.1 N sodium thiosulphate is equivalent to 8.885 mg of iron oxide.

Calculation

$$\% \text{ of Iron Oxide} = \frac{\text{Titer value} \times 8.885 \times \text{Strength of 0.1 N } Na_2S_2O_3}{\text{Weight taken}} \times 100$$

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No. RMSTP: REX/SP/I004
2	Revision No.: 01	Periodic Revision
3	Revision No.: 02	Periodic Revision

END OF DOCUMENT

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

SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S.No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009	Page 1 of 3 No. RMS: REX/SP/P014
	RAW MATERIAL SPECIFICATION	Revision No.: 02
Title:	POLYSORBATE 80 BP	Review Period: 3 Years
	Item Code: REX/SP/P014	Effective Date: 07/06/2024

GENERAL INFORMATION	
Molecular formula	NA
Molecular weight	NA
Pack container details	5 kg packed in plastic container.
Storage conditions	Store in an airtight container. Protected from light.
Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Avoid inhaling. Reseal the containers immediately after sampling.
Quantity of sample required for analysis	60 ml
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	07/06/2024	07/06/2024	07/06/2024
Department: Quality Control		Date of Issue: 07/06/2024	

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		No. RMS: REX/SP/P014
	RAW MATERIAL SPECIFICATION	Revision No.: 02
Title:	POLYSORBATE 80 BP	Review Period: 3 Years
	Item Code: REX/SP/P014	Effective Date: 07/06/2024

S. No.	TEST	LIMITS	METHOD
1	DESCRIPTION	Oily, colorless or brownish-yellow, clear or slightly opalescent liquid.	Follow section I of method of analysis
2	SOLUBILITY	Dispersible in water, in anhydrous ethanol, in ethyl acetate and in methanol, practically insoluble in fatty oils and in liquid paraffin.	
3	RELATIVE DENSITY	About 1.10	Follow section II of method of analysis
4	VISCOSITY	About 400 mPa.s at 25°C	Follow section III of method of analysis
5	IDENTIFICATION*		Follow section IV of method of analysis
	A. By IR	The IR absorption spectrum of the sample should be concordant with the spectrum of the Polysorbate 80 working standard.	
	B. By hydroxyl value	65 to 80	
	C. By saponification value	45 to 55	
	D. Composition of fatty acids By GC	See section of IX	
	E. By Chemical	The solution becomes blue.	
6	ACID VALUE	Maximum 2.0	Follow section V of method of analysis
7	HYDROXYL VALUE	65 to 80	Follow section VI of method of analysis
8	PEROXIDE VALUE	Maximum 10	Follow section VII of method of analysis
9	SAPONIFICATION VALUE	45 to 55	Follow section VIII of method of analysis

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
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Department: Quality Control		Date of Issue: 07/06/2024	

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	RAW MATERIAL SPECIFICATION	Revision No.: 02
Title:	POLYSORBATE 80 BP	Review Period: 3 Years
	Item Code: REX/SP/P014	Effective Date: 07/06/2024

S. No.	TEST	LIMITS	METHOD
10	COMPOSITION OF FATTY ACIDS By GC - myristic acid - palmitic acid - palmitoleic acid - stearic acid - oleic acid - linoleic acid - linolenic acid	 NMT 5.0 % NMT 16.0 % NMT 8.0 % NMT 6.0 % NMT 58.0 % NMT 18.0 % NMT 4.0 %	Follow section of IX method of analysis
11	ETHYLENE OXIDE AND DIOXAN By GC ethylene oxide dioxan	 NMT 1 ppm NMT 10 ppm	Follow section X of method of analysis
12	WATER (By KF/1.0 g)	NMT 3.0 %	Follow section XI of method of analysis
13	TOTAL ASH (2.0 g)	NMT 0.25 %	Follow section XII of method of analysis

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

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No. RMS: REX/SP/P014
2	Revision No.: 01	Periodic Revision
3	Revision No.: 02	Periodic Revision

END OF DOCUMENT

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
Date	07/06/2024	07/06/2024	07/06/2024
Department: Quality Control		Date of Issue: 07/06/2024	

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		No. RMSTP: REX/SP/P014
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	POLYSORBATE 80 BP	Review Period: 3 Years
	Item Code: REX/SP/P014	Effective Date: 07/06/2024

METHOD OF ANALYSIS

SECTION I

DESCRIPTION

By physical observation.

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

Oily, colourless or brownish-yellow, clear or slightly opalescent liquid.

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
10	Water	10	Dispersible
10	Anhydrous ethanol	10	Dispersible
0.01	Fatty oils	≥100	Practically insoluble
0.01	Liquid paraffin	≥100	Practically insoluble

SECTION II

RELATIVE DENSITY

Procedure

Weigh the empty & dried pycnometer (W_1). Then fill with water and insert the capillary tube and thermometer. Wipe the overflowed water with tissue paper and weigh (W_2). Calculate the weight of water by subtracting W_1 from W_2.
Note : 1 mL of water at 25° when weighed in air of density 0.0012 g/mL is 0.99602 g

Capacity of the Pycnometer

1 ml = 0.99602 g

$$\text{Capacity of the Pycnometer, } C_S = \frac{X}{0.99602}$$

Remove the water completely and rinse the pycnometer with sample to be examined twice and fill the sample. Insert

SECTION IV

IDENTIFICATION

A. By IR

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

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

B. By hydroxyl value

Refer section VI.

C. By saponification value

Refer section VIII.

D. By composition of fatty acids

Refer section IX.

E. By Chemical

Dissolve 0.1 g of sample in 5 mL of methylene chloride. Add 0.1 g of cobalt nitrate and 0.1 g of potassium thiocyanate. Stir with a glass rod. The solution becomes blue.

SECTION V

ACID VALUE

Dissolve 5 g of sample in 50 mL of mixture of equal volumes of ethanol (96%) and light petroleum, previously neutralized with 0.1 M potassium hydroxide or 0.1 M sodium hydroxide using 0.5 mL of phenolphthalein solution as indicator. If necessary, heat to about 90°C to dissolve the sample. When the sample has dissolved, titrate with 0.1 M

Calculation

$$\frac{(n1 - n2) \times M \times 1000}{m}$$

where,

n_1 = volume of 0.01 M sodium thiosulfate required for the substance to be examined, in millilitres;
n_2 = volume of 0.01 M sodium thiosulfate required for the blank titration, in millilitres;
M = molarity of the sodium thiosulfate solution, in moles per litre;
m = mass of substance to be examined, in grams.

SECTION VIII

SAPONIFICATION VALUE

Dissolve 35 to 40 g of potassium hydroxide in 20 mL of water and add sufficient ethanol (96%) to produce 1000 mL. Allow to stand overnight and pour off the clear liquid.

Weigh 4 g of the sample into a 200 mL flask, add 30 mL of 0.5 M alcoholic potassium hydroxide and boil under a reflux condenser for 1 hour, and add 50 ml of anhydrous ethanol. While the solution is still hot, titrate the excess of alkali with 0.5M hydrochloric acid using 1 mL of phenolphthalein solution as indicator. Repeat the operation without the substance being examined.

Calculation

$$\text{Saponification value} = \frac{28.05v}{w}$$

where ,

v = is the difference, in mL, between the titrations
w = is the weight in g of sample taken.

SECTION IX

COMPOSITION OF FATTY ACIDS

Chromatographic conditions:

Column : macrogol 20000, (5µm) (300 x 0.32 mm)

potassium hydroxide or 0.1 M sodium hydroxide until the pink colour persists for at least 15s. When heating has been applied to aid dissolution maintain the temperature at about 90°C during the titration.

Calculation

$$\text{Acid value} = 5.61 \times \frac{n}{W}$$

Where
n = Number of mL of 0.1 M potassium hydroxide or 0.1 M sodium hydroxide required.
w = Sample weight (g).

SECTION VI

HYDROXYL VALUE

Weigh accurately about 20 g of sample in a 150 mL acetylation flask fitted with condenser and add 5 mL of acetic anhydride solution. Boil for 1 h on a water bath, adjusting the level of the water to maintain it 2 to 3 cm above the level of the liquid in the flask all through. Cool, add 5 mL of water through the the top of the condenser; if this causes cloudiness, add sufficient pyridine to produce to produce a clear liquid. Shake, replace in the water bath for 10 min, remove and cool. Rinse the condenser and the walls of the flask with 5 mL of alcohol, previously neutralized to dilute phenolphthalein solution. Titrate with 0.5 M alcoholic potassium hydroxide using phenolphthalein solution as indicator. Carry out a blank titration.

Calculation

Hydroxyl value = Acid value +28.05 v/w

Where
V = Difference between the titrations, in mL.
W = Weight of sample (g).

SECTION VII

PEROXIDE VALUE

Introduce 10 g of sample into a 100 mL beaker and dissolve with 20 mL of glacial acetic acid. Add 1 mL of saturated potassium iodide solution, mix and allow to stand for 1 min. Add 50 mL of carbon dioxide-free water and a magnetic stirring bar. Titrate with 0.01 M sodium thiosulfate, determining the end-point potentiometrically. Carry out a blank titration.

Carrier gas : helium gas

Linear velocity : 50 cm/s

Temperature:

	Time (min)	Temperature (°C)
Column	0-14	80→220
	14-54	220
Injection port		250
Detector		250

Detection : Flame ionization

Injection : 1 µL

Preparation of test solution

Weigh 0.10 g of sample and dissolved in 2 mL of 20 g/L solution of sodium hydroxide in methanol in a 25 mL of conical flask and boil under a reflux condenser for 30 min. Add 2 mL of boron trifluoridemethanol solution through the condenser and boil for 30 min. Add 4 mL of heptanes through the condenser and boil for 5 min. Cool and add 10 mL of saturated sodium chloride solution. Shake for about 15 s and add a quantity of saturated sodium chloride solution such that the upper phase is brought into the neck of the flask. Collect 2 mL of the upper phase wash with 3 quantities, each of 2 mL of water and dry over anhydrous sodium sulfate.

Preparation of calibrating substances

Prepare a suitable quantity of a mixture of methyl myristate, methyl palmitate, methyl stearate, methyl arachidate, methyl oleate, methyl elcosenoate, methyl behenate and methyl ligocerate in the ratio 5:10:15:20:20:10:10:10

Preparation of reference solution (a)

Dissolve 0.50 g of mixture in heptanes and dilute to 50 mL with the same solvent.

Preparation of reference solution (b)

Dilute 1 mL of reference solution (a) to 10 mL with heptane.

the capillary tube and thermometer. Wipe the overflowed sample with tissue paper and weigh (W_4). Calculate the weight of sample (Y).

Calculation

$$\text{Weight per ml} = \frac{Y}{C_S}$$

Where

Weight of empty Pycnometer, (W_1)
Weight of Pycnometer + water, (W_2)
Weight of water (X) = (W_2 - W_1)
Weight of Pycnometer + sample, (W_4)
Weight of sample (Y) = (W_4- W_1)

SECTION III

VISCOSITY

Determine at 100°C by method I using a U –tube viscometer size E.

Fill the viscometer, previously washed and completely dried, with the sample through tube L to slightly above the mark G, using a long pipette to minimise wetting the tube above the mark. Place the tube vertically in a water bath maintained at the temperature indicated in the monograph and allow to stand for not less than 30 minutes to allow the temperature to reach equilibrium. Adjust the volume of the liquid so that the bottom of the meniscus settles at the mark G. Suck or blow the liquid to a point about 5 mm above the mark E. After releasing pressure or suction, measure the time taken for the bottom of the meniscus to fall from the top edge of mark E to the top edge of mark F.

Calculate, as required, either the kinematic viscosity (v) in square per second (mm^2s^{-1})from the expression

$$v = Kt$$

or the dynamic viscosity (h) in millipascal seconds (mPa.s) from the expression

$$n = KPt$$

Where

t = time in seconds for the meniscus to fall from E to F.
P = mass/volume ($g\ cm^{-3}$) obtained by multiplying the relative density, of the liquid under examination by 0.9982.
K = constant of the instrument determined on a liquid of known viscosity.

Preparation of reference solution (c)

Dissolve 0.50 g of mixture in heptanes and dilute to 50 mL with the same solvent.

Evaluation of system suitability
Inject the reference solution (a) and (b) into the chromatograph and record the chromatograms.
The system is suitable for analysis, if;
The resolution between methyl oleate and methyl stearate peak is not less than 1.8.
The signal-to-noise ratio is not less than 5.
The number of theoretical plates due to methyl stearate is not less than 30000.

SECTION X

ETHYLENE OXIDE AND DIOXAN

Chromatographic conditions:

Column : poly(dimethyl)(diphenyl)siloxane,(5 µm) (500 x 0.53 mm)

Carrier gas : helium for chromatography.

Flow rate : 4.0 mL/min.

Split ratio : 1:3.5.

Static head-space conditions that may be used:

equilibration temperature: 80 °C

Equilibration time: 30 min.

Temperature:

	Time(min)	Temperature(°C)
Column	0- 18	70→250
	18- 23	250
Injection port		85
Detector		250

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		No. RMSTP: REX/SP/P014
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	POLYSORBATE 80 BP	Review Period: 3 Years
	Item Code: REX/SP/P014	Effective Date: 07/06/2024

Detection : Flame ionisation.

Injection : 1.0 mL of test solutions (a) and (b) and of the reference solution.

Preparation of ethylene oxide stock solution

Dilute 0.5 mL of a commercially available solution of ethylene oxide in methylene chloride (50 mg/mL) to 50 mL with water. Allow to reach room temperature. Dilute 1 mL of this solution to 250 mL with water.

Preparation of dioxan stock solution

Dilute 1 mL of dioxan to 200 mL with water. Dilute 1 mL of this solution to 100 mL with water.

Preparation of acetaldehyde stock solution

Weigh about 0.100 g of acetaldehyde into a 100 mL volumetric flask and dilute to 100 mL with water. Dilute 1 mL of this solution to 100 mL with water.

Preparation of standard solution

To 6 mL of ethylene oxide stock solution add 2.5 mL of dioxan stock solution and dilute to 25 mL with water.

Preparation of test solution (a)

Weigh 1 g of the sample in 10 mL head- space vial. Add 2 mL of water, seal the vial immediately with a polytetrafluoroethylene coated silicon membrane and an aluminum cap. Mix carefully.

Preparation of test solution (b)

Weigh 1 g of the sample in 10 mL head- space vial. Add 2 mL of standard solution, seal the vial immediately with a polytetrafluoroethylene coated silicon membrane and an aluminum cap. Mix carefully.

Preparation of reference solution

Introduce 2 mL of acetaldehyde stock solution and 2 mL of ethylene oxide stock solution into a 10 mL head-space vial and seal the vial immediately with a polytetrafluoroethylene coated silicon membrane and an aluminum cap. Mix carefully.

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
Date	07/06/2024	07/06/2024	07/06/2024
Department: Quality Control		Date of Issue: 07/06/2024	

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		No. RMSTP: REX/SP/P014
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Title:	POLYSORBATE 80 BP	Review Period: 3 Years
	Item Code: REX/SP/P014	Effective Date: 07/06/2024

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 the peaks due to acetaldehyde and ethylene oxide is not less than 2.0.

Procedure

Inject test solution (a), test solution (b) and reference solution into the chromatograph and record the chromatograms. Examine the blank chromatogram for any extraneous peaks, and disregard any corresponding peaks observed in the chromatogram of the sample preparation. The retention time of ethylene oxide is about 6.5 min.
The relative retention times of the eluting peaks wrt Polysorbate 80 are as follow

S. No.	Name of the impurity	RRT
1	Acetaldehyde	0.9
2	Dioxan	1.9

Calculation

$$\text{Content of ethylene oxide} = \frac{2\, C_{EO} \times A_a}{A_b - A_a}$$

C_{EO} = concentration of ethylene oxide in test solution (b), in micrograms per millilitre
A_a = peak area of ethylene oxide in the chromatogram obtained with test solution (a)
A_b = peak area of ethylene oxide in the chromatogram obtained with test solution (b)

$$\text{Content of dioxin} = \frac{2 \times 1.03 \times C_D \times A_{a'}}{A_{b'} - A_{a'}}$$

C_D = concentration of dioxan in test solution (b), in microlitres per millilitre
1.03 = density of dioxan, in grams per millilitre
$A_{a'}$ = peak area of dioxan in the chromatogram obtained with test solution (a)
$A_{b'}$ = peak area of dioxan in the chromatogram obtained with test solution (b)

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		No. RMSTP: REX/SP/P014
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Title:	POLYSORBATE 80 BP	Review Period: 3 Years
	Item Code: REX/SP/P014	Effective Date: 07/06/2024

SECTION XI

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 1.00 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

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

SECTION XII

TOTAL 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 2.0 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.

	Prepared by	Checked by	Approved By
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Calculation

Total 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 + ash in g (after Ignition-I).
W_4 = Weight of crucible + ash in g (after Ignition-II).

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No. RMSTP: REX/SP/P014
2	Revision No.: 01	Periodic Revision
3	Revision No.: 02	Periodic Revision

END OF DOCUMENT

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		No. RMS: REX/SP/I005
	RAW MATERIAL SPECIFICATION	**Revision No.: 01**
Title:	**ISOPROPYL ALCOHOL BP**	**Review Period:3 Years**
	Item Code: REX/SP/I005	**Effective Date:** 12/10/2023

GENERAL INFORMATION	
Molecular formula	C_3H_8O
Molecular weight	60.1
Pack details	250 kg packed in metal drum
Storage conditions	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 analysis	600 ml
Quantity of reserve sample	NA
Sampling Instructions	SOP No.: QCGN/018
Retest period	NA

	Prepared by	Checked by	Approved By
Designation	**Executive QC**	**Sr.Executive QC**	**Manager QC**
Signature			
Date	12/10/2023	12/10/2023	12/10/2023
Department: Quality Control		**Date of Issue:** 12/10/2023	

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		No. RMS: REX/SP/I005
	RAW MATERIAL SPECIFICATION	Revision No.: 01
Title:	ISOPROPYL ALCOHOL BP	Review Period:3 Years
	Item Code: REX/SP/I005	Effective Date: 12/10/2023

S. No.	TEST	LIMITS	METHOD
1	DESCRIPTION	Clear, colourless liquid.	Follow section I of method of analysis
2	SOLUBILITY	Miscible with water and with alcohol.	Follow section II of method of analysis
3	IDENTIFICATION* A. Relative density B. Refractive index C. By IR D. By Chemical Reaction	 0.785 to 0.789 1.376 to1.379 Determine by infrared absorption spectrophotometry. Compare the spectrum with that obtained with Isopropyl alcohol RS or with the reference spectrum of Isopropyl alcohol. The colour changes to violet.	Follow section III of method of analysis
4	APPEARANCE	Sample is clear and colourless.	Follow section IV of method of analysis
5	ACIDITY OR ALKALINITY	NMT 0.6 ml of 0.01M NaOH is required to change the colur of the indicator to pale pink.	Follow section V of method of analysis
6	ABSORBANCE At 230 nm At 250 nm At 270 nm At 290 nm At 310 nm	 0.30 0.10 0.03 0.02 0.01	Follow section VI of method of analysis

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
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		No. RMS: REX/SP/I005
	RAW MATERIAL SPECIFICATION	Revision No.: 01
Title:	ISOPROPYL ALCOHOL BP	Review Period:3 Years
	Item Code: REX/SP/I005	Effective Date: 12/10/2023

S. No.	TEST	LIMITS	METHOD
7	BENZENE AND RELATED SUBSTANCES Benzene Total impurities (excluding 2-butanol)	 NMT 2 ppm NMT 0.3 %	Follow section VII of method of analysis
8	PEROXIDES	No colour develops.	Follow section VIII of method of analysis
9	NON VOLATILE SUBSTANCES	NMT 20 ppm	Follow section IX of method of analysis
10	WATER	NMT 0.5%	Follow section X of method of analysis

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

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No.RMS: REX/SP/I005
2	Revision No.: 01	Periodic Revision

END OF DOCUMENT

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
Date	12/10/2023	12/10/2023	12/10/2023
Department: Quality Control		Date of Issue: 12/10/2023	

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	RAW MATERIAL STANDARD TEST PROCEDURE	No. RMSTP: REX/SP/I005
Title:	ISOPROPYL ALCOHOL BP	Revision No.: 01
	Item Code: REX/SP/I005	Review Period:3 Years
		Effective Date: 12/10/2023

METHOD OF ANALYSIS

SECTION I

DESCRIPTION

By physical observation.

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

Clear, colourless liquid.

SECTION II

SOLUBILITY

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

Qty. to be taken (mL)	Solvent	Volume (mL)	Limit
5	Water	5	Miscible
5	Alcohol	5	Miscible

SECTION III

IDENTIFICATION

A. By Relative density

Procedure
Weigh the empty & dried pycnometer (W_1). Then fill with water and insert the capillary tube and thermometer. Wipe the overflowed water with tissue paper and weigh (W_2). Calculate the weight of water by subtracting W_1 from W_2.

Note : 1 mL of water at 25° when weighed in air of density 0.0012 g/ml is 0.99602 g

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Capacity of the Pycnometer

1 ml = 0.99602 g

$$\text{Capacity of the Pycnometer, } C_S = \frac{X}{0.99602}$$

Remove the water completely and rinse the pycnometer with sample to be examined twice and fill the sample. Insert the capillary tube and thermometer. Wipe the overflowed sample with tissue paper and weigh (W_4). Calculate the weight of sample (Y).

Calculation

$$\text{Weight per ml} = \frac{Y}{C_S}$$

Where

Weight of empty Pycnometer, (W_1)

Weight of Pycnometer + water, (W_2)

Weight of water (X) = (W_2 - W_1)

Weight of Pycnometer + sample, (W_3)

Weight of sample (Y) = (W_3- W_1)

B. By Refractive Index

Measure the refractive index by using suitable refractometer.

C. By IR

Record and compare the spectrum from 4000-650 cm^{-1} for the working standard and the sample.
The IR absorption spectrum of the sample should be concordant with the spectrum of the Dichloromethane working standard.

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D. By Chemical

To1 ml add 4 ml of water R and mix. Carefully add 2 ml of a 10 g/l solution of dimethylaminobenzaldehyde R in sulfuric acid R, ensuring that the liquids do not mix; a bright reddish-violet ring forms immediately at the junction of the 2 liquids. After 2-5 min, the entire sulfuric acid layer turns violet.

SECTION IV

APPEARANCE OF SOLUTION

Preparation of sample solution

Dilute 1 mL to 20 mL with water.

Clarity of solution

Take two matched, flat bottomed test tubes of colorless transparent, neutral glass. Place 20 mL of the sample solution in one test tube and 20 mL of freshly prepared reference suspension in another test tube. After 5 minutes of reference suspension preparation, compare the contents of the tubes against a black background by viewing in diffused day light down the vertical axes of the tubes.
A 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 sample solution in one test tube and 20 mL of reference solution in another test tube. Examine the colors of liquid in diffused daylight by viewing down the vertical axes of the tubes against a white background.
A solution is colourless; if it has the appearance of water,

SECTION V

ACIDITY OR ALKALINITY

Gently boil 25 mL for 5 min. Add 25 mL of carbon dioxide-free water and allow to cool protected from carbon dioxide in the air. Add 0.1 mL of phenolphthalein solution. The solution is colourless.

Not more than 0.6 mL of 0.01 M sodium hydroxide is required to change the colour of the indicator to pale pink.

SECTION VI

ABSORBANCE (By UV)

When examined in the range of 230 nm to 310 nm, the sample solution shows an absorption maximum only at about 230 nm.

Absorbance at about 230 nm is about 0.30 and 0.10 at 250 nm, 0.03 at 270 nm, 0.02 at 290 nm, 0.01 at 310 nm.

SECTION VII

BENZENE AND RELATED SUBSTANCES (By GC)

Chromatographic conditions:

Column:
- material: fused silica, size: l = 30 m, Ø = 0.32 mm,
- Stationary phase: poly [(cyanopropyl)(phenyl)][dimethyl]siloxane (film thickness 1.8 µm).

Carrier gas: helium

Auxiliary gas: nitrogen for chromatography or helium for chromatography.

Linear velocity: 35 cm/s.

Split ratio: 1:5.

Injection: 1 µL.

Retention time of benzene is about 10 min.

Detection: Flame ionization

Temperature programming:

	Time (minutes)	Temperature (°C)
Column	0 to 12	40
	12 to 32	40 to 240

		32 to 42	240
	Injection port	---	280
	Detector	---	280

Preparation of test solution (a).
The substance to be examined.

Preparation of test solution (b).
Dilute 1.0 mL of 2-butanol to 50.0 mL with test solution (a). Dilute 5.0 mL of the solution to 100.0 mL with test solution (a).

Preparation of reference solution (a).
Dilute 0.5 mL of 2-butanol and 0.5 mL of propanol to 50.0 mL with test solution (a). Dilute 5.0 mL of the solution to 50.0 mL with test solution (a).

Preparation of reference solution (b).
Dilute 100 µL of benzene to 100 mL with test solution (a). Dilute 0.20 mL of the solution to 100.0 mL with test solution (a).

Evaluation of system suitability:

Inject reference solution (a) into the chromatograph and record the chromatograms.
The system is suitable for analysis, if and only if;
The resolution between the first peak (propanol) and the second peak (2- butanol) is not less than 10.

SECTION VIII

PEROXIDES

In a 12 mL test-tube with a ground-glass stopper and a diameter of about 15 mm, introduce 8 mL of potassium iodide and starch solution. Fill completely with the substance to be examined. Shake vigorously and allow to stand protected from light for 30 min.

No colour develops.

SECTION IX

NON VOLATILE SUBSTANCES

Evaporate 100 g to dryness on a water-bath after having verified that it complies with the test for peroxides and dry in an oven at 100-105 °C. The residue weighs a maximum of 2 mg.

SECTION X

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 methanol in the titration vessel and titrate with the KF reagent to the end point. Quickly add about 5.0 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.

Calculation

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

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