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/C015
	RAW MATERIAL SPECIFICATION	**Revision No.: 01**
Title:	**CIPROFLOXACIN HYDROCHLORIDE BP**	**Review Period: 3 Years**
	Item Code: RAI/SP/C015	**Effective Date:** 14/10/2024

GENERAL INFORMATION	
Molecular formula	$C_{17}H_{19}ClFN_3O_3H_2O$
Molecular weight	367.8
Pack details	25 kg packed in PVC drum
Storage conditions	In an airtight container, protected from light.
Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
Quantity of sample required for analysis	10 g
Quantity of reserve sample	20 g
Sampling Instructions	SOP No.: QCGN/018
Retest period	12 months

	Prepared by	**Checked by**	**Approved By**
Designation	**Executive QC**	**Sr.Executive QC**	**Manager QC**
Signature			
Date	14/10/2024	14/10/2024	14/10/2024
Department: Quality Control		**Date of Issue:** 14/10/2024	

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	RAW MATERIAL SPECIFICATION	Revision No.: 01
	CIPROFLOXACIN HYDROCHLORIDE BP	Review Period: 3 Years
Title:	Item Code: RAI/SP/C015	Effective Date: 14/10/2024

S. No.	TEST	LIMITS	METHOD
1	DESCRIPTION	Pale yellow, crystalline, slightly hygroscopic powder.	Follow Section I of method of Analysis
2	SOLUBILITY	Soluble in water, Slightly soluble in methanol, Very slightly soluble in anhydrous ethanol, practically insoluble in acetone, in ethyl acetate and in methylene chloride.	Follow Section II of method of Analysis
3	IDENTIFICATION a. BY IR b. REACTION OF CLORIDE	 The infrared spectrum of sample is concordant with the spectrum obtained to that of standard. The paper turns violet-red.	Follow Section III of method of Analysis
4	APPEARANCE OF SOLUTION	The solution is clear, and not more intensely coloured than reference solution GY_5	Follow Section IV of method of Analysis
5	pH	3.5 to 4.5	Follow Section V of method of Analysis
6	IMPURITY A BY TLC	NMT 0.2 %	Follow Section VI of method of Analysis
7	RELATED SUBSTANCES Impurity E Impurity B Impurity C Impurity D Unspecified Impurity Total Impurity	 NMT 0.3% NMT 0.2% NMT 0.2% NMT 0.2% NMT 0.10% NMT 0.5%	Follow Section VII of method of Analysis

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	CIPROFLOXACIN HYDROCHLORIDE BP	Review Period: 3 Years
Title:	Item Code: RAI/SP/C015	Effective Date: 14/10/2024

S. No.	TEST	LIMITS	METHOD
8	WATER CONTENT (0.200 g)	NMT 6.7 %	Follow Section VIII of method of Analysis
9	SULPHATED ASH	NMT 0.1 %	Follow Section IX of method of Analysis
10	ASSAY (on anhydrous basis)	98.0% to 102.0%	Follow Section X of method of Analysis

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No. RMS: RAI/SP/C015
2.	Revision No.: 01	Periodic Revision

END OF DOCUMENT

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		No. RMSTP: RAI/SP/C015
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 01
	CIPROFLOXACIN HYDROCHLORIDE BP	Review Period: 3 Years
Title:	Item Code: RAI/SP/C015	Effective Date: 14/10/2024

METHOD OF ANALYSIS

SECTION I

DESCRIPTION

By Physical observation:

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

Pale yellow, crystalline, slightly hygroscopic 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	10 to 30	Soluble
0.01	Methanol	1 to10	Slightly soluble
0.01	Anhydrous ethanol	10 to 100	Very slightly soluble
0.01	Acetone	> 100	Practically insoluble
0.01	Ethyl acetate	>100	Practically insoluble
0.01	Methylene chloride	>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

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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 OF CHLORIDE

Weigh accurately 0.1 g of sample. Add 0.2 g of potassium dichromate and 1 mL of sulfuric acid. Place a filter paper strip impregnated with 0.1 mL of diphenylcarbazide solution over the opening of the test tube.

The paper turns violet red.

SECTION IV

Solution S

Dissolve 0.5 g in carbon dioxide free water and dilute to 20 mL of the same solvent.

APPEARANCE OF SOLUTION

Dilute 10 mL of solution S to 20 mL with carbon dioxide free water.

SECTION V

pH:

Measure the pH of solution S using pH meter. The pH should be between 3.5 - 4.5.

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SECTION VI

IMPURITY A (BY TLC)

Test solution:

Dissolve 50 mg of the substance to be examined in water R and dilute to 5 ml with the same solvent.

Reference solution:

Dissolve 10 mg of ciprofloxacin impurity A CRS in a mixture of 0.1 mL of dilute ammonia and dilute to 90 mL of water and dilute to 100 ml with water. Dilute 2 mL of the solution to 10 mL with water.

Plate: TLC silica gel F_{254} plate.

Mobile phase:

Acetonitrile, concentrated ammonia, methanol, methylene cloride (10:20:40:40 v/ v/v/v)

Application: 5 ul.

Development: At the bottom of a chromatographic tank, place an evaporating dish containing 50 mL of concentrated ammonia. Expose the plate to the ammonia vapour for 15 min in the closed tank. Withdraw the plate, transfer to a 2nd chromatographic tank and develop over 3/4 of the plate.Over a path of ¾ of the plate.

Drying : In air.

Detection: Examine in ultraviolet light at 254 nm.

Result:
the principle spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principle spot in the chromatogram obtained with the reference solution. Any spot in the obtained in sample solution is not more intense than reference solution.

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	Item Code: RAI/SP/C015	Effective Date: 14/10/2024

SECTION VII

RELATED SUBSTANCES (By HPLC)

Chromatographic conditions

Column	: C-18, 250 mm x 4.6 mm, 5µm
Temperature	: 40°C
Wavelength	: 278 nm
Flow rate	: 1.5 ml/min
Injection volume	: 50 µL of test solution and reference solution (b) and (c)
Run time	: 2.3 times the RT of Ciprofloxacin.

Preparation of Buffer

Weigh accurately 2.45 g of phosphoric acid in 1000 ml of water adjust pH 3.0 with triethylamine.

Preparation of Mobile phase:

Mixture of pH 3.0 of phosphoric acid buffer and acetonitrile in the ratio of 870:130. Mix well and degas.

Test solution

Weigh accurately and transfer about 25 mg of the sample to a 50 mL volumetric flask. Dissolve in mobile phase and make up the volume with mobile phase.

Reference solution (a)

Weigh accurately and transfer about 25 mg of ciprofloxacin hydrochloride into a 50 mL volumetric flask. Dissolve in mobile phase and make up the volume with mobile phase.

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Preparation of reference solution (b)

Dissolve 2.5 mg of ciprofloxacin hydrochloride for peak identification (containing impurities B, C, D and E) in the mobile phase and dilute to 5 mL with the mobile phase.

Preparation of reference solution (c)

Dilute 1.0 mL of the test solution to 50 mL with mobile phase. Dilute 1.0 mL of this solution to 10 mL with mobile phase.

System suitability:

Resolution: NLT 1.3 between the peaks due to impurities B and C.

Procedure

Separately inject equal volumes of solutions as per sequence of injection into the chromatogram and record the peak area responses for the major peaks and check for system suitability requirements.

SECTION VIII

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.

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

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Procedure

Place enough anhydrous methanol in the titration vessel and titrate with the KF reagent to the end point. Quickly add about 0.200 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 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.

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

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

Where
W_1 = Weight of empty crucible in g.

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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(By HPLC)

Chromatographic conditions

Column	: C-18(250 mm x 4.6 mm), 5µm
Temperature	: 40°C
Wavelength	: 278 nm
Flow rate	: 1.5 ml/min
Injection volume	: 10 µL of the test solution and reference solution (a)

Preparation of Buffer

Weigh accurately 2.45 g of phosphoric acid in 1000 ml of water adjust pH 3.0 with triethylamine.

Preparation of Mobile phase

Mixture of pH 3.0 of phosphoric acid buffer and acetonitrile in the ratio of 870:130. Mix well and degas.

Preparation of Test solution

Weigh accurately and transfer about 25 mg of the sample to a 50ml volumetric flask. Dissolve in mobile phase and make up the volume with mobile phase.

Preparation of Reference solution (a)

Weigh accurately and transfer about 25 mg of ciprofloxacin hydrochloride into a 50ml volumetric flask. Dissolve in mobile phase and make up the volume with mobile phase.

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	CIPROFLOXACIN HYDROCHLORIDE BP	Review Period: 3 Years
Title:	Item Code: RAI/SP/C015	Effective Date: 14/10/2024

Procedure

Inject one Blank, five replicates of standard solution and duplicate of test solution and record the chromatograms.

Calculation

$$= \frac{AT \times WS \times 50 \times P}{AS \times 50 \times SW \times 100} \times 100$$

Where

AT = Area of test solution
AS = Area of reference solution (a)
WS = Weight of working standard taken in mg
SW = Weight of sample taken in mg
P = Purity of working standard

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No.: RMSTP: RAI/SP/C015
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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Format No.: F/QCGN/041/01

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

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

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

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Format No.: F/QCGN/041/01

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Title:	MICROCRYSTALLINE CELLULOSE BP (PH 102)	Review Period: 2 Years
	Item Code: REX/SP/M010	Effective Date: 05/01/2023

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

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Signature			
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Title:	MICROCRYSTALLINE CELLULOSE BP (PH 102)	Review Period: 2 Years
	Item Code: REX/SP/M010	Effective Date: 05/01/2023

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

HISTORY

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

END OF DOCUMENT

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Title:	MICROCRYSTALLINE CELLULOSE BP (PH 102)	Review Period: 2 Years
	Item Code: REX/SP/M010	Effective Date: 05/01/2023

METHOD OF ANALYSIS

SECTION I

DESCRIPTION

By Physical observation:

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

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

SECTION II

SOLUBILITY

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

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

SECTION III

IDENTIFICATION

A.By IR

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

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

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

B. Reaction with iodinated zinc chloride solution

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

C. Degree of polymerisation

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

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

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

where
t_2 (k_2)
k_2 = viscometer constant.

Periodic Revision done: | 8/01/2025

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: | PP 04/01/2026

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

SECTION VII

ETHER-SOLUBLE SUBSTANCES

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

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

SECTION VIII

WATER-SOLUBLE SUBSTANCES

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

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

SECTION IX

LOSS ON DRYING

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

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

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

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

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Periodic Revision done: | 04/01/2025

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 5 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

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).

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

Periodic Revision done: 04/01/2026

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 6 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

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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Date	05/01/2023	05/01/2023	06/01/2023
Department: Quality Control		Date of Issue: 05/01/2023	

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Periodic Revision done by : RF 04/01/2025

Approved by QA: L.V 04/01/2025

Effective Date: 04/01/2025

Next Review: 03/01/2028

Revision Number: 02

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

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

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

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

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

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Designation	Executive QC	Sr. Executive QC	Manager QC
Signature			
Date	15/06/2024	15/06/2024	15/06/2024
Department: Quality Control		Date of Issue: 15/06/2024	

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

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

HISTORY

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

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Designation	Executive QC	Sr. Executive QC	Manager QC
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Date	15/06/2024	15/06/2024	15/06/2024
Department: Quality Control		Date of Issue: 15/06/2024	

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

METHOD OF ANALYSIS

SECTION I

DESCRIPTION

By Physical observation:

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

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

SECTION II

SOLUBILITY

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

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

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

SECTION III

IDENTIFICATION

A. pH

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

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Date	15/06/2024	15/06/2024	15/06/2024
Department: Quality Control		Date of Issue: 15/06/2024	

B. By Chemical

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

C. By Chemical

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

D. Test for sodium

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

A dense, white precipitate is formed.

SECTION IV

Preparation of solution S1

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

Preparation of solution S2

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

APPEARANCE OF SOLUTION S1

Clarity of solution

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

Color of solution

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

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

SECTION V

pH

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

SECTION VI

SODIUM GLYCOLATE

Note: Carry out the test protected from light.

Test solution

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

Reference solution

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

Procedure

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

SECTION VII

SODIUM CHLORIDE

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

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

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

SECTION VIII

IRON

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

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

SECTION IX

LOSS ON DRYING

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

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

Calculation

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

Where

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

SECTION X

ASSAY (By Potentiometric)

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

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

Calculation

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

Where

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

SECTION XI

MICROBIAL CONTAMINATION

Procedure:

Refer to General SOP No. : QCMB/006.

HISTORY

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

END OF DOCUMENT

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

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 2 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

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr. Executive QC	Manager QC
Signature			
Date	21/11/2023	21/11/2023	21/11/2023
Department: Quality Control		Date of Issue: 21/11/2023	

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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

END OF DOCUMENT

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Designation	Executive QC	Sr. Executive QC	Manager QC
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Date	21/11/2023	21/11/2023	21/11/2023
Department: Quality Control		Date of Issue: 21/11/2023	

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		No. RMSTP:REX/SP/C022
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 01
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.

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr. Executive QC	Manager QC
Signature			
Date	21/11/2023	21/11/2023	21/11/2023
Department: Quality Control		Date of Issue: 21/11/2023	

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		No. RMSTP:REX/SP/C022
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 01
Title:	COLLOIDAL SILICON DIOXIDE BP	Review Period: 3 Years
	Item Code: REX/SP/C022	Effective Date: 21/11/2023

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.

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

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr. Executive QC	Manager QC
Signature			
Date	21/11/2023	21/11/2023	21/11/2023
Department: Quality Control		Date of Issue: 21/11/2023	

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		No. RMSTP:REX/SP/C022
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 01
Title:	COLLOIDAL SILICON DIOXIDE BP	Review Period: 3 Years
	Item Code: REX/SP/C022	Effective Date: 21/11/2023

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

END OF DOCUMENT

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr. Executive QC	Manager QC
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Department: Quality Control		Date of Issue: 21/11/2023	

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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

	Prepared by	Checked by	Approved By
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	RAW MATERIAL SPECIFICATION	Revision No.: 02
Title:	MAGNESIUM STEARATE BP	Review Period:3 Years
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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

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

Calculation

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

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

Stearic acid and palmitic acid (By GC)

Chromatographic condition

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

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

Preparation of test solution

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

Preparation of reference solution

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

Evaluation of system suitability

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

The system is suitable for analysis, if;

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

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

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Procedure

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

SECTION XII

MICROBIAL CONTAMINATION

Refer SOP NO. QCMB/006

HISTORY

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

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		No. RMS: REX/SP/T002
	RAW MATERIAL SPECIFICATION	Revision No.: 02
Title:	TITANIUM DIOXIDE BP	Review Period: 3 Years
	Item Code: REX/SP/T002	Effective Date: 15/06/2024

GENERAL INFORMATION	
Molecular formula	TiO_2
Molecular weight	79.9
Pack container requirement	25kg or 50 kg packed in poly bags in fiber drums
Storage conditions	Store in a cool and dry place. Store in tightly closed containers.
Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
Quantity of sample required for analysis	50 g
Quantity of reserve sample	100 g
Sampling Instructions	SOP No.: QCGN/018
Retest period	12 months

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

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	RAW MATERIAL SPECIFICATION	No. RMS: REX/SP/T002
Title:	TITANIUM DIOXIDE BP	Revision No.: 02
	Item Code: REX/SP/T002	Review Period: 3 Years
		Effective Date: 15/06/2024

S. No.	TEST	LIMITS	METHOD
1	DESCRIPTION	White or almost white powder.	Follow section I of method of analysis
2	SOLUBILITY	Practically insoluble in water, It does not dissolve in dilute mineral acids but dissolves slowly in hot concentrated sulphuric acid.	Follow section II of method of analysis
3	IDENTIFICATION A. By Chemical B. By Chemical C. By Chemical	 Pale Yellow colour disappears on cooling. An orange-red colour appears The mixture has a violet-blue colour	Follow section III of method of analysis
4	APPEARANCE OF SOLUTION	Solution S is not more opalescent than reference suspension II and is colourless.	Follow section IV of method of analysis
5	ACIDITY OR ALKALINITY	NMT 1.0 ml of 0.01M HCl or 0.01M NaOH is required to change the color of the indicator.	Follow section V of method of analysis
6	WATER SOLUBLE SUBSTANCES	NMT 0.5 %	Follow section VI of method of analysis
7	ANTIMONY	NMT 20 ppm	Follow section VII of method of analysis
8	ARSENIC	NMT 1 ppm	Follow section VIII of method of analysis
9	BARIUM	NMT 20 ppm	Follow section IX of method of analysis
10	IRON	NMT 200 ppm	Follow section X of method of analysis
11	ASSAY	Between 98.0 % to 100.5 % w/w	Follow section XI of method of analysis

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr. Executive QC	Manager QC
Signature			
Date	15/06/2024	15/06/2024	15/06/2024
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		No. RMS: REX/SP/T002
	RAW MATERIAL SPECIFICATION	Revision No.: 02
Title:	TITANIUM DIOXIDE BP	Review Period: 3 Years
	Item Code: REX/SP/T002	Effective Date: 15/06/2024

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No.RMS: REX/SP/T002
2	Revision No.: 01	Periodic Revision
3	Revision No.: 02	Periodic Revision

END OF DOCUMENT

	Prepared by	Checked by	Approved By
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	RAW MATERIAL STANDARD TEST PROCEDURE	No. RMSTP:REX/SP/T002
Title:	TITANIUM DIOXIDE BP	Revision No.: 02
	Item Code: REX/SP/T002	Review Period: 3 Years
		Effective Date: 15/06/2024

METHOD OF ANALYSIS

SECTION I

APPEARANCE

By physical observation.

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

White or almost white powder.

SECTION II

SOLUBILITY

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

It does not dissolve in dilute mineral acids but dissolves slowly in hot concentrated sulphuric acid.

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

SECTION III

IDENTIFICATION

A. By Chemical

Take few mg of sample in a dried test tube and heat it strongly.
It becomes pale yellow and the colour disappears on cooling.

B. By Chemical

Take 5 ml of solution S in a test tube and add 0.1 ml of strong hydrogen peroxide solution.
An orange-red colour appears.

C. By Chemical

Take 5 ml of solution S in a test tube and add 0.5 g of zinc in granules.
After 45 min, the mixture has a violet-blue colour.

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

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		No. RMSTP:REX/SP/T002
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	TITANIUM DIOXIDE BP	Review Period: 3 Years
	Item Code: REX/SP/T002	Effective Date: 15/06/2024

Preparation of solution S

Mix 500 mg of sample with 5 g of anhydrous sodium sulphate in a 300 ml long-necked combustion flask. Add 10 ml of water and mix. Add 10 ml of sulphuric acid and boil vigorously, with the usual precautions, until a clear solution is obtained. Cool, add slowly a cooled mixture of 30 ml of water and 10 ml of sulphuric acid, cool again and dilute to 100 ml with water.

SECTION IV

APPEARANCE OF SOLUTION

Clarity of solution

Take two matched, flat bottomed test tubes of colourless transparent, neutral glass. Place 20 ml of the sample solution (Solution S2) 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.

Sample solution is considered clear if its clarity or opalescence is not more pronounced than that of reference suspension II

Preparation of reference suspension II
Mix 10 ml of standard of opalescence and 90 ml of water.

Standard of opalescence

Dissolve 1 g of hydrazine sulphate in sufficient water to produce 100 ml and allow to stand for 4 to 6 hours. Add 25.0 ml of this solution to a solution containing 2.5 g of hexamine in 25 ml of water, mix well and allow to stand for 24 hours. This suspension is stable for 2 months provided that it is stored in a glass container free from surface defects.

The suspension must not adhere to the glass and must be well mixed before use.

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

Colour of solution

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

The sample is considered colourless if it has the appearance of water.

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Signature			
Date	15/06/2024	15/06/2024	15/06/2024
Department: Quality Control		Date of Issue: 15/06/2024	

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		No. RMSTP:REX/SP/T002
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	TITANIUM DIOXIDE BP	Review Period: 3 Years
	Item Code: REX/SP/T002	Effective Date: 15/06/2024

SECTION V

ACIDITY OR ALKALINITY

Shake 5 g of sample with 50 ml of carbon dioxide-free water for 5 min. Centrifuge or filter until a clear solution is obtained. To 10 ml of the solution add 0.1 ml of bromothymol blue solution.

Not more than1 ml of 0.01M hydrochloric acid or 0.01M sodium hydroxide is required to change the colour of the indicator.

SECTION VI

WATER SOLUBLE SUBSTANCES

To 10 g (W1) of sample, add solution of 0.5 g of ammonium sulphate in 150 ml of water and boil for 5 min. Cool and dilute to 200 ml with water and filter until a clear solution is obtained . Take 100 ml of the filtrate, to a weighed evaporating dish (W2) and evaporate to dryness.

Cool and weigh the evaporating dish with residue (W3). The residue weighs not more than 25 mg.

Water soluble substances weight can be calculated by the following formula.

$$\text{Water soluble substances} = \frac{W3-W2}{W1} \times 100$$

SECTION VII

ANTIMONY

Add 10 ml of hydrochloric acid and 10 ml of water to 10 mL of solution S. Cool to 20°C, if necessary, and add 0.15 ml of sodium nitrite solution. After 5 min, add 5 ml of a 10 g/L solution of hydroxylamine hydrochloride and 10 ml of a freshly prepared 0.1 g/L solution of rhodamine B. Mix thoroughly after each addition. Shake vigorously with 10 ml of toluene for 1 min. Allow to separate and centrifuge for 2 min, if necessary. Any pink colour in the toluene phase is not more intense than that in the toluene phase of a standard prepared at the same time in the same manner using a mixture of 5 ml of antimony standard solution (1 ppm Sb), 10 ml of hydrochloric acid and 15 ml of a solution containing 0.5 g of anhydrous sodium sulphate and 2 ml of sulphuric acid instead of the mixture of 10 ml of solution S2, 10 ml of hydrochloric acid and 10 ml of water.

Antimony standard solution (1 ppm Sb)
Dissolve 274 mg of antimony potassium tartrate in 20 ml of 7 M hydrochloric acid and dilute the clear solution to 100 ml with *water*. To 10 ml of this solution, add 200 ml of 70 % w/v hydrochloric acid and dilute with water to 1000 ml. To

100 ml of this solution, add 300 ml of 70 % w/v hydrochloric acid and dilute to 1000 ml with water. Prepare the dilute solutions immediately before use.

SECTION VIII

ARSENIC

Test solution

Place 500 mg of sample in a 250 ml round-bottomed flask, fitted with a thermometer, a funnel with stopcock and a vapour-outlet tube connected to a flask containing 30 ml of water. Add 50 ml of water, 500 mg of hydrazine sulphate, 500 mg of potassium bromide and 20 g of sodium chloride. Through the funnel, add dropwise 25 ml of sulphuric acid. Heat and maintain the temperature of the liquid at 110°C to 115°C for 20 min. Collect the vapour in the flask containing 30 ml of water. Dilute to 50 ml with water.

Procedure

In the conical flask dissolve the 20 ml of sample solution adjust the volume to 25 ml with water. Add 15 ml of hydrochloric acid, 0.1 ml of stannous chloride solution and 5 ml of potassium iodide, allow to stand for 15 min and introduce 5 g of activated zinc. Assemble the apparatus immediately and immerse the flask in a bath of water at a temperature such that a uniform evolution of gas is maintained.

Standard solution

Prepare a standard in the same manner, using 1 ml of arsenic standard solution (1 ppm As), diluted to 25 ml with water.

Arsenic standard solution (1 ppm As)

Dilute 1 volume of arsenic standard solution (10 ppm As) to 10 mL with water immediately before use.

Arsenic standard solution (10 ppm As)

Dissolve 330 mg of As_2O_3 in 5 mL of dilute sodium hydroxide solution and dilute to 250 mL with water. Dilute 1 mL to 100 mL with water, immediately before use.

After not less than 2 h, the stain produced on the mercuric bromide paper in the test is not more intense than that in the standard.

SECTION IX

BARIUM

To 10 ml of solution S, add 1 ml of dilute sulphuric acid. After 30 min, any opalescence in the solution is not more intense than that in a mixture of 10 ml of solution S and 1 ml of distilled water.

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		No. RMSTP:REX/SP/T002
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Title:	TITANIUM DIOXIDE BP	Review Period: 3 Years
	Item Code: REX/SP/T002	Effective Date: 15/06/2024

SECTION X

IRON

To 8 mL of solution S, add 4 mL of water. Mix and add 0.05 mL of bromine water. Allow to stand for 5 min and remove the excess of bromine with a current of air. Add 3 mL of potassium thiocyanate solution.
Any color in the solution is not more intense than that in a standard prepared at the same time in the same manner using a mixture of 4 mL of iron standard solution (2 ppm Fe) and 8 mL of 200 g/L solution of sulfuric acid.

SECTION XI

ASSAY

To 300 g of zinc in granules (710) add 300 ml of a 20 g/L solution of mercuric nitrate and 2 ml of nitric acid, shake for 10 min and wash with water. Pack the amalgamated zinc into a glass tube about 400 mm long and about 20 mm in diameter fitted with a tap and a filter plate. Pass through the column 100 ml of dilute sulphuric acid followed by 100 ml of water, making sure that the amalgam is always covered with liquid. Pass slowly at a rate of about 3 mL/min through the column a mixture of 100 ml of dilute sulphuric acid and 100 ml of water followed by 100 ml of water. Collect the eluate in a 500 ml conical flask containing 50 ml of a 150 g/L solution of ferric ammonium sulphate in a mixture of sulphuric acid and water in the ratio of 1:3.

Add 0.1 ml of ferroin and titrate immediately with 0.1M ammonium and cerium nitrate until a greenish colour is obtained (n_1 mL). Pass slowly at a rate of about 3 ml/min through the column, a mixture of 50 ml of dilute sulphuric acid and 50 ml of water, followed by 20 ml of solution S2, a mixture of 50 ml of dilute sulphuric acid and 50 ml of water and finally 100 ml of water . Collect the eluate in a 500 ml conical flask containing 50 ml of a 150 g/L solution of ferric ammonium sulphate in a mixture of sulphuric acid and water in the ratio of 1:3. Rinse the lower end of the column with water, add 0.1 ml of ferroin and titrate immediately with 0.1M ammonium and cerium nitrate until a greenish colour is obtained (n_2 mL).

$$= \frac{3.99 \times (n_2 - n_1)}{m}$$

Where

m = Weight of sample used for the preparation of solution S (g)

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No. RMSTP: REX/SP/T002
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	15/06/2024	15/06/2024	15/06/2024
Department: Quality Control		Date of Issue: 15/06/2024	

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 2**
	RAW MATERIAL SPECIFICATION	**No. RMS: REX/SP/P006**
Title:	**PONCEAU 4R LAKE IH**	**Revision No.: 01**
	Item Code: REX/SP/P006	**Review Period:2 Years**
		Effective Date: 25/01/2023

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

	Prepared by	Checked by	Approved By
Designation	**Executive QC**	**Sr. Executive QC**	**Manager QC**
Signature			
Date	25/01/2023	25/01/2023	25/01/2023
Department: Quality Control		**Date of Issue:** 25/01/2023	

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	RAW MATERIAL SPECIFICATION	No. RMS: REX/SP/P006
Title:	PONCEAU 4R LAKE IH	Revision No.: 01
	Item Code: REX/SP/P006	Review Period:2 Years
		Effective Date: 25/01/2023

S. No.	TEST	LIMITS	METHOD
1	DESCRIPTION	A red coloured powder.	Follow Section I of method of Analysis
2	SOLUBILITY	Insoluble in water, soluble in dilute solutions of alkali hydroxides.	Follow Section II of method of Analysis
3	pH	3.0 to 5.0	Follow Section III of method of Analysis
4	LOSS ON DRYING	NMT 20.0 %	Follow Section IV of method of Analysis
5	BLEEDING	NMT 0.2 %	Follow Section V of method of Analysis
6	DYE CONTENT (OBD)	NLT 12.0 %	Follow Section VI of method of Analysis

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No.RMS: REX/SP/P006
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	25/01/2023	25/01/2023	25/01/2023
Department: Quality Control		Date of Issue: 25/01/2023	

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		No. RMSTP: REX/SP/P006
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 01
Title:	PONCEAU 4R LAKE IH	Review Period: 2 Years
	Item Code: REX/SP/P006	Effective Date: 25/01/2023

METHOD OF ANALYSIS

SECTION I

DESCRIPTION

By Physical observation.

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

A red coloured 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
1.0	Dilute alkali hydroxide solution	30	Soluble

SECTION III

pH

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

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr. Executive QC	Manager QC
Signature			
Date	25/01/2023	25/01/2023	25/01/2023
Department: Quality Control		Date of Issue: 25/01/2023	

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		No. RMSTP: REX/SP/P006
	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 01
Title:	PONCEAU 4R LAKE IH	Review Period: 2 Years
	Item Code: REX/SP/P006	Effective Date: 25/01/2023

SECTION IV

LOSS ON DRYING

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

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 V

BLEEDING

Weigh 2 g of sample and dissolve in 150 mL of beaker add 100 mL of deionized water (pH having range 7 ± 0.1) and stir with the help of glass rod for 10 minutes. Filter the suspension into a 100 mL volumetric flask by using two pieces of whatman filter paper no.4 into funnel. If the filtrate color is very dark then pipette out 1 mL from this filtrate and dilute up to 100 mL with deionized water. Find out absorbance of this filtrate at respective wavelength as per below table against deionized water as blank in a glass cell with 1 cm light path.

Measure the absorbance at 482 nm, taking 555 as the specific absorbance.

Calculation

$$\text{\% of bleeding} = \frac{A_{spl}}{555} \times \frac{1}{100} \times \frac{100}{\text{Sample weight (in g)}} \times \frac{100}{1} \times 100$$

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr. Executive QC	Manager QC
Signature		M. M.	
Date	25/01/2023	25/01/2023	25/01/2023
Department: Quality Control		Date of Issue: 25/01/2023	

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		No. RMSTP: REX/SP/P006
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Title:	PONCEAU 4R LAKE IH	Review Period: 2 Years
	Item Code: REX/SP/P006	Effective Date: 25/01/2023

SECTION VI

DYE CONTENT

Weigh 250 mg of sample and transfer in 250 mL volumetric flask. Add 100 mL of deionized water and 5 mL HCL. Heat the flask on hot plate until the sample appears to be dissolved. Removed the flask from hot plate and allow it to cool to room temperature. Dilute to volume with deionized water and shake to mix. If the solution is cloudy from an insoluble lake substratum, filter approximate 50 mL through a Buchner funnel discarding the first 10 mL of filtrate.

Pipette, 1 mL of this solution and dilute to 100 mL with Deionized water, to make a final concentration of 1 mg/100 mL.

Measure the absorbance at 482 nm, taking 555 as specific absorbance.

Calculation

$$\text{\% of Dry content (on as is basis)} = \frac{A_{spl}}{555} \times \frac{1}{100} \times \frac{250}{\text{Sample weight (in g)}} \times \frac{100}{1} \times 100$$

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

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No. RMSTP: REX/SP/P006
2	Revision No.: 01	Periodic Revision

END OF DOCUMENT

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr. Executive QC	Manager QC
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Date	25/01/2023	25/01/2023	25/01/2023
Department: Quality Control		Date of Issue: 25/01/2023	

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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

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr. Executive QC	Manager QC
Signature			
Date	24/08/2023	24/08/2023	24/08/2023
Department: Quality Control		Date of Issue: 24/08/2023	

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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

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr. Executive QC	Manager QC
Signature			
Date	24/08/2023	24/08/2023	24/08/2023
Department: Quality Control		Date of Issue: 24/08/2023	

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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
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

END OF DOCUMENT

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	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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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

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1	Revision No.: 00	New STP No. RMSTP: REX/SP/P017

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	RAW MATERIAL SPECIFICATION	No. RMS: REX/SP/P003
	POLYETHYLENE GLYCOL 6000 IP	Revision No.: 02
Title:	Item Code: REX/SP/P003	Review Period: 3 Years
		Effective Date: 28/12/2024

GENERAL INFORMATION	
Molecular formula	$HOCH_2[CH_2OCH_2]nCH_2OH$ Where n is between 112-158
Molecular weight	NA
Pack container requirement	1 kg packed in plastic container.
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 analysis	30 g
Quantity of reserve sample	60 g
Sampling Instructions	SOP No.: QCGN/018
To be retested before	24 months

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		No. RMS: REX/SP/P003
	RAW MATERIAL SPECIFICATION	Revision No.: 02
Title:	POLYETHYLENE GLYCOL 6000 IP	Review Period: 3 Years
	Item Code: REX/SP/P003	Effective Date: 28\12\2024

S. No.	TEST	LIMITS	METHOD
1	DESCRIPTION	A white to creamy white, wax-like solid or flakes.	Follow Section I of method of Analysis
2	SOLUBILITY	Freely soluble in water, in chloroform and in ethanol (95 %); practically insoluble in ether.	Follow Section II of method of Analysis
3	APPEARNCE OF SOLUTION	Solution is not more intensely colored than reference solution BYS6.	Follow Section III of method of Analysis
4	pH	4.5 – 7.5	Follow Section IV of method of Analysis
5	FREEZING POINT	56° C – 60°C	Follow Section V of method of Analysis
6	VISCOSITY	250 mm^2s^{-1} – 390 mm^2s^{-1}	Follow Section VI of method of Analysis
7	ARSENIC	NMT 3 ppm	Follow Section VII of method of Analysis
8	HEAVY METALS (Method A)	NMT 5 ppm	Follow Section VIII of method of Analysis
9	SULPHATED ASH	NMT 0.1 %	Follow Section IX of method of Analysis

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No.RMS: REX/SP/P003
2	Revision No.: 01	Periodic revision
3	Revision No.: 02	Periodic revision

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	RAW MATERIAL STANDARD TEST PROCEDURE	Revision No.: 02
Title:	POLYETHYLENE GLYCOL 6000 IP	Review Period: 3 Years
	Item Code: REX/SP/P003	Effective Date: 28\12\2024

METHOD OF ANALYSIS

SECTION I

DESCRIPTION

By Physical observation:

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

A white to creamy white, wax-like solid or flakes.

SECTION II

SOLUBILITY

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

Qty. to be taken (g)	Solvent	Volume (mL)	Limit
1.0	Water	1 to 10	Freely soluble
1.0	Chloroform	1 to 10	Freely soluble
1.0	Ethanol (95 %)	1 to 10	Freely soluble
0.01	Ether	≥ 100	Practically insoluble

SECTION III

APPEARANCE OF SOLUTION

Dissolve 15 g of sample in 100 mL 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.

Solution is not more intensely colored than reference solution BYS6.

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Preparation of reference solution BYS6

Mix 1.5 mL of FCS, 0.8 mL of CCS, 0.2 mL of CSS and 97.5 mL of 1% w/v solution of hydrochloric acid.

Preparation of ferric chloride colorimetric solution (FCS)

Dissolve 55 g of ferric chloride hexahydrate in about 900 mL of 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 0.045 g of $FeCl_3,6H_2O$ per mL by adding the same acidic mixture. Protect the solution from light.

Preparation of cobaltous chloride colorimetric solution (CCS)

Dissolve 65 g of cobaltous chloride in about 900 mL of 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 0.0595 g of $CoCl_2,6H_2O$ per mL by adding the same acidic mixture.

Preparation of cupric sulphate colorimetric solution (CSS)

Dissolve 65 g of cupric sulfate in about 900 mL of 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 0.0624 g of $CuSO_4,5H_2O$ per mL by adding the same acidic mixture. Protect the solution from light.

SECTION IV

pH

Dissolve 5 of sample in carbon dioxide free water and dilute to 100 mL with carbon dioxide free water. Measure the pH of resulting solution using pH meter.

SECTION V

FREEZING POINT

Place a quantity of the substance under examination 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 bath about 5° above the

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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, assemble the apparatus, 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.

SECTION VI

VISCOSITY

Determine at 100° by method A using a U –tube viscometer size F.

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 0.998203.

SECTION VII

ARSENIC

Mix 3.3 g with 3 g of anhydrous sodium carbonate, add 10 ml of bromine solution and mix thoroughly. Evaporate to dryness on a water bath, gently ignite and dissolve the cooled residue in 16 ml of brominated hydrochloric acid and 45 ml of water. Remove the excess of bromine with 2 ml of stannous chloride solution 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.

SECTION VIII

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

Mix 4 g of sample with 5 mL of a 1% w/v solution of hydrochloric acid and sufficient water to produce 25 mL, warm gently until the solution is complete and cool to room temperature. 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 IX

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 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).

HISTORY

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