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|---|---|---|
| SAI PRIMUS LIFE BIOTECH PVT. LTD. | SAI PRIMUS LIFE BIOTECH PVT LTD<br>Factory: R.S.No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009 | Page 1 of 3 |
| | RAW MATERIAL SPECIFICATION | No. RMS: RAI/SP/C018 |
| | CETIRIZINE HYDROCHLORIDE BP | Revision No.: 01 |
| Title: | Item Code: RAI/SP/C018 | Review Period:3 Years |
| | | Effective Date: 28 \| 11 \| 2023 |

| GENERAL INFORMATION | |
|---|---|
| Molecular formula | $C_{21}H_{27}Cl_3N_2O_3$ |
| Molecular weight | 461.8 |
| Pack details | 25 kg packed in plastic container. |
| Storage conditions | Store 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 | | | |
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| | | No. RMS: RAI/SP/C018 |
| | RAW MATERIAL SPECIFICATION | Revision No.: 01 |
| Title: | CETIRIZINE HYDROCHLORIDE BP | Review Period:3 Years |
| | Item Code: RAI/SP/C018 | Effective Date: 28/11/2023 |

| S. No. | TEST | LIMITS | METHOD |
|---|---|---|---|
| 1 | DESCRIPTION | White or almost white powder. | Follow Section I of method of analysis |
| 2 | SOLUBILITY | Freely soluble in water; practically insoluble in acetone and in methylene chloride. | Follow Section II of method of analysis |
| 3 | IDENTIFICATION*<br><br>A. By UV<br><br><br><br>B. By IR<br><br>C. By TLC<br><br><br><br>D: Test for Chlorides | <br><br>When examined in the range of 210 nm to 350 nm. The resulting solution shows an absorption maximum at about 231 nm. The specific absorbance at 231 nm is 359 to 381.<br><br>The IR absorption spectrum of sample should be concordant with the spectrum obtained with Cetirizine hydrochloride working standard.<br><br>The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot on the chromatogram obtained with reference solution (a).<br><br>A curdy white precipitate is formed. | Follow Section III of method of analysis |
| 4 | APPEARANCE OF SOLUTION | Solution S is clear and not more intensely colored than reference solution $BY_7$. | Follow Section IVof method of analysis |
| 5 | pH | 1.2 to 1.8 | Follow Section V of method of analysis |

| | Prepared by | Checked by | Approved By |
|---|---|---|---|
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| | RAW MATERIAL SPECIFICATION | Revision No.: 01 |
| Title: | CETIRIZINE HYDROCHLORIDE BP | Review Period:3 Years |
| | Item Code: RAI/SP/C018 | Effective Date: 28/11/2023 |

| S. No. | TEST | LIMITS | METHOD |
|---|---|---|---|
| 6 | RELATED SUBSTANCES (By HPLC)<br><br>- Any known impurity (A, B, C, D, E, F)<br><br>- Any unknown impurity<br><br>- Total impurities | <br><br>NMT 0.15 %<br><br>NMT 0.10 %<br><br>NMT 0.3 % | Follow Section VI of method of analysis |
| 7 | LOSS ON DRYING (1.000 g/105°C) | NMT 0.5 % | Follow Section VII of method of analysis |
| 8 | SULFATED ASH | NMT 0.2 % | Follow Section VIII of method of analysis |
| 9 | ASSAY (By Potentiometry) (on dried basis) | 99.0 % - 101.0 % | Follow Section IX of method of analysis |

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

**HISTORY**

| S. No. | Revision Number | Reason for Revision |
|---|---|---|
| 1 | Revision No.: 00 | New Specification No. RMS: RAI/SP/C018 |
| 2 | Revision No.: 01 | Periodic Revision |

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| | | No. RMSTP:RAI/SP/C018 |
| | RAW MATERIAL STANDARD TEST PROCEDURE | Revision No.: 01 |
| Title: | CETIRIZINE HYDROCHLORIDE BP | Review Period: 3 Years |
| | Item Code: RAI/SP/C018 | Effective Date: 28/11/2023 |

## 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 powder.

### SECTION II

### SOLUBILITY

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

| Qty. to be taken (g) | Solvent | Volume (mL) | Limit |
|---|---|---|---|
| 1.0 | Water | 1-10 | Freely soluble |
| 0.01 | Acetone | ≥100 | Practically insoluble |
| 0.01 | Methylene chloride | ≥100 | Practically insoluble |

### SECTION III

### IDENTIFICATION

**A. By UV**

Dissolve 20.0 mg of sample in 50 mL of a 1.03 % w/v solution of hydrochloric acid and dilute to 100 mL with the same acid. Dilute 10 mL of this solution to 100 mL with the 1.03 %w/v solution of hydrochloric acid.

When examined in the range of 210 nm to 350 nm. The resulting solution shows an absorption maximum at about 231 nm. The specific absorbance at 231 nm is 359 to 381.

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| Date | 28/11/2023 | 28/11/2023 | 28/11/2023 |
| Department: Quality Control | | Date of Issue: 28/11/2023 | |

**B. By IR**

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

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

**C. By TLC**

**Mobile phase**

Prepare a suitable quantity of mixture of ammonia, methanol and methylene chloride in the ratio of 1:10:90 Mix well.

**Test solution**

Dissolve 10 mg of substance to be examined in water and dilute to 5 mL with water.

**Reference solution (a)**

Dissolve 10 mg of Cetirizine hydrochloride working standard in water and dilute to 5 mL with water.

**Reference solution (b)**

Dissolve 10 mg of Chlorpheniramine maleate working standard in water and dilute to 5 mL with water. To 1 mL of this solution, add 1 mL of reference solution (a).

**Evaluation of system suitability:**
The test is not valid unless the chromatogram obtained with reference solution (b) shows two clearly separated spots.

**Procedure**
Apply separately to the plate 5 µL of each solution. After development dry the plate in a current of cold air and examine in UV light at 254 nm.

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

**D. Test for chlorides**

To 2 mL of solution S, acidify with the dilute nitric acid and add 0.4 mL of silver nitrate solution. Shake and allow to stand. A curled, white precipitate is formed. Centrifuge and wash the precipitate with three quantities, each of 1 mL of water. Carry out this operation rapidly in subdued light, disregarding the fact that the supernatant solution may not become perfectly clear. Suspend the precipitate in 2 mL of water and add 1.5 mL of ammonia. The precipitate dissolves easily with the possible exception of a few large particles which dissolves slowly.

**SECTION IV**

**APPEARANCE OF SOLUTION**

**Solution S:** Dissolve 1.0 g of sample in 20 mL of carbon dioxide-free water.

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

**Color of solution**
Take two matched, flat bottomed test tubes of colorless transparent, neutral glass. Place 20 mL of the solution S 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 S is clear and not more intensely colored than reference solution $BY_7$.

**Reference solution $BY_7$**

Add 2.5 mL of standard solution BY to 97.5 mL of 10 g/L hydrochloric acid.

**Standard solution BY**

Mix 2.4 mL of yellow solution, 1.0 mL of red solution, 0.4 mL blue solution and 6.2 mL of 10 g/L hydrochloric acid.

**Yellow solution**
Dissolve 46 g of ferric 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 45 mg of $FeCl_3$, 6H2O per mL by adding the same acidic mixture. Protect the solution from light.

**Red solution**
Dissolve 60 g of cobalt 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 59.5 mg of $CoCl_2$,
6H2O per mL by adding the same acidic mixture.

**Blue solution**
Dissolve 63 g of copper 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 62.4 mg of
$CuSO_4$, 5H2O per mL by adding the same acidic mixture. Protect the solution from light.

**SECTION V**

**pH**

Measure the pH of solution S using suitable pH meter.

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|---|---|---|
| | | No. RMSTP:RAI/SP/C018 |
| | RAW MATERIAL STANDARD TEST PROCEDURE | Revision No.: 01 |
| Title: | CETIRIZINE HYDROCHLORIDE BP | Review Period: 3 Years |
| | Item Code: RAI/SP/C018 | Effective Date: 28/11/2023 |

**SECTION VI**

**RELATED SUBSTANCES (By HPLC)**

**Chromatographic conditions:**

Column : A stainless steel column, silica gel for chromatography ,250 mm x 4.6 mm, 5µm

Wavelength : 230 nm

Flow rate : 1 mL/min

Injection volume : 20 µL

Run time : 3 times the retention time of Cetirizine

**Mobile phase**

Prepare a suitable quantity of a mixture of dilute sulphuric acid, water and acetonitrile in the ratio of 0.4:6.6:93. Mix well.

**Test solution**

Dissolve 20.0 mg of the substance to be examined in the mobile phase and dilute to 100 mL with mobile phase.

**Reference solution (a)**

Dissolve 2 mg each of Cetirizine dihydrochloride working standard and 2 mg of Cetirizine Impurity A standard in the mobile phase and dilute to 50 mL with the mobile phase. Dilute 1.0 mL of the solution to 100.0 mL with the mobile phase.

**Reference solution (b)**

Dilute 1.0 mL of test solution to 100.0 mL with mobile phase. Dilute 1.0 mL of this solution to 10.0 mL with the mobile phase.

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**Reference solution (c)**

Dissolve the contents of a vial of cetirizine for peak identification (containing impurities B, C, D, E and F) in 5 ml of mobile phase.

**Evaluation of system suitability:**

Inject reference solution (a) into the chromatograph and record the chromatograms.
The system is suitable for analysis, if and only if;
The resolution between Cetirizine and Impurity A peaks is not less than 3.0.
The symmetry factor for Cetirizine peak is not more than 2.0.

**Procedure**

Inject blank, sample solution and reference solution (b) into the chromatograph and record the chromatograms. Examine the blank chromatogram for any extraneous peaks, and disregard any corresponding peaks observed in the chromatogram of the sample solution. The relative retention time of cetirizine is about 10 min.

The relative retention times of the eluting peaks wrt Cetirizine hydrochloride are as follow

| S. No. | Name of the impurity | RRT |
|---|---|---|
| 1 | Impurity D | 0.6 |
| 2 | Impurity B | 0.8 |
| 3 | Impurity C | 0.9 |
| 4 | Impurity E | 1.2 |
| 5 | Impurity F | 1.37 |
| 6 | Impurity A | 1.42 |

**Identification of impurities:**

- use the chromatogram supplied with cetirizine for peak identification and the chromatogram obtained with reference solution (c).

- use the chromatogram obtained with reference solution (b) to identify the peak due to impurity A, B, C, D, E, F and any unkown.

Disregard limit: 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.05%).

**Calculation**

1. Any known impurity (A, B, C, D, E, F) And any unknown

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

3. Total impurities = Sum of all known + unknown impurities.

**Where**

AT = Area of any known impurity (A, B, C, D, E, F) peak in the chromatogram for sample solution.
AS = Average area of Cetirizine peak in the chromatogram for reference solution (b).
SW = Weight of sample (mg)
P = Percent purity of sample (on as is basis).

**SECTION VII**

**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**

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

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

**SECTION VIII**

**SULFATED ASH**

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

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

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

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

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| | | No. RMSTP:RAI/SP/C018 |
| | RAW MATERIAL STANDARD TEST PROCEDURE | Revision No.: 01 |
| Title: | CETIRIZINE HYDROCHLORIDE BP | Review Period: 3 Years |
| | Item Code: RAI/SP/C018 | Effective Date: 28/11/2023 |

## SECTION IX

### ASSAY (By Potentiometry)

Weigh accurately about 0.100 g of sample; dissolve in 70 mL mixture of 30 volumes of water and 70 volumes of acetone. Titrate with 0.1 M sodium hydroxide to the 2nd point of inflexion. Determine the end- point potentiometrically. Carry out a blank titration.

Each mL of 0.1 M sodium hydroxide is equivalent to 15.39 mg of Cetirizine.

### Calculation

$$\text{Assay (\%) (on dried basis)} = \frac{(Vs-Vb) \times M \times 15.39}{SW} \times \frac{100}{(100 - LOD)} \times 100$$

### Where

Vs = Volume consumed for sample (mL).
Vb = Volume consumed for blank (mL).
M = Molarity factor of sodium hydroxide.
LOD = Percent loss on drying of sample.
SW = Sample weight (mg).

### HISTORY

| S. No. | Revision Number | Reason for Revision |
|---|---|---|
| 1 | Revision No.: 00 | New Specification No.RMSTP: RAI/SP/C018 |
| 2 | Revision No.: 01 | Periodic revision |

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

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

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

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

**HISTORY**

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

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

## METHOD OF ANALYSIS

### SECTION I

### DESCRIPTION

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

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

### SECTION II

### BULK DENSITY

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

### SECTION III

### LOSS ON DRYING

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

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

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

**SECTION III**

**SIEVE SIZE**

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

**HISTORY**

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

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

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

| | **Prepared by** | **Checked by** | **Approved By** |
|---|---|---|---|
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| | **RAW MATERIAL SPECIFICATION** | **No.RMS: REX/SP/L003** |
| | **LACTOSE MONOHYDRATE 200 MESH BP** | **Revision No.: 02** |
| **Title:** | **Item Code: REX/SP/L003** | **Review Period:3 Years**<br>**Effective Date:** 22/11/2024 |

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

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

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

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

**HISTORY**

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

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

## METHOD OF ANALYSIS

### SECTION I

### DESCRIPTION

By physical observation.

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

White or almost white, crystalline powder.

### SECTION II

### SOLUBILITY

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

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

### SECTION III

### IDENTIFICATION

**A. By IR**

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

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

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**B. By TLC**

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

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

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

**Plate** TLC silica gel plate.

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

**Application** 2 µL; thoroughly dry the points of application.

**Development A** Over 3/4 of the plate.

**Drying** *A* In a current of warm air.

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

**Drying B** In a current of warm air.

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

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

**C. By Chemical**

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

A red color develops.

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

**D. WATER** See section IX.

**SECTION IV**

**APPEARANCE OF SOLUTION**

**Preparation of solution S**

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

**Clarity of solution**

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

**Color of solution**

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

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

**Preparation of reference solution $BY_7$**

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

**Preparation of standard solution BY**

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

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**Preparation of yellow solution**

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

**Preparation of red solution**

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

**Preparation of blue solution**

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

**SECTION V**

**ACIDITY OR ALKALINITY**

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

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

**SECTION VI**

**SPECIFIC OPTICAL ROTATION** (anhydrous substance).

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

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| | Item Code: REX/SP/L003 | Effective Date: 22/11/2024 |

**Calculation**

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

**Where**

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

**SECTION VII**

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

**Preparation of test solution (a)**

Solution S

**Preparation of test solution (b)**

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

**Procedure**

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

Results:

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

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

**SECTION VIII**

**WATER**

**Standardization of KF reagent**

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

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

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

**Procedure**

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

**Calculation**

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

**SECTION IX**

**SULPHATED ASH**

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

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

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

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

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

**SECTION X**

**MICROBIAL CONTAMINATION**

Refer general SOP no. QCMB/006.

**HISTORY**

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

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

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

| | **Prepared by** | **Checked by** | **Approved By** |
|---|---|---|---|
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| | | **No. RMS: REX/SP/C001** |
| | **RAW MATERIAL SPECIFICATION** | **Revision No.: 01** |
| **Title:** | **COLLOIDAL SILICON DIOXIDE USP** | **Review Period:3 Years** |
| | **Item Code: REX/SP/C001** | **Effective Date:** 15/09/2023 |

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

**HISTORY**

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

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

## METHOD OF ANALYSIS

### SECTION I

### DESCRIPTION

By Physical Observation:

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

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

### SECTION II

### SOLUBILITY

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

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

### SECTION III

### IDENTIFICATION

### A. BY CHEMICAL

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

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A deep yellow color is produced.

**B. BY CHEMICAL**

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

A greenish blue spot is produced.

**SECTION IV**

**pH**

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

**SECTION V**

**LOSS ON DRYING**

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

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

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

**Calculation**

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

**Where**

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

**SECTION VI**

**LOSS ON IGNITION**

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

**Calculation**

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

**Where**

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

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

**SECTION VII**

**ARSENIC**

**Sample solution**

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

**PROCEDURE**

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

**SECTION VIII**

**ASSAY**

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

**HISTORY**

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

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| | | No. RMS: REX/GH/C001 |
| | RAW MATERIAL SPECIFICATION | Revision No.: 02 |
| Title: | COLLOIDAL SILICON DIOXIDE BP | Review Period:3 Years |
| | Item Code: REX/GH/C001 | Effective Date: 16/03/2024 |

| GENERAL INFORMATION | |
|---|---|
| Molecular formula | $SiO_2$ |
| Molecular weight | 60.1 |
| Pack details | 10 kg packed in poly bags in fiber/HDPE drums or poly bags. |
| Storage conditions | Store in air tight container. |
| Precautions & Special instructions for sampling | Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling. |
| Quantity of sample required for analysis | 10 g |
| Quantity of reserve sample | 20 g |
| Sampling Instructions | SOP No.: QCGN/018 |
| Retest period | 24 months |

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| | | No. RMS: REX/GH/C001 |
| | RAW MATERIAL SPECIFICATION | Revision No.: 02 |
| Title: | COLLOIDAL SILICON DIOXIDE BP | Review Period:3 Years |
| | Item Code: REX/GH/C001 | Effective Date: 16/03/2024 |

| S.No. | TEST | LIMITS | METHOD |
|---|---|---|---|
| 1. | DESCRIPTION | White or almost white, light, fine, amorphous powder, not wettable by water with a particle size of about 15 nm. | Follow section I of Method of analysis |
| 2. | SOLUBILITY | Practically insoluble in water and in mineral acids except hydrofluoric acid. It dissolves in hot solutions of alkali hydroxides. | Follow section II of Method of analysis |
| 3. | IDENTIFICATION (Test for silicates) | A white ring is formed around the drop of water. | Follow section III of Method of analysis |
| 4. | pH | 3.5 to 5.5 | Follow section IV of Method of analysis |
| 5. | CHLORIDES | NMT 250 ppm | Follow section V of Method of analysis |
| 6. | LOSS ON IGNITION | NMT 5.0 % | Follow section VI of Method of analysis |
| 7.. | ASSAY (on ignited basis) | 99.0 % to 100.5 % | Follow section VII of Method of analysis |

HISTORY

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

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

## METHOD OF ANALYSIS

### SECTION I

### DESCRIPTION

By Physical Observation:

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

White or almost white, light, fine, amorphous powder, not wettable by water with a particle size of about 15 nm.

### SECTION II

### SOLUBILITY

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

| Qty. to be taken (g) | Solvent | Volume (mL) | Limit |
|---|---|---|---|
| 0.01 | Water | ≥ 100 | Practically insoluble |
| 0.01 | Mineral acids except hydrofluoric acid | ≥ 100 | Practically insoluble |
| 1.0 | Hot solutions of alkali hydroxides | 10-30 | Dissolves |

### SECTION III

### IDENTIFICATION (Test for Silicates)

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

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

SECTION IV

pH

Dissolve 1 g of sample in 30 ml of carbon dioxide-free water. Immerse the cleaned electrode of pH meter into the test solution. Measure the value of pH which is displayed on pH meter.

SECTION V

CHLORIDES

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

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

SECTION VI

LOSS ON IGNITION

Ignite a suitable crucible at 800±25°C for 30 minutes, allow to cool in a desiccator over silica gel or other suitable desiccant and weigh (W1). Place the 1.0 g of the substance under examination in the crucible and weigh (W2) and ignite. Allow the crucible to cool in a desiccator over silica gel or other suitable desiccant (W3), weigh it again and calculate the percentage of residue.

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| RAW MATERIAL STANDARD TEST PROCEDURE | Revision No.: 02 |
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**Calculation**

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

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

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

**Where**

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

**SECTION VII**

**ASSAY**

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

**Calculation**

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

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

Where

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

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

**HISTORY**

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

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

| GENERAL INFORMATION | |
|---|---|
| Molecular formula | NA |
| Molecular weight | NA |
| Pack container details | 5 kg packed in plastic container. |
| Storage conditions | Store in an airtight container, protected from light. |
| Precautions & Special instructions for sampling | Use hand gloves and nose mask while sampling. Avoid inhaling. Reseal the containers immediately after sampling. |
| Quantity of sample required for analysis | 15 g |
| Quantity of reserve sample | 70 g |
| Quantity of sample required for microbial analysis | 20 g |
| Sampling Instructions | SOP No.: QCGN/018 |
| Retest period | 12 months |

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

| 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<br><br>A. By pH<br><br>B. By Chemical<br><br>C. By Chemical<br><br>D. Test for sodium | <br><br>5.5 to 7.5<br><br>A suspension forms that settles after standing.<br><br>The solution becomes blue or violet.<br><br>A dense white precipitate is formed. | Follow Section III of method of Analysis |
| 4 | APPEARANCE OF SOLUTION S1 | Solution S1 is clear and colourless. | Follow Section IV of method of Analysis |
| 5 | pH | 5.5 to7.5 | Follow Section V of method of Analysis |
| 6 | SODIUM GLYCOLATE | NMT 2.0 % | Follow Section VI of method of Analysis |
| 7 | SODIUM CHLORIDE | NMT 7.0 % | Follow Section VII of method of Analysis |
| 8 | IRON | NMT 20 ppm | Follow Section VIII of method of Analysis |
| 9 | LOSS ON DRYING (1.000 g/130°C/1.5 h) | NMT 10.0 % | Follow Section IX of method of Analysis |
| 10 | ASSAY (calculated on the substance washed with ethanol (80% v/v) and dried) | 2.8 % - 4.2 % of sodium (Na) | Follow Section of X method of Analysis |

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| | | No. RMS: REX/GH/S001 |
| | RAW MATERIAL SPECIFICATION | Revision No.: 01 |
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| | Item Code: REX/GH/S001 | Effective Date: 16/03/2024 |

| S. No. | TEST | LIMITS | METHOD |
|---|---|---|---|
| 11 | MICROBIAL CONTAMINATION<br>Escherichia coli (per g) Salmonella (per 10 g) | Must be absent<br>Must be absent | Follow Section of XI method of Analysis |

HISTORY

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

## METHOD OF ANALYSIS

### SECTION I

### DESCRIPTION

By Physical observation:

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

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

### SECTION II

### SOLUBILITY

Measure the volume specified below in each test tube and check the solubility with appropriate solvent given.
It gives a translucent suspension in water.

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

### SECTION III

### IDENTIFICATION

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

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

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**C. By Chemical**

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

**D. Test for sodium**

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

A dense, white precipitate is formed.

**SECTION IV**

**Preparation of solution S1**

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

**Preparation of solution S2**

Place 2.5 g of sample in a silica or platinum crucible and add 2 mL of 500 g/l solution of sulfuric acid. Heat on a water bath, then cautiously over a naked flame raising the temperature progressively, then incinerate in a muffle furnace at 600± 25°C. Continue heating until all black particles have disappeared. Allow to cool, add few drops of dilute sulfuric acid. Heat and incinerate as above. Allow to cool, add a few drops of ammonium carbonate solution. Evaporate to dryness and incinerate cautiously. Allow to cool and dissolve the residue in 50 mL of water.

**APPEARANCE OF SOLUTION S1**

**Clarity of solution**

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

**Color of solution**

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

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

**SECTION V**

**pH**

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

**SECTION VI**

**SODIUM GLYCOLATE**

**Note: Carry out the test protected from light.**

**Test solution**

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

**Reference solution**

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

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

**Procedure**

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

SECTION VII

SODIUM CHLORIDE

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

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

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

SECTION VIII

IRON

Transfer 10 mL of the solution S2 to a Nessler cylinder. Add 2 mL of a 20 % w/v solution of citric acid and 0.1 mL of thioglycollic acid, mix and make alkaline with ammonia solution. Dilute to 20 mL with water and allow to stand for 5 minutes. Any pink colour in the test solution is not more intense than that of iron standard solution (1 ppm Fe).

SECTION IX

LOSS ON DRYING

Weigh a glass-stoppered, shallow weighing bottle that has been previously dried in an oven at 130°C for 30 min ($W_1$ g). Transfer to the bottle about 1.0 g of sample and distribute the sample evenly by gentle sidewise shaking. Weigh the

bottle and the sample ($W_2$ g). Dry the loaded weighing bottle in an oven at 130°C for 1.5 h, with its lid opened. After drying is completed, remove the weighing bottle from the oven and close the bottle properly. Allow it to cool to room temperature in a desiccator. Weigh the bottle and sample ($W_3$ g).

**Calculation**

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

**Where**

$W_1$ = Weight of empty weighing bottle in g.
$W_2$ = Weight of empty weighing bottle + sample in g.
$W_3$ = Weight of empty weighing bottle + sample in g (after drying-I).
W4 = Weight of empty weighing bottle + sample in g (after drying-II).

**SECTION X**

**ASSAY (By Potentiometry)**

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

Each ml of 0.1M perchloric acid is equivalent to 2.299 g of Na.

**Calculation**

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

| | | |
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| | RAW MATERIAL STANDARD TEST PROCEDURE | No.RMSTP:REX/GH/S001 |
| Title: | SODIUM STARCH GLYCOLATE BP | Revision No.: 01 |
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| | | Effective Date: 16/03/2024 |

Where

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

SECTION XI

MICROBIAL CONTAMINATION

Refer to SOP No. QCMB/006.

HISTORY

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

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

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| | | **No. RMS: REX/SP/P011** |
| | **RAW MATERIAL SPECIFICATION** | **Revision No.: 01** |
| **Title:** | **PURIIFIED TALC BP** | **Review Period: 3 Years** |
| | **Item Code: REX/SP/P011** | **Effective Date:** 22/01/2024 |

| 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 | 60 g |
| Sampling Instructions | SOP No. QCGN/018 |
| Retest period | 12 months |

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|---|---|---|---|
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| **Date** | 22/01/2024 | 22/01/2024 | 22/01/2024 |
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|---|---|---|
| | | No. RMS: REX/SP/P011 |
| | RAW MATERIAL SPECIFICATION | Revision No.: 01 |
| Title: | PURIIFIED TALC BP | Review Period: 3 Years |
| | Item Code: REX/SP/P011 | Effective Date: 22/01/2024 |

| 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. | |
| 3. | IDENTIFICATION*<br><br>A. By IR<br><br>B. By Chemical<br><br>C. Test for Silicates | <br><br>The IR absorption spectrum of the sample shows absorption bands at 3677±2 $cm^{-1}$, 1018±2$cm^{-1}$ and 669±2$cm^{-1}$.<br><br>A white crystalline precipitate is formed.<br><br>Within a short time, a white ring is rapidly formed around the drop of the water. | Follow section II 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.<br><br>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 III of method of analysis |
| 5. | WATER SOLUBLE SUBSTANCES | Maximum 0.2 % | Follow section IV of method of analysis |
| 6. | ALUMINIUM | Maximum 2.0 % | Follow section V of method of analysis |
| 7. | CALCIUM | Maximum 0.9 % | Follow section VI of method of analysis |
| 8. | IRON | Maximum 0.25 % | Follow section VII of method of analysis |
| 9. | LEAD | Maximum 10 ppm | Follow section VIII of method of analysis |
| 10. | MAGNESIUM | 17.0 % - 19.5 % | Follow section IX of method of analysis |

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|---|---|---|
| | | No. RMS: REX/SP/P011 |
| | RAW MATERIAL SPECIFICATION | Revision No.: 01 |
| Title: | PURIIFIED TALC BP | Review Period: 3 Years |
| | Item Code: REX/SP/P011 | Effective Date: 22/01/2024 |

| S.No. | TEST | LIMITS | METHOD |
|---|---|---|---|
| 11. | LOSS ON IGNITION | Maximum 7.0 % | Follow section X of method of analysis |
| 12. | MICROBIAL CONTAMINATION<br><br>If intended for oral administration<br><br>- Total aerobic microbial count (TAMC)<br>- Total yeast and mould count (TYMC) | <br><br><br><br>NMT $10^3$ CFU/g<br><br>NMT $10^2$ CFU/g | Follow section XI 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/P011 |
| 2 | Revision No.: 01 | Periodic Revision |

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| | | No. RMSTP: REX/SP/P011 |
| | RAW MATERIAL STANDARD TEST PROCEDURE | Revision No.: 01 |
| Title: | PURIFIED TALC BP | Review Period: 3 Years |
| | Item Code: REX/SP/P011 | Effective Date: 22/01/2024 |

## 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).

### 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 II

### IDENTIFICATION

**A. By IR**

Preparation: Discs of potassium bromide.
Absorption bands At 3677 ± 2 $cm^{-1}$, 1018 ± 2 $cm^{-1}$ and 669 ± 2 $cm^{-1}$.

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

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

**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 III**

**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 IV**

**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 V**

**ALUMINIUM (By Atomic Absorption Spectrometry)**

**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.

**Instrument conditions**

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

**SECTION VI**

**CALCIUM (By Atomic Absorption Spectrometry)**

**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.

**Instrument conditions**

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

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|---|---|---|
| | | No. RMSTP: REX/SP/P011 |
| | RAW MATERIAL STANDARD TEST PROCEDURE | Revision No.: 01 |
| Title: | PURIFIED TALC BP | Review Period: 3 Years |
| | Item Code: REX/SP/P011 | Effective Date: 22/01/2024 |

**SECTION VII**

**IRON (By Atomic Absorption Spectrometry)**

**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.

**Instrument conditions**

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

**SECTION VIII**

**LEAD (By Atomic Absorption Spectrometry)**

**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.

**Instrument conditions**

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

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## SECTION IX

**MAGNESIUM (By Atomic Absorption Spectrometry)**

**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.

**Instrument conditions**

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

## SECTION X

**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).

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 XI**

**MICROBIAL CONTAMINATION**

Refer to SOP No. QCMB/006.

**HISTORY**

| S. No. | Revision Number | Reason for Revision |
|---|---|---|
| 1 | Revision No.: 00 | New STP No. RMSTP: REX/SP/P011 |
| 2 | Revision No.: 01 | Periodic Revision |

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

| GENERAL INFORMATION | |
|---|---|
| Molecular formula | NA |
| Molecular weight | NA |
| Pack details | 25 kg packed in poly bags. |
| Storage conditions | Store in air tight container, protect from light. |
| Precautions & Special instructions for sampling | Use hand gloves and nose mask while sampling.<br>Reseal the containers immediately after sampling.<br>Avoid inhaling. |
| Quantity of sample required for chemical analysis | 20 g |
| Quantity of sample required for microbial analysis | 20 g |
| Quantity of reserve sample | 40 g |
| Sampling Instructions | SOP No.: QCGN/018 |
| Retest period | 12 months |

| | Prepared by | Checked by | Approved By |
|---|---|---|---|
| **Designation** | **Executive QC** | **Sr.Executive QC** | **Manager QC** |
| **Signature** | M Bly | | |
| **Date** | 25/07/2022 | 25/07/2022 | 25/07/2022 |
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| | | **No.RMS: REX/GH/M001** |
| | **RAW MATERIAL SPECIFICATION** | **Revision No.: 01** |
| **Title:** | **MAGNESIUM STEARATE BP** | **Review Period:2 Years** |
| | **Item Code: REX/GH/M001** | **Effective Date:** 25/07/2022 |

| 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*<br><br>A. Freezing point<br><br>B. Acid value<br><br>C. Assay of stearic acid and Palmitic acid (By GC)<br><br>D. Test for Magnesium | <br><br>NLT 53°C<br><br>195 to 210<br><br>The retention time of the 2 principal peaks obtained with test solution corresponds to the retention time of 2 principal peaks in reference solution.<br><br>A white crystalline precipitate is formed. | Follow section III of Method of analysis |
| 4 | ACIDITY OR ALKALINITY | Not more than 0.05 mL of 0.1 M HCl or 0.1 M NaOH is required to change the colour of the indicator. | Follow section IV of Method of analysis |
| 5 | CHLORIDES | NMT 0.1 % | Follow section V of Method of analysis |
| 6 | SULFATES | NMT 1.0 % | Follow section VI of Method of analysis |
| 7 | LEAD | NMT 10 ppm | Follow section VII of Method of analysis |
| 8 | NICKEL | NMT 5 ppm | Follow section VIII of Method of analysis |
| 9 | CADMIUM | NMT 3 ppm | Follow section IX of Method of analysis |

| | Prepared by | Checked by | Approved By |
|---|---|---|---|
| **Designation** | **Executive QC** | **Sr.Executive QC** | **Manager QC** |
| **Signature** | M. Bly. | AS | PP |
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|---|---|---|
| | | No.RMS: REX/GH/M001 |
| | RAW MATERIAL SPECIFICATION | Revision No.: 01 |
| Title: | MAGNESIUM STEARATE BP | Review Period:2 Years |
| | Item Code: REX/GH/M001 | Effective Date: 25/07/2022 |

| S.No. | TEST | LIMIT | METHOD |
|---|---|---|---|
| 10 | LOSS ON DRYING | NMT 6.0 % | Follow section X of Method of analysis |
| 11 | ASSAY<br><br>- Magnesium<br>- Stearic acid and Palmitic acid | <br><br>4.0 % - 5.0 % (on dried basis)<br>NLT 90.0 % | Follow section XI of Method of analysis |
| 12 | MICROBIAL CONTAMINATION<br><br>- Total aerobic microbial count (TAMC) (CFU/g)<br>- Total yeast and mould count (TYMC) (CFU/g)<br>- Escherichia coli<br>- Salmonella | <br><br>NMT $10^3$ (CFU/g)<br><br>NMT $10^2$ (CFU/g)<br><br>Must be absent<br>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/GH/M001 |
| 2 | Revision No.: 01 | Periodic Revision |

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| Signature | M.Bly. | A.S | BJ |
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|---|---|---|
| | | No. RMSTP:REX/GH/M001 |
| | RAW MATERIAL STANDARD TEST PROCEDURE | Revision No.: 01 |
| Title: | MAGNESIUM STEARATE BP | Review Period:2 Years |
| | Item Code : REX/GH/M001 | Effective Date: 25/07/2022 |

## METHOD OF ANALYSIS

**SECTION I**

**DESCRIPTION**

By Physical observation

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

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

**SECTION II**

**SOLUBILITY**

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

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

**SECTION III**

**IDENTIFICATION**

**A. Freezing point**

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

Combine the aqueous layers, wash with 15 mL of peroxide-free ether and dilute to 50 mL with water (Solution S).

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| Signature | M.Bly. | | |
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|---|---|---|
| | | No. RMSTP:REX/GH/M001 |
| | RAW MATERIAL STANDARD TEST PROCEDURE | Revision No.: 01 |
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| | Item Code : REX/GH/M001 | Effective Date: 25/07/2022 |

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

**Procedure**

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

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

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

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

**B. Acid value**

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

Calculate the acid value as given below

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

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

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

**D. Test for Magnesium**

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

A white crystalline precipitate is obtained

**SECTION IV**

**ACIDITY OR ALKALINITY**

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

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

**SECTION V**

**CHLORIDES**

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

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

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**SECTION VI**

**SULFATES**

Dilute 6.0 mL of solution S to 40 mL with water. Neutralize if necessary with hydrochloric acid using litmus as indicator. Add 1 mL of 3 M hydrochloric acid and 3 mL of barium chloride solution (120 g/L) and dilute to 50 mL with water. Mix and allow to stand for 10 min.
The turbidity is not greater than that produced in a solution containing 3 mL of 0.02 M sulfuric acid.

**SECTION VII**

**LEAD (By atomic absorption spectrometry)**

**Precautions to be taken before analysis**

For the preparation of all aqueous solutions and for the rinsing of glassware before use, employ water that has been passed through a strong-acid, strong-base, mixed- bed ion-exchange resin before use. Select all reagents to have as low a content of cadmium, lead and nickel as practicable and store all reagent solutions in containers of borosilicate glass. Clean glassware before use by soaking in warm 8 M nitric acid for 30 min and by rinsing with deionised water.

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

**Modifier solution**

Use the solution described in the test for cadmium.

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

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

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**Procedure**

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

**Instrument conditions**

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

**Operating conditions**

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

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

**SECTION VIII**

**NICKEL (By atomic absorption spectrometry)**
**Precautions to be taken before analysis**

For the preparation of all aqueous solutions and for the rinsing of glassware before use, employ water that has been passed through a strong-acid, strong-base, mixed- bed ion-exchange resin before use. Select all reagents to have as low a content of cadmium, lead and nickel as practicable and store all reagent solutions in containers of borosilicate glass. Clean glassware before use by soaking in warm 8 M nitric acid for 30 min and by rinsing with deionised water.

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

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

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

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

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

**Instrument conditions**

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

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

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**SECTION IX**

**CADMIUM**
**(By atomic absorption spectrometry)**

**Precautions to be taken before analysis**

For the preparation of all aqueous solutions and for the rinsing of glassware before use, employ water that has been passed through a strong-acid, strong-base, and mixed-bed ion-exchange resin before use. Select all reagents to have as low a content of cadmium, lead and nickel as practicable and store all reagent solutions in containers of borosilicate glass. Clean glassware before use by soaking in warm 8 M nitric acid for 30 min and by rinsing with deionised water

**Blank solution**

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

**Modifier solution**

Dissolve 20 g of ammonium dihydrogen phosphate and 1 g of magnesium nitrate in water and dilute to 100 mL with the same solvent. Alternatively, use an appropriate matrix modifier as recommended by the graphite furnace atomic absorption (GFAA) spectrometer manufacturer.

**Test solution**

Place 100 mg of sample in a polytetrafluoroethylene digestion bomb and add 2.5 mL of cadmium and lead-free nitric acid. Close and seal the bomb according to the manufacturer's operating. Heat the bomb in an oven at 170°C for 3 h. Cool the bomb slowly in air to room temperature according to the bomb manufacturer's instructions. Place the bomb in a hood and open carefully as corrosive gases may be expelled. Dissolve the residue in water and dilute to 10 mL with the same solvent.

**Reference solution**

Prepare a solution of 0.0030 µg/mL of Cd by suitable dilutions of a 0.00825 µg/mL solution of cadmium nitrate

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tetrahydrate in the blank solution.

**Procedure**

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

**Instrument conditions**

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

**Operating conditions**

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

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

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**SECTION X**

**LOSS ON DRYING**

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

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

**Calculation**

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

**Where**

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

**SECTION XI**

**ASSAY**

**Magnesium (By Titrimetry)**

Dissolve 500 mg of sample in a 250 mL conical flask. Add 50 mL of a mixture of anhydrous ethanol and butanol (in the ratio of 1:1), 5 mL of concentrated ammonia, 3 mL of ammonium chloride buffer solution pH 10, 30 mL of 0.1 M sodium edetate and 15 mg of mordant black 11 triturate. Heat at 45-50°C until the solution is clear. Titrate with 0.1 M Zinc sulfate until the colour changes from blue to violet. Carry out a blank titration.

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1 mL of 0.1 M sodium edetate is equivalent to 2.431 mg of Mg.

**Calculation**

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

**Where**

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

**Stearic acid and palmitic acid (By GC)**

**Preparation of test solution**

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

**Preparation of reference solution**

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

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**Chromatographic condition**

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

Column

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

**Evaluation of system suitability**

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

The system is suitable for analysis, if;

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

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

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**Procedure**

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

**SECTION XII**

**MICROBIAL CONTAMINATION**

Refer SOP No. QCGN/006

**HISTORY**

| S. No. | Revision Number | Reason for Revision |
|---|---|---|
| 1 | Revision No.: 00 | New STP No.RMSTP: REX/GH/M001 |
| 2 | Revision No.: 00 | Periodic Revision |

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| | | **No. RMS: REX/SP/I006** |
| | **RAW MATERIAL SPECIFICATION** | **Revision No.: 01** |
| **Title:** | **INSTACOAT UNIVERSAL IH** | **Review Period: 3 Years** |
| | **Item Code: REX/SP/I006** | **Effective Date:** 22/01/2024 |

| GENERAL INFORMATION | |
|---|---|
| Molecular formula | NA |
| Molecular weight | NA |
| Pack details | 5 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 | 15 g |
| Quantity of reserve sample | 30 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** |
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| | Item Code: REX/SP/I006 | Effective Date: 22/01/2024 |

| S. No. | TEST | LIMITS | METHOD |
|---|---|---|---|
| 1 | DESCRIPTION | White powder. | Follow Section I of method of Analysis |
| 2 | pH (2 % w/v slurry) | Between 4.0 to 7.5 | Follow Section II of method of Analysis |
| 3 | SIEVE TEST | NLT 99.0% passes through 100# | Follow Section III of method of Analysis |
| 4 | BULK DENSITY | Between 0.45 to 0.90 gm/ml | Follow Section IV of method of Analysis |
| 5 | ASH CONTENT | NMT 35.0 % | Follow Section V of method of Analysis |
| 6 | ARSENIC | NMT 2 ppm | Follow Section VI of method of Analysis |
| 7 | HEAVY METALS | NMT 10 ppm | 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/I006 |
| 2 | Revision No.: 01 | Periodic Revision |

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## 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.

White powder.

**SECTION II**

**pH**

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

**SECTION III**

**SIEVE SIZE**

Sieve test done on wet slurry. Prepare wet slurry by dispersing 5 g of the substance in 100 ml of water and pass through 100#. Not less than 99.0 % w/w passes.

**SECTION IV**

**BULK DENSITY**

Weigh accurately 10 g of powder in a 50 ml stoppered measuring cylinder. Fit the cylinder to the Bulk Density apparatus. Run the apparatus for 150 tapping. Check the volume occupied by the material. Calculate the Bulk Density accordingly.

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**Calculation**

$$\text{Bulk density} = \frac{\text{Weight of the powder}}{\text{Volume}}$$

**SECTION V**

**ASH CONTENT**

Pre ignite a silica crucible at 800 ± 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 for 30 h. 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.

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

**Where**
$W_1$ = Weight of empty crucible in g.
$W_2$ = 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 VI**

**ARSENIC**

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

**Arsenic trioxide Stock Solution**

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

**Standard arsenic Solution**

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

**Standard preparation**

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

**Test preparation**

Transfer 1.0 g of substance and add 5 ml of sulphuric acid and a few glass beads and digest in a fume hood, preferably on a hot plate and at a temperature not exceeding 120°C, until charring begins. Cautiously add drop wise 30 % hydrogen peroxide, allowing the reaction to subside and again heating between drops. Add the first few drops very slowly with sufficient mixing, in order to prevent a rapid reaction. Discontinue heating if foaming becomes excessive. When the reaction has abated, heat cautiously, rotating the flask occasionally to prevent the specimen from caking on glass exposed to heating unit. Maintain oxidizing conditions at all times during the digestion by adding small quantities of the hydrogen peroxide solution whenever the mixture turns brown or darkens. Continue the digestion until the organic matter is destroyed, gradually raising the temperature of the hot plate until fumes of Sulphur trioxide are copiously evolved and the solution becomes colourless or retains only a light straw color. Cool, add cautiously 10 ml water mix and again evaporate to strong fuming, repeating this procedure to remove any trace of hydrogen peroxide. Cool add cautiously 10 ml water wash the sides of the flask with few ml of water and dilute with water to 35 ml.

**Procedure**

Treat the standard preparation and the test preparation similarly as follows. Add 20 ml of 7N sulphuric acid, 2 ml of potassium iodide TS, 0.5 ml of stronger acid stannous chloride TS, and 1 ml of isoprophylalcohol and mix. Allow to

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

**Interfering chemicals**

Metals or salts of metals, such as chromium, cobalt, copper, mercury, molybdenum, nickel, palladium, and silver, may interfere with the evolution of arsine. antimony, which forms stibine, produces a positive interference in the color development with silver diethyldithiocarbamate ts; when the presence of antimony is suspected, the red colors produced in the two silver diethylthiocarbamate solutions may be compared at the wavelength of maximum absorbance between 535 and 540 nm, with a suitable colorimeter, since at this wavelength the interference due to stibine is negligible.

**SECTION VII**

**HEAVY METALS**

**Standard Solution (For checking heavy metals < x ppm)**

On the day of use, dilute 'X' ml of lead nitrate stock solution to 100 ml with distilled water. This solution contains 'X' mg of lead per ml solution (X ppm).

**Standard preparation (Solution A)**

Into a 50 ml of Nessler cylinder, pipette out 2 ml of standards lead solution, dilute with water to 25 ml. Adjust with dilute acetic acid or dilute ammonia solution to a pH 10 between 3.0 & 4.0. Dilute further with water to about 40 ml.

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|---|---|---|
| | | No. RMSTP: REX/SP/I006 |
| | RAW MATERIAL STANDARD TEST PROCEDURE | Revision No.: 01 |
| Title: | INSTACOAT UNIVERSEL IH | Review Period: 3 Years |
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**Test solution**

Weigh 2 gm of the sample, in a suitable crucible. Add sufficient sulphuric acid to moisten the sample and carefully ignite at a low temperature until thoroughly charred. Add to this carbonized mass, 2 ml of nitric acid and 5 drops of sulphuric acid, and cautiously heat until white fumes are no longer evolved. Ignite, preferably in muffle furnace, at 500°C to 600°C until the carbon is completely burnt off. If the carbon remains allow the residue to cool add few drop of sulphuric, evaporate and ignite again. Cool and add 5 ml of hydrochloric acid, cover and digest it on a water bath for 15 min. Uncover & slowly evaporated to dryness on a water bath.

**Procedure**

To each of the tubes contains the standard preparation add 2 ml of pH Acetate buffer, then add 1.2 ml of thioacetamide-glycerin base TS, dilute with water to 50 ml, mix, allow to stand for 2 minutes and view downward over a white surface.

The colour produced in test solution should not be darker than that of standard solution.

**HISTORY**

| S. No. | Revision Number | Reason for Revision |
|---|---|---|
| 1 | Revision No.: 00 | New STP No. RMSTP: REX/SP/I006 |
| 2 | Revision No.: 01 | Periodic Revision |

**END OF DOCUMENT**

| | Prepared by | Checked by | Approved By |
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| Designation | Executive QC | Sr.Executive QC | Manager QC |
| Signature | | | |
| Date | 22/01/2024 | 22/01/2024 | 22/01/2024 |
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