	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	CALCIUM HYDROGEN PHOSPHATE BP (DICALCIUM PHOSPHATE ANHYDROUS GRANULAR A-TAB)			
Specification No.	RMESD0014-01	**Revision No.**	01	**Item Code.:** RMED0014
Supersedes	RMESD0014-00	**Effective Date**	16/03/2023	**Page No.:** 1 of 4

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	$CaHPO_4$
2	Molecular weight	136.1
3	Storage conditions	NA
4	Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
5	Quantity of sample required for analysis	15 g
6	Quantity of reserve sample	30 g
7	Retest period	12 months from the date of release
8	Re-test Parameter	As mentioned in Specification
9	Reference	BP
10	Sampling instruction	Follow the standard operating procedure No.: ST/QC/040.
11	Destructions instructions	Follow the standard operating procedure No.: ST/QC/032.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	11/03/2023	13/03/2023	14/03/2023

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	CALCIUM HYDROGEN PHOSPHATE BP (DICALCIUM PHOSPHATE ANHYDROUS GRANULAR A-TAB)			
Specification No.	RMESD0014-01	**Revision No.**	01	**Item Code.:** RMED0014
Supersedes	RMESD0014-00	**Effective Date**	16/03/2023	**Page No.:** 2 of 4

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	White or almost white, crystalline powder, or colourless crystals.
2.	*Solubility	Practically insoluble in water and in ethanol (96 per cent). It dissolves in dilute hydrochloric acid and in dilute nitric acid.
3.	*Identification **A.** By Chemical test **B.** By Chemical test	 **A.** A white precipitate is produced. **B.** A yellow precipitate is produced
4.	Acid-insoluble substances	Not more than 0.2%
5.	Carbonates	No effervescence is produced.
6.	Chlorides	Not more than 0.25%
7.	Fluorides	Not more than 100ppm
8.	Sulfates	Not more than 0.5%
9.	Arsenic	Not more than 10ppm

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	11/03/2023	13/03/2023	14/03/2023

S.NO	TEST (s)	SPECIFICATION (s)
10.	Barium	No turbidity is produced.
11.	Iron	Not more than 400ppm.
12.	*Loss on ignition	Between 6.6% to 8.7%.
13.	*Assay	Not less than 97.5% and not more than 102.5%.

Remarks: The above * Marked tests are to be performed while retesting the material.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	11/03/2023	13/03/2023	14/03/2023

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
RMESD0014-01	Periodic review.	NA	16/03/2023

**** END OF THE DOCUMENT ****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	11/03/2023	13/03/2023	14/03/2023

	Safetab Life Science Puducherry			
	STANDARD TESTING PROCEDURE			MASTER COPY
Name of Product	CALCIUM HYDROGEN PHOSPHATE BP (DICALCIUM PHOSPHATE ANHYDROUS GRANULAR A-TAB)			
STP No.	RMETD0014-01	**Revision No.**	01	**Item Code.:** RMED0014
Supersedes	RMETD0014-00	**Effective Date**	16/03/2023	**Page No.:** 1 of 5

1. DESCRIPTION: < REFER GAM 001>

White or almost white, crystalline powder, or colourless crystals.

2. SOLUBILITY: < REFER GAM 002>

10mg of sample + 100mL of Water	Practically insoluble if the material not dissolves.
10mg of sample + 100mL of Ethanol (96%)	Practically insoluble if the material not dissolves.

It dissolves in dilute hydrochloric acid and in dilute nitric acid.

3. IDENTIFICATION:

A. By Chemical test:

Dissolve with heating 0.1 g in 10 mL of dilute hydrochloric acid. Add 2.5 mL of dilute ammonia, shake, and add 5 mL of a 35 g/L solution of ammonium oxalate. A white precipitate is produced.

B. By Chemical test:

Dissolve 0.1 g in 5 mL of dilute nitric acid, add 2 mL of ammonium molybdate solution and heat at 70 °C for 1-2 min. A yellow precipitate is produced.

SOLUTION S:

Dissolve 2.5 g in 20 mL of dilute hydrochloric acid, filter if necessary and add dilute ammonia until a precipitate is formed. Add just sufficient dilute hydrochloric acid to dissolve the precipitate and dilute to 50 mL with distilled water.

4. ACID INSOLUBLE SUBSTANCES:

Maximum 0.2 per cent.

Dissolve 5.0 g in 40 mL of water, add 10 mL of hydrochloric acid and heat to boiling for 5 min. Cool, then collect the insoluble substances using ashless filter paper. Wash with water until turbidity is no longer produced when silver nitrate solution is added.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	11/03/2023	13/03/2023	14/03/2023

Ignite the residue and the filter paper at 600 ± 50 °C. The residue weighs not more than 10 mg.

5. CARBONATES:

Shake 1.0 g with 5 mL of carbon dioxide-free water and add 2 mL of hydrochloric acid. No effervescence is produced.

6. CHLORIDES: < REFER GAM 008>

Maximum 0.25 per cent.

Test solution:

Dissolve 0.20 g in a mixture of 20 mL of water and 13 mL of dilute nitric acid by warming if necessary, dilute to 100 mL with water and filter if necessary. Use 50 mL of this solution.

Reference solution:

To 0.70 mL of 0.01 M hydrochloric acid, add 6 mL of dilute nitric acid and dilute to 50 mL with water R.

Add 1 mL of silver nitrate solution to the test solution and to the reference solution and mix. After standing for 5 min protected from light, any opalescence in the test solution, by viewing vertically or horizontally against a black background, is not more intense than that in the reference solution.

7. FLUORIDES:

Maximum 100 ppm.

Potentiometry (Method II).

Chelating solution: Dissolve 45 g of cyclohexylenedinitrilotetra-acetic acid in 75 mL of sodium hydroxide solution and dilute to 250 mL with water.

Test solution:

Dissolve 1.000 g in 4 mL of hydrochloric acid, add 20 mL of chelating solution, 2.7 mL of glacial acetic acid and 2.8 g of sodium chloride, adjust to pH 5-6 with sodium hydroxide solution and dilute to 50.0 mL with water.

Reference solution:

Dissolve 4.42 g of sodium fluoride, previously dried at 300 °C for 12 h, in water and dilute to 1000.0 mL with the same solvent. Dilute 50.0 mL of this solution to 500.0 mL with total-ionic-strength-adjustment buffer (200 ppm F).

Indicator electrode Fluoride-selective.

Reference electrode Silver-silver chloride.

Carry out the measurement on 20.0 mL of the test solution. Add at least 3 times 0.10 mL of the reference solution and carry out the measurement after each addition. Calculate the concentration of fluorides using the calibration curve

8. SULFATES:

Maximum 0.5 per cent.

Test solution:

Dissolve 0.5 g in a mixture of 5 mL of water and 5 mL of dilute hydrochloric acid and dilute to 100 mL with water. Filter if necessary. To 20 mL of this solution, add 1 mL of dilute hydrochloric acid and dilute to 50 mL with water.

Reference solution: To 1.0 mL of 0.005 M sulfuric acid, add 1 mL of dilute hydrochloric acid and dilute to 50 mL with water. Filter if necessary.

To the test solution and to the reference solution, add 2 mL of a 120 g/L solution of barium chloride and allow to stand for 10 min. Any opalescence in the test solution, by viewing vertically or horizontally against a black background, is not more intense than that in the reference solution.

9. ARSENIC:

Maximum 10 ppm, determined on 2 mL of solution S.

10. BARIUM:

To 0.5 g, add 10 mL of water and heat to boiling. While stirring, add 1 mL of hydrochloric acid dropwise. Allow to cool and filter if necessary. Add 2 mL of a 10 g/L solution of dipotassium sulfate and allow to stand for 10 min. No turbidity is produced.

11. IRON:

Maximum 400 ppm.

Dilute 0.5 mL of solution S to 10 mL with water.

12. LOSS ON IGNITION: < REFER GAM 033>

6.6 per cent to 8.7 per cent, determined on 1.000 g to constant mass at 800-825 °C.

13. ASSAY:

Dissolve 0.4 g in 12 mL of dilute hydrochloric acid by heating on a water bath if necessary and dilute to 200.0 mL with water. To 20.0 mL of this solution add 25.0 mL of 0.02 M sodium edetate, 50 mL of water, 5 mL of ammonium chloride buffer solution pH 10.7 and about 25 mg of mordant black II triturate. Titrate the excess of sodium edetate with 0.02 M zinc sulfate. Carry out a blank titration.

1 mL of 0.02 M sodium edetate is equivalent to 0.002721g of $CaHPO_4$.

Calculation:

$$= \frac{\text{Titer value - Blank x 0.02 M sodium edetate x 0.002721 x 100}}{\text{Sample weight in (g) x 0.02}}$$

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	11/03/2023	13/03/2023	14/03/2023

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
RMETD0014-01	Periodic review.	NA	16/03/2023

****END OF THE DOCUMENT****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	11/03/2023	13/03/2023	14/03/2023

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	GLICLAZIDE BP			
Specification No.	RMASG0014-01	**Revision No.**	01	**Item Code.:** RMAG0014
Supersedes	RMASG0014-00	**Effective Date**	09/03/2023	**Page No.:** 1 of 3

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	$C_{15}H_{21}N_3O_3S$
2	Molecular weight	323.4
3	Storage conditions	NA
4	Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
5	Quantity of sample required for analysis	5 g
6	Quantity of reserve sample	10 g
7	Retest period	12 months from the date of release
8	Re-test Parameter	As mentioned in Specification
9	Reference	BP
10	Sampling instruction	Follow the standard operating procedure No.: ST/QC/040.
11	Destructions instructions	Follow the standard operating procedure No.: ST/QC/032.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	04/03/2023	06/03/2023	07/03/2023

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	GLICLAZIDE BP			
Specification No.	RMASG0014-01	**Revision No.**	01	**Item Code.:** RMAG0014
Supersedes	RMASG0014-00	**Effective Date**	09/03/2023	**Page No.:** 2 of 3

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	White or almost white powder.
2.	*Solubility	Practically insoluble in water, freely soluble in methylene chloride, sparingly soluble in acetone, slightly soluble in ethanol (96 per cent).
3.	*Identification ➢ By IR	The Infrared absorption spectrum of sample should be concordant with that of reference spectrum or with the spectrum obtained from Gliclazide RS.
4.	*Related substances (By HPLC) (i) Impurity F (ii) Unspecified impurity (iii) Sum of impurities other than impurity F	 Not more than 0.15% Not more than 0.10% Not more than 0.2%
5.	Impurity B	Not more than 2ppm
6.	Sulphated Ash	Not more than 0.1% w/w
7.	*Loss on drying	Not more than 0.25% w/w
8.	*Assay By Titration (On dried basis)	Not less than 99.0% and not more than 101.0% w/w.

Remarks: The above * Marked tests are to be performed while retesting the material.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	04/03/2023	06/03/2023	07/03/2023

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
RMASG0014-01	Periodic review.	NA	09/03/2023

**** END OF THE DOCUMENT ****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	04/03/2023	06/03/2023	07/03/2023

	Safetab Life Science Puducherry			MASTER COPY
	STANDARD TESTING PROCEDURE			
Name of Product	GLICLAZIDE BP			
STP No.	RMATG0014-01	**Revision No.**	01	**Item Code.:** RMAG0014
Supersedes	RMATG0014-00	**Effective Date**	09/02/2023	**Page No.:** 1 of 8

1. DESCRIPTION: < REFER GAM 001>

White or almost white powder.

2. SOLUBILITY: < REFER GAM 002>

10mg of sample + 100mL of Water	Practically insoluble if the material not dissolves.
100mg of sample + 1mL of Methylene chloride	Freely soluble if the material dissolves.
100mg of sample + 10mL of Acetone	Sparingly soluble if the material dissolves.
10mg of sample + 10mL of Ethanol (96%)	Slightly soluble if the material dissolves.

3. IDENTIFICATION:

By IR: < REFER GAM 003>

The Infrared absorption spectrum of sample should be concordant with that of reference spectrum or with the spectrum obtained from Gliclazide WS.

4. RELATED SUBSTANCES: (BY HPLC)

Chemicals/Reagents/Standards:

Gliclazide	:	Working standard
Gliclazide Impurity F	:	Reference standard
Acetonitrile	:	HPLC grade
Triethylamine	:	AR grade
Trifluoroacetic acid	:	AR grade
Purified water	:	Milli-Q water (or) equivalent

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	04/03/2023	06/03/2023	07/03/2023

Chromatographic Conditions:

Column	:	Waters Xterra C8, 250mm x 4.0mm, (4µm) or equivalent.
Flow Rate	:	0.9ml/min
Wavelength	:	235nm
Injection volume	:	20µl
Run time	:	Twice the retention time of Gliclazide
Retention time	:	Retention time of Gliclazide peak is at about 16.0 minutes

Solvent Mixture:

Acetonitrile and water (45:55 V/V).

Mobile phase:

Triethylamine, Trifluoroacetic acid, Acetonitrile, Water (0.1:0.1:45:55 V/V/V/V)

Note: Prepare the solution immediately before use.

Test solution:

Weigh accurately and dissolve about 50.0 mg of the substance to be examined in 23 mL of acetonitrile and dilute to 50.0 mL with water.

Reference solution (a):

Dilute 1.0 mL of the test solution to 100.0 mL with the solvent mixture. Dilute 10.0 mL of this solution to 100.0 mL with the solvent mixture.

Reference solution (b):

Weigh accurately and dissolve about 5 mg of the substance to be examined and 15 mg of Gliclazide impurity F RS in 23 mL of acetonitrile and dilute to 50 mL with water. Dilute 1 mL of the solution to 20 mL with the solvent mixture.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	04/03/2023	06/03/2023	07/03/2023

Reference solution (c):

Weigh accurately and dissolve about 15.0 mg of Gliclazide impurity F RS in 45 mL of acetonitrile and dilute to 100.0 mL with water. Dilute 1.0 mL of the solution to 100.0 mL with the solvent mixture.

Identification of impurities:

Use the chromatogram obtained with reference solution (b) to identify the peak due to impurity F.

Relative retention With reference to Gliclazide (retention time = about 16 min): impurity F = about 0.9.

System suitability Reference solution (b):

— **resolution:** minimum 1.8 between the peaks due to impurity F and Gliclazide.

Limits:

— **impurity F:** not more than the area of the corresponding peak in the chromatogram obtained with reference solution (c) (0.15 per cent);

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

— **sum of impurities other than impurity F**: not more than twice the area of the principal peak in the chromatogram obtained with reference solution (a) (0.2 per cent);

— **disregard limit:** 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.05 per cent).

Inject 20µl of the above solution as per following sequence.

Injection sequence:

S. No	Sample Name	No. of injections
1	Solvent mixture (Blank)	1
2	Reference solution (b)	1
3	Reference solution (c)	1
4	Reference solution (a)	1
5	Blank	1
6	Test solution	1

Calculations:

Impurity F: (NMT 0.15%)

$$= \frac{AT_F}{AS_F} \times \frac{WS}{100} \times \frac{1}{100} \times \frac{50}{WT} \times \frac{P}{100} \times 100$$

Where,

AT_F = Area of Impurity F peak in Test solution.

AS_F = Area of the Impurity F peak in the Reference solution (c)

WT = Weight of the sample taken in mg.

WS = Weight of Impurity F Reference standard in mg.

P = Potency of Impurity F reference standard (% on as such basis).

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	04/03/2023	06/03/2023	07/03/2023

Unspecified impurity: (NMT 0.10%)

$$= \frac{AT_I}{AS} \times \frac{WT}{50} \times \frac{1}{100} \times \frac{10}{100} \times \frac{50}{WT} \times 100$$

Where,

AT_I = Area of unspecified impurity peak in Test solution.

AS = Area of the principal peak in the Reference solution (a)

WT = Weight of the sample taken in mg.

Sum of impurities other than impurity F: (NMT 0.2%)

$$= \frac{AT_T}{AS} \times \frac{WT}{50} \times \frac{1}{100} \times \frac{10}{100} \times \frac{50}{WT} \times 100$$

Where,

AT_T = Area of Total impurities peak in Test solution.

AS = Area of the principal peak in the Reference solution (a)

WT = Weight of the sample taken in mg.

5. IMPURITY B:

Note: ***Liquid chromatography as described in the test for related substances with the following modifications. Except injection volume 50µl.***

Test solution:

Weigh accurately and dissolve about 0.400 g of the substance to be examined in 2.5 mL of dimethyl sulfoxide and dilute to 10.0mL with water. Stir for 10 min, store at 4 °C for 30 min and filter.

Reference solution:

Weigh accurately and dissolve about 20.0 mg of Gliclazide impurity B RS in dimethyl sulfoxide and dilute to 100.0 mL with the same solvent. To 1.0 mL of the solution, add 12 mL of dimethyl sulfoxide and dilute to 50.0 mL with water. To 1.0 mL of this solution, add 12 mL of dimethyl sulfoxide and dilute to 50.0 mL with water.

Identification of impurities: Use the chromatogram obtained with the reference solution to identify the peak due to impurity B.

Retention time Impurity B = about 7 min.

Limit:

— **impurity B:** not more than the area of the corresponding peak in the chromatogram obtained with the reference solution (2 ppm).

Calculations:

Impurity B: (NMT 2ppm)

$$= \frac{AT_B}{AS_B} \times \frac{WS}{100} \times \frac{1}{50} \times \frac{1}{50} \times \frac{10}{WT} \times \frac{P}{100} \times 1000 \times 1000$$

Where,

AT_B = Area of Impurity B peak in Test solution.

AS_B = Area of the Impurity B peak in the Reference solution.

WT = Weight of the sample taken in mg.

WS = Weight of Impurity B Reference standard in mg.

P = Potency of Impurity B Reference standard (% on as such basis).

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	04/03/2023	06/03/2023	07/03/2023

6. SULPHATED ASH: < REFER GAM 032>

Maximum 0.1%. Determine on 1.0g of sample.

7. LOSS ON DRYING: < REFER GAM 026>

Maximum 0.25 per cent, determined on 1.000 g by drying in an oven at 105 °C for 2 h.

8. ASSAY: (By Titration)

Dissolve 0.250g in 50mL of anhydrous acetic acid. Titrate with 0.1 M Perchloric acid, determining the end-point potentiometrically

1 mL of 0.1 M perchloric acid is equivalent to 32.34 mg of $C_{15}H_{21}N_3O_3S$.

Calculation:

$$= \frac{\text{Titer value} - \text{Blank value} \times \text{Molarity of 0.1M Perchloric acid} \times 0.03234 \times 100 \times 100}{\text{Sample weight in (g)} \times (100 - \text{Sample LOD}) \times 0.1}$$

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	04/03/2023	06/03/2023	07/03/2023

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
RMATG0014-01	Periodic review.	NA	09/03/2023

****END OF THE DOCUMENT****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	04/03/2023	06/03/2023	07/03/2023

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	HYPROMELLOSE BP (METHOCEL K 100M PREMIUM)			
Specification No.	SPEC-RMEM0035-00	**Revision No.**	00	**Item Code.:** RMEM0035
Supersedes	RMESM0035-00	**Effective Date**	25/07/2023	**Page No.:** 1 of 3

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	NA
2	Molecular weight	NA
3	Storage conditions	NA
4	Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
5	Quantity of sample required for analysis	15 g
6	Quantity of reserve sample	30 g
7	Retest period	12 months from the date of release
8	Re-test Parameter	As mentioned in Specification
9	Reference	BP
10	Sampling instruction	Follow the standard operating procedure No.: ST/QC/040.
11	Destructions instructions	Follow the standard operating procedure No.: ST/QC/032.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	20/07/2023	21/07/2023	22/7/23

Safetab Life Science QUALITY ASSURANCE Puducherry-607

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	HYPROMELLOSE BP (METHOCEL K 100M PREMIUM)			
Specification No.	SPEC-RMEM0035-00	**Revision No.**	00	**Item Code.:** RMEM0035
Supersedes	RMESM0035-00	**Effective Date**	25/07/2023	**Page No.:** 2 of 3

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	White, yellowish-white or greyish-white powder or granules, hygroscopic after drying.
2.	*Solubility	Practically insoluble in hot water, in acetone, in anhydrous ethanol and in toluene. It dissolves in cold water giving a colloidal solution.
3.	*Identification	
	A. By Chemical test	The powdered material aggregates on the surface.
	B. By Chemical test	A clear or slightly turbid solution occurs with its thickness dependent on the viscosity grade.
	C. By Chemical test	A red colour develops at first and changes to purple within 100 min.
	D. By Chemical test	A coherent, clear film forms on the glass slide.
	E. By Chemical test	The flocculation temperature is higher than 50 °C.
4.	Appearance of solution	The solution is not more opalescent than reference suspension III and not more intensely coloured than reference solution Y_6
5.	*pH	Between 5.0 to 8.0
6.	Viscosity	Between 75% to 140%

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	20/07/2023	21/07/2023	22/7/23

Safetab Life Science QUALITY ASSURANCE Puducherry-607

UNCONTROLLED COPY

S.NO	TEST (s)	SPECIFICATION (s)
7.	Sulfated ash	Not more than 1.5%
8.	*Loss on drying	Not more than 5.0%
9.	*Assay (i) Methoxyl content (ii) Hydroxypropoxyl	 Between 19.0 – 24.0% Between 4.0 – 12.0%

Remarks: The above * Marked tests are to be performed while retesting the material.

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-RMEM0035-00	(i) New Specification prepared. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/016	25/01/2023

**** END OF THE DOCUMENT ****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	20/07/2023	21/07/2023	22/7/23

Safetab Life Science QUALITY ASSURANCE Puducherry-107

UNCONTROLLED COPY

1. DESCRIPTION: < REFER GAM 001>

White, yellowish-white or greyish-white powder or granules, hygroscopic after drying.

2. SOLUBILITY: < REFER GAM 002>

10mg of sample + 100mL of Hot water	Practically insoluble if the material not dissolves.
10mg of sample + 100mL of Acetone	Practically insoluble if the material not dissolves.
10mg of sample + 100mL of Anhydrous ethanol	Practically insoluble if the material not dissolves.
10mg of sample + 100mL of toluene	Practically insoluble if the material not dissolves.

It dissolves in cold water giving a colloidal solution.

3. IDENTIFICATION:

A. By Chemical test:

Evenly distribute 1.0 g onto the surface of 100 mL of water in a beaker, tapping the top of the beaker gently if necessary to ensure a uniform layer on the surface. Allow to stand for 1-2 min: the powdered material aggregates on the surface.

B. By Chemical test:

Evenly distribute 1.0 g into 100 mL of boiling water, and stir the mixture using a magnetic stirrer with a bar 25 mm long a slurry is formed and the particles do not dissolve. Allow the slurry to cool to 10 °C and stir using a magnetic stirrer a clear or slightly turbid solution occurs with its thickness dependent on the viscosity grade.

C. By Chemical test:

To 0.1 mL of the solution obtained in identification test B add 9 mL of a 90 per cent V/V solution of sulfuric acid, shake, heat on a water-bath for exactly 3 min, immediately cool in an ice-bath, carefully add 0.6 mL of a 20 g/L solution of ninhydrin, shake and allow to stand at 25 °C a red colour develops at first and changes to purple within 100 minutes.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	20/07/2023	21/07/2023	22/07/2023

Safetab Life Science QUALITY ASSURANCE Puducherry-107

D. By Chemical test:

Place 2-3 mL of the solution obtained in identification test B onto a glass slide as a thin film and allow the water to evaporate a coherent, clear film forms on the glass slide.

E. By Chemical test:

Add 50.0 mL of the solution obtained in identification test B to 50.0 mL of water in a beaker. Insert a thermometer into the solution. Stir the solution on a magnetic stirrer/hot plate and begin heating, increasing the temperature at a rate of 2-5 °C per minute. Determine the temperature at which a turbidity increase begins to occur and designate the temperature as the flocculation temperature the flocculation temperature is higher than 50 °C.

4. APPEARANCE OF SOLUTION:

The solution is not more opalescent than reference suspension III and not more intensely coloured than reference solution Y_6

While stirring, introduce a quantity of the substance to be examined equivalent to 1.0 g of the dried substance into 50 g of carbon dioxide-free water heated to 90 °C. Allow to cool, adjust the mass of the solution to 100 g with carbon dioxide-free water and stir until dissolution is complete.

5. pH: < REFER GAM 030>

5.0 to 8.0 for the solution prepared as described under Viscosity.

Read the indicated pH value after the probe has been immersed for 5 ± 0.5 min.

6. VISCOSITY:

75 per cent to 140 per cent of the nominal value for samples with a viscosity of 600 mPa·s (or) higher (Method 2)

Method 2:

To be applied to samples with a viscosity of 600 mPa·s or higher Weigh a quantity of the substance to be examined equivalent to 10.00g of the dried substance.

Transfer into a wide-mouthed bottle, and adjust the total mass of the sample and the water to 500.0g with hot water (90-99°C). Capping the bottle, stir by mechanical means at 400 ± 50 r/min for 10-20 min until the particles are thoroughly dispersed and wetted. Scrape down the insides of the bottle with a spatula if necessary, to ensure that there is no undissolved material on the sides of the bottle, and continue the stirring in a cooling water-bath maintained at a temperature below 10 °C for another 20-40 min. Adjust the solution mass if necessary to 500.0g using cold water. Centrifuge the solution if necessary to expel any entrapped air bubbles. Using a spatula, remove any foam. Determine the viscosity of this solution at 20 ± 0.1°C using a rotating viscometer.

Allow the spindle to rotate for 2 min before taking the measurement. Allow a rest period of at least 2 min between subsequent measurements. Repeat the measurement twice and determine the mean of the 3 readings.

7. SULPHATED ASH: < REFER GAM 032>

Maximum 1.5 per cent, determined on 1.0 g.

8. LOSS ON DRYING: < REFER GAM 026>

Maximum 5.0 per cent, determined on 1.000 g by drying in an oven at 105 °C for 1h

9. ASSAY: (Gas Chromatography)

Chromatographic Conditions:

Column	:	30mm x 0.53mm, Methyl polysiloxane (3µm).
Flow Rate	:	4.3ml/min
Injection volume	:	1-2 µl
Retention time	:	About 10 minutes
Detection	:	Flame ionisation (or) thermal conductivity

Temperature:

	Time (min)	Temperature (°C)
Column	0 - 3	50
	3 - 8	50 → 100
	8 - 12.3	100 → 250
	12.3 - 20.3	250
Injection port		250
Detector		280

Apparatus:

Reaction vial:

A 5 mL pressure-tight vial, 50 mm in height, 20 mm in external diameter and 13 mm in internal diameter at the mouth, equipped with a pressure-tight butyl rubber membrane stopper coated with polytetrafluoroethylene and secured with an aluminium crimped cap or another sealing system providing a sufficient air-tightness.

Heater:

A heating module with a square aluminium block having holes 20 mm in diameter and 32 mm in depth, so that the reaction vials fit; mixing of the contents of the vial is effected using a magnetic stirrer equipped in the heating module or using a reciprocal shaker that performs approximately 100 cycles/min.

Internal standard solution 30 g/L solution of octane in o-xylene.

Test solution:

Weigh 65.0 mg of the substance to be examined, place in a reaction vial, add 0.06-0.10 g of adipic acid, 2.0 mL of the internal standard solution and 2.0 mL of hydriodic acid, immediately cap and seal the vial, and weigh accurately. Mix the contents of the vial continuously for 60 min while heating the block so that the temperature of the contents is maintained at 130 ± 2 °C. If a reciprocal shaker or magnetic stirrer cannot be used, shake the vial thoroughly by hand at 5 min intervals during the initial 30 min of the heating time. Allow the vial to cool, and again weigh accurately. If the loss of mass is less than 26 mg and there is no evidence of a leak, use the upper layer of the mixture as the test solution.

Reference solution:

Place 0.06-0.10 g of adipic acid, 2.0 mL of the internal standard solution and 2.0 mL of hydriodic acid in another reaction vial, cap and seal the vial, and weigh accurately. Add 15-22 µL of isopropyl iodide through the septum with a syringe, weigh accurately, add 45 µL of methyl iodide in the same manner, and weigh accurately. Shake the reaction vial thoroughly and use the upper layer as the reference solution.

Detection:

Flame ionisation or thermal conductivity.

Relative retention:

With reference to octane (retention time = about 10 min): methyl iodide = about 0.4; isopropyl iodide = about 0.7.

System suitability Reference solution:

Resolution:

Minimum 5.0 between the peaks due to methyl iodide and isopropyl iodide and between the peaks due to isopropyl iodide and octane.

Repeatability:

Maximum relative standard deviation of 2.0 per cent for the ratios of the areas of the peaks respectively due to methyl iodide and isopropyl iodide to the area of the peak due to octane, determined on 6 injections.

Calculate the ratios (Q_1 and Q_2) of the areas of the peaks due to methyl iodide and isopropyl iodide to the area of the peak due to the internal standard in the chromatogram obtained with the test solution, and the ratios (Q_3 and Q_4) of the areas of the peaks due to methyl iodide and isopropyl iodide to the area of the peak due to the internal standard in the chromatogram obtained with the reference solution.

Calculate the percentage content of methoxy groups using the following expression:

$$Q_1/Q_3 \times m_1/m \times 21.864$$

Calculate the percentage content of hydroxypropoxy groups using the following expression:

$$Q_2/Q_4 \times m_2/m \times 44.17$$

m_1 = mass of methyl iodide in the reference solution, in milligrams;

m_2 = mass of isopropyl iodide in the reference solution, in milligrams;

m = mass of the sample (dried substance), in milligrams.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	20/07/2023	21/07/2023	22/07/2023

Safetab Life Science QUALITY ASSURANCE Puducherry-107

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMEM0035-00	(i) New STP prepared. (ii) STP numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/016	25/07/2023

****END OF THE DOCUMENT****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	20/07/2023	21/07/2023	22/07/2023

Safetab Life Science QUALITY ASSURANCE Puducherry-107

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Material	IRON OXIDE RED (FERRIC OXIDE USP/NF-RED)			
Specification No.	SPEC-RMEI0004-00	**Revision No.**	00	**Item Code.:** RMEI0004
Supersedes	RMESI0004-02	**Effective Date**	29/03/2025	**Page No.:** 1 of 4

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	NA
2	Molecular weight	NA
3	Storage conditions	Preserve in well closed containers.
4	Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
5	Quantity of sample required for analysis	15g
6	Quantity of reserve sample	30g
7	Retest period	12 months from the date of release
8	Re-test Parameter	As mentioned in Specification
9	Reference	USP
10	Sampling instruction	Follow the standard operating procedure No.: ST/QC/040.
11	Destructions instructions	Follow the standard operating procedure No.: ST/QC/032.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	26/03/2025	27/03/2025	29/03/2025

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Material	IRON OXIDE RED (FERRIC OXIDE USP/NF-RED)			
Specification No.	SPEC-RMEI0004-00	**Revision No.**	00	**Item Code.:** RMEI0004
Supersedes	RMESI0004-02	**Effective Date**	29/03/2025	**Page No.:** 2 of 4

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	A fine red powder.
2.	*Solubility	Insoluble in water and organic solvents.
3.	*Identification By Chemical test	A deep red colour is produced.
4.	Water soluble substances	Not more than 1.0% w/w
5.	Acid insoluble substances	Not more than 0.3% w/w
6.	Arsenic	Not more than 3ppm
7.	**Lead	Not more than 10ppm
8.	**Mercury	Not more than 3ppm
9.	**Organic colors and lakes	No peak above the noise level with a slope greater than +0.001 absorbance unit/nm is found.
10.	*Loss on ignition	Not more than 13.0% w/w

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	26/03/2025	27/03/2025	29/03/2025

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Material	IRON OXIDE RED (FERRIC OXIDE USP/NF-RED)			
Specification No.	SPEC-RMEI0004-00	**Revision No.**	00	**Item Code.:** RMEI0004
Supersedes	RMESI0004-02	**Effective Date**	29/03/2025	**Page No.:** 3 of 4

S.NO	TEST (s)	SPECIFICATION (s)
11.	*Assay (On ignited basis)	Not less than 97.0% and not more than 100.5% w/w.
12.	#pH	5.0 to 7.5

Remarks: The above * Marked tests are to be performed while retesting the material.

The above ** Marked tests shall be documented based on vendor COA.

The above # Marked test are to be performed on information only.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	26/03/2025	27/03/2025	29/03/2025

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-RMEI0004-00	(i) Periodic review. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	29/03/2025

**** END OF THE DOCUMENT ****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	26/03/2025	27/03/2025	29/03/2025

	Safetab Life Science Puducherry			MASTER COPY
	STANDARD TESTING PROCEDURE			
Name of Material	IRON OXIDE RED (FERRIC OXIDE USP/NF-RED)			
STP No.	STP-RMEI0004-02	**Revision No.**	02	**Item Code.:** RMEI0004
Supersedes	RMETI0004-02	**Effective Date**	29/03/2025	**Page No.:** 1 of 7

1. DESCRIPTION: < REFER GAM 001>

A fine red powder.

2. SOLUBILITY: < REFER GAM 002>

10mg of sample + 100ml of water	Insoluble if the material does not dissolves
10mg of sample + 100ml of organic solvents	Insoluble if the material does not dissolves

3. IDENTIFICATION:

Weigh accurately about 0.5g of sample dissolved in 50ml of Hydrochloric acid and dilute with water to 200ml. To 10ml of this solution add 2ml of potassium ferrocyanide. A dark blue precipitate is produced. With an excess of 1N NaOH, a reddish brown precipitate is formed. Solutions of ferric salts produce with Ammonium thiocyanate TS a deep red colour which is not destroyed by dilute mineral acids.

4. WATER SOLUBLE SUBSTANCES:

Not more than 1.0% w/w, not more than 20mg of residue.

Weigh accurately about 2.0g of sample dissolved in 100ml of water on a boiling water bath for 2 hours, filter and wash the filter with water. Evaporate the filtrate and washings, and dry the residue at 105° for 1 hour.

5. ACID INSOLUBLE SUBSTANCES: < REFER GAM 017>

Not more than 0.3% w/w, the residue weighs not more than 6mg.

Weigh accurately about 2.0g of sample dissolved in 25ml of hydrochloric acid by boiling for 20 minutes. Add 100ml of hot water and filter quantitatively through a tared filtering crucible with the aid of hot wash water, until the filtrate tests negative for chloride. Dry the crucible and contents at 105° for 1 hour.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	26/03/2025	27/03/2025	29/03/2025

6. ARSENIC: < REFER GAM 004>

Lead acetate cotton:

Immerse absorbent cotton pled gets in a mixture of lead acetate TS and 2 N acetic acid (10:1). Free the cotton pledgets from excess liquid by expression, and allow to air-dry

Sodium borohydride solution:

30 mg/ml of sodium borohydride in 0.25 N sodium hydroxide. Store in a loosely covered container protected from direct sunlight.

Mercuric bromide paper:

Immerse several filter paper disks with a 15-mm diameter in alcoholic mercuric bromide TS, remove the disks from the solution, and allow to dry, protected from light. Store in a glass-stoppered container protected from light.

Arsenic trioxide stock solution:

Dissolve 132.0 mg of arsenic trioxide in 2.0 ml of 2 N sodium hydroxide, and dilute with water to 100 ml.

Standard stock solution:

On the day of use, dilute 1.0 mL of Arsenic trioxide stock solution with water to 1000 ml.

Standard solution:

Dilute 1.5 ml of the Standard stock solution with hydrochloric acid to 10 ml. This solution contains 0.15 µg/ml of arsenic.

Sample solution:

Dissolve 0.5 g of sample dissolved in several mL of hydrochloric acid with the aid of heat, and dilute with hydrochloric acid to 10.0 ml.

Apparatus:

Prepare a 300-mL, side-arm conical flask containing a magnetic stirring bar. Attach to the conical flask a ground-glass stopper. Pass through the ground glass stopper a glass tube 20 cm long with an internal diameter of 5 mm. The lower end of this tube is inside the conical flask, and it has been drawn to a tip with an internal diameter of 1 mm. There is an orifice, 2.5 mm in diameter, 15 mm from the tip, and at least 3 mm below the lower surface of the stopper. The upper end of the tube has a flat ground surface at a right angle to the axis of the tube.

A second glass tube, 30 mm long with an internal diameter of 5 mm and with a similar flat ground surface, is placed in contact with the ground surface of the first tube and is held in position by a clamp and springs.

Into the lower tube insert 55 mg of loosely packed Lead acetate cotton. Between the flat surfaces of the tubes place a disk of Mercuric bromide paper.

Analysis:

Before placing the tube assembly into the flask, transfer the Sample solution to the flask, and add 5.0 mL of potassium iodide TS and 20 mL of water. Assemble the apparatus immediately, and stir while slowly adding, over a period of 20 min, 40 mL of Sodium borohydride solution through the side arm of the flask. Examine the stain produced on the Mercuric bromide paper. Perform the same Analysis using the Standard solution.

Acceptance criteria:

Not more than 3µg/g; the stain produced on the Mercuric bromide paper from the Sample solution is not more intense than that from the Standard solution.

7. LEAD: (Atomic absorption spectroscopy)

Chromatographic Condition:

Mode	:	Atomic absorption spectrophotometer equipped with a flow spoiler
Analytical wavelength	:	217.0 nm (lead emission line)

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	26/03/2025	27/03/2025	29/03/2025

Lamp : Lead hollow-cathode

Flame : Air–acetylene oxidizing

Lead nitrate stock solution:

1.598 mg/mL of lead nitrate in 0.5M nitric acid. Prepare and store this solution in glass containers free from soluble lead salts.

Standard stock solution:

On the day of use, combine 5.0mL of Lead nitrate stock solution and 10mL of 1N hydrochloric acid, and dilute with water to 100mL

Standard solution:

Transfer 1.0mL of the Standard stock solution to a 100mL volumetric flask, add 10mL of 1N hydrochloric acid, and dilute with water to volume. This solution contains 0.5 µg/mL of lead.

Sample solution:

Transfer 2.5g of Ferric Oxide to a 100mL, glass-stoppered conical flask. Add 35mL of 0.1N hydrochloric acid, and stir for 1 h. Filter, collecting the filtrate in a 50mL volumetric flask, and dilute with 0.1N hydrochloric acid to volume.

Acceptance criteria:

Not more than 0.001%; the absorbance of the Sample solution does not exceed that of the Standard solution.

8. MERCURY:

Standard solution:

Take 2.0ml of Mercury standard solution into a 100ml beaker and add 35ml of water, 3ml of sulphuric acid and 1ml of potassium permanganate solution. Cover the beaker with a watch glass boil for a few seconds and cool.

Test solution:

Weigh accurately about 0.67g of sample and add 35ml of 0.5N hydrochloric acid. Heat to boiling and allow to cool. Add 2 drops of phenolphthalein and if necessary slowly neutralize with constant stirring using 1N sodium hydroxide or 1N sulphuric acid. Add 3ml of sulphuric acid and 1ml of potassium permanganate solution. Cover the beaker with a watch glass boil for a few seconds and cool.

Procedure:

Assemble the aeration apparatus with the aeration vessel and the trap empty and the stopcock in the bypass position. Connect the apparatus to the absorption cell and adjust the air or nitrogen flow rate so that in the following procedure maximum absorption and reproducibility are obtained without excessive foaming in the test solution. Obtain a smooth baseline reading at 253.6.

Treat the standard solution and the test solution similarly as follows. Destroy the excess permanganate by adding hydroxylamine hydrochloride solution dropwise until the solution is colourless. Immediately wash the solution into the aeration vessel with water and dilute with water to 100ml. Add 2ml of stannous chloride solution and immediately reconnect the aeration vessel to the aeration apparatus. Turn the stopcock from the bypass position to the aerating position and continue the aeration until the absorption peak has been passed and the recorder pen returns to the baseline. Disconnect the aeration vessel from the apparatus and wash with water after each use. After correcting for any reagent blank any absorbance produced by the test solution does not exceed that produced by the standard solution.

Acceptance criteria:

Not more than 3ppm.

9. ORGANIC COLORS AND LAKES:

Place 1.0g of the Sample in each of 3 beakers, and add 25mL of each of the following reagents, one reagent to each beaker: 1-chloronaphthalene, alcohol, and chloroform. Heat the beakers containing alcohol and chloroform just to boiling. Heat the other beaker on a boiling water bath for 15 min, with occasional swirling. Pass the contents of the beakers through retentive, solvent-resistant filter paper. If any of the filtrates shows visible turbidity, centrifuge for 15 min.

Record the spectra against respective solvent blanks in 1-cm cells from 350 to 750 nm.

Acceptance criteria:

No peak above the noise level with a slope greater than +0.001 absorbance unit/nm is found.

10. LOSS ON IGNITION: < REFER GAM 027>

Not more than 13.0%, determined 2.0g of sample at 800°C±25°C to constant weight.

11. ASSAY: (IGNITED BASIS)

Procedure :

Take ignited basis 1.5g of sample accurately weighed in 25ml of Concentrate hydrochloric acid on water bath until dissolved. Add 10ml of Hydrogen peroxide Ts and evaporate on a water bath almost to dryness in order to volatilize all Hydrogen peroxide. Dissolve the residue by warming with 5ml Hydrochloric acid, add 25ml of water, filter into 250ml volumetric flask, washing the filter with water and add water to volume. Transfer a 50ml aliquot to a glass stoppered flask, add 3g Potassium iodide and 5ml of Hydrochloric acid and insert the stopper into the flask. Allow the mixture to stand for 15 minutes, add 50ml of water and titrate the liberated iodine with 0.1N Sodium thiosulphate VS, using starch solution as indicator. Perform a blank test with same quantities of reagent in the same manner and make any necessary corrections. Each ml of 0.1N Sodium thiosulphate is equivalent to 7.985 mg of ferric oxide.

Calculation:

Calculate the content of ferric oxide:

$$\frac{\text{Titer value} - \text{Blank value} \times \text{Molarity of 0.1N sodium thiosulphate} \times 7.985 \times 250 \times 100}{0.1 \times \text{sample weight in mg} \times 50}$$

12. pH: < REFER GAM 030>

5.0 to 7.5

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	26/03/2025	27/03/2025	29/03/2025

Weigh accurately about 1.0g of the sample and transfer to a clean and dry 100ml beaker. Add 100ml water and make suspension of the sample. Determine the pH of the sample by using a standardized pH meter.

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMEI0004-00	(i) Periodic review. (ii) STP numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	29/03/2025

****END OF THE DOCUMENT****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	26/03/2025	27/03/2025	29/03/2025

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	ISOPROPYL ALCOHOL BP			
Specification No.	SPEC-RMEI0010-01	**Revision No.**	01	**Item Code.:** RMEI0010
Supersedes	RMESI0010-00	**Effective Date**	23/05/2023	**Page No.:** 1 of 4

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	C_3H_8O
2	Molecular weight	60.1
3	Storage conditions	Protected from light.
4	Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
5	Quantity of sample required for analysis	300ml
6	Quantity of reserve sample	600ml
7	Retest period	12 months from the date of release
8	Re-test Parameter	As mentioned in Specification
9	Reference	BP
10	Sampling instruction	Follow the standard operating procedure No.: ST/QC/040.
11	Destructions instructions	Follow the standard operating procedure No.: ST/QC/032.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	18/05/2023	19/05/2023	20/05/2023

Safetab Life Science QUALITY ASSURANCE Puducherry-107

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	A clear, colourless liquid.
2.	*Solubility	Miscible with water and with ethanol (96 percent).
3.	*Identification **A.** By Relative density **B.** By Refractive index **C.** By IR **D.** By Chemical test	 **A.** Between 0.785 to 0.789 **B.** Between 1.376 to 1.379 **C.** The Infrared absorption spectrum of sample should be concordant with that of reference spectrum of Isopropyl alcohol RS. **D.** A bright reddish-violet ring forms immediately at the junction of the 2 liquids.
4.	Appearance of solution	The solution is clear.
5.	Acidity or alkalinity	The solution is colourless. Not more than 0.6ml of 0.01M sodium hydroxide is required to change the colour of the indicator to pale pink.
6.	Absorbance	Maximum 0.30 at 230 nm Maximum 0.10 at 250 nm Maximum 0.03 at 270 nm Maximum 0.02 at 290 nm Maximum 0.01 at 310 nm

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	18|05|2023	19|05|2023	20|05|2023

Safetab Life Science QUALITY ASSURANCE Puducherry-107

UNCONTROLLED COPY

S.NO	TEST (s)	SPECIFICATION (s)
7.	**Benzene and related substances: A. Benzene B. Total impurities	 Not more than 2 ppm Not more than 0.3 %
8.	**Peroxides	No colour develops.
9.	Non-volatile substances	Maximum 20 ppm.
10.	*Water content (By KFR)	Maximum 0.5%

Remarks: The above * Marked tests are to be performed while retesting the material.

The above ** marked test value shall be documented from vendor COA.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	18/05/2023	19/05/2023	20/5/23

Safetab Life Science QUALITY ASSURANCE Puducherry-107

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-RMEI0010-01	(i) Periodic review. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	23/05/2023

**** END OF THE DOCUMENT ****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	18/05/2023	19/05/2023	20/05/2023

Safetab Life Science QUALITY ASSURANCE Puducherry-107

UNCONTROLLED COPY

1. DESCRIPTION: < REFER GAM 001>

A clear, colourless liquid.

2. SOLUBILITY: < REFER GAM 002>

10 mL of sample + 10 mL of water	Miscible
10 mL of sample + 10 mL of Ethanol (96 per cent)	Miscible

3. IDENTIFICATION:

A. By Relative density: < REFER GAM 031>

Between 0.785 to 0.789

B. By Refractive index: < REFER GAM 025>

Between 1.376 to 1.379

C. By IR: < REFER GAM 003>

The Infrared absorption spectrum of sample should be concordant with that of reference spectrum or with the spectrum obtained from Isopropyl Alcohol RS.

D. By Chemical test:

To 1ml add 4ml of water and mix. Carefully add 2ml of a 10g/l solution of dimethylaminobenzaldehyde in sulfuric acid, ensuring that the liquids do not mix; a bright reddish-violet ring forms immediately at the junction of the 2 liquids. After 2-5 min, the entire sulfuric acid layer turns violet.

4. APPEARANCE OF SOLUTION:

The substance to be examined is clear and colourless. Dilute 1 ml to 20 ml with water. After 5 min, the solution is clear.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	18/05/2023	19/05/2023	20/05/2023

Safetab Life Science QUALITY ASSURANCE Puducherry-107

5. ACIDITY OR ALKALINITY:

Gently boil 25 ml for 5 min. Add 25 ml of carbon dioxide-free water and allow to cool protected from carbon dioxide in the air. Add 0.1 ml of phenolphthalein solution. The solution is colourless. Not more than 0.6 ml of 0.01 M sodium hydroxide is required to change the colour of the indicator to pale pink.

6. ABSORBANCE:

Maximum 0.30 at 230 nm, 0.10 at 250 nm, 0.03 at 270 nm, 0.02 at 290 nm, 0.01 at 310 nm.

The absorbance is measured between 230 nm and 310 nm using water as the compensation liquid. The spectrum shows a steadily descending curve with no observable peaks or shoulders.

7. BENZENE AND RELATED SUBSTANCES: (Determine by gas chromatography)

Test solution (a):

The substance to be examined.

Test solution (b):

Dilute 1.0 ml of 2-butanol to 50.0 ml with test solution (a). Dilute 5.0 ml of this solution to 100.0 ml with test solution (a).

Reference solution (a):

Dilute 0.5 ml of 2-butanol and 0.5 ml of propanol to 50.0 ml with test solution (a). Dilute 5.0 ml of this solution to 50.0 ml with test solution (a).

Reference solution (b):

Dilute 100µl of benzene to 100.0ml with test solution (a). Dilute 0.20ml of this solution to 100.0ml with test solution (a).

Chromatographic Condition:

Coloum	:	Fused silica
Size	:	I=30m,Ø=0.32mm;
Stationary phase	:	Poly[(cyanopropyl)(phenyl)][dimethyl]siloxane (Film thickness 1.8 µm)
Injection Volume	:	1µl
Linear velocity	:	35 cm/s
Retention time	:	Benzene= about 10 min
Split ratio	:	1:5
Detection	:	Flame ionization
Auxiliary gas	:	Nitrogen or helium

Temperature:

	Time (min)	Temperature (°c)
Column	0-12	40
	12-32	40-→240
	32-42	240
Injection port		280
Detector		280

System suitability reference solution (a):

Resolution:

Minimum 10 between the 1st peak (propanol) and the 2nd peak (2-butanol).

Limits:

Benzene: Test solution (a):

Not more than 0.5 times the area of the corresponding peak in the chromatogram obtained with reference solution (b) (2 ppm), after the sensitivity has been adjusted so that the height of the peak due to benzene in the chromatogram obtained with reference solution (b) represents at least 1O per cent of the full scale of the recorder.

Total of impurities apart from 2-butanol: (Test solution (b)

Not more than 3 times the area of the peak due to 2-butanol in the chromatogram obtained with test solution (b) (0.3 per cent), after the sensitivity has been adjusted so that the height of the 2 peaks following the principal peak in the chromatogram obtained with reference solution (a) represents at least 50 per cent of the full scale of the recorder.

8. PEROXIDES:

In a 12 ml test-tube with a ground-glass stopper and a diameter of about 15 mm, introduce 8 ml of potassium iodide and starch solution. Fill completely with the substance to be examined. Shake vigorously and allow to stand protected from light for 30 min. No colour develops.

9. NON-VOLATILE SUBSTANCES:

Evaporate 100 g to dryness on a water-bath after having verified that it complies with the test for peroxides and dry in an oven at 100-105 °C. The residue weighs a maximum of 2 mg. (Maximum 20 ppm).

10. WATER: < REFER GAM 010>

Not more than 0.5 per cent, determined on 5.0 g.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	18/05/2023	19/05/2023	20/05/2023

Safetab Life Science QUALITY ASSURANCE Puducherry-107

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMEI0010-01	(i) Periodic review. (ii) STP numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	23|05|2023

****END OF THE DOCUMENT****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	18|05|2023	19|05|2023	20|05|2023

Safetab Life Science QUALITY ASSURANCE Puducherry-107

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	MAGNESIUM STEARATE BP			
Specification No.	SPEC-RMEM0033-00	**Revision No.**	00	**Item Code.:** RMEM0033
Supersedes	RMESM0033-01	**Effective Date**	14/03/2024	**Page No.:** 1 of 4

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	$(C_{17}H_{35}CO_2)_2$ Mg
2	Molecular weight	591.27
3	Storage conditions	Store at ambient temperature.
4	Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
5	Quantity of sample required for analysis	20 g
6	Quantity of reserve sample	40 g
7	Retest period	12 months from the date of release
8	Re-test Parameter	As mentioned in Specification
9	Reference	BP
10	Sampling instruction	Follow the standard operating procedure No.: ST/QC/040.
11	Destructions instructions	Follow the standard operating procedure No.: ST/QC/032.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Dy. Manager-QC	GM-QC	AGM-QA
Signature			
Date	12/03/2024	13/03/2024	12/03/2024

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	MAGNESIUM STEARATE BP			
Specification No.	SPEC-RMEM0033-00	**Revision No.**	00	**Item Code.:** RMEM0033
Supersedes	RMESM0033-01	**Effective Date**	14/03/2024	**Page No.:** 2 of 4

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	A white or almost white, very fine, light powder, greasy to the touch.
2.	*Solubility	Practically insoluble in water and in anhydrous ethanol.
3.	*Identification **A.** By Freezing point **B.** By Acid value **C.** By Fatty acid composition **D.** By Chemical test	 Not less than 53°. The acid value of the fatty acids is 195 to 210. The principle peaks in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution. A white crystalline precipitate is formed.
4.	Acidity or alkalinity	Not more than 0.05ml of 0.1M Hydrochloric acid or 0.1M Sodium hydroxide is required to change the colour of the indicator.
5.	Chlorides	Not more than 0.1%.
6.	Sulfates	Not more than 1.0%.
7.	Cadmium	Not more than 3 ppm

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Dy. Manager-QC	GM-QC	AGM-QA
Signature			
Date	12/03/2024	13/03/2024	13/03/2024

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	MAGNESIUM STEARATE BP			
Specification No.	SPEC-RMEM0033-00	**Revision No.**	00	**Item Code.:** RMEM0033
Supersedes	RMESM0033-01	**Effective Date**	14/03/2024	**Page No.:** 3 of 4

S.NO	TEST (s)	SPECIFICATION (s)
8.	Lead	Not more than 10 ppm
9.	Nickel	Not more than 5 ppm
10.	*Loss on drying	Not more than 6.0% w/w.
11.	*Assay for Magnesium (On dried basis)	Not less than 4.0% and not more than 5.0% w/w
12.	Stearic acid and Palmitic acid (i) Stearic acid (ii) Sum of Stearic acid and Palmitic acid	 Not less than 40.0% Not less than 90.0%
13.	*Microbial contamination (i) Total aerobic microbial count (ii) Total yeast and mold count iii) Escherichia coli iv) Salmonella species	 Not more than 1000 cfu/g Not more than 100 cfu/g Should be absent Should be absent

Remarks: The above * Marked tests are to be performed while retesting the material.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Dy. Manager-QC	GM-QC	AGM-QA
Signature			
Date	12/03/2024	13/03/2024	13/03/2024

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-RMEM0033-00	(i) Specification numbering procedure revised as per SOP No. ST/QC/058. (ii) There is no changes in specification as per current monograph.	ST/CC/23/063 ST/CC/24/067	14/03/2024

**** END OF THE DOCUMENT ****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Dy. Manager-QC	GM-QC	AGM-QA
Signature			
Date	12/03/2024	13/03/2024	13/03/2024

1. DESCRIPTION: < REFER GAM 001>

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

2. SOLUBILITY: < REFER GAM 002>

10mg of sample + 100mL of Water	Practically insoluble if the material does not dissolves.
10mg of sample + 100mL of Anhydrous ethanol	Practically insoluble if the material does not dissolves.

3. IDENTIFICATION: < REFER GAM 003>

First identification : C and D

Second identification: A, B and D

To 5.0g of sample add 50 ml of peroxide-free ether, 20ml of dilute nitric acid and 20ml of water and 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 2 quantities, each of 4ml of water. Combine the aqueous layers, wash with 15ml of peroxide-free ether and dilute to 50ml with water (Solution S). Evaporate the organic layer to dryness and dry the residue at 100-105°C. Keep the residue for identification tests A and B.

A. By Freezing point:

Determined on the residue obtained in the preparation of solution S has a freezing point not less than 53°C.

B. By Acid value:

The acid value of the fatty acids is 195 to 210, dissolved on 0.2g of the residue obtained in the preparation of solution S in 25ml of the mixture of equal volumes of ethanol (96 per cent) and light petroleum, previously neutralised with 0.1M potassium hydroxide or 0.1M sodium hydroxide, unless otherwise specified, using 0.5mL of phenolphthalein solution as indicator. If necessary, heat to about 90°C to dissolve the substance to be examined. When the substance to be examined has dissolved, titrate with 0.1M potassium hydroxide or 0.1M sodium hydroxide until the pink colour persists for at least 15s (n mL of titrant). When heating has been applied to aid dissolution maintain the temperature at about 90°C during the titration.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Dy. Manager-QC	GM-QC	AGM-QA
Signature			
Date	12/03/2024	13/03/2024	13/03/2024

$$I_A = \frac{5.61n}{m}$$

C. By Fatty acid composition:

Examine the chromatograms obtained in the assay of stearic acid and palmitic acid.

The two principle peaks in the chromatogram obtained with the test solution are similar in retention time to the two principal peaks in the chromatogram obtained with the reference solution.

D. By Chemical test:

Take 1ml of Solution S, add 1ml of dilute ammonia; a white precipitate is formed that dissolves on addition 1ml of ammonium chloride solution. Add 1ml of 120g/L solution of disodium hydrogen phosphate dodecahydrate; a white crystalline precipitate is formed.

4. ACIDITY OR ALKALINITY:

To 1.0g of sample, add 20ml of carbon dioxide free water and boil for 1 minute with continuous shaking. Cool and filter. To 10ml of filtrate add 0.05ml of bromothymol blue solution. Not more than 0.05ml of 0.1M hydrochloric acid or 0.1M sodium hydroxide is required to change the colour of the indicator.

5. CHLORIDES: < REFER GAM 008>

Not more than 0.1%.

Dilute 10.0mL of Solution S to 40mL with water. Neutralise if necessary with nitric acid using litmus as indicator. Add 1mL of nitric acid and 1mL of 0.1M silver nitrate and dilute to 50mL with water. Mix and allow to stand for 5 min protected from light. The turbidity, if any, is not greater than that produced in a solution containing 1.4mL of 0.02M hydrochloric acid.

6. SULFATES: < REFER GAM 009>

Not more than 1.0%.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Dy. Manager-QC	GM-QC	AGM-QA
Signature			
Date	12/03/2024	13/03/2024	13/03/2024

Dilute 6.0 ml of Solution S to 40.0 ml with water. Neutralise if necessary with hydrochloric acid using litmus as indicator. Add 1mL of 3M hydrochloric acid and 3mL of a 120g/L solution of barium chloride and dilute to 50mL with water. Mix and allow to stand for 10 min. The turbidity, if any, is not greater than that produced in a solution containing 3.0mL of 0.02M sulfuric acid.

7. CADMIUM: (ATOMIC ABSORPTION SPECTROMETRY)

Not more than 3ppm.

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

Blank solution:

Dilute 25mL of cadmium and lead-free nitric acid to 100.0 mL with water.

Modifier solution:

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

Test solution:

Place 0.100g of the substance to be examined in a polytetrafluoroethylene digestion bomb and add 2.5mL of cadmium- and lead-free nitric acid. Close and seal the bomb according to the manufacturer's operating instructions (when using a digestion bomb, be thoroughly familiar with the safety and operating instructions. Carefully follow the bomb manufacturer's instructions regarding care and maintenance of these digestion bombs. Do not use metal jacketed bombs or liners which have been used with hydrochloric acid due to contamination from corrosion of the metal jacket by hydrochloric acid). 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 fume cupboard and open carefully as corrosive gases may be expelled. Dissolve the residue in water R and dilute to 10.0 mL with the same solvent.

Reference solution:

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

Dilute 1.0mL of the test solution to 10.0mL 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 50µL of modifier solution and mix. These solutions contain respectively 0µg, 0.00075µg and 0.0015µg of cadmium per millilitre from the reference solution (keep the remaining test solution for use in the test for lead and nickel).

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 spectrometer 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

8. LEAD: (ATOMIC ABSORPTION SPECTROMETRY)

Not more than 10 ppm.

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 8M 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) R with the blank solution.

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 millilitre from the reference solution.

Source: Lead hollow-cathode lamp.

Wavelength: 283.3 nm.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Dy. Manager-QC	GM-QC	AGM-QA
Signature			
Date	12/03/2024	13/03/2024	13/03/2024

Atomisation device: Furnace.

Platform: Pyrolytically coated with integrated tube.

Operating conditions:

Use the temperature programme recommended for lead by the GFAA spectrometer 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

9. NICKEL: (ATOMIC ABSORPTION SPECTROMETRY)

Not more than 5 ppm.

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

Blank solution:

Use the solution described in the test for cadmium.

Modifier solution:

Dissolve 20g of ammonium dihydrogen phosphate in water R and dilute to 100mL 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.

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.

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 spectrometer manufacturer. An example of temperature parameters for GFAA analysis of nickel is shown below.

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

10. LOSS ON DRYING: < REFER GAM 026>

Not more than 6.0 per cent, determined on 1.0g by drying in an oven at 105°C.

11. ASSAY:

Magnesium:

Weigh 0.5g of sample in a 250ml conical flask, add 50ml of a mixture of equal volumes of anhydrous ethanol and butanol, 5ml of concentrated ammonia, 3ml of ammonium chloride buffer solution pH 10.0, 30.0ml of 0.1M sodium edetate and 15mg of mordant black II triturate. Heat at 45°C to 50°C until the solution is clear and titrate with 0.1M zinc sulphate until the colour changes from blue to violet. Carry out a blank titration.

1ml of 0.1 M sodium edetate is equivalent to 2.431 g of Mg.

Calculation:

$$= \frac{\text{Titer value-Blank value x Molarity of 0.1M disodium edetate x 2.431 x 100 x 100}}{\text{0.1 x Sample weight in mg x (100 – Sample LOD)}}$$

12. STEARIC ACID AND PALMITIC ACID:

Determine by gas chromatography:

Test solution:

In a conical flask fitted with a reflux condenser, dissolve 0.10g of the substance to be examined in 5mL of boron trifluoride-methanol solution. Boil under a reflux condenser for 10 min. Add 4 mL of heptane through the condenser and boil again under a reflux condenser for 10 min. Allow to cool. Add 20 mL of saturated sodium chloride solution. Shake and allow the layers to separate. Dry the organic layer over 0.1g of anhydrous sodium sulfate (previously washed with heptane). Dilute 1.0mL of the solution to 10.0mL with heptane.

Reference solution:

Prepare the reference solution in the same manner as the test solution using 50.0 mg of palmitic acid CRS and 50.0mg of stearic acid CRS instead of the substance to be examined.

Chromatographic conditions:

Material	:	Fused silica;
Size	:	l = 30 m, Ø = 0.32 mm;
Stationary phase	:	Macrogol 20,000 (film thickness 0.5 µm).
Carrier gas	:	Helium for chromatography.
Flow rate	:	2.4 mL/min.
Detection	:	Flame ionisation.
Injection	:	1 µL.

Temperature:

	Time (min)	Temperature (°C)
Column	0 - 2	70
	2 - 36	70 → 240
	36 - 41	240
Injection port		220
Detector		260

Relative retention:

With reference to methyl stearate: methyl palmitate = about 0.9.

System suitability: Reference solution.

Resolution: Minimum 5.0 between the peaks due to methyl palmitate and methyl stearate;

Relative standard deviation:

Maximum 3.0 per cent for the areas of the peaks due to methyl palmitate and methyl stearate, determined on 6 injections; maximum 1.0 per cent for the ratio of the areas of the peaks due to methyl palmitate to the areas of the peaks due to methyl stearate, determined on 6 injections.

13. MICROBIAL CONTAMINATION:

Total Viable aerobic count and Pathogen test refer as per the current SOP No: ST/MB/011.

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMEM0033-00	(i) STP numbering procedure revised as per SOP No. ST/QC/058. (ii) Testing procedure for acid value has been incorporated in the identification test.	ST/CC/23/063 ST/CC/24/067	14/03/2024

**** END OF THE DOCUMENT****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Dy. Manager-QC	GM-QC	AGM-QA
Signature			
Date	12/03/2024	13/03/2024	13/03/2024

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	METFORMIN HYDROCHLORIDE BP			
Specification No.	SPEC-RMAM0030-01	**Revision No.**	01	**Item Code.:** RMAM0030
Supersedes	RMASM0030-00	**Effective Date**	03/06/2023	**Page No.:** 1 of 3

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	$C_4H_{12}ClN_5$
2	Molecular weight	165.6
3	Storage conditions	Store protected from light and moisture
4	Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
5	Quantity of sample required for analysis	6 g
6	Quantity of reserve sample	12 g
7	Retest period	12 months from the date of release
8	Re-test Parameter	As mentioned in Specification
9	Reference	BP
10	Sampling instruction	Follow the standard operating procedure No.: ST/QC/040.
11	Destructions instructions	Follow the standard operating procedure No.: ST/QC/032.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	30/05/2023	31/05/2023	01/06/2023

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	METFORMIN HYDROCHLORIDE BP			
Specification No.	SPEC-RMAM0030-01	**Revision No.**	01	**Item Code.:** RMAM0030
Supersedes	RMASM0030-00	**Effective Date**	03/06/2023	**Page No.:** 2 of 3

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	White or almost white crystals.
2.	*Solubility	Freely soluble in water, slightly soluble in ethanol (96 percent), practically insoluble in acetone and in methylene chloride.
3.	*Identification	
	A. By Melting point	Between 222°C to 226°C
	B. By IR	The Infrared absorption spectrum of sample should be concordant with that of reference spectrum or with the spectrum obtained from Metformin Hydrochloride WS.
	C. By Thin-layer chromatography	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.
	D. By Chemical test	A pink colour develops.
	E. By Chlorides test	A curdled, white precipitate is formed.
4.	Appearance of solution	Solution S is clear and colourless
5.	Impurity F	Not more than 0.05%

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	30/05/2023	31/05/2023	01/06/2023

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	METFORMIN HYDROCHLORIDE BP			
Specification No.	SPEC-RMAM0030-01	**Revision No.**	01	**Item Code.:** RMAM0030
Supersedes	RMASM0030-00	**Effective Date**	03/06/2023	**Page No.:** 3 of 3

S.NO	TEST (s)	SPECIFICATION (s)
6.	*Related substances (By HPLC) (i) Impurity A (ii) Unspecified impurities (iii) Total impurities	 Not more than 0.02% Not more than 0.05% Not more than 0.2%
7.	*Sulfated ash	Not more than 0.1%
8.	*Loss on drying	Not more than 0.5%
9.	*Assay by Titration (On dried basis)	Not less than 98.5% and not more than 101.0% w/w.

Remarks: The above * Marked tests are to be performed while retesting the material.

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-RMAM0030-01	(i) Periodic review. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	03/06/2023

**** END OF THE DOCUMENT ****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	30/05/2023	31/05/2023	01/06/2023

	Safetab Life Science Puducherry			MASTER COPY
	STANDARD TESTING PROCEDURE			
Name of Product	METFORMIN HYDROCHLORIDE BP			
STP No.	STP-RMAM0030-01	**Revision No.**	01	**Item Code.:** RMAM0030
Supersedes	RMATM0030-00	**Effective Date**	03/06/2023	**Page No.:** 1 of 10

1. DESCRIPTION: < REFER GAM 001>

White or almost white crystals.

2. SOLUBILITY: < REFER GAM 002>

100mg of sample + 1mL of water	Freely soluble if the material dissolves.
10mg of sample + 10mL of ethanol (96%)	Slightly soluble if the material dissolves.
10mg of sample + 100mL of acetone	Practically insoluble if the material does not dissolve.
10mg of sample + 100mL of Methylene chloride	Practically insoluble if the material does not dissolve.

3. IDENTIFICATION:

First identification: B, E.

Second identification: A, C, D, E.

A. By Melting point: < REFER GAM 028>

Melting point 222 °C to 226 °C.

B. By IR : < REFER GAM 003>

The Infrared absorption spectrum of sample should be concordant with that of reference spectrum or with the spectrum obtained from Metformin Hydrochloride WS.

C. By Thin-layer Chromatography:

Test solution:

Dissolve 20 mg of the substance to be examined in water and dilute to 5 mL with the same solvent.

Reference solution:

Dissolve 20 mg of Metformin hydrochloride WS in water and dilute to 5 mL with the same solvent.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	30/05/2023	31/05/2023	01/06/2023

Plate: TLC silica gel G plate.

Mobile phase:

Glacial acetic acid, butanol, water (10:40:50 *V/V/V*); use the upper layer.

Application 5 µL.

Development Over 3/4 of the plate.

Drying At 100-105 °C for 15 min.

Detection Spray with a mixture of equal volumes of a 100 g/L solution of sodium nitroprusside, a 100 g/L solution of potassium ferricyanide and a 100 g/L solution of sodium hydroxide, prepared 20 min before use.

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.

D. By Chemical test:

Dissolve about 5 mg in water and dilute to 100 mL with the same solvent. To 2 mL of the solution add 0.25 mL of strong sodium hydroxide solution and 0.10 mL of α-naphthol solution. Mix and allow to stand in iced water for 15 min. Add 0.5 mL of sodium hypobromite solution and mix. A pink colour develops.

E. By Chlorides:

Dissolve 9.3mg of sample in 2ml of water and Acidify with dilute nitric acid and add 0.4 mL of silver nitrate solution. Shake and allow to stand. A curdled, 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 dissolve slowly.

SOLUTION S:

Dissolve 2.0 g in water and dilute to 20 mL with the same solvent.

4. APPEARANCE OF SOLUTION:

Solution S is clear and colourless. Heat the solution to 50°C and cool to room temperature.

5. IMPURITY F:

Chemicals/Reagents/Standards:

Metformin impurity F	:	Reference standard
Fluorodinitrobenzene	:	AR grade
Triethylamine	:	AR grade
Orthophosphoric acid	:	AR grade
Acetonitrile	:	HPLC grade
Purified water	:	Milli-Q water (or) equivalent

Chromatographic Conditions:

Column	:	Purospher RP-18, 125mm x 3mm, 5µm (or) equivalent
Flow Rate	:	0.7 mL/min.
Wavelength	:	Spectrophotometer at 380nm
Injection volume	:	5µl
Temperature	:	30 °C

Mobile phase preparation:

Mobile phase A:

OrthoPhosphoric acid, water (0.1:99.9 V/V)

Mobile phase B:

Acetonitrile

Gradient Program:

Time (min)	Mobile phase A (% v/v)	Mobile phase B (% v/v)
0-10	60→45	40→55
10-11	45→25	55→75
11-15	25	75

Derivatisation solution:

Prepare the solution immediately before use.

Dissolve 1 mL of fluorodinitrobenzene in 100.0 mL of acetonitrile.

Blank solution:

To 5.0 mL of acetonitrile add 100 µL (0.1ml) of Triethylamine and 1.0 mL of the derivatisation solution. Shake well and heat at 60 °C for 30 min. After cooling, dilute to 10.0 mL with acetonitrile.

Test solution:

Prepare the solution immediately before use.

Suspend 10.0 mg of the substance to be examined in 5.0 mL of acetonitrile and sonicate for 5 min. Add 100 µL (0.1ml) of triethylamine and 1.0 mL of the derivatisation solution. Shake well and heat at 60 °C for 30 min. After cooling, dilute to 10.0 mL with acetonitrile. Filter or centrifuge at 800 RPM for 5 min before use.

Reference solution:

Dissolve 1.0 mL of Metformin impurity F RS in 100.0 mL of acetonitrile. Dilute 2.5 mL of the solution to 100.0 mL with acetonitrile. To 1.0 mL of this solution add successively 5.0 mL of acetonitrile, 100 µL (0.1ml) of triethylamine and 1.0 mL of the derivatisation solution. Shake well and heat at 60 °C for 30 min. After cooling, dilute to 10.0 mL with acetonitrile.

Identification of impurities:

Use the chromatograms obtained with the blank solution and the reference solution to identify the peak due to the impurity F derivative.

Retention time Impurity F derivative = about 4 min.

System suitability:

Reference solution:

— **Resolution**: minimum 3.0 between the peak due to the impurity F derivative and the nearby eluting peaks due to the derivatisation reagent.

Limit:

— **Impurity F:** not more than the area of the corresponding peak in the chromatogram obtained with the reference solution (0.05 per cent).

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	30/05/2023	31/05/2023	01/06/2023

6. RELATED SUBSTANCES:

Chemicals/Reagents/Standards:

Metformin impurity A	:	Reference standard
Impurity D (Melamine)	:	Reference standard
Ammonium dihydrogen phosphate	:	AR grade
OrthoPhosphoric acid	:	AR grade
Purified water	:	Milli-Q water (or) equivalent

Chromatographic Conditions:

Column	:	Partisil 10 scx 250mmx4.6, 10 µm (or) equivalent
Flow Rate	:	1.0 mL/min.
Wavelength	:	Spectrophotometer at 218nm
Injection volume	:	20µl

Mobile phase:

17g/L solution of ammonium dihydrogen phosphate and adjusted to pH 3.0±0.05 with Orthophosphoric acid.

Test solution:

Weigh accurately about 0.50 g of the substance to be examined in the mobile phase and dilute to 100.0 mL with the mobile phase.

Reference solution (a):

Weigh accurately about 20.0 mg of metformin impurity A RS in water and dilute to 100.0 mL with the same solvent. Dilute 1.0 mL of the solution to 200.0 mL with the mobile phase.

Reference solution (b):

Dilute 1.0 mL of the test solution to 50.0 mL with the mobile phase. Dilute 1.0 mL of this solution to 20.0 mL with the mobile phase.

Reference solution (c):

Weigh accurately about 10 mg of melamine (impurity D) in about 90 mL of water. Add 5 mL of the test solution and dilute to 100 mL with water. Dilute 1 mL of this solution to 50 mL with the mobile phase.

Run time Twice the retention time of metformin.

Identification of impurities:

Use the chromatogram obtained with reference solution (a) to identify the peak due to impurity A. Use the chromatogram obtained with reference solution (c) to identify the peak due to impurity D.

Relative retention With reference to metformin (retention time = about 14 min): impurity A = about 0.3; impurity D = about 0.4.

System suitability:

Reference solution (c):

— **Resolution:** minimum 10 between the peaks due to impurity D and metformin.

Limits:

— **impurity A:** not more than the area of the corresponding peak in the chromatogram obtained with reference solution (a) (0.02 per cent);

— **unspecified impurities:** for each impurity, not more than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.05 per cent);

— **total:** maximum 0.2 per cent;

— **disregard limit:** 0.3 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.03 per cent); do not disregard the peak due to impurity A.

Inject 20µl of the above solution as per following sequence.

Injection sequence:

S. No	Sample Name	No. of injections
1	Mobile phase (Blank)	1
2	Reference solution (a)	1
3	Reference solution (c)	1
4	Reference solution (b)	1
5	Test solution	1

Calculation:

Impurity A: [NMT 0.02%]

$$= \frac{AT_A}{AS} \times \frac{WS}{100} \times \frac{1}{200} \times \frac{100}{WT} \times \frac{P}{100} \times 100$$

Where,

AT_A = Area of Impurity A peak in Test solution.

AS = Area of the Impurity A peak in the Reference solution (a).

WS = Weight of the Impurity A Reference standard in mg.

WT = Weight of sample taken in mg.

P = Potency of the Impurity A Reference standard in % on as such basis.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	20/05/2023	31/05/2023	01/06/2023

Unspecified impurities: [NMT 0.05%]

$$= \frac{AT_U}{AS} \times \frac{WT}{100} \times \frac{1}{50} \times \frac{1}{20} \times \frac{100}{WT} \times 100$$

Where,

AT_U = Area of Unspecified impurities peak in Test solution.

AS = Area of the principal peak in the Reference solution (b).

WT = Weight of sample taken in mg.

Total impurities: [NMT 0.2%]

$$= \frac{AT_T}{AS} \times \frac{WT}{100} \times \frac{1}{50} \times \frac{1}{20} \times \frac{100}{WT} \times 100$$

Where,

AT_T = Area of Total impurities peak in Test solution.

AS = Area of the principal peak in the Reference solution (b).

WT = Weight of sample taken in mg.

7. SULFATED ASH: <REFER GAM 032>

Not more than 0.1% w/w. Determine on 1.0g of sample.

8. LOSS ON DRYING: <REFER GAM 026>

Not more than 0.5 per cent, determined on 1.0 g by drying in an oven at 105°C for 5 hours.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	30/05/2023	31/05/2023	01/06/2023

9. ASSAY:

Dissolve 0.100 g in 4 mL of anhydrous formic acid. Add 80 mL of acetonitrile. Carry out the titration immediately. Titrate with 0.1M perchloric acid, determining the end-point Potentiometrically.

Each 1ml of 0.1M Perchloric acid is equivalent to 0.01656g of Metformin hydrochloride.

Calculation:

$$= \frac{\text{Titer value - Blank x Molarity of 0.1M perchloric acid x 0.01656 x 100 x 100}}{\text{Sample weight in (g) x (100 – Sample LOD) x 0.1}}$$

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMAM0030-01	(i) Periodic review. (ii) STP numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	03/06/2023

****END OF THE DOCUMENT****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	30/05/2023	31/05/2023	01/06/2023

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	HYPROMELLOSE BP (METHOCEL K 100M PREMIUM LVCR)			
Specification No.	SPEC-RMEM0036-00	**Revision No.**	00	**Item Code.:** RMEM0036
Supersedes	RMESM0036-00	**Effective Date**	28/07/2023	**Page No.:** 1 of 3

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	NA
2	Molecular weight	NA
3	Storage conditions	NA
4	Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
5	Quantity of sample required for analysis	15 g
6	Quantity of reserve sample	30 g
7	Retest period	12 months from the date of release
8	Re-test Parameter	As mentioned in Specification
9	Reference	BP
10	Sampling instruction	Follow the standard operating procedure No.: ST/QC/040.
11	Destructions instructions	Follow the standard operating procedure No.: ST/QC/032.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	24/07/2023	25/07/2023	26/07/23

	Safetab Life Science Puducherry RAW MATERIAL SPECIFICATION			MASTER COPY
Name of Product	HYPROMELLOSE BP (METHOCEL K 100M PREMIUM LVCR)			
Specification No.	SPEC-RMEM0036-00	**Revision No.**	00	**Item Code.:** RMEM0036
Supersedes	RMESM0036-00	**Effective Date**	28/07/2023	**Page No.:** 2 of 3

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	White, yellowish-white or greyish-white powder or granules, hygroscopic after drying.
2.	*Solubility	Practically insoluble in hot water, in acetone, in anhydrous ethanol and in toluene. It dissolves in cold water giving a colloidal solution.
3.	*Identification	
	A. By Chemical test	The powdered material aggregates on the surface.
	B. By Chemical test	A clear or slightly turbid solution occurs with its thickness dependent on the viscosity grade.
	C. By Chemical test	A red colour develops at first and changes to purple within 100 min.
	D. By Chemical test	A coherent, clear film forms on the glass slide.
	E. By Chemical test	The flocculation temperature is higher than 50 °C.
4.	Appearance of solution	The solution is not more opalescent than reference suspension III and not more intensely coloured than reference solution Y_6
5.	*pH	Between 5.0 to 8.0
6.	Viscosity	Between 80% to 120%
7.	Sulfated ash	Not more than 1.5%

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	24/07/2023	25/07/2023	26/07/23

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	HYPROMELLOSE BP (METHOCEL K 100M PREMIUM LVCR)			
Specification No.	SPEC-RMEM0036-00	**Revision No.**	00	**Item Code.:** RMEM0036
Supersedes	RMESM0036-00	**Effective Date**	28/07/2023	**Page No.:** 3 of 3

S.NO	TEST (s)	SPECIFICATION (s)
8.	*Loss on drying	Not more than 5.0%
9.	*Assay (i) Methoxyl content (ii) Hydroxypropoxyl	 Between 19.0 – 24.0% Between 4.0 – 12.0%

Remarks: The above * Marked tests are to be performed while retesting the material.

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-RMEM0036-00	(i) Periodic review. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	NA	28/07/2023

**** END OF THE DOCUMENT ****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	24/07/2023	25/07/2023	26/07/23

1. DESCRIPTION: < REFER GAM 001>

White, yellowish-white or greyish-white powder or granules, hygroscopic after drying.

2. SOLUBILITY: < REFER GAM 002>

10mg of sample + 100mL of Hot water	Practically insoluble if the material not dissolves.
10mg of sample + 100mL of Acetone	Practically insoluble if the material not dissolves.
10mg of sample + 100mL of Anhydrous ethanol	Practically insoluble if the material not dissolves.
10mg of sample + 100mL of toluene	Practically insoluble if the material not dissolves.

It dissolves in cold water giving a colloidal solution.

3. IDENTIFICATION:

A. By Chemical test:

Evenly distribute 1.0 g onto the surface of 100 mL of water in a beaker, tapping the top of the beaker gently if necessary to ensure a uniform layer on the surface. Allow to stand for 1-2 min: the powdered material aggregates on the surface.

B. By Chemical test:

Evenly distribute 1.0 g into 100 mL of boiling water, and stir the mixture using a magnetic stirrer with a bar 25 mm long a slurry is formed and the particles do not dissolve. Allow the slurry to cool to 10 °C and stir using a magnetic stirrer a clear or slightly turbid solution occurs with its thickness dependent on the viscosity grade.

C. By Chemical test:

To 0.1 mL of the solution obtained in identification test B add 9 mL of a 90 per cent V/V solution of sulfuric acid, shake, heat on a water-bath for exactly 3 min, immediately cool in an ice-bath, carefully add 0.6 mL of a 20 g/L solution of ninhydrin, shake and allow to stand at 25 °C a red colour develops at first and changes to purple within 100 minutes.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	24/07/2023	25/07/2023	26/07/23

D. By Chemical test:

Place 2-3 mL of the solution obtained in identification test B onto a glass slide as a thin film and allow the water to evaporate a coherent, clear film forms on the glass slide.

E. By Chemical test:

Add 50.0 mL of the solution obtained in identification test B to 50.0 mL of water in a beaker. Insert a thermometer into the solution. Stir the solution on a magnetic stirrer/hot plate and begin heating, increasing the temperature at a rate of 2-5 °C per minute. Determine the temperature at which a turbidity increase begins to occur and designate the temperature as the flocculation temperature the flocculation temperature is higher than 50 °C.

4. APPEARANCE OF SOLUTION:

The solution is not more opalescent than reference suspension III and not more intensely coloured than reference solution Y_6

While stirring, introduce a quantity of the substance to be examined equivalent to 1.0 g of the dried substance into 50 g of carbon dioxide-free water heated to 90 °C. Allow to cool, adjust the mass of the solution to 100 g with carbon dioxide-free water and stir until dissolution is complete.

5. pH: < REFER GAM 030>

5.0 to 8.0 for the solution prepared as described under Viscosity.

Read the indicated pH value after the probe has been immersed for 5 ± 0.5 min.

6. VISCOSITY:

80 per cent to 120 per cent of the nominal value for samples with a viscosity less than 600 mPa·s (Method 1)

Method 1:

Method 1, to be applied to samples with a viscosity of less than 600 mPa·s Weigh a quantity of the substance to be examined equivalent to 4.000 g of the dried substance.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	24/07/2023	25/07/2023	26/07/23

Transfer into a wide-mouthed bottle, and adjust the total mass of the sample and the water to 200.0 g with hot water (90-99 °C). Capping the bottle, stir by mechanical means at 400 ± 50 r/min for 10-20 min until the particles are thoroughly dispersed and wetted. Scrape down the insides of the bottle with a spatula if necessary, to ensure that there is no undissolved material on the sides of the bottle, and continue the stirring in a cooling water-bath maintained at a temperature below 10 °C for another 20-40 min. Adjust the solution mass if necessary to 200.0 g using Coldwater. Centrifuge the solution if necessary to expel any entrapped air bubbles. Using a spatula, remove any foam. Determine the kinematic viscosity (v) of this solution using the capillary viscometer method. Separately determine the density (ρ) of the solution and calculate the dynamic viscosity (η), as $\eta = \rho v$.

Allow the spindle to rotate for 2 min before taking the measurement. Allow a rest period of at least 2 min between subsequent measurements. Repeat the measurement twice and determine the mean of the 3 readings.

7. SULPHATED ASH: < REFER GAM 032>

Maximum 1.5 per cent, determined on 1.0 g.

8. LOSS ON DRYING: < REFER GAM 026>

Maximum 5.0 per cent, determined on 1.000 g by drying in an oven at 105 °C for 1 h

9. ASSAY: (Gas Chromatography)

Chromatographic Conditions:

Column	:	30mm x 0.53mm, Methyl polysiloxane (3µm).
Flow Rate	:	4.3ml/min
Injection volume	:	1-2 µl
Retention time	:	About 10 minutes
Detection	:	Flame ionisation (or) thermal conductivity

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	24/07/2023	25/07/2023	26/07/23

Temperature:

	Time (min)	Temperature (°C)
Column	0 - 3	50
	3 - 8	50 → 100
	8 - 12.3	100 → 250
	12.3 - 20.3	250
Injection port		250
Detector		280

Apparatus:

Reaction vial:

A 5 mL pressure-tight vial, 50 mm in height, 20 mm in external diameter and 13 mm in internal diameter at the mouth, equipped with a pressure-tight butyl rubber membrane stopper coated with polytetrafluoroethylene and secured with an aluminium crimped cap or another sealing system providing a sufficient air-tightness.

Heater:

A heating module with a square aluminium block having holes 20 mm in diameter and 32 mm in depth, so that the reaction vials fit; mixing of the contents of the vial is effected using a magnetic stirrer equipped in the heating module or using a reciprocal shaker that performs approximately 100 cycles/min.

Internal standard solution 30 g/L solution of octane in o-xylene.

Test solution:

Weigh 65.0 mg of the substance to be examined, place in a reaction vial, add 0.06-0.10 g of adipic acid, 2.0 mL of the internal standard solution and 2.0 mL of hydriodic acid, immediately cap and seal the vial, and weigh accurately. Mix the contents of the vial continuously for 60 min while heating the block so that the temperature of the contents is maintained at 130 ± 2 °C. If a reciprocal shaker or magnetic stirrer cannot be used, shake the vial thoroughly by hand at 5 min intervals during the initial 30 min of the heating time. Allow the vial to cool, and again weigh accurately. If the loss of mass is less than 26 mg and there is no evidence of a leak, use the upper layer of the mixture as the test solution.

Reference solution:

Place 0.06-0.10 g of adipic acid, 2.0 mL of the internal standard solution and 2.0 mL of hydriodic acid in another reaction vial, cap and seal the vial, and weigh accurately. Add 15-22 µL of isopropyl iodide through the septum with a syringe, weigh accurately, add 45 µL of methyl iodide in the same manner, and weigh accurately. Shake the reaction vial thoroughly and use the upper layer as the reference solution.

Detection:

Flame ionisation or thermal conductivity.

Relative retention:

With reference to octane (retention time = about 10 min): methyl iodide = about 0.4; isopropyl iodide = about 0.7.

System suitability Reference solution:

Resolution:

Minimum 5.0 between the peaks due to methyl iodide and isopropyl iodide and between the peaks due to isopropyl iodide and octane.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	24/07/2023	25/07/2023	26/07/23

Repeatability:

Maximum relative standard deviation of 2.0 per cent for the ratios of the areas of the peaks respectively due to methyl iodide and isopropyl iodide to the area of the peak due to octane, determined on 6 injections.

Calculate the ratios (Q_1 and Q_2) of the areas of the peaks due to methyl iodide and isopropyl iodide to the area of the peak due to the internal standard in the chromatogram obtained with the test solution, and the ratios (Q_3 and Q_4) of the areas of the peaks due to methyl iodide and isopropyl iodide to the area of the peak due to the internal standard in the chromatogram obtained with the reference solution.

Calculate the percentage content of methoxy groups using the following expression:

$$Q_1/Q_3 \times m_1/m \times 21.864$$

Calculate the percentage content of hydroxypropoxy groups using the following expression:

$$Q_2/Q_4 \times m_2/m \times 44.17$$

m_1 = Mass of methyl iodide in the reference solution, in milligrams;

m_2 = Mass of isopropyl iodide in the reference solution, in milligrams;

m = Mass of the sample (dried substance), in milligrams.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	24/07/2023	25/07/2023	26/07/23

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMEM0036-00	(i) Periodic review. (ii) STP numbering procedure revised as per SOP No. ST/QC/058.	NA	28/07/2023

****END OF THE DOCUMENT****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	24/07/2023	25/07/2023	26/07/23

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	METHYLENE DICHLORIDE BP			
Specification No.	SPEC-RMEM0029-00	**Revision No.**	00	**Item Code.:** RMEM0029
Supersedes	RMESM0029-01	**Effective Date**	06/09/2024	**Page No.:** 1 of 4

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	CH_2Cl_2
2	Molecular weight	84.9
3	Storage conditions	In an airtight container, protected from light.
4	Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
5	Quantity of sample required for analysis	200ml
6	Quantity of reserve sample	NA
7	Retest period	12 months from the date of release
8	Re-test Parameter	As mentioned in Specification
9	Reference	BP
10	Sampling instruction	Follow the standard operating procedure No.: ST/QC/040.
11	Destructions instructions	Follow the standard operating procedure No.: ST/QC/032.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	03/09/2024	04/09/2024	05/09/2024

Safetab Life Science QUALITY ASSURANCE Puducherry-607

UNCONTROLLED COPY

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	METHYLENE DICHLORIDE BP			
Specification No.	SPEC-RMEM0029-00	**Revision No.**	00	**Item Code.:** RMEM0029
Supersedes	RMESM0029-01	**Effective Date**	06/09/2024	**Page No.:** 2 of 4

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	Clear, colourless, volatile liquid.
2.	*Solubility	Sparingly soluble in water, miscible with ethanol (96%).
3.	*Identification **A.** Relative density **B.** Refractive index **C.** By IR **D.** By Chemical test **E.** By Chemical test	 Between 1.320 to 1.332 Between 1.423 to 1.425 The Infrared absorption spectrum of sample should be concordant with that of reference spectrum or with the spectrum obtained from Methylene chloride WS. A violet colour is produced. A curdled, white precipitate is formed.
4.	Appearance of solution	It is clear and colourless.
5.	Acidity	Not more than 0.15ml of 0.1M sodium hydroxide is required to change the colour of the indicator to blue.
6.	Relative density	Between 1.320 to 1.332
7.	Refractive index	Between 1.423 to 1.425

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	03/09/2024	04/09/2024	05/09/2024

Safetab Life Science QUALITY ASSURANCE Puducherry-607

UNCONTROLLED COPY

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	METHYLENE DICHLORIDE BP			
Specification No.	SPEC-RMEM0029-00	**Revision No.**	00	**Item Code.:** RMEM0029
Supersedes	RMESM0029-01	**Effective Date**	06/09/2024	**Page No.:** 3 of 4

S.NO	TEST (s)	SPECIFICATION (s)
8.	Ethanol, 2-methylbut-2-ene and volatile impurities	
	(i) Ethanol	Not more than 2.0%.
	(ii) 2-methylbut-2-ene	Not more than 300ppm.
	(iii) Impurity A	Not more than 10ppm
	(iv) Impurity B	Not more than 50ppm
	(v) Total impurities other than Ethanol & 2-methylbut-2-ene	Not more than 0.1%
9.	Free chlorine	No blue colour develops.
10.	Residue on evaporation	Not more than 20ppm.
11.	*Water content	Not more than 0.02% w/w.

Remarks: The above * Marked tests are to be performed while retesting the material.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	03/09/2024	04/09/2024	05/09/2024

Safetab Life Science QUALITY ASSURANCE Puducherry-607

UNCONTROLLED COPY

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-RMEM0029-00	(i) Periodic review. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	06/09/2024

**** END OF THE DOCUMENT ****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	03/09/2024	04/09/2024	05/09/2024

Safetab Life Science QUALITY ASSURANCE Puducherry-607

UNCONTROLLED COPY

	Safetab Life Science Puducherry			MASTER COPY
	STANDARD TESTING PROCEDURE			
Name of Product	METHYLENE DICHLORIDE BP			
STP No.	STP-RMEM0029-00	**Revision No.**	00	**Item Code.:** RMEM0029
Supersedes	RMETM0029-01	**Effective Date**	06/09/2024	**Page No.:** 1 of 5

1. DESCRIPTION: < REFER GAM 001>

Clear, Colourless, volatile liquid.

2. SOLUBILITY: < REFER GAM 002>

Sparingly soluble in water, miscible with ethanol (96%).

3. IDENTIFICATION: < REFER GAM 003>

A. Relative density:

Between 1.320 to 1.332

B. Refractive index:

Between 1.423 to 1.425

C. By IR:

The Infrared absorption spectrum of sample should be concordant with that of reference spectrum or with the spectrum obtained from Methylene chloride WS.

D. By Chemical test:

Heat 2mL with 2g of potassium hydroxide and 20mL of ethanol (96 per cent) under a reflux condenser for 30 min. Allow to cool. Add 15mL of dilute sulfuric acid and filter. To 1mL of the filtrate add 1mL of a 15g/L solution of chromotropic acid, sodium salt, 2mL of water and 8 mL of sulfuric acid. A violet colour is produced.

E. By Chemical test:

Dissolve in 2mL of the filtrate obtained in identification test D. Acidify with dilute nitric acid and add 0.4mL of silver nitrate solution. Shake and allow to stand. A curdled, white precipitate is formed.

4. APPEARANCE OF SOLUTION: < REFER GAM 023>

It is clear and colourless.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	03/09/2024	04/09/2024	05/09/2024

Safetab Life Science QUALITY ASSURANCE Puducherry-107

5. ACIDITY:

To 50mL of methanol previously neutralised to 0.1mL of bromothymol blue solution, add 50g of the substance to be examined. Not more than 0.15mL of 0.1M sodium hydroxide is required to change the colour of the indicator to blue.

6. RELATIVE DENSITY: < REFER GAM 031>

Between 1.320 to 1.332

7. REFRACTIVE INDEX: < REFER GAM 025>

Between 1.423 to 1.425

8. ETHANOL, 2-METHYLBUT-2-ENE AND VOLATILE IMPURITIES:

Chromatographic Conditions:

Column	:	30 cm x 0.32 mm; poly[(cyanopropyl)(phenyl)][dimethyl]siloxane (film thickness 1.8 µm) fused silica.
Flow Rate	:	1ml/min, constant flow
Detection	:	Flame ionisation; make-up gas flow rate: 25 mL/min.
Carrier gas	:	nitrogen for chromatography
Split ratio	:	1:40
Injection volume	:	2µl

Temperature:

	Time (min)	Temperature (°C)
Column	0 - 5	40
	5 - 12.5	40 -> 55
	12.5 - 18	55 -> 100

	18 - 20	100
Injection port		260
Detector		300

Test solution:

The substance to be examined.

Reference solution (a):

Dilute 100µL of carbon tetrachloride (impurity A), 500µL of chloroform (impurity B), 3.0mL of 2-methylbut-2-ene and 5.0mL of methanol (impurity D) to 100.0mL with the test solution.

Reference solution (b):

Dilute 2.0mL of anhydrous ethanol and 1.0mL of reference solution (a) to 100.0mL with the test solution.

Relative retention:

With reference to methylene chloride (retention time = about 7 min): impurity D = about 0.6; ethanol = about 0.8; 2-methylbut-2-ene = about 0.9; impurity B = about 1.7; impurity A = about 1.8.

System suitability: (Reference solution (b)):

Resolution: minimum 3.0 between the peaks due to ethanol and 2-methylbut-2- ene;

Signal-to-noise ratio: minimum 5 for the peak due to impurity A.

Calculation of percentages contents:

For ethanol, 2-methylbut-2-ene and impurities A and B, use the respective concentration of these substances in reference solution (b) correct the areas of the peaks in the chromatogram obtained with reference solution (b) by subtracting the area of the corresponding peak in the chromatogram obtained with the test solution.

For any other impurity use the concentration of impurity D in reference solution (b) correct the area of the due to impurity D in the chromatogram obtained with reference solution (b) by subtracting the area of the corresponding peak in the chromatogram obtained with the test solution.

Limits:

Ethanol: Not more than 2.0%.

2-methylbut-2-ene: Not more than 300ppm.

Impurity A: Not more than 10ppm.

Impurity B: Not more than 50ppm.

Total of impurities other than ethanol and 2-methylbut-2-ene: Not more than 0.1%.

Reporting threshold: 50ppm v/v, the reporting threshold does not apply to impurity A.

9. FREE CHLORINE:

Place 5mL of sample in a ground-glass-stoppered tube. Add 5mL of a 100g/L solution of potassium iodide and 0.2g of soluble starch. Shake for 30s and allow to stand for 5 min. No blue colour develops.

10. RESIDUE ON EVAPORATION:

Not more than 20ppm.

Evaporate 50.0g to dryness on a water-bath and dry at 100-105°C for 30 min. The residue weighs a maximum of 1mg.

11. WATER: < REFER GAM 010>

Not more than 0.02 per cent, determined on 10.0g of sample.

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMEM0029-00	(i) Periodic review. (ii) STP numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	06/09/2024

**** END OF THE DOCUMENT****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	03/09/2024	04/09/2024	05/09/2024

Safetab Life Science QUALITY ASSURANCE Puducherry-107

UNCONTROLLED COPY

	Safetab Life Science Puducherry			
	RAW MATERIAL SPECIFICATION			MASTER COPY
Name of Product	POVIDONE K 30 BP			
Specification No.	SPEC-RMEP0049-00	**Revision No.**	00	**Item Code.:** RMEP0049
Supersedes	RMESP0049-00	**Effective Date**	05/08/2023	**Page No.:** 1 of 4

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	$C_6nH_9n_{+2}NnOn$
2	Molecular weight	NA
3	Storage conditions	In an air-tight containers.
4	Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
5	Quantity of sample required for analysis	20 g
6	Quantity of reserve sample	40 g
7	Retest period	12 months from the date of release
8	Re-test Parameter	As mentioned in Specification
9	Reference	BP
10	Sampling instruction	Follow the standard operating procedure No.: ST/QC/040.
11	Destructions instructions	Follow the standard operating procedure No.: ST/QC/032.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	01/08/2023	02/08/2023	02/08/2023

Safetab Life Science QUALITY ASSURANCE Puducherry-107

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	POVIDONE K 30 BP			
Specification No.	SPEC-RMEP0049-00	**Revision No.**	00	**Item Code.:** RMEP0049
Supersedes	RMESP0049-00	**Effective Date**	05/08/2023	**Page No.:** 2 of 4

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	White or yellowish-white, hygroscopic powder or flakes.
2.	*Solubility	Freely soluble in water, in ethanol (96%) and in methanol, very slightly soluble in acetone.
3.	*Identification **A.** By IR	The infrared absorption spectrum of sample should be concordant with that of reference spectrum or with the spectrum obtained from Povidone K 30.
	B. By Chemical test	A pink colour is produced.
	C. By Chemical test	A red colour is produced.
	D. By Chemical test	The substance dissolves.
4.	Appearance of solution	Solution S is clear, and not more intensely coloured than reference solution B_6, BY_6 or R_6.
5.	*pH	Between 3.0 to 5.0
6.	Viscosity (Expressed as K- value)	Between 27.0 to 32.4
7.	Aldehydes (Expressed as Acetaldehyde)	Not more than 500ppm

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	01/08/2023	02/08/2023	02/08/2023

Safetab Life Science QUALITY ASSURANCE Puducherry-107

S.NO	TEST (s)	SPECIFICATION (s)
8.	Peroxides	Not more than 400 ppm
9.	Formic Acid	Not more than 0.5%
10.	Hydrazine	Not more than 1ppm.
11.	Impurity A (Vinylpyrrolidone)	Not more than 10ppm.
12.	Impurity B (2-Pyrrolidone)	Not more than 3.0%
13.	*Water content (By KFR)	Not more than 5.0%
14.	Sulphated ash	Not more than 0.1%
15.	*Assay on anhydrous basis	Not less than 11.5% and not more than 12.8% of Nitrogen content.

Remarks: The above * Marked tests are to be performed while retesting the material.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	01/08/2023	02/08/2023	02/08/2023

UNCONTROLLED COPY

Safetab Life Science QUALITY ASSURANCE Puducherry-107

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-RMEP0049-00	(i) Periodic review. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/016	05/08/2023

**** END OF THE DOCUMENT ****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	01/08/2023	02/08/2023	02/08/2023

Safetab Life Science QUALITY ASSURANCE Puducherry-107

UNCONTROLLED COPY

1. DESCRIPTION: < REFER GAM 001>

White or yellowish-white, hygroscopic powder or flakes.

2. SOLUBILITY: < REFER GAM 002>

100mg of sample + 1ml of Water	Freely soluble if the material dissolves.
100mg of sample + 1ml of Ethanol (96%)	Freely soluble if the material dissolves.
100mg of sample + 1ml of Methanol	Freely soluble if the material dissolves.
10mg of sample + 100ml of Acetone	Very slightly soluble if the material dissolves.

3. IDENTIFICATION:

First identification test: A and D.

Second identification test: B,C and D

A. By IR: < REFER GAM 003>

Previously dried at 105°C for 6 hour.

The infrared absorption spectrum of sample should be concordant with that of reference spectrum or with the spectrum obtained from Povidone K 30 WS.

B. By Chemical test:

To 1ml of Solution S1, add 0.2ml of dimethylaminobenzaldehyde solution and 0.1ml of sulfuric acid. A pink colour is produced.

C. By Chemical test:

To 0.1ml of Solution S1, add 5ml of water and 0.2ml of 0.05M iodine. A red colour is produced.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	01/08/2023	02/08/2023	02/08/

Safetab Life Science QUALITY ASSURANCE Puducherry-107

D. By Chemical test:

Weigh about 0.5g of sample dissolved in 10ml of water and shake. The substances dissolves.

4. APPEARANCE OF SOLUTION:

SOLUTION S:

Dissolve 1.0g of sample in carbon dioxide free water and dilute to 20ml with the same solvent. Add the substance to be examined to the water in small portions, stirring using a magnetic stirrer.

SOLUTION S1:

Dissolve 2.5 g in carbon dioxide-free water and dilute to 25 mL with the same solvent. Add the substance to be examined to the water in small portions, stirring using a magnetic stirrer.

Solution S is clear and not more intensely coloured than reference solution B_6, BY_6 or R_6.

5. pH: < REFER GAM 030>

Between 3.0 to 5.0 for Solution S.

6. VISCOSITY (EXPRESSED AS K-VALUE):

Procedure:

Dissolve a 1.0 g of substance in 100 ml of water. Allow to stand for 1 hr. and determine the viscosity of the solution at 25°C, using a size no.1 viscometer with a minimum flow time of 100 s.

The time required for the level of the liquid to drop from one mark to the other is measured with a stop-watch to the nearest one-fifth of a second. The result is valid only if two consecutive readings do not differ by more than 1 per cent. The average of not fewer than three readings gives the flow time of the liquid to be examined.

Calculate the K-value using the following expression:

$$\frac{1.5\log v_{rel} - 1}{0.15 + 0.003c} + \frac{\sqrt{300c \log v_{rel} + (c+1.5c \log v_{rel})^2}}{0.15c + 0.003c^2}$$

Where,

c = concentration of the substance to be examined (anhydrous substance), in grams per 100 ml.

v_{rel} = kinematic viscosity of the solution relative to that of water.

Acceptance criteria:

Between 27.0 to 32.4

7. ALDEHYDES:

Test solution:

Dissolve a quantity of the substance to be examined equivalent to 1.0g of the anhydrous substance to be examined in phosphate buffer solution pH 9.0 and dilute to 100.0ml with the same solvent. Stopper the flask tightly and heat at 60°C for 1 hrs. Allow to cool to room temperature.

Reference solution:

Dissolve 0.140g of acetaldehyde ammonia trimer trihydrate in water and dilute to 200.0ml with the same solvent. Dilute 1.0ml of this solution to 100.0ml with phosphate buffer solution pH 9.0.

Into 3 identical spectrophotometric cells with a path length of 1 cm, introduce separately 0.5 ml of the test solution, 0.5 ml of the reference solution and 0.5 ml of water (blank). To each cell, add 2.5 ml of phosphate buffer solution pH 9.0 and 0.2 ml of nicotinamide-adenine dinucleotide solution. Mix and stopper tightly. Allow to stand at 22 ± 2°C for 2-3 min.

Measure the absorbance of each solution at 340 nm using water as the compensation liquid. To each cell add 0.05 mL of aldehyde dehydrogenase solution, mix and stopper tightly. Allow to stand at 22 ± 2 °C for 5 min. Measure the absorbance of each solution at 340 nm using water as the compensation liquid.

Calculate the content of using the following expression:

$$= \frac{(A_{t2} - A_{t1}) - (A_{b2} - A_{b1})}{(A_{s2} - A_{s1}) - (A_{b2} - A_{b1})} \times \frac{100\,000 \times C}{m}$$

Where,

A_{t1} = absorbance of the test solution before the addition of aldehyde dehydrogenase.

A_{t2} = absorbance of the test solution after the addition of aldehyde dehydrogenase.

A_{s1} = absorbance of the reference solution before the addition of aldehyde dehydrogenase.

A_{s2} = absorbance of the reference solution after the addition of aldehyde dehydrogenase.

A_{b1} = absorbance of the blank solution before the addition of aldehyde dehydrogenase.

A_{b2} = absorbance of the blank solution after the addition of aldehyde dehydrogenase.

m = mass of the substance to be examined (anhydrous substance) in the test solution, in grams

C = concentration of acetaldehyde in the reference solution, calculated from the weight of the acetaldehyde ammonia trimer trihydrate with the factor 0.72, in milligrams per millimeter.

Acceptance criteria: Not more than 500ppm, expressed as acetaldehyde.

8. PEROXIDES:

Maximum 400 ppm, expressed as H_2O_2.

Dissolve a quantity of the substance to be examined equivalent to 4.0g of the anhydrous substance in water and dilute to 100ml with same solvent (stock solution). To 25ml of the stock solution, add 2ml of titanium trichloride-sulfuric acid reagent.

Allow to stand for 30 min. The absorbance of the solution, measured at 405 nm using a mixture of 25ml of the stock solution and 2ml of a 13% V/V solution of sulfuric acid as the compensation liquid, is not greater than 0.35.

9. FORMIC ACID: (By HPLC)

Chromatographic Condition:

Columns	:	30-cm x 7.8-mm; 9-µm
Detector	:	UV 210 nm
Stationary phase	:	Strongly acidic ion-exchange resin
Columns temperature	:	35°C
Flow rate	:	1.0 ml/min
Injection Volume	:	50µl
Retention time	:	About 8 minutes

Mobile phase:

Dilute 1.0ml of perchloric acid to 700ml with water.

Test solution:

Dissolve a quantity of the substance to examined equivalent to 2.0g of the anhydrous substance in water and dilute to 100.0ml with the same solvent (Test stock solution). Transfer a suspension of strongly acidic ion exchange resin for column chromatography in water to a column of about 0.8cm in internal diameter to give a packing of about 20 mm in length and keep the strongly acidic ion exchange resin layer constantly immersed in water. Pour 5ml of water and adjust the flow rate to about 1ml/min. When the level of the water comes down to near the top of the strongly acidic ion exchange resin layer, introduce the stock solution into the column.

Discard the first 2ml of the eluate, then collect 1.5ml of the solution and use this solution as the test solution.

Reference solution:

Dissolve 0.100g of anhydrous formic acid in water and dilute to 100ml with same solvent. Dilute 1.0ml of this solution to 100ml with water.

Suitability requirements:

Repeatability: maximum relative standard deviation of 2.0 per cent determined on 6 injections of Reference solution.

Column efficiency:

NLT 1000 theoretical plates for the formic acid peak

Symmetry factor:

0.5-1.5 for the formic acid for six injections

Calculate the percentage of formic acid using the following expression:

$$\text{Result} = A_1/A_2 \times M/m$$

A_1 = Area of the peak due to formic acid in the chromatogram obtained with the Test solution.

A_2 = Area of the peak due to formic acid in the chromatogram obtained with the Reference solution.

m = Mass of the substance to be examined (anhydrous substances) in the test solution, in grams.

M = Mass of anhydrous formic acid in the reference solution, in grams.

Acceptance criteria:

Not more than 0.5%

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	01/08/2023	02/08/2023	02/08/2023

Safetab Life Science QUALITY ASSURANCE Puducherry-107

10. **HYDRAZINE:** (By Thin-layer chromatography)

Chromatographic conditions:

Plate	: TLC silanised silica gel plate. F_{254}.
Mobile phase	: Water and methanol (1:2 V/V).
Application	: 10µl
Development	: Over 3/4 of the plate.
Drying	: In air
Detection	: Examine in ultraviolet light at 365 nm.
Retardation factor	: salicylaldehyde azine = about 0.3

Note: Use freshly prepared solutions.

Test solution:

Dissolve a quantity of the substance to examined equivalent 2.5 g of the anhydrous substance in 25 ml of water. Add 0.5 ml of a 50g /L solution of salicylaldehyde in methanol, mix and heat in a water-bath at 60 °C for 15 min. Allow to cool, add 2.0 ml of toluene, shake vigorously for 2 minutes and centrifuge. Use the upper layer.

Reference solution:

Dissolve 90 mg of salicylaldehyde azine in toluene and dilute to 100 ml with the same solvent. Dilute 1 ml of the solution to 100 ml with toluene.

Limit:

Any spot corresponding to salicylaldehyde azine obtained with the test solution is not more intense than the spot obtained with the reference solution (Not more than 1ppm).

11. IMPURITY A: (Vinylpyrrolidone)

Chromatographic conditions:

Precolumn	:	Size: l = 10mm, Ø = 4.0 mm
Stationary phase	:	Base deactivated end capped octadecylsilyl silica gel for chromatography (5 µm).
Column	:	Size: l = 150mm, Ø = 4.6 mm
Stationary phase	:	Base deactivated end capped octadecylsilyl silica gel for chromatography (5 µm).
Temperature	:	40°C.
Detection	:	UV at 235 nm.
Injection	:	20µl.
Flow rate	:	1.0ml /min.
Mobile phase	:	Acetonitrile, Water (10:90 V/V).

Test solution:

Dissolve a quantity of the substance to be examined equivalent to 0.250g of the anhydrous substance in the mobile phase and dilute to 10.0ml with the mobile phase.

Reference solution (a):

Dissolve 50mg of 1-vinylpyrrolidin-2-one (Impurity A) in mobile phase and dilute to 100.0ml with the mobile phase. Dilute 1.0ml of the solution to 100.0ml with mobile phase. Dilute 5.0ml of this solution to 100.0ml with mobile phase.

Reference solution (b):

Dissolve 10mg of 1-vinylpyrrolidin-2-one (Impurity A) and 0.5g of vinyl acetate in methanol and dilute to 100.0ml with the same solvent. Dilute 1.0ml of the solution to 100.0ml with mobile phase.

*** Note:** after each injection of the test solution, wait for about 2 min and wash the precolumn by passing the mobile phase through the column backwards for 30 min at the same flow rate as applied in the test.

Relative retention time with reference to vinyl acetate (retention time = about 14 min.) impurity A = about 0.6 min.

System suitability:

Resolution: minimum 2.0 between the peaks due to impurity A and vinyl acetate in the chromatogram obtained with reference solution (b);

Repeatability: maximum relative standard deviation of 2.0 per cent determined on 6 injections of reference solution (a).

Calculate the percentage of content of impurity A in parts per million using the following expression:

$$\text{Result} = \frac{A1}{A2} \times \frac{2.5}{m}$$

Where,

A_1 : Area of the peak due to impurity A in the chromatogram obtained with the test solution.

A_2 : Area of the peak due to impurity A in the chromatogram obtained with the reference solution (a).

m : Mass of the substance to be examined (anhydrous substance) in the test solution in grams.

Acceptance criteria: Not more than 10ppm.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	01/08/2023	08/08/2023	02/08/

Safetab Life Science QUALITY ASSURANCE Puducherry-107

12. IMPURITY B: (2-Pyrrolidone)

Chromatographic conditions:

Precolumn	:	Size: l = 10mm, Ø = 3 mm
Stationary phase	:	Base deactivated end capped octadecylsilyl silica gel for chromatography (5 µm).
Column	:	Size: l = 150mm, Ø = 4.6 mm
Stationary phase	:	Base deactivated end capped octadecylsilyl silica gel for chromatography (5 µm).
Temperature	:	40°C.
Detection	:	UV Spectrophotometer at 205 nm.
Flow rate	:	0.8 ml / min.
Injection	:	50 µl.
Retention time	:	Impurity B about 7 minutes.
Mobile phase	:	Methanol and water in the ratio (5:95 V/V)

Test solution:

Dissolve a quantity of the substance to be examined equivalent to 0.500 g of the anhydrous substance in the mobile phase and dilute to 100.0 ml with the mobile phases.

Reference solution:

Dissolve 0.150 g of 2-pyrrolidone (Impurity B) in mobile phase and dilute to 100.0 ml with the mobile phase. Dilute 2.0 ml of the solution to 100.0 ml with the mobile phase.

*** Note:** After each injection of the test solution, wait for about 2 min. and wash the precolumn by passing the mobile phase through the column backward for about 30 min. at the same flow rate as applied in the test.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	01/08/2023	08/08/2023	02/08/2023

Safetab Life Science QUALITY ASSURANCE Puducherry-107

System suitability: Reference solution:

Repeatability: maximum relative standard deviation of 2.0% determined on 6 injections;

Number of theoretical plates: minimum 5000.

Calculate the percentage of content of impurity B using the following expression:

$$\text{Result} = \frac{A1}{A2} \times \frac{0.3}{m}$$

Where,

A_1 : Area of the peak due to impurity B in the chromatogram obtained with the test solution

A_2 : Area of the peak due to impurity B in the chromatogram obtained with the reference solution

m : Mass of the substance to be examined (anhydrous substance) in the test solution in grams

Acceptance criteria: Not more than 3.0%.

13. WATER: < REFER GAM 010>

Not more than 5.0%, determined on 0.5g of sample.

14. SULFATED ASH: < REFER GAM 032>

Not more than 0.1% w/w, determined on 1.0g of sample.

15. ASSAY: (Nitrogen Determination)

Place 100.0mg of the substance to be examined in a combustion flask, add 5g of a mixture of 1g of copper sulfate pentahydrate, 1g of titanium dioxide and 33g of dipotassium sulfate, and 3 glass beads. Wash any adhering particles from the neck into the flask with a small quantity of water.

Add 7ml of sulfuric acid, allowing it to run down the insides of the flask. Heat the flask gradually until the solution has a clear, yellowish-green colour, and the insides wall of the flask is free from a carbonised material and then heat for a further 45 min. after cooling, and cautiously 20ml of water, and connects the flask to the distillation apparatus which has been previously washed by passing steam through it. To the absorption flask add 30ml of a 40 g / L solution of boric acid, 3 drops of bromocresol green-methyl red solution and sufficient water to immerse the lower end of the condenser tube. Add 30ml of strong sodium hydroxide solution through the lower the funnel, rinse the funnel cautiously with 10 ml of water, immediately close the clamp on the rubber tube, and then start distillation with steam to obtain 80 to 100ml of distillate. Remove the absorption flask from the lower end of the condenser tube, rinsing the end part with a small quantity of water and titrate the distillate with 0.025M Sulfuric acid until the colour of the solution changes from green through pale greyish blue to pale greyish reddish-purple. Carry out a blank determination.

1 ml of 0.025 M Sulfuric acid is equivalent to 0.700 mg of Nitrogen.

Calculation:

$$= \frac{\text{Titer value} \times \text{Molarity of 0.025N sulphuric acid} \times 0.700 \times 100 \times 100}{\text{Sample weight in mg} \times 0.025 \times (100 - \% \text{ of Water})}$$

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	01/08/2023	02/08/2023	02/08

Safetab Life Science QUALITY ASSURANCE Puducherry-107

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMEP0049-00	(i) Periodic review. (ii) STP numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/016	05/08/2023

****END OF THE DOCUMENT****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	01/08/2023	02/08/2023	02/08/2023

Safetab Life Science QUALITY ASSURANCE Puducherry-107

UNCONTROLLED COPY

	Safetab Life Science Puducherry			
	RAW MATERIAL SPECIFICATION MASTER COPY			
Name of Product	POVIDONE K 90 BP (BOVIDONE K 90)			
Specification No.	SPEC-RMEP0045-00	**Revision No.**	00	**Item Code.:** RMEP0045
Supersedes	RMESP0045-00	**Effective Date**	25/08/2023	**Page No.:** 1 of 4

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	$(C_6H_9NO)_n$
2	Molecular weight	NA
3	Storage conditions	Store in well-closed, air-tight containers.
4	Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
5	Quantity of sample required for analysis	25 g
6	Quantity of reserve sample	50 g
7	Retest period	12 months from the date of release
8	Re-test Parameter	As mentioned in Specification
9	Reference	BP
10	Sampling instruction	Follow the standard operating procedure No.: ST/QC/040.
11	Destructions instructions	Follow the standard operating procedure No.: ST/QC/032.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	21/08/2023	22/08/2023	22/08/23

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	POVIDONE K 90 BP (BOVIDONE K 90)			
Specification No.	SPEC-RMEP0045-00	**Revision No.**	00	**Item Code.:** RMEP0045
Supersedes	RMESP0045-00	**Effective Date**	25/08/2023	**Page No.:** 2 of 4

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	White or yellowish-white, hygroscopic powder or flakes.
2.	*Solubility	Freely soluble in water, in ethanol (96%) and in methanol, very slightly soluble in acetone.
3.	*Identification **A.** By IR **B.** By Chemical test **C.** By Chemical test **D.** By Chemical test	 The infrared absorption spectrum of sample should be concordant with that of reference spectrum or with the spectrum obtained from Povidone K 25. A pink colour is produced. A red colour is produced. The substance dissolves.
4.	Appearance of solution	Solution S is clear, and not more intensely coloured than reference solution B_6, BY_6 or R_6.
5.	*pH	Between 4.0 to 7.0
6.	Viscosity (Expressed as K- value)	Between 81.0 to 96.3
7.	Aldehydes (Expressed as Acetaldehyde)	Not more than 500ppm

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	21/08/2023	22/08/2023	22/08/23

	Safetab Life Science Puducherry			
	RAW MATERIAL SPECIFICATION			MASTER COPY
Name of Product	POVIDONE K 90 BP (BOVIDONE K 90)			
Specification No.	SPEC-RMEP0045-00	**Revision No.**	00	**Item Code.:** RMEP0045
Supersedes	RMESP0045-00	**Effective Date**	25/08/2023	**Page No.:** 3 of 4

S.NO	TEST (s)	SPECIFICATION (s)
8.	Peroxides	Not more than 400 ppm
9.	Formic Acid	Not more than 0.5%
10.	Limit of Hydrazine	Not more than 1ppm.
11.	Impurity A	Not more than 10ppm.
12.	Impurity B	Not more than 3.0%
13.	*Water content (By KFR)	Not more than 5.0%
14.	Sulphated ash	Not more than 0.1%
15.	*Assay on anhydrous basis	Not less than 11.5% and not more than 12.8% of Nitrogen content.

Remarks: The above * Marked tests are to be performed while retesting the material.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	21/08/2023	22/08/2023	22/08/23

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-RMEP0045-00	(i) Periodic review. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/016	25/08/2023

**** END OF THE DOCUMENT ****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	21/08/2023	22/08/2023	22/08/23

	Safetab Life Science Puducherry			MASTER COPY
	STANDARD TESTING PROCEDURE			
Name of Product	POVIDONE K 90 BP (BOVIDONE K 90)			
STP No.	STP-RMEP0045-00	**Revision No.**	00	**Item Code.:** RMEP0045
Supersedes	RMETP0045-00	**Effective Date**	25/08/2023	**Page No.:** 1 of 12

1. DESCRIPTION: < REFER GAM 001>

White or yellowish-white, hygroscopic powder or flakes.

2. SOLUBILITY: < REFER GAM 002>

100mg of sample + 1ml of Water	Freely soluble if the material dissolves.
100mg of sample + 1ml of Ethanol (96%)	Freely soluble if the material dissolves.
100mg of sample + 1ml of Methanol	Freely soluble if the material dissolves.
10mg of sample + 100ml of Acetone	Very slightly soluble if the material dissolves.

3. IDENTIFICATION: < REFER GAM 003>

First identification test: A and D.

Second identification test: B,C and D

Solution S1: Dissolve 2.5g of sample in carbon dioxide-free water and dilute to 25ml with the same solvent. Add the substance to be examined to the water in small portions, stirring using a magnetic stirrer. **Note:** Solution S1 will be used in Identification B & C tests.

A. By IR:

Previously dried at 105°C for 6 hour.

The infrared absorption spectrum of sample should be concordant with that of reference spectrum or with the spectrum obtained from Povidone K 25 WS.

B. By Chemical test:

To 1ml of Solution S1, add 0.2ml of dimethylaminobenzaldehyde solution and 0.1ml of sulfuric acid. A pink colour is produced.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	21/08/2023	22/08/2023	22/08/23

C. By Chemical test:

To 0.1ml of Solution S1, add 5ml of water and 0.2ml of 0.05M iodine. A red colour is produced.

D. By Chemical test:

Weigh about 0.5g of sample dissolved in 10ml of water and shake. The substances dissolves.

SOLUTION S:

Dissolve 1.0g of sample in carbon dioxide free water and dilute to 20ml with the same solvent. Add the substance to be examined to the water in small portions, stirring using a magnetic stirrer.

4. APPEARANCE OF SOLUTION:

Solution S is clear and not more intensely coloured than reference solution B_6, BY_6 or R_6.

5. pH: < REFER GAM 030>

Between 4.0 to 7.0 for Solution S.

6. VISCOSITY (EXPRESSED AS K-VALUE):

Procedure:

Dissolve a 1.0 g of substance in 100 ml of water. Allow to stand for 1 hr. and determine the viscosity of the solution at 25°C, using viscometer no.1 with a minimum flow time of 100 s.

The time required for the level of the liquid to drop from one mark to the other is measured with a stop-watch to the nearest one-fifth of a second. The result is valid only if two consecutive readings do not differ by more than 1 per cent. The average of not fewer than three readings gives the flow time of the liquid to be examined.

Calculate the K-value using the following expression:

$$1.5\log v_{rel} - 10.15 + 0.003c + 300c\log v_{rel} + (c + 1.5c\log v_{rel})2\sqrt{0.15c + 0.003c^2}$$

Where,

c = concentration of the substance to be examined (anhydrous substance, in grams per 100 ml.

v_{rel} = kinematic viscosity of the solution relative to that of water.

Acceptance criteria:

Between 81.0 to 96.3.

7. ALDEHYDES:

Test solution:

Dissolve a quantity of the substance to be examined equivalent to 1.0g of the anhydrous substance to be examined in phosphate buffer solution pH 9.0 and dilute to 100.0ml with the same solvent. Stopper the flask tightly and heat at 60°C for 1 hrs. Allow to cool to room temperature.

Reference solution:

Dissolve 0.140g of acetaldehyde ammonia trimer trihydrate in water and dilute to 200.0ml with the same solvent. Dilute 1.0ml of this solution to 100.0ml with phosphate buffer solution pH 9.0.

Into 3 identical spectrophotometric cells with a path length of 1 cm, introduce separately 0.5 ml of the test solution, 0.5 ml of the reference solution and 0.5 ml of water (blank). To each cell, add 2.5 ml of phosphate buffer solution pH 9.0 and 0.2 ml of nicotinamide-adenine dinucleotide solution. Mix and stopper tightly. Allow to stand at 22 ± 2°C for 5 min. measure the absorbance of each solution at 340 nm using water as the compensation liquid. To each cell add 0.05 mL of aldehyde dehydrogenase solution, mix and stopper tightly. Allow to stand at 22 ± 2 °C for 5 min. Measure the absorbance of each solution at 340 nm using water as the compensation liquid.

Calculate the content of using the following expression:

$$= \frac{(A_{t2} - A_{t1}) - (A_{b2} - A_{b1})}{(A_{s2} - A_{s1}) - (A_{b2} - A_{b1})} \times 100000 \times Cm$$

Where,

A_{t1} = absorbance of the test solution before the addition of aldehyde dehydrogenase.
A_{t2} = absorbance of the test solution after the addition of aldehyde dehydrogenase.
A_{s1} = absorbance of the reference solution before the addition of aldehyde dehydrogenase.
A_{s2} = absorbance of the reference solution after the addition of aldehyde dehydrogenase.
A_{b1} = absorbance of the blank solution before the addition of aldehyde dehydrogenase.
A_{b2} = absorbance of the blank solution after the addition of aldehyde dehydrogenase.
m = mass of the substance to be examined (anhydrous substance) in the test solution, in grams
C = concentration of acetaldehyde in the reference solution, calculated from the weight of the acetaldehyde ammonia trimer trihydrate with the factor 0.72, in milligrams per millimeter.

Acceptance criteria: Not more than 500ppm, expressed as acetaldehyde.

8. PEROXIDES:

Dissolve a quantity of the substance to be examined equivalent to 4.0g of the anhydrous substance in 100ml of water. To 25ml of this solution, add 2ml of titanium trichloride-sulfuric acid reagent. Allow to stand for 30 min. The absorbance of the solution, measured at 405 nm using a mixture of 25ml of the stock solution and 2ml of a 13% V/V solution of sulfuric acid as the compensation liquid, is not greater than 0.35.

9. FORMIC ACID: (By HPLC)

Chromatographic Condition:

Columns : 30-cm x 7.8-mm; 9-µm

Detector	:	UV 210 nm
Columns temperature	:	35°C
Flow rate	:	1.0 ml/min
Injection Volume	:	50µl
Retention time	:	About 8 minutes

Mobile phase:

Dilute 1.0ml of perchloric acid to 700ml with water.

Test solution:

Dissolve a quantity of the substance to examined equivalent to 2.0g of the anhydrous substance in water and dilute to 100.0ml with the same solvent (Test stock solution). Transfer a suspension of strongly acidic ion exchange resin for column chromatography in water to a to a column of about 0.8cm in internal diameter to give a packing of about 20 mm in length and keep the strongly acidic ion exchange resin layer constantly immersed in water. Pour 5ml of water and adjust the flow rate to about 1ml/min. When the level of the water comes down to near the top of the strongly acidic ion exchange resin layer, introduce the stock solution into the column.

Discard the first 2ml of the eluate, then collect 1.5ml of the solution and use this solution as the test solution.

Reference solution:

Dissolve 0.100g of anhydrous formic acid in water and dilute to 100ml with same solvent. Dilute 1.0ml of this solution to 100ml with water.

Suitability requirements:

Repeatability: maximum relative standard deviation of 2.0 per cent determined on 6 injections.

Column efficiency:

NLT 1000 theoretical plates for the formic acid peak

Symmetry factor:

0.5-1.5 for the formic acid for six injections

Calculate the percentage of formic acid using the following expression:

$$\text{Result} = A_1A_2 \times Mm$$

A_1 = Area of the peak due to formic acid in the chromatogram obtained with the Test solution.

A_2 = Area of the peak due to formic acid in the chromatogram obtained with the Reference solution.

m = Mass of the substance to be examined (anhydrous substances) in the test solution, in grams.

M = Mass of anhydrous formic acid in the reference solution, in grams.

Acceptance criteria:

Not more than 0.5%

10. HYDRAZINE: (By Thin-layer chromatography)

Chromatographic conditions:

Plate	:	TLC silanised silica gel plate. F_{254}.
Mobile phase	:	Water and methanol (1:2 V/V).
Application	:	10µl
Development	:	Over 3/4 of the plate.
Drying	:	In air

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	21/08/2023	22/08/2023	22/08/23

	Detection	: Examine in ultraviolet light at 365 nm.
	Retardation factor	: salicylaldehyde azine = about 0.3

Note: Use freshly prepared solutions.

Test solution:

Dissolve a quantity of the substance to examined equivalent 2.5 g of the anhydrous substance in 25 ml of water. Add 0.5 ml of a 50g /L solution of salicylaldehyde in methanol, mix and heat in a water-bath at 60 °C for 15 min. Allow to cool, add 2.0 ml of toluene, shake for 2 min. and centrifuge. Use the upper layer of the mixture.

Reference solution:

Dissolve 90 mg of salicylaldehyde azine in toluene and dilute to 100 ml with the same solvent. Dilute 1 ml of the solution to 100 ml with toluene.

Limit:

Any spot corresponding to salicylaldehyde azine obtained with the test solution is not more intense than the spot obtained with the reference solution (Not more than 1ppm).

11. IMPURITY A: (By HPLC)

Chromatographic conditions:

Precolumn	:	Size: l = 10mm, Ø = 4.0 mm
Stationary phase	:	Base deactivated end capped octadecylsilyl silica gel for chromatography (5 µm).
Column	:	Size: l = 150mm, Ø = 4.6 mm
Stationary phase	:	Base deactivated end capped octadecylsilyl silica gel for chromatography (5 µm).
Temperature	:	40°C.
Detection	:	UV at 235 nm.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	21/08/2023	22/08/2023	22/08/23

Injection : 20µl.

Flow rate : 1.0ml /min.

Mobile phase : Acetonitrile, Water (10:90 V/V).

Test solution:

Dissolve a quantity of the substance to be examined equivalent to 0.250g of the anhydrous substance in the mobile phase and dilute to 10.0ml with the mobile phase.

Reference solution (a):

Dissolve 50mg of 1-vinylpyrrolidin-2-one in mobile phase and dilute to 100.0ml with the mobile phase. Dilute 1.0ml of the solution to 100.0ml with mobile phase. Dilute 5.0ml of this solution to 100.0ml with mobile phase.

Reference solution (b):

Dissolve 10mg of 1-vinylpyrrolidin-2-one and 0.5g of vinyl acetate in methanol and dilute to 100.0ml with the same solvent. Dilute 1.0ml of the solution to 100.0ml with mobile phase.

* **Note:** After injection of the test solution, wait for about 2 min and wash the precolumn by passing the mobile phase backwards, at the same flow rate applied in the test, for 30 min.

Relative retention time with reference to vinyl acetate (retention time = about 14 min.) impurity A = about 0.6 min.

System suitability:

In the chromatogram obtained with reference solution (b), Resolution: minimum 2.0 between the peaks due to impurity A and to vinyl acetate.

In the chromatogram obtained with reference solution (a), Repeatability: maximum relative standard deviation of 2.0 %.

In the chromatogram obtained with reference solution (a), the symmetry factor for peak due to 1-vinylpyrrolidin-2-one (impurity A) is between 0.8 to 1.5.

Calculate the percentage of content of impurity A in parts per million using the following expression:

$$\text{Result} = A_1A_2 \times 2.5m$$

Where,

A_1 = area of the peak due to impurity A in the chromatogram obtained with the test solution.

A_2 = area of the peak due to impurity A in the chromatogram obtained with the reference solution (a).

m = mass of the substance to be examined (anhydrous substance) in the test solution in grams.

Acceptance criteria: Not more than 10ppm.

12. IMPURITY B: (By HPLC)

Chromatographic conditions:

Precolumn	:	Size: l = 10mm, Ø = 3 mm
Stationary phase	:	Base deactivated end capped octadecylsilyl silica gel for chromatography (5 µm).
Column	:	Size: l = 150mm, Ø = 4.6 mm
Stationary phase	:	Base deactivated end capped octadecylsilyl silica gel for chromatography (5 µm).
Temperature	:	40°C.
Detection	:	UV Spectrophotometer at 205 nm.
Flow rate	:	0.8 ml / min.
Injection	:	50 µl.
Retention time	:	Impurity B about 7 minutes.
Mobile phase	:	Methanol and water in the ratio (5:95 V/V)

Test solution:

Dissolve a quantity of the substance to be examined equivalent to 0.500 g of the anhydrous substance in the mobile phase and dilute to 100.0 ml with the mobile phases.

Reference solution:

Dissolve 0.150 g of 2-pyrrolidone in mobile phase and dilute to 100.0 ml with the mobile phase. Dilute 2.0 ml of the solution to 100.0 ml with the mobile phase.

* **Note:** After each injection of the test solution, wait for about 2 min. and wash the precolumn by passing the mobile phase through the column backward for about 30 min. at the same flow rate as applied in the test.

System suitability: Reference solution:

Repeatability: maximum relative standard deviation of 2.0%.

The symmetry factor for peak due to 2-pyrrolidone (impurity B) is between 0.8 to 1.5.

Calculate the percentage of content of impurity B using the following expression:

$$\text{Result} = A_1A_2 \times 0.3m$$

Where,

A_1 = area of the peak due to impurity B in the chromatogram obtained with the test solution

A_2 = area of the peak due to impurity B in the chromatogram obtained with the reference solution

m = mass of the substance to be examined (anhydrous substance) in the test solution in grams

Acceptance criteria: Not more than 3.0%.

13. WATER: < REFER GAM 010>

Not more than 5.0%, determined on 0.5g of sample.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	21/08/2023	22/08/2023	22/08/23

14. SULFATED ASH: < REFER GAM 032>

Not more than 0.1% w/w, determined on 1.0g of sample.

15. ASSAY: (Nitrogen Determination)

Place 100.0mg of the substance to be examined (m mg) in a combustion flask, add 5g of a mixture of 1g of copper sulfate pentahydrate, 1g of titanium dioxide and 33g of dipotassium sulfate, and 3 glass beads. Wash any adhering particles from the neck into the flask with a small quantity of water. Add 7ml of sulfuric acid, allowing it to run down the insides of the flask. Heat the flask gradually until the solution has a clear, yellowish-green colour, and the insides wall of the flask is free from a carbonized material and then heat for a further 45 min. after cooling, and cautiously 20ml of water, and connects the flask to the distillation apparatus previously washed by passing steam through it. To the absorption flask add 30ml of a 40 g / L solution of boric acid, 3 drops of bromocresol green-methyl red solution and sufficient water to immerse the lower end of the condenser tube. Add 30ml of strong sodium hydroxide solution through the lower the funnel, rinse the funnel cautiously with 10 ml of water, immediately close the clamp on the rubber tube, and then start distillation with steam to obtain 80 to 100ml of distillate. Remove the absorption flask from the lower end of the condenser tube, rinsing the end part with a small quantity of water and titrate the distillate with 0.025M Sulfuric acid until the colour of the solution changes from green through pale greyish blue to pale greyish reddish-purple. Carry out a blank determination.

1 ml of 0.025 M Sulfuric acid is equivalent to 0.700 mg of Nitrogen.

Calculation:

$$= \frac{\text{Titer value} \times \text{Molarity of 1ml 0.025N sulphuric acid} \times 0.700 \times 100 \times 100}{\text{Sample weight in mg} \times 0.025 \times (100 - \%\ \text{of LOD})}$$

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	21/08/2023	22/08/2023	22/08/23

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMEP0045-00	(i) Periodic review. (ii) STP numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/016	25/08/2023

****END OF THE DOCUMENT****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	21/08/2023	22/08/2023	22/08/23

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Material	PURIFIED WATER			
Specification No.	SPEC-RMEP0033-01	**Revision No.**	01	**Item Code.:** RMEP0033
Supersedes	SPEC-RMEP0033-00	**Effective Date**	17/07/2025	**Page No.:** 1 of 4

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	H_2O
2	Molecular weight	18.02
3	Storage conditions	Not applicable
4	Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
5	Quantity of sample required for analysis	1000 ml for chemical Analysis 500 ml for Microbial analysis
6	Quantity of reserve sample	Nil
7	Retest period	Not applicable
9	Reference	IP/BP
10	Sampling instruction	Follow the standard operating procedure No.: ST/QC/040.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	14/07/2025	15/07/2025	16/07/2025

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Material	PURIFIED WATER			
Specification No.	SPEC-RMEP0033-01	**Revision No.**	01	**Item Code.:** RMEP0033
Supersedes	SPEC-RMEP0033-00	**Effective Date**	17/07/2025	**Page No.:** 2 of 4

S.NO	TEST (s)	SPECIFICATION (s)
1.	Description	A Clear, colourless and odourless liquid.
2.	Acidity or alkalinity **A.** Methyl Red **B.** Bromothymol Blue	 The resulting solution is not red. The resulting solution is not blue.
3.	Heavy metals	Not more than 0.1ppm.
4.	Nitrates	Not more than 0.2ppm.
5.	Oxidisable substances	The solution remains faintly pink.
6.	pH at 25°C	Between 5.0 and 7.0
7.	Conductivity at 25°C	Not more than 2.1µS.cm^{-1}

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	14/07/2025	15/07/2025	16/07/2025

S.NO	TEST (s)	SPECIFICATION (s)
8.	Microbial contamination	
	Total aerobic microbial count	Not more than 100 cfu /ml
	Pathogen tests:	
	(i) E. Coli	Should be absent/ml
	(ii) Salmonella species	Should be absent/10ml
	(iii) Pseudomonas	Should be absent/ml
	(iv) Staphylococcus aureus	Should be absent/ml

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	14/07/2025	15/07/2025	16/07/2025

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-RMEP0033-00	(i) Specification numbering procedure revised as per SOP No. ST/QC/058. (ii) There is no changes in specification as per current monographs.	ST/CC/23/063 ST/CC/24/067	15-03-2024
SPEC-RMEP0033-01	Ammonium, Calcium and Magnesium, Chlorides, Sulphates and Residue on evaporation specification has been removed as per current monographs (IP/BP).	ST/CC/25/162	17/07/2025

**** END OF THE DOCUMENT ****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	14/07/2025	15/07/2025	16/07/2025

	Safetab Life Science Puducherry			MASTER COPY
	STANDARD TESTING PROCEDURE			
Name of Material	PURIFIED WATER			
STP No.	STP-RMEP0033-01	**Revision No.**	01	**Item Code.:** RMEP0033
Supersedes	STP-RMEP0033-00	**Effective Date**	17/07/2025	**Page No.:** 1 of 4

1. DESCRIPTION: < REFER GAM 001>

A clear, colourless and odourless liquid.

2. ACIDITY OR ALKALINITY:

Acidity: Take about 50 ml of the sample in clean dry glass flask, boil and cool. Pipette out 10 ml of sample and add 0.05 ml of methyl red solution. Check the colour of the solution. The solution should not become red coloured.

Alkalinity: Take about 50 ml of the sample in clean dry glass flask, boil and cool .Pipette out 10 ml of sample and add 0.1 ml of bromothymol blue solution. Check the colour of the solution. The solution should not become blue coloured.

3. HEAVY METALS: < REFER GAM 006>

Sample preparation:

Transfer 200ml sample in a evaporating dish. Add 0.15mL of 0.1 nitric acid Heat on water-bath until the volume is reduced to 20ml. Take 12mL of the concentrated solution.

Standard preparation:

Take 10ml of Lead standard solution (1 ppm Pb), adding 0.075mL of 0.1M nitric acid and add 2ml of concentrated sample in a test-tube.

Blank preparation:

Take 10ml of Distilled water, add 0.075mL of 0.1M nitric acid and mix 2ml of concentrated sample.

Procedure:

To each of the above solutions, add 2ml of acetate buffer pH 3.5, and add the mixtures to 1.2ml of thioacetamide reagent separately and allow to stand for 2 minutes.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	14/07/2025	15/07/2025	16/07/2025

Observation:

After 2 minutes, any brown colour produced by the sample is not more intense than that the standard solution.

4. NITRATES:

Sample preparation:

Take 5ml of sample in a test-tube and immersed in ice water. Add 0.4ml of Potassium Chloride solution (10g of Potassium chloride in 100ml of water), 0.1ml of diphenylamine solution and add 5ml of nitrogen-free sulphuric acid drop wise with shaking. Transfer the tube to water bath at 50°C and keep it for 15 minutes.

Standard preparation:

Take 4.5ml of nitrate free water and 0.5ml Nitrate standard solution (2 ppm NO_3) in test tube. Add 0.4ml of potassium chloride solution (10g of Potassium chloride in 100ml of water), 0.1ml of diphenylamine solution and add 5ml of nitrogen-free sulphuric acid drop wise with shaking. Transfer the tube to water bath at 50°C and keep it for 15 minutes.

Observation:

After 15 minutes, Any blue colour produced by the sample is not more intense than the standard solution.

5. OXIDISABLE SUBSTANCES:

Take 100 ml of sample in a conical flask, add 10 ml of dilute sulphuric acid and 0.1ml of 0.02M potassium permanganate and boil for 5 minutes. The solution remains faintly pink.

6. pH: < REFER GAM 030>

Between 5.0 and 7.0

Take 100ml of sample in a clean dry beaker and measure the pH by calibrated pH meter at 25°C as per operating procedure No: ST/QC/085.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	14/07/2025	15/07/2025	16/07/2025

7. CONDUCTIVITY:

Not more than 2.1 $\mu S.cm^{-1}$

Rinse the conductivity electrode two to three times with purified water and wipe dry with tissue paper. Take 100ml of sample in a clean dry beaker and measure the conductivity by calibrated Conductivity meter at 25°C as per operating procedure No: ST/QC/086.

8. MICROBIAL CONTAMINATION:

Total Viable aerobic count and Pathogen test refer as per the current SOP No: ST/MB/011.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	14/07/2025	15/07/2025	16/07/2025

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMEP0033-00	(i) STP numbering procedure revised as per SOP No. ST/QC/058. (ii) Testing procedure for ammonium has been changed as per current monograph.	ST/CC/23/063 ST/CC/24/067	15-03-2024
STP-RMEP0033-01	Ammonium, Calcium and Magnesium, Chlorides, Sulphates and Residue on evaporation testing procedure has been removed as per current monographs (IP/BP).	ST/CC/25/162	17/07/2025

****END OF THE DOCUMENT****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	14/07/2025	15/07/2025	16/07/2025