	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Material	0 SIZE RED/RED HEG CAPSULES (GHPL PRINTED LOGO)			
Specification No.	SPEC-RMER0012-01	**Revision No.**	01	**Item Code.:** RMER0012
Supersedes	SPEC-RMER0012-00	**Effective Date**	05/08/2024	**Page No.:** 1 of 4

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	NA
2	Molecular weight	NA
3	Storage conditions	Store protected from moisture at a temperature not exceeding 30°
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	35g
6	Quantity of reserve sample	70g
7	Retest period	12 months from the date of release
8	Re-test Parameter	As mentioned in Specification
9	Reference	IHS
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	01/08/2024	02/08/2024	05/08/2024

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Material	0 SIZE RED/RED HEG CAPSULES (GHPL PRINTED LOGO)			
Specification No.	SPEC-RMER0012-01	**Revision No.**	01	**Item Code.:** RMER0012
Supersedes	SPEC-RMER0012-00	**Effective Date**	05/08/2024	**Page No.:** 2 of 4

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	0 Size hard gelatin capsule having Red coloured plain cap and Red coloured plain body with GHPL Printed logo.
2.	*Identification	A precipitate is produced.
3.	*Odour	The shells do not develop any foreign odour
4.	Average Weight	96.0mg ± 10% (86.4-105.6mg)
5.	Dimensions of empty capsule shells ➢ Outside diameter Cap: Body: ➢ Length Cap: Body: ➢ Single wall thickness Cap: Body:	 7.60-7.72 mm 7.28-7.40 mm 10.20-11.20 mm 18.00-19.00 mm 0.095-0.125 mm 0.090-0.120 mm
6.	Disintegration time	Not more than 15 minutes

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	01/08/2024	02/08/2024	05/08/2024

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Material	0 SIZE RED/RED HEG CAPSULES (GHPL PRINTED LOGO)			
Specification No.	SPEC-RMER0012-01	**Revision No.**	01	**Item Code.:** RMER0012
Supersedes	SPEC-RMER0012-00	**Effective Date**	05/08/2024	**Page No.:** 3 of 4

S.NO	TEST (s)	SPECIFICATION (s)
7.	*Loss on drying	12.5% to 16.0% w/w
8.	*Microbial contamination (i) Total viable aerobic count (ii) Escherichia coli (iii) Salmonella species (iv) Shigella	 Not more than 1000cfu/g Should be absent in 1g Should be absent in 10g Should be absent in 10g

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	01/08/2024	02/08/2024	05/08/2024

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Material	0 SIZE RED/RED HEG CAPSULES (GHPL PRINTED LOGO)			
Specification No.	SPEC-RMER0012-01	**Revision No.**	01	**Item Code.:** RMER0012
Supersedes	SPEC-RMER0012-00	**Effective Date**	05/08/2024	**Page No.:** 4 of 4

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-RMER0012-00	(i) Periodic review. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	24-02-2024
SPEC-RMER0012-01	In description printed text GHPL logo has been revised as per customer requirement.	ST/CC/24/163	05/08/2024

**** 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	01/08/2024	02/08/2024	05/08/2024

	Safetab Life Science Puducherry			MASTER COPY
	STANDARD TESTING PROCEDURE			
Name of Material	0 SIZE RED/RED HEG CAPSULES (GHPL PRINTED LOGO)			
STP No.	STP-RMER0012-01	**Revision No.**	01	**Item Code.:** RMER0012
Supersedes	STP-RMER0012-00	**Effective Date**	05/08/2024	**Page No.:** 1 of 2

1. DESCRIPTION: < REFER GAM 001>

0 Size hard gelatin capsule having Red coloured plain cap and Red coloured plain body with GHPL printed logo.

2. IDENTIFICATION: < REFER GAM 003>

Boil one capsule shell with 20ml of water allow to cool and centrifuge. To 5ml of the supernatant liquid add 1ml of picric acid solution and to another 5ml add 1ml of tannic acid solution, a precipitate is produced in each case.

3. ODOUR:

Keep 100 capsule shells in a well closed bottle for 24 hours at a temperature between 30° and 40°. The shells do not develop any foreign odour.

4. AVERAGE WEIGHT:

Weigh 100 capsule shells and determine the average weight of a capsule. The average weight is within ±10 per cent of the target weight.

5. DIMENSION OF EMPTY CAPSULE SHELL:

Dimension of hard empty gelatin capsules is determined using vernier scale.

6. DISINTEGRATION:

Not more than 15 minutes, using discs.

7. LOSS ON DRYING: < REFER GAM 026>

12.5 to 16.0% w/w, determined on 1.0g by drying in an oven at 105°C for 4 hours or to constant weight.

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	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	01/08/2024	02/08/2024	05/08/2024

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMER0012-00	(i) Periodic review. (ii) STP numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	24-02-2024
STP-RMEP0012-01	In description printed text GHPL logo has been revised as per customer requirement.	ST/CC/24/163	05/08/2024

****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	01/08/2024	02/08/2024	05/08/2024

	Safetab Life Science Puducherry RAW MATERIAL SPECIFICATION			MASTER COPY
Name of Product	ALPHA TOCOPHERYL ACETATE CONCENTRATE 50% BP (POWDER FORM)			
Specification No.	SPEC-RMAA0030-00	**Revision No.**	00	**Item Code.:** RMAA0030
Supersedes	RMASA0030-00	**Effective Date**	30/12/2023	**Page No.:** 1 of 3

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	NA
2	Molecular weight	NA
3	Storage conditions	In an airtight, well-filled 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	2 g
6	Quantity of reserve sample	4 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	C.K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	26/12/2023	27/12/2023	28/12/2023

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	ALPHA TOCOPHERYL ACETATE CONCENTRATE 50% BP (POWDER FORM)			
Specification No.	SPEC-RMAA0030-00	**Revision No.**	00	**Item Code.:** RMAA0030
Supersedes	RMASA0030-00	**Effective Date**	30/12/2023	**Page No.:** 2 of 3

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	Almost white, yellowish or light brown, small particles.
2.	*Solubility	Practically insoluble or swells or forms a dispersion water, depending on the formulation.
3.	*Identification **A.** By Thin-layer chromatography **B.** By Assay	 The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution. The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (a); In the chromatogram obtained with reference solution (c) no additional principal peak is observed when compared with the chromatogram obtained with the test solution.
4.	*Assay (By Gas chromatography)	Not less than 90.0% to not more than 115.0% 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	26/12/2023	27/12/2023	28/12/2023

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-RMAA0030-00	(i) Periodic review. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	30/12/2023

**** 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	26/12/2023	27/12/2023	28/12/2023

	Safetab Life Science Puducherry			MASTER COPY
	STANDARD TESTING PROCEDURE			
Name of Product	ALPHA TOCOPHERYL ACETATE CONCENTRATE 50% BP (POWDER FORM)			
STP No.	STP-RMAA0030-00	**Revision No.**	00	**Item Code.:** RMAA0030
Supersedes	RMATA0030-00	**Effective Date**	30/12/2023	**Page No.:** 1 of 5

1. DESCRIPTION: <REFER GAM 001>

Almost white, yellowish or light brown, small particles.

2. SOLUBILITY: <REFER GAM 002>

Practically insoluble or swells or forms a dispersion water, depending on the formulation.

3. IDENTIFICATION: <REFER GAM 003>

First identification: B

Second identification: A

By Thin-layer chromatography:

Plate: TLC silica gel F_{254} plate.

Mobile phase preparation:

A mixture of 20 volumes of ether and 80 volumes of cyclohexane.

Test solution:

To a quantity of the preparation to be examined corresponding to 50mg of α-Tocopheryl acetate add 5ml of 0.01M hydrochloric acid and treat with ultrasound at 60°C. Add 5ml of anhydrous ethanol and 10ml of cyclohexane, shake for 1 minutes and centrifuge for 5 minutes. Use the upper layer.

Reference solution:

Dissolve 50mg of α-Tocopheryl acetate in cyclohexane and dilute to 10ml with the same solvent.

Application: 10µl.

Development: 3/4 of the plate.

Drying: in a current of air.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	26/12/2023	27/12/2023	28/12/2023

Detection: examine in ultraviolet light at 254nm.

Results:

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

B. By Assay:

Examine the chromatograms obtained in the assay.

The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (a); In the chromatogram obtained with reference solution (c) no additional principal peak is observed when compared with the chromatogram obtained with the test solution.

4. ASSAY (By Gas chromatography):

Chemicals/Reagents/Standards:

α-Tocopheryl acetate	:	Reference standard
α-Tocopheryl	:	Reference standard
Squalane	:	AR grade
Cyclohexane	:	AR grade
Hydrochloric acid	:	AR grade
Anhydrous ethanol	:	AR grade

Chromatographic Condition:

Column	:	300mm x 0.25mm, poly(dimethyl)siloxane (film thickness 0.25µm or equivalent
Flow rate	:	1.0 mL / minute

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	26/12/2023	27/12/2023	28/12/2023

Carrier gas	:	Helium for chromatography
Split ratio	:	1:100
Column temperature	:	280°C
Injection port and detector	:	290°C
Detection	:	Flame ionisation
Runtime	:	1.1 times the retention time of α-Tocopheryl acetate
Injection	:	1µl; inject directly onto the column or via a sufficiently inert, glass-lined injection port

Internal standard solution:

Dissolve 1.0g of Squalane in cyclone and dilute to 500ml with the same solvent.

Test solution:

Weigh accurately a quantity of the preparation to be examine corresponding to about 0.100g of α-Tocopheryl acetate into a 250ml conical flask. Add 20ml of 1M hydrochloric acid and sonicate at 70°C for 20 minutes. Add 50ml of anhydrous ethanol and 50.0ml of the internal standard solution. Mix thoroughly for 30 minutes using a magnetic stirrer. Allow the 2 layers to separate and use the upper layer.

Reference solution (a):

Dissolve 0.100g of α-Tocopheryl acetate in 50.0ml of the internal standard solution.

Reference solution (b):

Dissolve 10mg of α-Tocopheryl and 10mg of α-Tocopheryl acetate CRS in 5.0ml of cyclohexane.

Reference solution (c):

Mix 1.0ml of the test solution and 1.0ml of reference solution (a).

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	26/12/2023	27/12/2023	28/12/2023

Relative retention:

With reference to α-Tocopheryl acetate (retention time = about 12minutes); squalane = about 0.5; α-Tocopheryl = about 0.9.

System suitability:

Resolution: minimum 3.5 between the peaks due to α-Tocopheryl and α-Tocopheryl acetate in the chromatogram obtained with reference solution (b);

In the chromatogram obtained with reference solution (a), the area of the peak due to α-Tocopheryl is not greater than 0.002 times the area of the peak due to α-Tocopheryl acetate (0.2%)

Calculate the percentage content of α-Tocopheryl acetate from the declared content of α-Tocopheryl acetate.

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	26/12/2023	27/12/2023	28/12/2023

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMAA0030-00	(i) Periodic review. (ii) STP numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	30/12/2023

**** 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	26/12/2023	27/12/2023	28/12/2023

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	ASCORBIC ACID BP			
Specification No.	SPEC-RMAA0029-00	**Revision No.**	00	**Item Code.:** RMAA0029
Supersedes	RMASA0029-00	**Effective Date**	05/02/2024	**Page No.:** 1 of 4

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	$C_6H_8O_6$.
2	Molecular weight	176.1
3	Storage conditions	In a non-metallic 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	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	C.K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	01/02/2024	02/02/2024	03/02/2024

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	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	ASCORBIC ACID BP			
Specification No.	SPEC-RMAA0029-00	**Revision No.**	00	**Item Code.:** RMAA0029
Supersedes	RMASA0029-00	**Effective Date**	05/02/2024	**Page No.:** 2 of 4

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	White or almost white, crystalline powder or colourless crystals, becoming discoloured on exposure to air and moisture.
2.	*Solubility	Freely soluble in water, sparingly soluble in ethanol (96%).
3.	*Identification **A.** By UV **B.** By IR **C.** By pH **D.** By Chemical test	 Between 545 to 585. The Infrared absorption spectrum of sample should be concordant with that of reference spectrum or with the spectrum obtained from Ascorbic acid WS. Between 2.1 to 2.6. A grey precipitate is formed.
4.	Appearance of solution	Solution S is clear and not more intensely coloured than reference solution BY7.
5.	*Specific optical rotation	Between +20.5° to +21.5°
6.	Impurity E	Not more than 0.2%

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	01/02/2024	02/02/2024	05/02/2024

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	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	ASCORBIC ACID BP			
Specification No.	SPEC-RMAA0029-00	**Revision No.**	00	**Item Code.:** RMAA0029
Supersedes	RMASA0029-00	**Effective Date**	05/02/2024	**Page No.:** 3 of 4

S.NO	TEST (s)	SPECIFICATION (s)
7.	*Related substances:	
	A. Impurities C	Not more than 0.15%
	B. Impurities D	Not more than 0.15%
	C. Unspecified impurities	Not more than 0.10%
	D. Sum of impurities other than C and D	Not more than 0.20%
8.	Copper	Not more than 5 ppm
9.	Iron	Not more than 2 ppm
10.	Sulfated ash	Not more than 0.1% w/w.
11.	*Assay	Not less than 99.0 per cent and not more than 100.5% 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	01/02/2024	02/02/2024	03/02/2024

Safetab Life Science QUALITY ASSURANCE Puducherry-607

	Safetab Life Science Puducherry RAW MATERIAL SPECIFICATION			MASTER COPY
Name of Product	ASCORBIC ACID BP			
Specification No.	SPEC-RMAA0029-00	**Revision No.**	00	**Item Code.:** RMAA0029
Supersedes	RMASA0029-00	**Effective Date**	05/02/2024	**Page No.:** 4 of 4

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-RMAA0029-00	(i) Periodic review. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	05/02/2024

**** 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	01/02/2024	02/02/2024	05/02/2024

Safetab Life Science QUALITY ASSURANCE Puducherry-10

	Safetab Life Science Puducherry			MASTER COPY
	STANDARD TESTING PROCEDURE			
Name of Product	ASCORBIC ACID BP			
STP No.	STP-RMAA0029-00	**Revision No.**	00	**Item Code.:** RMAA0029
Supersedes	RMASA0029-00	**Effective Date**	05/02/2024	**Page No.:** 1 of 7

1. DESCRIPTION: < REFER GAM 001>

White or almost white, crystalline powder or colourless crystals, becoming discoloured on exposure to air and moisture.

2. SOLUBILITY: <REFER GAM 002>

100mg of sample + 1mL of water	Freely soluble if the material dissolves.
100mg of sample + 10mL of ethanol (96%)	Sparingly soluble if the material dissolves.

3. IDENTIFICATION: <REFER GAM 003>

First identification: B and C

Second identification: A,C and D

A. By UV:

Dissolve 0.10 g of sample in water and dilute immediately to 100.0 mL with the same solvent. Add 1.0mL of the solution to 10mL of a 10.3 g/L solution of hydrochloric acid and dilute to 100.0mL with water. Absorption maximum at 243 nm, determined immediately after dissolution. Specific absorbance at the absorption maximum 545 to 585.

B. By IR:

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

C. By pH:

Between 2.1 to 2.6 for solution S.

D. By Chemical test:

To 1 mL of solution S add 0.2 mL of dilute nitric acid and 0.2 mL of silver nitrate solution R2. A grey precipitate is formed.

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	01/08/2024	02/08/2024	05/08/2024

Safetab Life Science QUALITY ASSURANCE Puducherry-107

Solution S:

Weigh accurately about 1.0g of sample dissolved in carbon Dioxide-free water and dilute to 20ml with the same solvent.

4. APPEARANCE OF SOLUTION: <REFER GAM 024>

Solution S is clear and not more intensely coloured than reference solution BY7.

5. SPECIFIC OPTICAL ROTATION: <REFER GAM 029>

Between +20.5° to +21.5°

Dissolve 2.50g of sample in water and dilute to 25.0 mL with the same solvent.

6. IMPURITY E:

Maximum 0.2 per cent.

Test solution:

Dissolve 0.25g of sample in 5mL of water. Neutralise using dilute sodium hydroxide solution, then add 1mL of dilute acetic acid and 0.5mL of calcium chloride solution.

Reference solution:

Dissolve 70mg of oxalic acid in water and dilute to 500mL with the same solvent; To 5mL of the solution add 1mL of dilute acetic acid and 0.5mL of calcium chloride solution.

Allow the solutions to stand for 1 h. Any opalescence in the test solution is not more intense than that in the reference solution.

7. RELATED SUBSTANCES: (BY HPLC)

Chemicals/Reagents/Standards:

Ascorbic acid	:	Working standard
Ascorbic acid impurity C	:	Reference standard
Ascorbic acid impurity D	:	Reference standard
Potassium dihydrogen phosphate	:	AR grade
Purified water	:	Milli-Q water (or) equivalent
Acetonitrile	:	HPLC grade

Chromatographic Conditions:

Column	:	250mm x 4.6mm, aminopropylsilyl silca gel, 5µ or equivalent.
Temperature	:	45°C
Flow Rate	:	1.0ml/min
Wavelength	:	UV at 210nm
Injection volume	:	20µl

Note: Prepare the solution immediately before use.

Phosphate buffer solution:

Dissolve 6.8g of Potassium dihydrogen phosphate in water and dilute to about 175ml with the same solvent, filter through a membrane filter (nominal pore size 0.45µm) and dilute to 1000ml with water.

Mobile phase:

A mixture of 25 volumes of Phosphate buffer solution and 75 volumes of acetonitrile.

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	01/02/2024	02/02/2024	05/02/2024

Safetab Life Science QUALITY ASSURANCE Puducherry-107

Test solution:

Dissolve 0.5g of the substance to be examined in the mobile phase and dilute to 10.0ml with the mobile phase.

Reference solution (a):

Dissolve 10.0mg of Ascorbic acid impurity C in the mobile phase and dilute to 5.0ml with the mobile phase.

Reference solution (b):

Dissolve 5.0mg of Ascorbic acid impurity D and 5.0mg of Ascorbic acid WS in the mobile phase, add 2.5ml of reference solution (a) and dilute to 100.0ml with the mobile phase.

Reference solution (c):

Dilute 1.0ml of the test solution to 200.0ml with the mobile phase. Mix 1.0ml of this solution with 1.0ml of reference solution (a).

Run time:

2.5 times the retention time of ascorbic acid.

Identification of impurities:

Use the chromatogram obtained with reference solution (b) to identify the peaks due to impurities C and D.

Relative retention:

With reference to ascorbic acid (retention time = about 11 min): impurity D = about 0.4; impurity C = about 1.7.

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	01/08/2024	08/08/2024	03/08/2024

Safetab Life Science QUALITY ASSURANCE Puducherry-107

System suitability:

Resolution:

Minimum 3.0 between the peaks due to ascorbic acid and impurity C in the chromatogram obtained with reference solution (c)

Signal-to-noise ratio:

Minimum 20 for the peak due to impurity C in the chromatogram obtained with reference solution (b).

Limits:

Impurities C, D: For each impurity, not more than 1.5 times the area of the corresponding peak in the chromatogram obtained with reference solution (b) (0.15 per cent)

Unspecified impurities: For each impurity, not more than the area of the peak due to ascorbic acid in the chromatogram obtained with reference solution (b) (0.10 per cent)

Sum of impurities other than C and D: Not more than twice the area of the peak due to ascorbic acid in the chromatogram obtained with reference solution (b) (0.20 per cent)

Disregard limit: 0.5 times the area of the peak due to ascorbic acid in the chromatogram obtained with reference solution (b) (0.05 per cent).

8. COPPER: (ATOMIC ABSORPTION SPECTROMETRY)

Maximum 5 ppm.

Test solution:

Dissolve 2.0 g in 0.1 M nitric acid and dilute to 25.0 mL with the same acid.

Reference solutions:

Prepare the reference solutions (0.2 ppm, 0.4 ppm and 0.6 ppm) using copper standard solution (10 ppm Cu) R, diluting with 0.1 M nitric acid.

	Source	: Copper hollow-cathode lamp.
	Wavelength	: 324.8 nm.
	Atomisation device	: Air-acetylene flame.

Adjust the zero of the apparatus using 0.1 M nitric acid.

9. IRON: (ATOMIC ABSORPTION SPECTROMETRY)

Maximum 2 ppm.

Test solution:

Dissolve 5.0 g in 0.1 M nitric acid and dilute to 25.0 mL with the same acid.

Reference solutions:

Prepare the reference solutions (0.2 ppm, 0.4 ppm and 0.6 ppm) using iron standard solution (20 ppm Fe) R, diluting with 0.1 M nitric acid.

Source	:	Iron hollow-cathode lamp.
Wavelength	:	248.3 nm.
Atomisation device	:	Air-acetylene flame.

Adjust the zero of the apparatus using 0.1 M nitric acid.

10. SULFATED ASH: <REFER GAM 032>

Maximum 0.1 per cent, determined on 1.0g of sample.

11. ASSAY:

Weigh accurately about 0.150g of sample dissolved in a mixture of 10mL of dilute sulfuric acid and 80mL of carbon dioxide-free water. Add 1mL of starch solution .Titrate with 0.05M iodine until a persistent violet-blue colour is obtained.

1 ml of 0.05M iodine is equivalent to 8.81mg of $C_6H_8O_6$.

Calculation:

$$= \frac{\text{Titer value} \times \text{Molarity of 0.05M iodine} \times 8.81 \times 100}{\text{Sample weight in mg} \times 0.05}$$

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMAA0029-00	(i) Periodic review. (ii) STP numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	05/02/2024

**** 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	01/02/2024	02/02/2024	02/02/2024

Safetab Life Science QUALITY ASSURANCE Puducherry-107

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	RAW MATERIAL SPECIFICATION			
Name of Product	CALCIUM HYDROGEN PHOSPHATE (DCP ANHYDROUS) BP			
Specification No.	SPEC-RMED0015-00	**Revision No.**	00	**Item Code.:** RMED0015
Supersedes	RMESD0015-00	**Effective Date**	24/04/2025	**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	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	21/04/2025	22/04/2025	23/04/2025

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	CALCIUM HYDROGEN PHOSPHATE (DCP ANHYDROUS) BP			
Specification No.	SPEC-RMED0015-00	**Revision No.**	00	**Item Code.:** RMED0015
Supersedes	RMESD0015-00	**Effective Date**	24/04/2025	**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 white precipitate is produced. 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	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	21/04/2025	22/04/2025	23/04/2025

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	CALCIUM HYDROGEN PHOSPHATE (DCP ANHYDROUS) BP			
Specification No.	SPEC-RMED0015-00	**Revision No.**	00	**Item Code.:** RMED0015
Supersedes	RMESD0015-00	**Effective Date**	24/04/2025	**Page No.:** 3 of 4

S.NO	TEST (s)	SPECIFICATION (s)
10.	Barium	No turbidity is produced.
11.	Iron	Not more than 400ppm.
12.	*Loss on ignition	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	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	21/04/2025	22/04/2025	23/04/2025

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-RMED0015-00	(i) Periodic review. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	24/04/2025

**** 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	21/04/2025	22/04/2025	23/04/2025

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	STANDARD TESTING PROCEDURE			
Name of Product	CALCIUM HYDROGEN PHOSPHATE (DCP ANHYDROUS) BP			
STP No.	STP-RMED0015-00	**Revision No.**	00	**Item Code.:** RMED0015
Supersedes	RMETD0015-00	**Effective Date**	24/04/2025	**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	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	21/04/2025	22/04/2025	23/04/2025

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.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
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Signature			
Date	21/04/2025	22/04/2025	23/04/2025

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

13. ASSAY:

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

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

Calculation:

$$= \frac{\text{Titer value - Blank x 0.02M sodium edetate x 0.0027212 x 100}}{\text{Sample weight in g x 0.02}}$$

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	21/04/2025	22/04/2025	23/04/2025

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMED0015-00	(i) Periodic review. (ii) STP numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	24/04/2025

****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	21/04/2025	22/04/2025	23/04/2025

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	CARBONYL IRON USP			
Specification No.	SPEC-RMAC0073-00	**Revision No.**	00	**Item Code.:** RMAC0073
Supersedes	RMASC0073-00	**Effective Date**	20/04/2024	**Page No.:** 1 of 3

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	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	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	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	16/04/2024	17/04/2024	18/04/2024

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	RAW MATERIAL SPECIFICATION			
Name of Product	CARBONYL IRON USP			
Specification No.	SPEC-RMAC0073-00	**Revision No.**	00	**Item Code.:** RMAC0073
Supersedes	RMASC0073-00	**Effective Date**	20/04/2024	**Page No.:** 2 of 3

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	Grey coloured free flowing powder without any palpable grittiness. Has no odour or taste.
2.	*Solubility	Practically insoluble in organic solvents and water.
3.	*Identification **A.** By Chemical test **B.** By Microscopic	 Hydrogen is evolved. It appears as spheres built up with concentric shells. Its particle size is 45-75µm.
4.	Acid-insoluble substances	Not more than 0.2% (The residue weighs not more than 2mg).
5.	Elemental impurities (i) Arsenic (ii) Lead (iii) Mercury	 Not more than 3 µg/g Not more than 4 µg/g Not more than 2 µg/g
6.	Particle size distribution	Passing Not less than 100% in 200 mesh Sieve. Passing Not less than 95% in 325 mesh Sieve.
7.	*Assay (As such basis)	Not less than 98.0%

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	16/04/2024	17/04/2024	18/04/2024

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	CARBONYL IRON USP			
Specification No.	SPEC-RMAC0073-00	**Revision No.**	00	**Item Code.:** RMAC0073
Supersedes	RMASC0073-00	**Effective Date**	20/04/2024	**Page No.:** 3 of 3

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-RMAC0073-00	(i) Periodic review. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	20/04/2024

**** 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	16/04/2024	17/04/2024	18/04/2024

	Safetab Life Science Puducherry			MASTER COPY
	STANDARD TESTING PROCEDURE			
Name of Product	CARBONYL IRON USP			
STP No.	STP-RMAC0073-00	**Revision No.**	00	**Item Code.:** RMAC0073
Supersedes	RMATC0073-00	**Effective Date**	20/04/2024	**Page No.:** 1 of 3

1. DESCRIPTION: < REFER GAM 001>

Grey coloured free flowing powder without any palpable grittiness. Has no odour or taste.

2. SOLUBILITY: < REFER GAM 002>

10mg of sample + 100mL of organic solvents	Practically insoluble if the material does not dissolve
10mg of sample + 100mL of water	Practically insoluble if the material does not dissolve

3. IDENTIFICATION:

A. By Chemical test:

Weigh accurately about 100.0mg of sample dissolved in a dilute mineral acid. Hydrogen is evolved, and the resulting solutions give a positive test.

B. By Microscopic:

A small amount of sample under a microscope having a magnifying power of 500 or greater.

It appears as spheres built up with concentric shells. Its particle size is 45-75µm.

4. ACID INSOLUBLE SUBSTANCES:

Weigh accurately about 1.0g of sample dissolved in 25ml of 2N sulfuric acid, and heat on a steam bath until the evolution of hydrogen ceases. Filter through a tared filter crucible, wash the residue with water until free from sulfate, dry at 105°C for 1 hour, cool to room temperature and weigh.

Acceptance criteria: Not more than 0.2% (the residue weigh not more than 2mg).

5. ELEMENTAL IMPURITIES:

(i) Arsenic: Not more than 3 µg/g.
(ii) Lead: Not more than 4 µg/g.
(iii) Mercury: Not more than 2 µg/g.

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	16/04/2024	17/04/2024	18/04/2024

6. PARTICLE SIZE DISTRIBUTION:

Arrange the sample collector, 200 ASTM sieve and 325 ASTM sieve. Weigh and transfer around 10.0g of the sample into 200 ASTM sieve and shake for 5 minutes. Collect the 200 ASTM passing (W200) from 200mesh and passing to 325 ASTM (W325).

$$\% \text{ Passing on 200 ASTM} = \frac{\text{W200 in gram} \times 100}{\text{Weight of sample in g}}$$

$$\% \text{ Passing on 325 ASTM} = \frac{\text{W325 in gram} \times 100}{\text{Weight of sample in g}}$$

Limit:

Passing Not less than 100% in 200 mesh Sieve.

Passing Not less than 95% in 325 mesh Sieve.

7. ASSAY: (AS SUCH BASIS)

Electrode system: platinum indicating electrode and silver-silver chloride reference electrode (or an equivalent combination electrode).

End point detection: Potentiometric.

Weigh accurately about 200.0mg of sample transfer into 300ml Erlenmeyer flask. Add 50mL of 2N Sulphuric acid and close the flask with a stopper containing a Bunsen valve (made by inserting a glass tube connected to a short piece of rubber tubing with a slit on the side and a glass rod inserted in the other end and arranged so that gases can escape but air cannot enter). Heat on a steam bath to completely dissolve the sample. Remove the flask from the steam bath and allow the solution to cool at room temperature with the stopper in place.

Add a stir bar and 50ml of recently boiled and cooled water to the flask. Titrate the solution with 0.1N Cerric sulphate through the inflection point. Perform a blank determination.

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	16/04/2024	17/04/2024	18/04/2024

1 ml of 0.1N Cerric sulphate is equivalent to 55.85mg of iron.

Calculation:

$\{[(V_S - V_B) \times N \times F]/W\} \times 100$

V_S = Titrant volume consumed by the Sample (ml)

V_B = Titrant volume consumed by the Blank (ml)

N = Actual titrant normality (mEq/ml)

F = Equivalent factor, 55.85 mg/mEq

W = Sample weight (mg)

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMAC0073-00	(i) Periodic review. (ii) STP numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	20/04/2024

****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	16/04/2024	17/04/2024	18/04/2024

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	COLLOIDAL ANHYDROUS SILICA BP			
Specification No.	SPEC-RMEC0017-00	**Revision No.**	00	**Item Code.:** RMEC0017
Supersedes	RMESC0017-01	**Effective Date**	18/11/2023	**Page No.:** 1 of 3

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	SiO_2
2	Molecular weight	60.1
3	Storage conditions	Store 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	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	S.MARAN
Designation	Dy. Manager-QC	GM-QC	AGM-QA
Signature			
Date	14/11/2023	15/11/2023	17/11/2023

Format No: ST/QC/058:A1

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	RAW MATERIAL SPECIFICATION			
Name of Product	COLLOIDAL ANHYDROUS SILICA BP			
Specification No.	SPEC-RMEC0017-00	**Revision No.**	00	**Item Code.:** RMEC0017
Supersedes	RMESC0017-01	**Effective Date**	18/11/2023	**Page No.:** 2 of 3

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	White or almost white, light, fine, amorphous powder, with a particle size of about 15nm.
2.	*Solubility	Practically insoluble in water and in mineral acids except hydrofluoric acid. It dissolves in hot solutions of alkali hydroxides.
3.	*Identification By Silicates	Within a short time a white ring is rapidly formed around the drop of water.
4.	*pH	Between 3.5 to 5.5
5.	Chlorides	Not more than 250ppm.
6.	*Loss on ignition	Not more than 5.0% w/w.
7.	*Assay (On ignited basis)	Not less than 99.0% and not more than 100.5% 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	S.MARAN
Designation	Dy. Manager-QC	GM-QC	AGM-QA
Signature			
Date	14/11/2023	15/11/2023	17/11/2023

Format No: ST/QC/058:A1

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REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-RMEC0017-00	(i) The Product name has been corrected as per BP monograph. (ii) Specification format revised as per SOP No. ST/QC/058.	ST/CC/23/243 ST/CC/23/063	18/11/2023

**** 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	14/11/2023	15/11/2023	17/11/2023

Safetab Life Science QUALITY ASSURANCE Puducherry-607

	Safetab Life Science Puducherry			MASTER COPY
	STANDARD TESTING PROCEDURE			
Name of Product	COLLOIDAL ANHYDROUS SILICA BP			
STP No.	STP-RMEC0017-00	**Revision No.**	00	**Item Code.:** RMEC0017
Supersedes	RMETC0017-01	**Effective Date**	18/11/2023	**Page No.:** 1 of 3

1. DESCRIPTION: < REFER GAM 001>

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

2. SOLUBILITY: < REFER GAM 002>

10mg of sample + 100mL of Water	Practically insoluble if the material does not dissolves.
10mg of sample + 100mL of Mineral acids except hydrofluoric acid.	Practically insoluble if the material does not dissolves.

It dissolves in hot solutions of alkali hydroxides.

3. IDENTIFICATION: < REFER GAM 003>

By Silicates:

About 25mg of sample ignited in a platinum crucible at 900±50ºC for 2hour, cool and add about 10 mg of sodium fluoride and a few drops of sulfuric acid to give a thin slurry. Cover the crucible with a thin, transparent plate of plastic under which a drop of water is suspended and warm gently. Within a short time a white ring is rapidly formed around the drop of water.

4. pH: < REFER GAM 030>

Between 3.5 to 5.5

Weigh accurately about 1.0g of sample dissolved in 100ml carbon dioxide free water and stirring continuously. Determine the pH when a homogeneous solution is obtained.

Rinse the electrodes with distilled water and wipe dry with tissue paper. Set the instrument using buffer solution pH 6.87 by following instrument Operating Procedure. Clean the electrode. Immerse the electrode in the solution being examined and measure the pH.

5. CHLORIDES: <REFER GAM 008>

Not more than 250 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	14/11/2023	15/11/2023	17/11/2023

Safetab Life Science QUALITY ASSURANCE Puducherry-107

To 1.0 g add 30 mL of methanol and 20 mL of dilute nitric acid, Heat on a water-bath for 15 min stirring frequently. Cool, dilute to 50 mL with water and filter. Dilute 10 mL of the filtrate to 15 mL with water.

6. LOSS ON IGNITION: <REFER GAM 027>

Not more than 5.0 per cent, determined on 0.200 g by ignition in a platinum crucible at 900 ± 50 °C for 2 h. It is advisable to place the crucible in a cold oven and then to heat up the oven. Allow to cool in a desiccator before weighing.

7. ASSAY (ON IGNITED BASIS):

To the residue obtained in the test for loss on ignition add 0.2ml of sulphuric acid and sufficient ethanol (96 per cent) to moisten the residue completely. Add 6 mL of hydrofluoric acid and evaporate to dryness on a hot-plate at 95-105 °C, taking care to avoid loss from sputtering. Wash down the sides of the platinum crucible with 6 mL of hydrofluoric acid and evaporate to dryness. Ignite at 900 ± 50 °C, allow to cool in a desiccator and weigh.

The difference between the mass of the residue and the mass of the final residue obtained in the test for loss on ignition gives the amount of SiO_2 in the quantity of the substance to be examined.

Calculation:

Calculate the silicon dioxide % w/w on ignited basis.

$$\frac{(LR - AR) \times 100 \times 100}{WT \times (100 - \%\ LOI)}$$

Where,

LR = Weight of residue from loss on ignition.
AR = Weight of residue from assay.
LOI = Loss on ignition.
WT = Weight of sample taken for Loss on ignition.

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMEC0017-00	(i) The Product name has been corrected as per BP monograph. (ii) STP format revised as per SOP No. ST/QC/058.	ST/CC/23/243 ST/CC/23/063	18/11/2023

****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	14/11/2023	15/11/2023	17/11/2023

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	RAWMATERIAL SPECIFICATION			
Name of Product	CYANOCOBALAMIN BP			
Specification No.	SPEC-RMAC0066-01	**Revision No.**	01	**Item Code.:** RMAC0066
Supersedes	SPEC-RMAC0066-00	**Effective Date**	05/06/2024	**Page No.:** 1 of 3

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	$C_{63}H_{88}CoN_{14}O_{14}P$
2	Molecular weight	1355.0
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	400 mg
6	Quantity of reserve sample	800 mg
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	01/06/2024	03/06/2024	04/06/2024

	Safetab Life Science Puducherry			MASTER COPY
	RAWMATERIAL SPECIFICATION			
Name of Product	CYANOCOBALAMIN BP			
Specification No.	SPEC-RMAC0066-01	**Revision No.**	01	**Item Code.:** RMAC0066
Supersedes	SPEC-RMAC0066-00	**Effective Date**	05/06/2024	**Page No.:** 2 of 3

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	Dark red, crystalline powder or dark red crystals.
2.	*Solubility	Sparingly soluble in water and in ethanol (96%), practically insoluble in acetone. The anhydrous substance is very hygroscopic.
3.	*Identification	
	A. By UV Absorption	**A**361/**A**547-559 =3.15 to 3.45 **A**361/**A**278 =1.70 to 1.90
	B. By HPLC	The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (c).
4.	*Related substances (By HPLC)	
	(i) Impurity C	Not more than 1.5%
	(ii) Impurity A	Not more than 0.7%
	(iii) Impurity B	Not more than 0.5%
	(iv) Impurity D	Not more than 0.5%
	(v) Impurity E	Not more than 0.5%
	(vi) Impurity F	Not more than 0.5%
	(vii) Unspecified impurities	Not more than 0.2%
	(viii) Total impurities	Not more than 3.0%

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	01/06/2024	03/06/2024	04/06/2024

S.NO	TEST (s)	SPECIFICATION (s)
5.	*Loss on drying	Not more than 12.0% w/w.
6.	*Assay: By UV (On dried basis)	Not less than 96.0% and not more than 102.0% 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-RMAC0066-00	(i) Periodic review. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	05-01-2024
SPEC-RMAC0066-01	Related substances limit has been changed as per current BP monograph	ST/CC/24/148	05/06/2024

**** 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	01/06/2024	03/06/2024	04/06/2024

1. DESCRIPTION: < REFER GAM 001>

Dark red, crystalline powder or dark red crystals.

2. SOLUBILITY: < REFER GAM 002>

100mg of sample + 10mL of Water	Sparingly soluble if the material dissolve.
100mg of sample + 10mL of Ethanol (96%)	Sparingly soluble if the material dissolve.
10mg of sample + 100mL of Acetone	Practically insoluble if the material does not dissolve.

The anhydrous substance is very hygroscopic.

3. IDENTIFICATION:

A. By UV absorption: < REFER GAM 003>

Test solution: Dissolve 2.5 mg in water R and dilute to 100.0 mL with the same solvent.

Spectral range: 260-610 nm.

Absorption: maxima 278 nm, 361 nm and 547-559 nm.

Absorbance ratios:

— $A_{361} / A_{547-559}$ = 3.15 to 3.45;

— A_{361} / A_{278} = 1.70 to 1.90.

B. By HPLC:

Examine the chromatograms obtained in the test for related substances.

Results: The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (c).

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	01/06/2024	03/06/2024	04/06/2024

4. RELATED SUBSTANCES: (Determine by liquid chromatography)

Note: Use the normalisation procedure. **Store the solutions at 2-8°C, protected from light, and use them within 24 h.**

Chemicals/Reagents/Standards:

Cyanocobalamin system suitability (containing impurities A, C, E and F)	:	Reference standard
Cyanocobalamin	:	Working standard/ Reference standard
Cyanocobalamin peak identification (containing impurities B and D)	:	Reference standard
Ammonium formate	:	AR grade
Anhydrous formic acid	:	AR grade
Purified Water	:	Milli Q water (or) equivalent
Methanol	:	HPLC grade

Chromatographic Condition:

Column	:	C8, 150mm x 2.1mm (1.7µm)
Column temperature	:	60°C
Flow rate	:	0.4ml/min
Wavelength	:	361nm
Injection volume	:	3µl

Mobile phase:

Mobile phase A:

1.0g/L solution of ammonium formate adjusted to pH 3.5±0.05 with anhydrous formic acid.

Mobile phase B: Methanol

Gradient programme:

Time (min)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0 – 1	90	10
1 - 16	90 ------> 80	10 ------> 20
16 - 23	80 ------> 60	20 ------> 40

Test solution:

Dissolve 25.0 mg of the substance to be examined in water and dilute to 50.0ml with the same solvent.

Reference solution (a):

Dilute 1.0ml of the test solution to 100.0ml with water. Dilute 1.0ml of this solution to 10.0ml with water.

Reference solution (b):

Dissolve 5mg of Cyanocobalamin for system suitability CRS (containing impurities A, C, E and F) in water and dilute to 10.0mL with the same solvent.

Reference solution (c):

Dissolve 5.0mg of Cyanocobalamin CRS in water and dilute to 10.0mL with the same solvent.

Reference solution (d):

Dissolve 5mg of Cyanocobalamin for peak identification CRS (containing impurities B and D) in water and dilute to 10mL with the same solvent.

Identification of impurities:

Use the chromatogram supplied with Cyanocobalamin for system suitability and the chromatogram obtained with reference solution (b) to identify the peaks due to impurities A, C, E and F; use the chromatogram supplied with Cyanocobalamin for peak identification and the chromatogram obtained with reference solution (d) to identify the peaks due to impurities B and D.

Relative retention:

With reference to cyanocobalamin (retention time = about 10 min): impurity F = about 1.06; impurity D = about 1.18; impurity C = about 1.23; impurity A = about 1.26; impurity E = about 1.33; impurity B = about 1.45.

System suitability Reference solution (b):

Peak-to-valley ratio: minimum 4.5, where H_p = height above the baseline of the peak due to impurity A and H_v = height above the baseline of the lowest point of the curve separating this peak from the peak due to impurity C; minimum 2.5, where H_p = height above the baseline of the peak due to impurity F and H_v = height above the baseline of the lowest point of the curve separating this peak from the peak due to cyanocobalamin.

Inject 3µl of the above solution as per following sequence.

Injection sequence:

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

Calculation:

Impurity C: (NMT 1.5%)

$$= \frac{\text{Area of impurity C}}{\text{Sample area}} \times 100$$

Impurity A: (NMT 0.7%)

$$= \frac{\text{Area of impurity A}}{\text{Sample area}} \times 100$$

Impurity B: (NMT 0.5%)

$$= \frac{\text{Area of impurity B}}{\text{Sample area}} \times 100$$

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	01/06/2024	03/06/2024	04/06/2024

Impurity D: (NMT 0.5%)

$$= \frac{\text{Area of impurity D}}{\text{Sample area}} \times 100$$

Impurity E: (NMT 0.5%)

$$= \frac{\text{Area of impurity E}}{\text{Sample area}} \times 100$$

Impurity F: (NMT 0.5%)

$$= \frac{\text{Area of impurity F}}{\text{Sample area}} \times 100$$

Unspecified impurities: (NMT 0.2%)

$$= \frac{\text{Area of unspecified impurities}}{\text{Sample area}} \times 100$$

Total impurities: (NMT 3.0%)

$$= \frac{\text{Area of total impurity}}{\text{Sample area}} \times 100$$

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	01/06/2024	03/06/2024	04/06/2024

Limits:

(i) impurity C: Not more than 1.5 per cent;

(ii) impurity A: Not more than 0.7 per cent;

(iii) impurities B, D, E, F: for each impurity, Not more than 0.5 per cent;

(iv) unspecified impurities: for each impurity, Not more than 0.2 per cent;

(v) total: Not more than 3.0 per cent;

(vi) reporting threshold: 0.10 per cent (reference solution (a)).

5. LOSS ON DRYING: <REFER GAM 026>

Not more than 12.0 per cent, determined on 0.400g of sample by drying in vacuum at 105°C for 2 hours.

6. ASSAY: By UV (On dried basis)

Weigh accurately about 100.0mg of sample, dissolved in water to produce 500ml. Dilute 25.0ml of the solution to 200.0ml with water. Measure the absorbance of the solution at the maximum at about 361nm. Calculate the content of Cyanocobalamin taking the specific absorbance to be 207.

Calculation:

$$\frac{ABS}{0.207} \times \frac{10}{1000} \times \frac{500}{WT} \times \frac{200}{25} \times \frac{100}{(100 - LOD)} \times 100$$

Where,

ABS = Absorbance of Cyanocobalamin in Sample Preparation.

WT = Weight of sample taken in mg.

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	01/06/2024	03/06/2024	04/06/2024

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMAC0066-00	(i) Periodic review. (ii) STP numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	05-01-2024
STP-RMAC0066-01	Related substances testing procedure has been changed as per current BP monograph	ST/CC/24/148	05/06/2024

**** 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	01/06/2024	03/06/2024	04/06/2024

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	FOLIC ACID BP			
Specification No.	SPEC-RMAF0018-00	**Revision No.**	00	**Item Code.:** RMAF0018
Supersedes	RMASF0018-00	**Effective Date**	07/11/2023	**Page No.:** 1 of 3

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	$C_{19}H_{19}N_7O_6$, xH_2O
2	Molecular weight(anhydrous substance)	441.4
3	Storage conditions	Protected from light, under inert gas.
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	3 g
6	Quantity of reserve sample	6 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	C.K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	02/11/2023	03/11/2023	06/11/2023

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	FOLIC ACID BP			
Specification No.	SPEC-RMAF0018-00	**Revision No.**	00	**Item Code.:** RMAF0018
Supersedes	RMASF0018-00	**Effective Date**	01/11/2023	**Page No.:** 2 of 3

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	Yellowish or orange, crystalline powder.
2.	*Solubility	Practically insoluble in water and in most organic solvents. It dissolves in dilute acids and in alkaline solutions.
3.	*Identification	
	A. By Specific optical rotation	Between +18° to +22°
	B. By IR	The Infrared absorption spectrum of sample should be concordant with that of reference spectrum or with the spectrum obtained from Folic acid WS.
	C. By Thin-layer chromatography	The principle spot in the chromatogram obtained with the test solution is similar in position, fluorescence and size to the principal spot in the chromatogram obtained with the reference solution.
	D. By Water content	Between 5.0 to 8.5%
4.	*Related substances (By HPLC)	
	a) Impurity A	Not more than 0.5%
	b) Impurity D	Not more than 0.4%
	c) Impurity C	Not more than 0.3%
	d) Impurity E	Not more than 0.3%
	e) Impurity G	Not more than 0.3%
	f) Impurity H	Not more than 0.15%

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	02/11/2023	03/11/2023	06/11/2023

S.NO	TEST (s)	SPECIFICATION (s)
	g) Impurity I **h)** Any individual impurity **i)** Total impurities	Not more than 0.15% Not more than 0.10% Not more than 1.20%
5.	Sulphated ash	Not more than 0.2% w/w
6.	*Water content (By KFR)	Between 5.0 to 8.5% w/w
7.	*Assay by HPLC (On anhydrous basis)	Not less than 96.0% and not more than 102.0% 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-RMAF0018-00	(i) Periodic review. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	01/11/2023

**** 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	02/11/2023	03/11/2023	06/11/2023

1. DESCRIPTION: < REFER GAM 001>

Yellowish or orange, crystalline powder.

2. SOLUBILITY: < REFER GAM 002>

10mg of sample +100mL of water and in most organic solvents	Practically insoluble if the material not dissolves
100mg sample + 3ml of dilute acids and in alkaline solutions.	Soluble if the material dissolve.

3. IDENTIFICATION:

A. SPECIFIC OPTICAL ROTATION : < REFER GAM 032>

Between +18.0° to +22.0°.

Weigh accurately about 0.25g of sample dissolved in 4.2g/L solution of sodium hydroxide and dilute to 25.0ml with the same solution.

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 Folic acid WS.

C. By Thin-Layer Chromatography: < REFER GAM 003>

Plate TLC silica gel plate.

Mobile phase:

A Mixture of 20 volumes of Concentrated ammonia, 20 volumes of Propanol and 60 volumes Ethanol (96 percent).

Solvent mixture:

A mixture of 2 volumes of concentrated ammonia and 9 volumes of methanol.

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	02/11/2023	03/11/2023	06/11/2023

Test solution:

Dissolve 50mg of the substance under examination in 100ml of the solvent mixture.

Reference solution:

Dissolve 50mg of Folic acid WS in 100ml of the solvent mixture.

Application: 2 µL.

Development: Over 3/4 of the plate.

Drying: In air.

Detection: Examine in ultraviolet light at 365 nm.

Results:

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

D. WATER: <REFER GAM 010>

Between 5.0 to 8.5%,

4. RELATED SUBSTANCES: (By HPLC)

Chemicals/Reagents/Standards:

Folic acid	:	Working standard
Folic acid system suitability solution	:	Reference standard
Folic acid impurity A	:	Reference standard
Folic acid impurity D	:	Reference standard
Folic acid impurity I	:	Reference standard

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	02/11/2023	03/11/2023	06/11/2023

Potassium dihydrogen phosphate	:	AR Grade
Dipotassium hydrogen phosphate	:	AR Grade
Sodium carbonate	:	AR Grade
Purified Water	:	Milli Q water (or) Equivalent
Methanol	:	HPLC grade

Chromatographic Condition:

Column	: ZORBAX RX-C8 250mm x 4.0mm, (5 µm) or equivalent
Flow rate	: 0.6 mL / minute
Detector wavelength	: 280 nm
Injection Volume	: 5µl
Run time	: 3.3 times the retention time of folic acid.
Retention Time	: About 8.0 minutes

Buffer solution:

Dissolve 11.16g of Potassium dihydrogen phosphate and 5.50g of Dipotassium hydrogen phosphate in 1000mL of water and Adjust to pH 6.4 with dilute phosphoric acid.

Mobile phase:

A Mixture of 12 volumes of methanol and 88 volumes of Buffer solution.

Solution A:

Dissolve 28.6g of Sodium carbonate in 1000ml of water.

Test solution:

Weigh accurately about 50.0mg of the substance under examination in 2.5ml of solution A and dilute to 50.0mL with the mobile phase. Dilute 2.0mL of this solution to 10.0mL with the mobile phase.

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	02/11/2023	03/11/2023	06/11/2023

Reference solution (a):

Weigh accurately about 50.0mg of Folic acid WS in 2.5ml of solution A and dilute 50.0mL with the mobile phase. Dilute 2.0mL of this solution to 10.0mL with the mobile phase.

Reference solution (b):

Weigh accurately about 5.0mg of folic acid for system suitability RS (containing impurities C, E, G and H) in 1ml of solution A and dilute to 25.0ml with the mobile phase.

Reference solution (c):

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

Reference solution (d):

Weigh accurately about 10mg of Folic acid impurity A in 1ml of solution A and dilute to 100ml with the mobile phase. Dilute 1.0ml of this solution to 100.0ml with the mobile phase.

Reference solution (e):

Weigh accurately about 4.0mg of Folic acid impurity D in solution A and dilute to 100ml with the solution A. Dilute 1.0ml of this solution to 100ml with the mobile phase.

Reference solution (f):

Weigh accurately about 5.0mg of Folic acid for impurity I identification RS in 1ml of solution A and dilute to 25.0ml with the mobile phase.

Identification of impurities:

Use the chromatogram obtained with reference solution (d) to identify the peak due to impurity A; use the chromatogram supplied with folic acid for system suitability RS and the chromatogram obtained with reference solution (b) to identify the peaks due to impurities C, E, G and H; use the chromatogram obtained with reference solution (e) to identify the peak due to impurity D; use the chromatogram supplied with folic acid for impurity I identification RS and the chromatogram obtained with reference solution (f) to identify the peak due to impurity I.

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	02/11/2023	03/11/2023	06/11/2023

Relative retention time:

With reference to folic acid (retention time = about 8.5 minutes); impurity A = about 0.5; impurity C = about 0.9; impurity E = about 1.3; impurity D = about 1.5; impurity I = about 2.15; impurity G = about 2.4; impurity H = about 2.5.

System suitability Reference solution (b):

Resolution: minimum 2.0 between the peaks due to folic acid and impurity E;

Peak to valley ratio:

Minimum 1.5, where H_p = height above the baseline of the peak due to impurity C and H_v = height above the baseline of the lowest point of the curve separating this peak from the peak due to folic acid; minimum 1.5, where H_p = height above the baseline of the peak due to impurity G and H_v = height above the baseline of the lowest point of the curve separating this peak from the peak due to impurity H.

Calculation of percentage contents:

For impurity A, use the concentration of impurity A in reference solution (d);

For impurity D, use the concentration of impurity D in reference solution (e);

For impurities other than A and D, use the concentration of folic acid in reference solution (c).

Inject 5µl 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 (b)	1
3	Reference solution (c)	1
4	Reference solution (d)	1
5	Reference solution (e)	1
6	Reference solution (f)	1
7	Test solution	1

Calculation:

Impurity A: [NMT 0.5%]

$$= \frac{AT_A}{AS_A} \times \frac{WS}{100} \times \frac{1}{100} \times \frac{50}{WT} \times \frac{10}{2} \times \frac{P_A}{100} \times 100$$

Where,

AT_A = Area of impurity A peak in Test solution.

AS_A = Area of the impurity A peak in the Reference solution (d).

WS = Weight of the Folic acid impurity A reference standard in mg.

WT = Weight of sample taken in mg.

P_A = Potency of the Folic acid impurity A reference standard in % on as such basis.

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Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	02/11/2023	03/11/2023	06/11/2023

Impurity D: (NMT 0.4%)

$$= \frac{AT_D}{AS_D} \times \frac{WS}{100} \times \frac{1}{100} \times \frac{50}{WT} \times \frac{10}{2} \times \frac{P_D}{100} \times 100$$

Where,

AT_D = Area of impurity D peak in Test solution.

AS_D = Area of the impurity D peak in the Reference solution (e).

WS = Weight of the Folic acid impurity D reference standard in mg.

WT = Weight of sample taken in mg.

P_D = Potency of the Folic acid impurity D reference standard in % on as such basis.

Impurity C: (NMT 0.3%)

$$= \frac{AT_C}{AS} \times \frac{WT}{50} \times \frac{2}{10} \times \frac{1}{100} \times \frac{1}{10} \times \frac{50}{WT} \times \frac{10}{2} \times 100$$

Where,

AT_C = Area of impurity C peak in Test solution.

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

WT = Weight of sample taken in mg.

Impurity E (NMT 0.3%)

$$= \frac{AT_E}{AS} \times \frac{WT}{50} \times \frac{2}{10} \times \frac{1}{100} \times \frac{1}{10} \times \frac{50}{WT} \times \frac{10}{2} \times 100$$

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Where,

ATE = Area of impurity E peak in Test solution.

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

WT = Weight of sample taken in mg.

Impurity G: (NMT 0.3%)

$$= \frac{AT_G}{AS} \times \frac{WT}{50} \times \frac{2}{10} \times \frac{1}{100} \times \frac{1}{10} \times \frac{50}{WT} \times \frac{10}{2} \times 100$$

Where,

ATG = Area of impurity G peak in Test solution.

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

WT = Weight of sample taken in mg.

Impurity H: (NMT 0.15%)

$$= \frac{AT_H}{AS} \times \frac{WT}{50} \times \frac{2}{10} \times \frac{1}{100} \times \frac{1}{10} \times \frac{50}{WT} \times \frac{10}{2} \times 100$$

Where,

ATH = Area of impurity H peak in Test solution.

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

WT = Weight of sample taken in mg.

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Impurity I: (NMT 0.15%)

$$= \frac{AT_I}{AS} \times \frac{WT}{50} \times \frac{2}{10} \times \frac{1}{100} \times \frac{1}{10} \times \frac{50}{WT} \times \frac{10}{2} \times 100$$

Where,

AT_I = Area of impurity I peak in Test solution.

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

WT = Weight of sample taken in mg.

Any individual impurity: [NMT 0.10%]

$$= \frac{AT_I}{AS} \times \frac{WT}{50} \times \frac{2}{10} \times \frac{1}{100} \times \frac{1}{10} \times \frac{50}{WT} \times \frac{10}{2} \times 100$$

Where,

AT_I = Area of any individual impurity peak in Test solution.

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

WT = Weight of sample taken in mg.

Total impurities: [NMT 1.20%]

$$= \frac{AT_T}{AS} \times \frac{WT}{50} \times \frac{2}{10} \times \frac{1}{100} \times \frac{1}{10} \times \frac{50}{WT} \times \frac{10}{2} \times 100$$

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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Date	02/11/2023	03/11/2023	06/11/2023

Where,

AT_T = Area of Total impurities peak in Test solution.

A_S = Area of the principal peak in the Reference solution (c)

WT = Weight of sample taken in mg.

Total impurities: sum of known impurity + unknown impurity

5. SULPHATED ASH: <REFER GAM 032>

Not more than 0.2%, Determined on 1.0g of sample,

6. WATER (BY KFR): <REFER GAM 010>

Between 5.0 to 8.5%, determined on 0.15g.

7. ASSAY: (BY HPLC)

Note: Chromatographic condition, mobile phase preparation, reference solution (a) and test solution described under related substances.

Inject the reference solution (a) and test solution.

Inject 5µl of the above solution as per following sequence.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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Injection sequence:

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

Calculations:

Calculate the assay in % of Folic acid on as such basis of the sample as below.

$$= \frac{AT}{AS} \times \frac{WS}{50} \times \frac{2}{10} \times \frac{50}{WT} \times \frac{10}{2} \times \frac{P}{100} \times 100$$

Where,

AT = Average area of the principal peak in Test solution.

AS = Average area of the principal peak in the Reference solution (a).

WS = Weight of the Folic acid Working standard in mg.

WT = Weight of sample taken in mg.

P = Potency of the Folic acid Working standard in % on as such basis.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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Calculate the assay in % of Folic acid on anhydrous basis of the sample as below.

$$= \frac{\text{Assay as such basis}}{(100 - \%\ \text{water})} \times 100$$

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMAF0018-00	(i) Periodic review. (ii) STP numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	07/11/2023

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

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	02/11/2023	03/11/2023	06/11/2023

	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**	14/02/2024	**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**
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Designation	**Dy. Manager-QC**	**GM-QC**	**AGM-QA**
Signature			
Date	18/03/2024	13/03/2024	13/03/2024

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
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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.:** 4 of 4

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
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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.

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

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%.

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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.

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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:

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

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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Signature			
Date	12/03/2024	13/03/2024	13/03/2024

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	MICROCRYSTALLINE CELLULOSE BP (PHARMACEL TYPE 102)			
Specification No.	SPEC-RMEM0038-00	**Revision No.**	00	**Item Code.:** RMEM0038
Supersedes	RMESM0038-00	**Effective Date**	18/11/2023	**Page No.:** 1 of 4

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	$C_6nH_{10}n_{+2}O_5n_{+1}$
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	36 g
6	Quantity of reserve sample	72 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	C.K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	14/11/2023	15/11/2023	17/11/23

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	MICROCRYSTALLINE CELLULOSE BP (PHARMACEL TYPE 102)			
Specification No.	SPEC-RMEM0038-00	**Revision No.**	00	**Item Code.:** RMEM0038
Supersedes	RMESM0038-00	**Effective Date**	18/11/2023	**Page No.:** 2 of 4

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	White or almost white, fine or granular, slightly hygroscopic powder.
2.	*Solubility	Practically insoluble in water, in acetone, in anhydrous ethanol, in toluene, in dilute acids and in a 50 g/L solution of sodium hydroxide
3.	*Identification **A.** By IR **B.** By Chemical test **C.** By degree of polymerisation	 The Infrared absorption spectrum of sample should be concordant with that of reference spectrum or with the spectrum obtained from Microcrystalline Cellulose WS. The substance becomes violet-blue. The degree of polymerisation is not more than 350
4.	Solubility (Ammoniacal copper tetrammine)	It dissolves completely, leaving no residue
5.	*pH	Between 5.0 to 7.5
6.	*Conductivity	Not more than 75 $\mu S \cdot cm^{-1}$
7.	Ether-soluble substances	Not more than 0.05%

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	14/11/2023	15/11/2023	17/11/23

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	MICROCRYSTALLINE CELLULOSE BP (PHARMACEL TYPE 102)			
Specification No.	SPEC-RMEM0038-00	**Revision No.**	00	**Item Code.:** RMEM0038
Supersedes	RMESM0038-00	**Effective Date**	18/11/2023	**Page No.:** 3 of 4

S.NO	TEST (s)	SPECIFICATION (s)
8.	Water-soluble substances	Not more than 0.25%
9.	Sulphated Ash	Not more than 0.1% w/w
10.	*Loss on drying	Not more than 7.0% w/w
11.	*Microbial contamination	
	i) Total Viable aerobic count	
	a) Total aerobic microbial count	Not more than 1000 cfu/g
	b) Total yeast and mould count	Not more than 100 cfu/g
	iii) Esherichia Coli	Should be absent/g
	iv) Salmonella Species	Should be absent/10g
	v) Staphylococcus aureus	Should be absent/g
	vi) Pseudomonas aeruginosa	Should be absent/g

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	14/11/2023	15/11/2023	17/11/23

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-RMEM0038-00	(i) Periodic review. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	18/11/2023

**** 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	14/11/2023	15/11/2023	17/11/23

1. DESCRIPTION: < REFER GAM 001>

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

2. SOLUBILITY: < REFER GAM 002>

10mg of sample + 100mL of 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.
10mg of sample + 100mL of Dilute acids	Practically insoluble if the material not dissolves.
10mg of sample + 100mL of Sodium hydroxide	Practically insoluble if the material not dissolves.

3. IDENTIFICATION:

A. 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 Microcrystalline Cellulose WS.

B. By Chemical test:

Place about 10 mg on a watch-glass and disperse in 2 mL of iodinated zinc chloride solution. The substance becomes violet-blue.

C. By Degree of polymerisation:

The degree of polymerisation is not more than 350.

Transfer 1.300g to a 125 mL conical flask. Add 25.0 mL of water and 25.0 mL of cupriethylenediamine hydroxide solution. Immediately purge the solution with nitrogen, insert the stopper and shake until completely dissolved. Transfer an appropriate volume of the solution to a suitable capillary viscometer.

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	14/11/2023	15/11/2023	17/11/23

Equilibrate the solution at 25 ± 0.1 °C for at least 5 min. Record the flow time (t_1) in seconds between the 2 marks on the viscometer. Calculate the kinematic viscosity (v_1) of the solution using the following expression:

$$t1(k1)$$

k_1 = viscometer constant.

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

$$t2(k2)$$

k_2 = viscometer constant.

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

$$v1/v2$$

Determine the intrinsic viscosity ($[\eta]_c$) by interpolation, using the intrinsic viscosity table (Table 0316.-1).

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

$$95[\eta]cm[(100-b)/100]$$

m = mass of the substance to be examined in grams;

b = loss on drying in per cent.

4. SOLUBILITY:

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

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	14/11/2023	15/11/2023	17/11/23

5. **pH: < REFER GAM 030>**

5.0 to 7.5 for the supernatant.

Shake 5g with 40 mL of carbon dioxide-free water for 20 min and centrifuge.

6. **CONDUCTIVITY:**

The conductivity of the test solution does not exceed the conductivity of the water by more than 75 $\mu S \cdot cm^{-1}$.

Use as test solution the supernatant obtained in the test for pH. Measure the conductivity of the supernatant after a stable reading has been obtained and measure the conductivity of the water used to prepare the test solution.

7. **ETHER-SOLUBLE SUBSTANCES:**

Maximum 0.05 per cent (5.0 mg) for the difference between the mass of the residue and the mass obtained from a blank determination.

Place 10.0g in a chromatography column about 20 mm in internal diameter and pass 50 mL of peroxide-free ether through the column. Evaporate the eluate to dryness in a previously dried and tared evaporating dish, with the aid of a current of air in a fume cupboard. After all ether has evaporated, dry the residue at 105 °C for 30 min, allow to cool in a desiccator and weigh. Carry out a blank determination.

8. **WATER-SOLUBLE SUBSTANCES:**

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

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

9. **SULPHATED ASH: < REFER GAM 032>**

Maximum 0.1%. Determine on 1.0g of sample.

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	14/11/2023	15/11/2023	17/11/23

10. LOSS ON DRYING: < REFER GAM 026>

Maximum 7.0 per cent, determined on 1.000 g by drying in an oven at 105 °C for 3 h.

11. 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-RMEM0038-00	(i) Periodic review. (ii) STP numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	18/11/2023

****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	14/11/2023	15/11/2023	17/11/23

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	PURIFIED TALC BP			
Specification No.	RMEST0012-01	**Revision No.**	01	**Item Code.:** RMET0012
Supersedes	RMEST0012-00	**Effective Date**	24/02/2023	**Page No.:** 1 of 3

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	$Mg_3Si_4O_{10}(OH)_2$
2	Molecular weight	379.26
3	Storage conditions	Store protected from 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	27 g
6	Quantity of reserve sample	54 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	20/02/2023	21/02/2023	22/02/2023

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	PURIFIED TALC BP			
Specification No.	RMEST0012-01	**Revision No.**	01	**Item Code.:** RMET0012
Supersedes	RMEST0012-00	**Effective Date**	24/02/2023	**Page No.:** 2 of 3

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	Light, homogeneous, white or almost white powder, greasy to the touch (non abrasive).
2.	*Solubility	Practically insoluble in water, in ethanol (96 per cent) and in dilute solutions of acids and alkali hydroxides.
3.	*Identification **A.** By IR **B.** By Chemical test **C.** By Silicates	 The Infrared absorption spectrum of sample should be concordant with that of reference spectrum or with the spectrum obtained from Purified Talc WS. A white crystalline precipitate is formed. Within a short time a white ring is rapidly formed around the drop of water.
4.	Acidity or alkalinity	Not more than 0.4 mL of 0.01M Hydrochloric acid is required to change the colour of the indicator to green. Not more than 0.3 mL of Sodium hydroxide is required to change the colour of the indicator to pink.
5.	Water soluble substance	Not more than 0.2%
6.	Aluminium	Not more than 2.0%
7.	Calcium	Not more than 0.9%

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	20/02/2023	21/02/2023	22/02/2023

S.NO	TEST (s)	SPECIFICATION (s)
8.	Iron	Not more than 0.25%.
9.	Lead	Not more than 10 ppm.
10.	Magnesium	Between 17.0% to 19.5%
11.	*Loss on ignition	Not more than 7.0% w/w.
12.	*Microbial contamination i) Total aerobic microbial count ii) Total yeast and mould count	 Not more than 1000 cfu/g Not more than 100 cfu/g

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
RMEST0012-01	Periodic review.	NA	24/02/2023

**** 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	20/02/2023	21/02/2023	22/02/2023

1. DESCRIPTION: < REFER GAM 001>

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

2. SOLUBILITY: < REFER GAM 002>

10mg of sample + 100mL of water	Practically insoluble if the material does not dissolves.
10mg of sample + 100mL of Ethanol (96%)	Practically insoluble if the material does not dissolves.
10mg of sample + 100mL of dilute acids	Practically insoluble if the material does not dissolves.
10mg of sample + 100mL of dilute alkali hydroxides	Practically insoluble if the material does not dissolves.

3. IDENTIFICATION:

A) 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 Purified Talc WS.

B) By Chemical test:

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

C) By Silicates:

Mix the residue obtained from Identification test B in a lead or platinum crucible mix by means of a copper wire with about 10 mg of sodium fluoride and a few drops of sulfuric acid to give a thin slurry.

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	20/02/2023	21/02/2023	22/02/2023

Cover the crucible with a thin, transparent plate of plastic under which a drop of water is suspended and warm gently. Within a short time a white ring is rapidly formed around the drop of water.

Solution S1:

Weigh 10.0 g into a conical flask fitted with a reflux condenser, gradually add 50 mL of 0.5 M hydrochloric acid while stirring and heat on a water-bath for 30 min. Allow to cool. Transfer the mixture to a beaker and allow the undissolved material to settle. Filter the supernatant through medium-speed filter paper into a 100 mL volumetric flask, retaining as much as possible of the insoluble material in the beaker. Wash the residue and the beaker with 3 quantities, each of 10 mL, of hot water. Wash the filter with 15 mL of hot water, allow the filtrate to cool and dilute to 100.0 mL with the same solvent.

Solution S2:

Perchlorates mixed with heavy metals are known to be explosive. Take proper precautions while performing this procedure Weigh 0.5 g in a 100 mL polytetrafluoroethylene dish, add 5 mL of hydrochloric acid , 5 mL of lead-free nitric acid and 5 mL of perchloric acid. Stir gently then add 35 mL of hydrofluoric acid and evaporate slowly to dryness on a hot plate. To the residue, add 5 mL of hydrochloric acid, cover with a watch-glass, heat to boiling and allow to cool. Rinse the watch-glass and the dish with water. Transfer into a volumetric flask, rinse the dish with water and dilute to 50.0 mL with the same solvent.

4. ACIDITY OR ALKALINITY:

Boil 2.5 g with 50 mL of carbon dioxide-free water under reflux. Filter in vacuo. To 10 mL of the filtrate add 0.1 mL of bromothymol blue solution; not more than 0.4 mL of 0.01 M hydrochloric acid is required to change the colour of the indicator to green. To 10 mL of the filtrate add 0.1 mL of phenolphthalein solution; not more than 0.3 mL of 0.01 M sodium hydroxide is required to change the colour of the indicator to pink.

5. WATER SOLUBLE SUBSTANCES:

Not more than 0.2%. To 10.0 g add 50 mL of carbon dioxide-free water, heat to boiling and maintain boiling under a reflux condenser for 30 min. Allow to cool, filter through a medium-speed filter paper and dilute to 50.0 mL with water.

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	20/02/2023	21/02/2023	22/02/2023

Take 25.0 mL of the filtrate, evaporate to dryness and heat 105 °C for 1h. The residue weighs a maximum of 10 mg.

6. ALUMINIUM: (ATOMIC ABSORPTION SPECTROMETRY)

Not more than 2.0%

Test solution:

To 5.0 mL of solution S2 add 10 mL of a 25.34 g/L solution of caesium chloride, 10.0 mL of hydrochloric and dilute to 100.0 mL with water.

Reference solutions:

Into 4 identical volumetric flasks, each containing 10.0 mL of hydrochloric acid and 10 mL of a 25.34 g/L solution of caesium chloride, introduce respectively 5.0 mL, 10.0 mL, 15.0 mL and 20.0 mL of aluminium standard solution (100 ppm Al) and dilute to 100.0 mL with water.

Source: Aluminium hollow-cathode lamp.

Wavelength: 309.3 nm.

Atomization device: Nitrous oxide-acetylene flame.

7. CALCIUM: (ATOMIC ABSORPTION SPECTROMETRY)

Not more than 0.9 per cent.

Test solution:

To 5.0 mL of solution S2 add 10.0 mL of hydrochloric acid, 10 mL of lanthanum chloride solution and dilute to 100.0 mL with water.

Reference solutions :

Into 4 identical volumetric flasks, each containing 10.0 mL of hydrochloric acid and 10 mL of lanthanum chloride solution, introduce respectively 1.0 mL, 2.0 mL, 3.0 mL and 5.0 mL of calcium standard solution (100 ppm Ca) and dilute to 100.0 mL with water.

Source: Calcium hollow-cathode lamp.

Wavelength:422.7 nm.

Atomisation device: Nitrous oxide-acetylene flame.

8. IRON: < REFER GAM 007> (ATOMIC ABSORPTION SPECTROMETRY)

Not more than 0.25 percent.

Test solution:

To 2.5 mL of solution S1, add 50.0 mL of 0.5 M hydrochloric acid and dilute to 100.0 mL with water.

Reference solutions:

Into 4 identical volumetric flasks, each containing 50.0 mL of 0.5 M hydrochloric acid, introduce respectively 2.0 mL, 2.5 mL, 3.0 mL and 4.0 mL of iron standard solution (250 ppm Fe) and dilute to 100.0 mL with water.

Source: Iron hollow-cathode lamp.

Wavelength: 248.3 nm.

Atomization device: Air-acetylene flame. Correction Deuterium lamp.

9. LEAD: (ATOMIC ABSORPTION SPECTROMETRY)

Not more than 10 ppm.

Test solution: Use solution S1.

Reference solutions:

Into 4 identical volumetric flasks, each containing 50.0 mL of 0.5 M hydrochloric acid, introduce respectively 5.0 mL, 7.5 mL, 10.0 mL and 12.5 mL of lead standard solution (10 ppm Pb) and dilute to 100.0 mL with water.

Source: Lead hollow-cathode lamp.

Wavelength: 217.0 nm.

Atomisation device: Air-acetylene flame.

10. MAGNESIUM: (ATOMIC ABSORPTION SPECTROMETRY)

17.0 per cent to 19.5 per cent.

Test solution:

Dilute 0.5 mL of solution S2 to 100.0 mL with water. To 4.0 mL of the solution, add 10.0 mL of hydrochloric acid, 10 mL of lanthanum chloride solution and dilute to 100.0 mL with water.

Reference solutions:

Into 4 identical volumetric flasks, each containing 10.0 mL of hydrochloric acid and 10 mL of lanthanum chloride solution, introduce respectively 2.5 mL, 3.0 mL, 4.0 mL and 5.0 mL of magnesium standard solution (10 ppm Mg) and dilute to 100.0 mL with water.

Source: Magnesium hollow-cathode lamp.

Wavelength: 285.2 nm.

Atomisation device: Air-acetylene flame.

11. LOSS ON IGNITION: < REFER GAM 027>

Maximum 7.0 per cent, determined on 1.00 g by ignition to constant weight at 1050-1100°C.

12. MICROBIAL CONTAMINATION:

Use 1.0g of sample for Total Microbial count.

Total Aerobic microbial count:

Procedure: Proceed as per the current general testing procedure GAM-035.

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	20/02/2023	21/02/2023	22/02/2023

Total Yeast and mold count:

Procedure: Proceed as per the current general testing procedure GAM-036

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
RMETT0012-01	Periodic review.	NA	24/02/2023

****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	20/02/2023	21/02/2023	22/02/2023

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	SODIUM SELENATE			
Specification No.	SPEC-RMAS0028-00	**Revision No.**	00	**Item Code.:** RMAS0028
Supersedes	RMASS0028-00	**Effective Date**	25/11/2024	**Page No.:** 1 of 3

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	Na_2O_4Se
2	Molecular weight	188.947
3	Storage conditions	Store protected from 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	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	In-house
10	Sampling instruction	Follow the standard operating procedure No.: ST/QC/040.
11	Destruction 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	21/11/2024	22/11/2024	23/11/2024

	Safetab Life Science Puducherry RAW MATERIAL SPECIFICATION			MASTER COPY
Name of Product	SODIUM SELENATE			
Specification No.	SPEC-RMAS0028-00	**Revision No.**	00	**Item Code.:** RMAS0028
Supersedes	RMASS0028-00	**Effective Date**	25/11/2024	**Page No.:** 2 of 3

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	A White to off white crystalline powder.
2.	*Solubility	Freely soluble in water.
3.	*Identification By Sodium test	A yellow crystalline precipitate in formed.
4.	Bulk density	Between 1.0 to 2.0 g/cc.
5.	Sieve size	100% should be passes through 40 mesh
6.	*Loss on drying	Not more than 0.5%
7.	*Assay (i) Content of Selenite (as such basis) (ii) Sodium selenate (as such basis)	 Not more than 1.0% Not less than 99.0%

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	21/11/2024	22/11/2024	23/11/2024

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-RMAS0028-00	(i) Periodic review. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	25/11/2024

**** 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	21/11/2024	22/11/2024	23/11/2024

	Safetab Life Science Puducherry			MASTER COPY
	STANDARD TESTING PROCEDURE			
Name of Product	SODIUM SELENATE			
STP No.	STP-RMAS0028-00	**Revision No.**	00	**Item Code.:** RMAS0028
Supersedes	NIL	**Effective Date**	25/11/2024	**Page No.:** 1 of 3

1. DESCRIPTION: < REFER GAM 001>

A White to off white crystalline powder.

2. SOLUBILITY: < REFER GAM 002>

100mg of sample + 1mL of Water	Freely soluble if the material dissolves.

3. IDENTIFICATION: < REFER GAM 003>

By Sodium test:

Weigh accurately about 100.0mg of sample dissolved in 2ml of water, acidify with 1ml acetic acid and add large excess of magnesium uranyl acetate. A yellow crystalline precipitate in formed.

4. BULK DENSITY:

Procedure:-

Weigh 10.0g sample for Bulk Density, note down sample weight, and add in 50mL Measuring Cylinder. A Class Measuring Cylinder. Measure the Volume and Calculate Bulk Density by using following Formula,

$$\text{Bulk Density} = \frac{\text{Wt. of sample in g}}{\text{Volume in mL}}$$

5. SIEVE SIZE:

Weigh and transfer around 10.0g of the sample into 40 ASTM sieve and shake for 5 minutes. Collect the 40 ASTM passes (W40) from the sample collector.

$$\%\ \text{passes on 40 ASTM} = \frac{\text{W40 in gram}}{\text{Weight of sample in g}} \times 100$$

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6. LOSS ON DRYING: < REFER GAM 026>

Not more than 0.5%, determined on 1.0g of sample dried at 100°C±2°C for 3 hours to constant weight.

7. ASSAY:

(i) Content of Selenite (as such basis):

Weigh accurately about 80mg of sample, dissolve in 50ml of carbon dioxide-free water. Add 1.0ml of anhydrous formic acid, 25.0ml of 0.1M sodium thiosulphate and 0.5g of potassium iodide. Titrate immediately with 0.05M iodine using starch solution as indicator. Carry out a blank titration.

1ml of 0.1M Sodium thiosulphate is equivalent to 4.323mg of Sodium selenate.

Calculation:

$$= \frac{\text{Titre value} - \text{Blank Value} \times \text{Molarity of 0.1M Sodium thiosulphate} \times 4.323 \times 100}{\text{Sample weight in mg} \times 0.1}$$

(ii) Sodium selenate calculation:

% of Sodium selenate (as such basis) = 100 - % of selenite.

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Date	21/11/2024	22/11/2024	23/11/2024

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMAS0028-00	(i) Periodic review. (ii) STP numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	25/11/2024

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

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Date	21/11/2024	22/11/2024	23/11/2024

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	ZINC SULPHATE MONOHYDRATE BP			
Specification No.	SPEC-RMAZ0009-00	**Revision No.**	00	**Item Code.:** RMAZ0009
Supersedes	RMASZ0009-00	**Effective Date**	30/12/2023	**Page No.:** 1 of 3

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	$ZNSO_4$, H_2O
2	Molecular weight	179.5
3	Storage conditions	In a non-metallic container.
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	4 g
6	Quantity of reserve sample	8 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.

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Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	25/12/2023	26/12/2023	27/12/2023

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	ZINC SULPHATE MONOHYDRATE BP			
Specification No.	SPEC-RMAZ0009-00	**Revision No.**	00	**Item Code.:** RMAZ0009
Supersedes	RMASZ0009-00	**Effective Date**	30/12/2023	**Page No.:** 2 of 3

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	White or almost white, crystalline powder or colourless, transparent crystals.
2.	*Solubility	Very soluble in water and practically insoluble in ethanol (96%).
3.	*Identification **A.** By Sulfates **B.** By Zinc **C.** Limits of the assay	 A white precipitate is formed. A flocculent white precipitate is produced. Not less than 99.0% and Not more than 101.0% w/w.
4.	Appearance of solution	Solution S is clear and colourless
5.	*pH	Between 4.0 to 5.6
6.	Chlorides	Not more than 300ppm.
7.	Iron	Not more than 100ppm.
8.	*Assay (By titration)	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.

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Date	25/12/2023	26/12/2023	27/12/2023

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-RMAZ0009-00	(i) Periodic review. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	30/12/2023

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	Safetab Life Science Puducherry			MASTER COPY
	STANDRAD TESTING PROCEDURE			
Name of Product	ZINC SULPHATE MONOHYDRATE BP			
STP No.	STP-RMAZ0009-00	**Revision No.**	00	**Item Code.:** RMAZ0009
Supersedes	RMATZ0009-00	**Effective Date**	30/12/2023	**Page No.:** 1 of 3

1. DESCRIPTION: < REFER GAM 001>

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

2. SOLUBILITY: < REFER GAM 002>

1g of sample + 1mL of water	Very soluble if the material dissolves.
10mg of sample + 100mL of ethanol (96%)	Practically insoluble if the material does not dissolves.

3. IDENTIFICATION: < REFER GAM 003>

A. By Sulfates:

Take 5ml of solution S, add 1ml of dilute hydrochloric acid and 1ml of barium chloride solution; a white precipitate is formed.

B. By Zinc:

Take 5ml of the Solution S, add 0.2ml of strong sodium hydroxide solution; a white precipitate is formed. Add a further 2ml of strong sodium hydroxide solution; the precipitate dissolves. Add 10ml of ammonium chloride solution; the solution remains clear. Add 0.1ml of sodium sulfide solution; a flocculent white precipitate is formed.

C. Limits of the assay:

Not less than 99.0% and Not more than 101.0% w/w.

SOLUTION S:

Weigh accurately about 2.5g of sample dissolved in 50ml of carbon dioxide-free water (Solution S).

4. APPEARANCE OF SOLUTION: < REFER GAM 023>

Solution S is clear and colourless.

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5. pH: < REFER GAM 030>

Between 4.0 to 5.6, Determined on solution S.

Rinse the electrodes with distilled water and wipe dry with tissue paper. Set the instrument using buffer solution pH 4.01 and 6.87 by following instrument Operating Procedure. Clean the electrode. Immerse the electrode in the solution being examined and measure the pH.

6. CHLORIDES: < REFER GAM 008>

Maximum 300ppm.

Dilute 3.3ml of solution S to 15.0ml with water.

7. IRON: <REFER GAM 007>

Maximum 100ppm.

Dilute 2ml of solution S to 10ml with water. Using 0.5ml of thioglycollic acid.

8. ASSAY: (By Titration)

Weigh accurately about 0.160g of sample dissolved in 5ml of dilute acetic acid into a 500ml conical flask and dilute to 200ml with water. Add about 50mg of xylenol orange triturate and hexamethylenetetramine until the solution becomes violet-pink; add 2g of hexamethylenetetramine in excess. Titrate with 0.1M sodium edetate until the violet-pink colour changes to yellow.

Each mL of 0.1M sodium edetate is equivalent to 17.95mg of $ZnSO_4$ H_2O.

Calculation:

$$= \frac{\text{Titer value x Molarity of 0.1M sodium edetate x 17.95 x 100}}{\text{Sample weight in (mg) x 0.1}}$$

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REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMAZ0009-00	(i) Periodic review. (ii) STP numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	30/12/2023

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