	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Material	LEMON LIME PREMASEAL FLAVOUR (75412-71)			
Specification No.	SPEC-RMEL0025-00	**Revision No.**	00	**Item Code.:** RMEL0025
Supersedes	RMESL0025-00	**Effective Date**	27/03/2025	**Page No.:** 1 of 3

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	NA
2	Molecular weight	NA
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	12g
6	Quantity of reserve sample	24g
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	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	24/03/2025	25/03/2025	26/03/2025

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Material	LEMON LIME PREMASEAL FLAVOUR (75412-71)			
Specification No.	SPEC-RMEL0025-00	**Revision No.**	00	**Item Code.:** RMEL0025
Supersedes	RMESL0025-00	**Effective Date**	27/03/2025	**Page No.:** 2 of 3

S.NO	TEST (S)	SPECIFICATION (S)
1.	*Description	Almost white to very slightly yellow fine powder.
2.	*Odour	Pleasant lemon smell.
3.	*Water content by KFR	Not more than 6.0%
4.	Particle size #45 mesh (350 microns)	Between 99.0% to 100.0%

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

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	24/03/2025	25/03/2025	26/03/2025

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-RMEL0025-00	(i) Periodic review. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	27/03/2025

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

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	24/03/2025	25/03/2025	26/03/2025

	Safetab Life Science Puducherry			MASTER COPY
	STANDARD TESTING PROCEDURE			
Name of Material	LEMON LIME PREMASEAL FLAVOUR (75412-71)			
STP No.	STP-RMEL0025-00	**Revision No.**	00	**Item Code.:** RMEL0025
Supersedes	RMETL0025-00	**Effective Date**	27/03/2025	**Page No.:** 1 of 2

1. DESCRIPTION: < REFER GAM 001>

Almost white to very slightly yellow fine powder.

2. ODOUR AND TASTE:

Pleasant lemon smell.

3. WATER: <REFER GAM 010>

Not more than 6.0%, determined on 1.0g of sample.

4. PARTICLE SIZE:

Weigh and transfer 10.0g of the sample into a 350 micron (#45 mesh), shake for 15 minutes. After that weigh the passing sample in 350 micron. Calculate the % passes from the 350 micron mesh by using below formula.

$$\% \text{ Passing} = \frac{\text{Weight of the passing sample in g}}{\text{Weight of the sample taken in g}} \times 100$$

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	24/03/2025	25/03/2025	26/03/2025

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-RMEL0025-00	(i) Periodic review. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	24/03/2025

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

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	24/03/2025	25/03/2025	26/03/2025

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Material	MALTODEXTRIN BP			
Specification No.	SPEC-RMEM0047-00	**Revision No.**	00	**Item Code.:** RMEM0047
Supersedes	RMESM0047-00	**Effective Date**	17/05/2025	**Page No.:** 1 of 3

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	NA
2	Molecular weight	NA
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	40 g
6	Quantity of reserve sample	80 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	14/05/2025	15/05/2025	16/05/2025

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Material	MALTODEXTRIN BP			
Specification No.	SPEC-RMEM0047-00	**Revision No.**	00	**Item Code.:** RMEM0047
Supersedes	RMESM0047-00	**Effective Date**	17/05/2025	**Page No.:** 2 of 3

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	White or almost white, slightly hygroscopic powder or granules.
2.	*Solubility	Freely soluble in water.
3.	*Identification **A.** By Chemical test **B.** By Chemical test **C.** By Appearance **D.** By Dextrose equivalent	 A red precipitate is formed. Observe the colour of the reactive pad; within 60s a colour change is observed, characteristic of the hydrogen-donating substance used (from yellow to green or blue if tetramethylbenzidine is used). It is a powder or granules. Less than 20 (Nominal value)
4.	*pH	4.0 to 7.0
5.	Sulfur dioxide	Not more than 20ppm
6.	Sulfated ash	Not more than 0.5% w/w.
7.	*Loss on drying	Not more than 6.0% w/w.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	14/05/2025	15/05/2025	16/05/2025

S.NO	TEST (s)	SPECIFICATION (s)
8.	*Dextrose equivalent	Less than 20 (Nominal value)
9.	*Microbial contamination (i) Total aerobic microbial count (ii) Total yeast and mould count (iii) Escherichia coli (iv) Salmonella species	 Not more than 1000cfu/g Not more than 100cfu/g Should be absent in 1g Should be absent in 10g

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-RMEM0047-00	(i) Periodic review. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	17/05/2025

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

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	14/05/2025	15/05/2025	16/05/2025

	Safetab Life Science Puducherry			MASTER COPY
	STANDARD TESTING PROCEDURE			
Name of Material	MALTODEXTRIN BP			
STP No.	STP-RMEM0047-00	**Revision No.**	00	**Item Code.:** RMEM0047
Supersedes	RMETM0047-00	**Effective Date**	17/05/2025	**Page No.:** 1 of 4

1. DESCRIPTION: < REFER GAM 001>

White or almost white, slightly hygroscopic powder or granules.

2. SOLUBILITY: < REFER GAM 002>

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

3. IDENTIFICATION:

A. By Chemical test:

Weigh accurately about 0.1g of sample dissolved in 2.5ml of water and heat with 2.5ml of cupri-tartaric solution. A red precipitate is formed.

B. By Chemical test:

Dip, for 1s, a suitable stick with a reactive pad containing glucose-oxidase, peroxidase and a hydrogen-donating substance, such as tetramethylbenzidine, in a 100 g/L solution of the substance to be examined. Observe the colour of the reactive pad; within 60 s a colour change is observed, characteristic of the hydrogen-donating substance used (from Yellow to green or blue if tetramethylbenzidine is used).

C. By Appearance:

It is a powder or granules.

D. By Dextrose equivalent:

Less than 20.

SOLUTION S:

Weigh accurately about 12.5g of sample dissolved in carbon dioxide-free water and dilute to 50.0ml with the sample solvent.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	14/05/2025	15/05/2025	16/05/2025

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

Between 4.0 to 7.0

Mix 1ml of a 223.6g/L solution of potassium chloride and 30ml of solution S.

5. **SULFUR DIOXIDE:**

Not more than 20ppm.

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

Not more than 0.5% w/w, Determined on 1.0g of sample.

7. **LOSS ON DRYING: < REFER GAM 026>**

Not more than 6.0% w/w, Determined on 10.0g of sample by drying in an oven at 105°C.

8. **DEXTROSE EQUIVALENT:**

(DE): within 2 DE units of the nominal value.

Weigh an amount of the substance to be examined equivalent to 2.85-3.15 g of reducing carbohydrates, calculated as dextrose equivalent, into a 500mL volumetric flask. Dissolve in water and dilute to 500.0mL with the same solvent. Transfer the solution to a 50mL burette.

Pipette 25.0mL of cupri-tartaric solution into a 250mL flask and add 18.5mL of the test solution from the burette, mix and add a few glass beads. Place the flask on a hot plate, previously adjusted so that the solution begins to boil within 2 min ± 15s. Allow to boil for exactly 120s, add 1mL of a 1 g/L solution of methylene blue and titrate with the test solution (V_1) until the blue colour disappears. Maintain the solution at boiling throughout the titration.

Standardise the cupri-tartaric solution using a 6.0g/L solution of glucose (V_0).

Calculate the dextrose equivalent using the following expression:

$$= \frac{300 \times V_0 \times 100}{V_1 \times M \times D}$$

Where,

V_0 = Total volume of glucose standard solution, in millilitres;

V_1 = Total volume of test solution, in millilitres;

M = Sample mass, in grams;

D = Percentage content of dry matter in the substance.

9. MICROBIAL CONTAMINATION:

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

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	14/05/2025	15/05/2025	16/05/2025

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMEM0047-00	(i) Periodic review. (ii) STP numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	17/05/2025

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

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	14/05/2025	15/05/2025	16/05/2025

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	ORANGE PEKOE EXTRACT			
Specification No.	SPEC-RMEO0027-00	**Revision No.**	00	**Item Code.:** RMEO0027
Supersedes	RMESO0027-00	**Effective Date**	10/05/2025	**Page No.:** 1 of 3

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	NA
2	Molecular weight	NA
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	35 g
6	Quantity of reserve sample	70 g
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	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	07/05/2025	08/05/2025	09/05/2025

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	ORANGE PEKOE EXTRACT			
Specification No.	SPEC-RMEO0027-00	**Revision No.**	00	**Item Code.:** RMEO0027
Supersedes	RMESO0027-00	**Effective Date**	10/05/2025	**Page No.:** 2 of 3

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	Dark amber powder.
2.	*Odour and Taste	Characteristic of tea.
3.	*Identification By HPLC	The retention time of Caffeine obtained in sample chromatogram corresponding to the retention time of Caffeine in standard chromatogram as obtained in the assay.
4.	Particle size	100.0% passing through 40 mesh.
5.	Heavy metals	Not more than 10ppm.
6.	Ash Content	Not more than 15.0% w/w.
7.	*Loss on drying	Not more than 10.0% w/w.
8.	*Assay Caffeine by HPLC	Not less than 3.0%

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	07/05/2025	08/05/2025	09/05/2025

S.NO	TEST (s)	SPECIFICATION (s)
9.	*Microbial contamination	
	(i) Total aerobic microbial count	Not more than 1000cfu/g
	(ii) Total yeast and mould count	Not more than 100cfu/g
	(iii) Escherichia coli	Should be absent
	(iv) Salmonella species	Should be absent /10g
	(v) Staphylococcus aureus	Should be absent

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-RMEO0027-00	(i) Periodic review. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	10/05/2025

**** 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	07/05/2025	08/05/2025	09/05/2025

	Safetab Life Science Puducherry			MASTER COPY
	STANDARD TESTING PROCEDURE			
Name of Material	ORANGE PEKOE EXTRACT			
STP No.	STP-RMEO0027-00	**Revision No.**	00	**Item Code.:** RMEO0027
Supersedes	RMETO0027-00	**Effective Date**	10/05/2025	**Page No.:** 1 of 5

1. DESCRIPTION: < REFER GAM 001>

Dark amber powder.

2. ODOUR AND TASTE:

Characteristic of tea.

3. IDENTIFICATION:

By HPLC:

The retention time of Caffeine obtained in sample chromatogram corresponding to the retention time of Caffeine in standard chromatogram as obtained in the assay.

4. PARTICLE SIZE:

100.0% passing through 40 mesh.

Arrange the sample collector, Weigh and transfer around 10.0g of the sample into 40 Mesh and shake for 5 minutes. Collect the 40 Mesh passes from the sample collector.

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

5. HEAVY METALS: < REFER GAM 006>

Not more than 10ppm, determined on 1.0g of sample.

6. ASH CONTENT: < REFER GAM 032>

Not more than 15.0%, determined on 1.0g of sample.

7. LOSS ON DRYING: < REFER GAM 026>

Not more than 10.0%, determined on 1.0g of sample.

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	07/05/2025	08/05/2025	09/05/2025

8. Assay:

Caffeine by HPLC:

Chemicals/Reagents/Standards:

Caffeine	:	Working standard
Orthophosphoric acid	:	AR grade
Purified Water	:	Milli Q water (or) Equivalent
Acetonitrile	:	HPLC grade
Methanol	:	HPLC grade

Chromatographic Condition:

Column	:	C18, 250mm x 4.6 mm, 5µm
Column temperature	:	25°
Flow rate	:	1.0mL / minute
Detector wavelength	:	UV at 274 nm
Injection Volume	:	20µl
Run time	:	10 minutes
Retention time	:	About 5.5 ± 0.5 minutes

Mobile phase:

A Mixture of 80 volumes of 0.1% v/v Orthophosphoric acid and 20 volumes of Acetonitrile.

Diluent:

A mixture of 10 volumes of Water and 90 volumes of Methanol.

Standard solution:

Weigh accurately about 40mg of Caffeine WS into a 100ml volumetric flask. Add 75ml of diluent, shake and sonicate for 5minutes to dissolve makeup the volume with diluent. Further dilute 5.0ml of this solution to 100.0ml with diluent.

Sample solution:

Weigh accurately about 50mg of sample into a 50ml volumetric flask. Add 35ml of diluent, shake and sonicate for 5minutes to dissolve makeup the volume with diluent.

Procedure:

Filter the standard solution and Sample solution through 0.45µ nylon membrane filter. Inject the blank in single, standard in five replicates and test in duplicate. Calculate the system suitability parameters from standard chromatogram as follows.

System suitability requirements:

The theoretical plates for Caffeine peak in replicate standard injection should not be less than 2000.

Tailing factor for replicates standard injections should not be more than 2.0

RSD for replicate injections of standard should not be more than 2.0%.

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

Injection sequence:

S. No	Sample Name	No. of injections
1	Blank (Diluent)	1
2	Standard solution	5
3	Sample solution (PPN-1)	2
4	Sample solution (PPN-2)	1

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	07/05/2025	08/05/2025	09/05/2025

Calculations:

Calculate the assay in % of Caffeine as such basis of the sample as below.

$$= \frac{AT}{AS} \times \frac{WS}{100} \times \frac{5}{100} \times \frac{50}{WT} \times \frac{P}{100} \times 100$$

Where,

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

AS = Average area of the principal peak in the Standard solution.

WS = Weight of the Caffeine Working standard in mg.

WT = Weight of sample taken in mg.

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

9. MICROBIAL CONTAMINATION:

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

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	C.K.SARAVANAN	S.PALANICHAMY	S.MARAN
Designation	Asst. Manager-QC	Asst. Manager-QC	AGM-QA
Signature			
Date	07/05/2025	08/05/2025	09/05/2025

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMEO0027-00	(i) Periodic review. (ii) STP numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	10/05/2025

**** 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	07/05/2025	08/05/2025	09/05/2025

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	SUCRALOSE BP			
Specification No.	SPEC-RMES0034-00	**Revision No.**	00	**Item Code.:** RMES0034
Supersedes	RMESS0034-00	**Effective Date**	25/09/2023	**Page No.:** 1 of 3

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	$C_{12}H_{19}Cl_3O_8$
2	Molecular weight	397.6 g/mol
3	Storage conditions	Store in well closed container, in dry and cool place, at a temperature not exceeding 21°C.
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	10 g
6	Quantity of reserve sample	20 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	S.PALANICHAMY	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	21/09/2023	22/09/2023	22/09/2023

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	SUCRALOSE BP			
Specification No.	SPEC-RMES0034-00	**Revision No.**	00	**Item Code.:** RMES0034
Supersedes	RMESS0034-00	**Effective Date**	25/09/2023	**Page No.:** 2 of 3

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	White or almost white crystalline powder.
2.	*Solubility	Freely soluble in water, soluble in anhydrous ethanol and slightly soluble in ethyl acetate.
3.	*Identification **A.** By Specific optical rotation **B.** By IR	 +84.0° to +87.5° (anhydrous substances) The infrared absorption spectrum of sample should be concordant with that of reference spectrum or with the spectrum obtained from Sucralose WS.
4.	*Specific optical rotation	+84.0° to +87.5° (anhydrous substances)
5.	Impurities H and I	Not more than 0.1%
6.	*Related substances Impurities A,B,D,E,F,G	 Not more than 0.5%
7.	Sulfated ash	Not more than 0.7% w/w.
8.	*Water by KFR	Not more than 2.0% w/w.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	S.PALANICHAMY	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	21/09/2023	22/09/2023	22/09/2023

S.NO	TEST (s)	SPECIFICATION (s)
9.	*Assay By HPLC (anhydrous substances)	Not less than 98.0% 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-RMES0034-00	(i) Periodic review. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	25/09/2023

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

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	S.PALANICHAMY	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	21/09/2023	22/09/2023	22/09/2023

	Safetab Life Science Puducherry			MASTER COPY
	STANDARD TESTING PROCEDURE			
Name of Product	SUCRALOSE BP			
STP No.	STP-RMES0034-00	**Revision No.**	00	**Item Code.:** RMES0034
Supersedes	RMESS0034-00	**Effective Date**	25/09/2023	**Page No.:** 1 of 7

1. DESCRIPTION: < REFER GAM 001>

White or almost white crystalline powder.

2. SOLUBILITY: < REFER GAM 002>

100mg of sample + 1mL of Water	Freely soluble if the material dissolves
100mg of sample + 3mL of Anhydrous ethanol	Soluble if the material dissolves
10mg of sample + 10mL of Ethyl acetate	Slightly soluble if the material dissolves

3. IDENTIFICATION:

A. SPECIFIC OPTICAL ROTATION: < REFER GAM 029>

+84.0º to +87.5º (anhydrous substances).

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 Sucralose WS.

4. SPECIFIC OPTICAL ROTATION: < REFER GAM 029>

+84.0º to +87.5º (anhydrous substances), Dissolve 2.5g of sample in water and dilute 25ml with same solvent.

5. IMPURITIES H AND I:

Determine by thin-layer chromatography, coating the plate with silica gel.

Note: This test does not require a developing solvent.

Test solution:

Dissolve about 2.5g of the substance to be examined in methanol and dilute to 10ml with the same solvent.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	S.PALANICHAMY	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	21/09/2023	22/09/2023	22/09/2023

Reference solution (a):

Dissolve 1.0g of Mannitol in water and dilute to 10.0ml with the same solvent.

Reference solution (b):

Dissolve 1.0g of Mannitol and 4.0mg of Fructose in water and dilute to 10.0ml with the same solvent.

Plate: TLC silica gel plate.

Application:

5µl by applying the solution slowly in 1µl aliquots and allowing the plate to dry between applications; the 3 spots must be of a similar size.

Detection Spray with a solution prepared as follows:

Dissolve 1.23g of p-anisidine and 1.66g of phthalic acid in 100ml of methanol store the solution in darkness and in a refrigerator to prevent it becoming discoloured: discard if the solution become discoloured; heat the plate at 100 ±2°C for 15 min and examine immediately against a dark background.

System suitability:

The spot due to mannitol obtained with reference solution (a) is colourless; darkening of the mannitol spot indicates that the plate has been held for too long in the oven and a 2nd plate has to be prepared.

Limit:

Sum of impurities H and I:

Any spot is not more intense than the spot due to fructose obtained with reference solution (b) (0.1 per cent).

6. RELATED SUBSTANCES: (THIN-LAYER CHROMATOGRAPHY):

Plate	:	TLC octadecylsilyl silica gel plate
Application	:	5 µL.
Development	:	Over 3/4 of the plate.
Drying	:	In air.

Mobile phase:

A mixture of 30 volumes of Acetonitrile and 70 volumes of 50g/L solution of Sodium chloride.

Test solution:

Dissolve 1.0 g of the substance to be examined in methanol and dilute to 10.0 mL with the same solvent.

Reference solution (a):

Dilute 0.5 mL of the test solution to 100.0 mL with methanol

Reference solution (b):

Dissolve the contents of a vial of sucralose impurity B RS in 1.0 mL of the test solution.

Detection:

Spray with a 15 per cent V/V solution of sulfuric acid in methanol Rand heat at 125°C for 10 min.

Retardation factors:

Impurity A = about 0.3; impurity B = about 0.35; sucralose = about 0.45; impurity F = about 0.67; impurity G = about 0.70; impurity E = about 0.72; impurity D = about 0.8.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	S.PALANICHAMY	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	21/09/2023	22/09/2023	22/09/2023

System suitability

Reference solution (b):

The chromatogram shows 2 clearly separated spots due to impurity B and Sucralose.

Limits:

Impurities A, B, D, E, F, and G: any spot, apart from the principal spot, is not more intense than the spot in the chromatogram obtained with reference solution (a) (0.5 per cent).

7. SULPHATED ASH: < REFER GAM 032>

Not more than 0.7 per cent, determined 1.0g of sample.

8. WATER CONTENT: < REFER GAM 010>

Not more than 2.0 per cent, determined on 0.5g of sample.

9. ASSAY: (DETERMINED BY LIQUID CHROMATOGRAPHY)

Chemicals/Reagents/Standards:

Sucralose	:	Working standard
Acetonitrile	:	HPLC grade
Purified water	:	Milli Q water (or) Equivalent

Chromatographic Conditions:

Column	:	A stainless steel column 10cmx4mm, packed with octadecylsilane bonded to porous silica (5µm)
Detector	:	Refractive index
Injection volume	:	20µl

Flow rate : 1.5ml/min

Retention time : About 3 minutes

Mobile phase:

A mixture of 15 volumes of Acetonitrile and 85 volumes of Water.

Test solution:

Dissolve 250mg of the substance to be examination in the mobile phase and dilute to 25.0ml with the mobile phase.

Standard solution:

Dissolve 250mg of Sucralose WS in the mobile phase and dilute to 25.0ml with the mobile phase.

Inject the Standard solution. The test is not valid unless the tailing factor is not more than 2.0 per cent.

Inject the Standard solution and test solution.

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

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	21/09/2023	22/09/2023	22/09/2023

Injection sequence:

S. No	Sample Name	No. of injections
1	Blank	1
2	Standard solution	5
3	Test solution (PPN-1)	2
4	Test solution (PPN-2)	1

Calculations:

Calculate the assay % of Sucralose on as such basis as follows.

$$= \frac{AT}{AS} \times \frac{WS}{25} \times \frac{25}{WT} \times \frac{P}{100} \times 100$$

Where,

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

AS = Average area of the principal peak in the Standard solution.

WS = Weight of the Sucralose Working standard in mg.

WT = Weight of sample taken in mg.

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

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	S.PALANICHAMY	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	21/09/2023	22/09/2023	22/09/2023

Calculate the assay % of Sucralose on anhydrous basis as follows:

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

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMES0034-00	(i) Periodic review. (ii) STP numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	25/09/2023

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

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	S.PALANICHAMY	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	21/09/2023	22/09/2023	22/09/2023

	Safetab Life Science Puducherry			MASTER COPY
	PACKING MATERIAL SPECIFICATION			
Name of Product	**380 x 365 x 430MM GHPL PRINTED 5 PLY SHIPPER**			
Specification No.	SPEC-PTMT0018-00	**Revision No.**	00	**Item Code:** PTMT0018
Supersedes	NIL	**Effective Date**	13/09/2023	**Page No.:** 1 of 4

S.NO	PACKING MATERIAL GENERAL SPECIFICATION (s)	
1.0	Storage condition	Store in room temperature.
2.0	Precautions, Handling hazards & Special instructions for sampling if any	No special instructions.
3.0	Total Quantity of sample required for analysis	1 number of Shipper.
4.0	Quantity of reserve sample	Not applicable.
5.0	Sampling Instructions	Follow the Standard operating procedure number: ST/QC/041.
6.0	Destruction Instructions	Follow the Standard operating procedure number: ST/QC/032.
7.0	Retest period	NA

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	08/09/2023	09/09/2023	11/09/23

	Safetab Life Science Puducherry			MASTER COPY
	PACKING MATERIAL SPECIFICATION			
Name of Product	**380 x 365 x 430MM GHPL PRINTED 5 PLY SHIPPER**			
Specification No.	SPEC-PTMT0018-00	**Revision No.**	00	**Item Code:** PTMT0018
Supersedes	NIL	**Effective Date**	13/09/2023	**Page No.:** 2 of 4

S.NO	TEST (s)	SPECIFICATION (s)
1.0	Description	Golden yellow colour 5ply shipper and printed on all sides of the shipper.
2.0	**Dimensions**:	
	Length	377 to 383 mm
	Breadth	362 to 368 mm
	Height	427 to 433 mm
3.0	**Total Grammage:**	
	Outside Linear kraft	Not less than 180 g/sq.m
	Flute 1	Not less than 180 g/sq.m
	Middle Linear kraft	Not less than 180 g/sq.m
	Flute 2	Not less than 180 g/sq.m
	Inner Linear kraft	Not less than 180 g/sq.m

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	08/09/2023	09/09/2023	11/09/23

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	PACKING MATERIAL SPECIFICATION			MASTER COPY
Name of Product	**380 x 365 x 430MM GHPL PRINTED 5 PLY SHIPPER**			
Specification No.	SPEC-PTMT0018-00	**Revision No.**	00	**Item Code:** PTMT0018
Supersedes	NIL	**Effective Date**	13/09/2023	**Page No.:** 3 of 4

S.NO	TEST (s)	SPECIFICATION (s)
4.0	Flute Percentage	Not less than 25.0%
5.0	Staples	Clean and free from rust copper pin to be applied in pairs. Pairs of staples shall be applied at approximate equal distance.
6.0	Flaps	No gap or overlaps between two flaps.
7.0	Moisture content	Not more than 10.0%
8.0	Bursting Strength	Not less than 15.0 Kg/Cm^2
9.0	Printing Quality	Should comply
10.0	Cleanliness check	Should comply

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	08/09/2023	09/09/2023	11/09/23

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-PTMT0018-00	New Specification prepared.	ST/CC/23/175	13/09/2023

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

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	08/09/2023	09/09/2023	11/09/23

	Safetab Life Science Puducherry			MASTER COPY
	STANDARD TESTING PROCEDURE			
Name of Product	**380 x 365 x 430MM GHPL PRINTED 5 PLY SHIPPER**			
STP No.	STP-PTMT0018-00	**Revision No.**	00	**Item Code:** PTMT0018
Supersedes	NIL	**Effective Date**	13/09/2023	**Page No.:** 1 of 4

1.0 DESCRIPTION:

Golden yellow colour 5ply shipper and printed on all sides of the shipper.

2.0 DIMENSIONS:

Length:

Measure the length of the shipper by using calibrated scale (in mm).

Breadth:

Measure the breadth of the shipper by using calibrated scale (in mm).

Height:

Measure the Height of the shipper by using calibrated scale (in mm).

3.0 TOTAL GRAMMAGE:

Using calibrated scale mark 10 x 10cm cut the shipper and soak in water for 15 minutes, separate the layers and dry in hot air oven at 105° for 15 minutes. After drying weigh the each layer (W gms) and calculate the GSM for each layer using the following formula.

CALCULATION:

$$GSM = \frac{W\ (gms) \times 100 \times 100}{Length\ (in\ cm) \times Height\ (in\ cm)}$$

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	08/09/2023	09/09/2023	11/09/23

4.0 FLUTE PERCENTAGE:

After determination of GSM for each layer, weigh the flute 1 and flute 2 layer (W1 gm) and cut in 10 x 10cm and weigh (W2 gm). Calculate the flute 1 and flute 2 percentage using the following formula.

Calculation:

$$= \frac{(W1 - W2)}{W1} \times 100$$

Where,

W1 – Weight of the flute before cutting.
W2 – Weight of the flute after cutting.

5.0 STAPLES:

Check the shipper is clean and free from rust copper pin to be applied in pairs. Pairs of staples shall be applied at approximate equal distance.

6.0 FLAPS:

Check for gap or overlap between two flaps and report the observation.

7.0 MOISTURE CONTENT:

Using calibrated scale mark 10 x 10cm and weigh the shipper (W1 gm), cut into small pieces and dry in an oven at a temperature 105°C for 30 minutes. After drying, cool in desiccator and weigh the small pieces of shipper (W2 gm) and calculate the moisture content in percentage using the formula,

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	08/09/2023	09/09/2023	11/09/23

Calculation:

$$= \frac{(W1 - W2)}{\text{Weight of Shipper (W1)}} \times 100$$

8.0 BURSTING STRENGTH:

Carry out this using a bursting strength apparatus. Check the bursting strength of the sample in three different places and find the average.

9.0 PRINTING QUALITY:

Check the pasting Quality randomly.

10.0 CLEANLINESS CHECK:

Check the cleanliness of the shipper. The test passes if the shipper is not dirty, mutilated, torn or stained.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	08/09/2023	09/09/2023	11/09/23

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-PTMT0018-00	New STP prepared	ST/CC/23/175	13/09/2023

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

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	AGM-QC	AGM-QA
Signature			
Date	08/09/2023	09/09/2023	11/09/23

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	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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	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

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	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

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	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

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	RAW MATERIAL SPECIFICATION			
Name of Product	CHLORPHENAMINE MALEATE BP			
Specification No.	RMASC0064-01	**Revision No.**	01	**Item Code.:** RMAC0064
Supersedes	RMASC0064-00	**Effective Date**	20/02/2023	**Page No.:** 1 of 3

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	$C_{20}H_{23}ClN_2O_4$
2	Molecular weight	390.9
3	Storage conditions	Protected from light.
4	Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
5	Quantity of sample required for analysis	6 g
6	Quantity of reserve sample	12 g
7	Retest period	12 months from the date of release
8	Re-test Parameter	As mentioned in Specification
9	Reference	BP
10	Sampling instruction	Follow the standard operating procedure No.: ST/QC/040.
11	Destructions instructions	Follow the standard operating procedure No.: ST/QC/032.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	15/02/2023	16/02/2023	17/02/2023

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	CHLORPHENAMINE MALEATE BP			
Specification No.	RMASC0064-01	**Revision No.**	01	**Item Code.:** RMAC0064
Supersedes	RMASC0064-00	**Effective Date**	20/02/2023	**Page No.:** 2 of 3

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	White or almost white, crystalline powder.
2.	*Solubility	Freely soluble in water, soluble in ethanol (96 per cent).
3.	*Identification **A.** By Melting point **B.** By IR **C.** Optical rotation	 Between 130 °C to 135 °C. The Infrared absorption spectrum of sample should be concordant with that of reference spectrum or with the spectrum obtained from Chlorphenamine Maleate WS. Between -0.10° to + 0.10°
4.	Appearance of solution	Solution S is clear and not more intensely coloured than reference solution BY_6.
5.	Optical rotation	Between -0.10° to + 0.10°
6.	*Related substances (By HPLC) (i) Impurity A (ii) Impurity B (iii) Impurity C (iv) Impurity D (v) Unspecified impurities (vi) Total impurities	 Not more than 0.2% Not more than 0.1% Not more than 0.1% Not more than 0.1% Not more than 0.1% Not more than 0.5%

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	15/02/2023	16/02/2023	17/02/2023

S.NO	TEST (s)	SPECIFICATION (s)
7.	Sulphated Ash	Not more than 0.1% w/w
8.	*Loss on drying	Not more than 0.5% w/w
9.	*Assay By Titration (On dried basis)	Not less than 98.0% and not more than 101.0% w/w.

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

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
RMASC0064-01	Periodic review.	NA	20/02/2023

**** 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	15/02/2023	16/02/2023	17/02/2023

1. DESCRIPTION: < REFER GAM 001>

White or almost white, crystalline powder.

2. SOLUBILITY: < REFER GAM 002>

100mg of sample + 1mL of Water	Freely soluble if the material dissolves.
100mg of sample + 3mL of Ethanol (96%)	Soluble if the material dissolves.

3. IDENTIFICATION:

A. By Melting point: < REFER GAM 028>

Between 130°C to 135°C.

B. By IR: < REFER GAM 003>

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

C. By Optical rotation:

Between -0.10° to + 0.10°.

4. APPEARANCE OF SOLUTION:

Solution S:

Dissolve 2.0 g in water and dilute to 20.0 mL with the same solvent.

Solution S is clear and not more intensely coloured than reference solution BY_6.

5. OPTICAL ROTATION:

Between -0.10° to + 0.10°, determined on solution S.

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	15/02/2023	16/02/2023	17/02/2023

6. RELATED SUBSTANCES: (BY HPLC)

Chemicals/Reagents/Standards:

Chlorphenamine maleate	:	Working standard
Impurity A	:	Reference standard
Impurity B	:	Reference standard
Impurity C	:	Reference standard
Ammonium dihydrogen phosphate	:	AR grade
Phosphoric acid	:	AR grade
Acetonitrile	:	HPLC grade

Chromatographic Conditions:

Column	:	µ-BondaPak C18, 300mm x 3.9mm, (10µm) or equivalent.
Flow Rate	:	1.2ml/min
Wavelength	:	225nm
Injection volume	:	20µl
Run time	:	3.5 times the retention time of Chlorphenamine and relative retention time for maleic acid = about 0.2; impurity A = about 0.3; impurity B = about 0.4; impurity C = about 0.9; impurity D = about 3.0
Retention time	:	Retention time of Chlorphenamine peak is at about 11.0 minutes

Mobile phase:

Mix 20 volumes of acetonitrile and 80 volumes of a 8.57 g/L solution of ammonium dihydrogen phosphate previously adjusted to pH 3.0 with phosphoric acid.

Test solution:

Weigh accurately and dissolve about 0.100 g of the substance to be examined in the mobile phase and dilute to 100.0 mL with the mobile phase.

Reference solution (a):

Dilute 1.0 mL of the test solution to 200.0 mL with the mobile phase.

Reference solution (b):

Dilute 1.0 mL of reference solution (a) to 10.0 mL with the mobile phase.

Reference solution (c):

Weigh accurately and dissolve about 5 mg of chlorphenamine impurity C RS in 5 mL of the test solution and dilute to 50.0 mL with the mobile phase. Dilute 2 mL of this solution to 20 mL with the mobile phase.

Reference solution (d):

Weigh accurately and dissolve about 5 mg of 2,2′-dipyridylamine (impurity B) in the mobile phase and dilute to 100 mL with the mobile phase.

Reference solution (e):

Dissolve the contents of a vial of Chlorphenamine impurity A RS in 2 mL of the test solution. Sonicate for 5 min

System suitability Reference solution (c):

— **resolution:** minimum 1.5 between the peaks due to impurity C and chlorphenamine.

Limits:

— **correction factors:** for the calculation of contents, multiply the peak areas of the following impurities by the corresponding correction factor: impurity A = 1.5; impurity B = 1.4;

— impurity A: not more than 0.4 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.2 per cent);

— impurities B, C, D: for each impurity, not more than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.1 per cent);

— **unspecified impurities:** for each impurity, not more than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.10 per cent);

— total: not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (0.5 per cent);

— disregard limit: the area of the principal peak in the chromatogram obtained with reference solution (b) (0.05 per cent); disregard the peak due to maleic acid

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

Injection sequence:

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

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	15/02/2023	16/02/2023	17/02/2023

Calculations:

Impurity A : (NMT 0.2%)

$$= \frac{AT_A}{AS} \times \frac{WT}{100} \times \frac{1}{200} \times \frac{100}{WT} \times 1.5 \times 100$$

Where,

AT_A = Area of Impurity A peak in Test solution.

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

WT = Weight of the sample taken in mg.

Impurity B: (NMT 0.1%)

$$= \frac{AT_B}{AS} \times \frac{WT}{100} \times \frac{1}{200} \times \frac{100}{WT} \times 1.4 \times 100$$

Where,

AT_B = Area of Impurity B peak in Test solution.

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

WT = Weight of the sample taken in mg.

Impurity C: (NMT 0.1%)

$$= \frac{AT_C}{AS} \times \frac{WT}{100} \times \frac{1}{200} \times \frac{100}{WT} \times 100$$

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	15/02/2023	16/02/2023	17/02/2023

Where,

AT_C = Area of Impurity C peak in Test solution.

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

WT = Weight of the sample taken in mg.

Impurity D: (NMT 0.1%)

$$= \frac{AT_D}{AS} \times \frac{WT}{100} \times \frac{1}{200} \times \frac{100}{WT} \times 100$$

Where,

AT_D = Area of Impurity D peak in Test solution.

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

WT = Weight of the sample taken in mg.

Unspecified impurity: (NMT 0.10%)

$$= \frac{AT_I}{AS} \times \frac{WT}{100} \times \frac{1}{200} \times \frac{100}{WT} \times 100$$

Where,

AT_I = Area of Unspecified impurity peak in Test solution.

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

WT = Weight of the sample taken in mg.

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	15/02/2023	16/02/2023	17/02/2023

Total impurities: (NMT 0.5%)

$$= \frac{AT_T}{AS} \times \frac{WT}{100} \times \frac{1}{200} \times \frac{100}{WT} \times 100$$

Where,

AT_T = Area of All impurities peak in Test solution.

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

WT = Weight of the sample taken in mg.

Note: Calculate the content of Impurity A and Impurity B areas with multiply the respective correction factor.

7. SULPHATED ASH: < REFER GAM 032>

Maximum 0.1%. Determine on 1.0g of sample.

8. LOSS ON DRYING: < REFER GAM 026>

Not more than 0.5 per cent, determined on 1.000 g by drying in an oven at 105 °C for 4h.

9. ASSAY: (By Titration)

Weigh accurately and dissolve about 0.150g in 25 mL of anhydrous acetic acid. Titrate with 0.1M perchloric acid, determining the end-point potentiometrically.

1 mL of 0.1 M perchloric acid is equivalent to 19.54 mg of $C_{20}H_{23}ClN_2O_4$.

Calculation:

$$= \frac{\text{Titer value} \times \text{Molarity of 0.1M Perchloric acid} \times 0.01954 \times 100 \times 100}{\text{Sample weight in (g)} \times (100 - \text{Sample LOD}) \times 0.1}$$

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	15/02/2023	16/02/2023	17/02/2023

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
RMATC0064-01	Periodic review.	NA	20/02/2023

****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	15/02/2023	16/02/2023	17/02/2023

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	RAW MATERIAL SPECIFICATION			
Name of Product	CITRIC ACID MONOHYDRATE BP			
Specification No.	SPEC-RMEC0020-00	**Revision No.**	00	**Item Code.:** RMEC0020
Supersedes	RMESC0020-00	**Effective Date**	14/11/2024	**Page No.:** 1 of 3

S.NO	RAW MATERIAL GENERAL SPECIFICATION (S)	
1	Molecular formula	$C_6H_8O_7$, H_2O
2	Molecular weight	210.1
3	Storage conditions	In an airtight 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	35 g
6	Quantity of reserve sample	70 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	11/11/2024	12/11/2024	13/11/2024

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	RAW MATERIAL SPECIFICATION			
Name of Product	CITRIC ACID MONOHYDRATE BP			
Specification No.	SPEC-RMEC0020-00	**Revision No.**	00	**Item Code.:** RMEC0020
Supersedes	RMESC0020-00	**Effective Date**	14/11/2024	**Page No.:** 2 of 3

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	White or almost white, crystalline powder, colourless crystals or granules, efflorescent.
2.	*Solubility	Very soluble in water; freely soluble in ethanol (96 per cent).
3.	*Identification **A.** By Chemical test **B.** By IR **C.** By Chemical test **D.** By Chemical test **E.** Water (By KFR)	 The solution is strongly acidic. The Infrared absorption spectrum of sample should be concordant with that of reference spectrum or with the spectrum obtained from Citric acid monohydrate WS. A red colour develops. A white precipitate is formed. 7.5% to 9.0% w/w.
4.	Appearance of solution	The solution is clear and colourless or not more intensely coloured than reference solution Y_7, BY_7 or GY_7.
5.	Readily carbonisable substances	The solution is not more intensely coloured than a mixture of 1ml of red primary solution and 9ml of yellow primary solution.
6.	Oxalic acid	Not more than 360ppm.
7.	Sulfates	Not more than 150ppm.

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	11/11/2024	12/11/2024	13/11/2024

Safetab Life Science QUALITY ASSURANCE Puducherry

S.NO	TEST (s)	SPECIFICATION (s)
8.	Aluminium	Not more than 0.2ppm
9.	Sulfated ash	Not more than 0.1% w/w
10.	* Water (By KFR)	7.5% to 9.0% w/w.
11.	*Assay (On Anhydrous basis)	Not less than 99.5 per cent and not more than 100.5% 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-RMEC0020-00	(i) Periodic review. (ii) Specification numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	14/11/2024

**** 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	11/11/2024	12/11/2024	

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	STANDRAD TESTING PROCEDURE			
Name of Product	CITRIC ACID MONOHYDRATE BP			
STP No.	STP-RMEC0020-00	**Revision No.**	00	**Item Code.:** RMEC0020
Supersedes	RMETC0020-00	**Effective Date**	14/11/2024	**Page No.:** 1 of 4

1. DESCRIPTION: < REFER GAM 001>

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

2. SOLUBILITY: < REFER GAM 002>

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

3. IDENTIFICATION:

First identification: B, E.

Second identification: A, C, D, E.

A. By Chemical test:

Weigh accurately about 1.0g of sample dissolved in 10ml of water. The solution is strongly acidic.

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 Citric acid monohydrate WS.

C. By Chemical test:

Add about 5.0mg of sample to a mixture of 1ml of acetic anhydride and 3ml of pyridine. A red colour develops.

D. By Chemical test:

Weigh accurately about 0.5g of sample dissolved in 5ml of water, neutralise using 1M sodium hydroxide (about 7ml), add 10ml of calcium chloride solution and heat to boiling. A white 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	11/11/2024	12/11/2024	

Safetab Life Science QUALITY ASSURANCE Puducherry-107

E. Water (By KFR)

7.5% to 9.0% w/w.

4. APPEARANCE OF SOLUTION: < REFER GAM 023>

Weigh accurately about 2.0g of sample dissolved in 10ml of water. The solution is clear and colourless or not more intensely coloured than reference solution Y_7, BY_7 or GY_7.

5. READILY CARBONISABLE SUBSTANCES:

To 1.0g of sample in cleaned test tube, add 10ml of sulfuric acid and immediately heat the mixture in a water bath at 90°C ± 1°C for 60 minutes. Cool rapidly immediately afterwards. The solution is not more intensely coloured than a mixture of 1ml of red primary solution and 9ml of yellow primary solution.

6. OXALIC ACID:

Dissolve 0.8g of sample in 4ml of water, add 3 ml of hydrochloric acid and 1g of zinc in granules. Boil for 1 minutes. Allow to stand for 2 minutes. Transfer the supernatant to a test-tube containing 0.25ml of a 10g/L solution of phenylhydrazine hydrochloride and heat to boiling. Cool rapidly, transfer to a graduated cylinder and add an equal volume of hydrochloric acid and 0.25ml of a 50g/L solution of potassium ferricyanide. Shake and allow to stand for 30 minutes. Any pink colour in the solution is not more intense than that in a standard prepared at the same time in the same manner using 4ml of a 0.1g/L solution of oxalic acid.

7. SULFATES: <REFER GAM 009>

Dissolve 2.0g in sufficient distilled water to produce 30mL. The resulting solution complies with the limit test for Sulfates (NMT 150ppm).

8. ALUMINIUM:

Not more than 0.2ppm, (if intended for use in the manufacture of dialysis solutions.

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	11/11/2024	18/11/2024	

Safetab Life Science QUALITY ASSURANCE Puducherry-107

Sample solution:

Weigh accurately about 20.0g of sample dissolved in 100ml of water and add 10ml of acetate buffer solution pH 6.0.

Standard solution:

Take 2ml of aluminium standard solution (2ppm Al) and add 10ml of acetate buffer solution pH 6.0 and 98ml of water.

Blank solution:

A mixture of 10ml of acetate buffer solution pH 6.0 and 100ml of water.

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

Not more than 0.1% w/w, Determined on 1g of sample.

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

7.5% to 9.0% w/w, Determined on 0.5g of sample.

11. **ASSAY: (ON ANHYDROUS BASIS)**

Weigh accurately about 0.550g of sample, dissolved in 50ml of water. Titrate with 1M sodium hydroxide using 0.5ml of phenolphthalein solution as indicator.

1ml of 1M sodium hydroxide is equivalent to 64.03mg of $C_6H_8O_7$.

Calculation:

$$= \frac{\text{Titer value} \times \text{Molarity of 1M sodium hydroxide} \times 64.03 \times 100 \times 100}{\text{Sample weight in mg} \times (100 - \text{Sample Water}) \times 1.0}$$

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	11/11/2024	12/11/2024	

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Safetab Life Science QUALITY ASSURANCE Puducherry-107

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMEC0020-00	(i) Periodic review. (ii) STP numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/063	14/11/2024

****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	11/11/2024	12/11/2024	

Safetab Life Science QUALITY ASSURANCE Puducherry-107 14/11/2024

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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.:** 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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	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.:** 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

	Safetab Life Science Puducherry			
	RAW MATERIAL SPECIFICATION			MASTER COPY
Name of Product	PARACETAMOL BP			
Specification No.	SPEC-RMAP0030-02	**Revision No.**	02	**Item Code.:** RMAP0030
Supersedes	RMASP0030-01	**Effective Date**	08/06/2023	**Page No.:** 1 of 3

S.NO	RAW MATERIAL GENERAL SPECIFICATION (S)	
1	Molecular formula	$C_8H_9NO_2$
2	Molecular weight	151.2
3	Storage conditions	Protected from light.
4	Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
5	Quantity of sample required for analysis	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	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			QUALITY ASSURANCE
Date	06/06/2023	07/06/2023	07/06/2023

	Safetab Life Science Puducherry			
	RAW MATERIAL SPECIFICATION			MASTER COPY
Name of Product	PARACETAMOL BP			
Specification No.	SPEC-RMAP0030-02	**Revision No.**	02	**Item Code.:** RMAP0030
Supersedes	RMASP0030-01	**Effective Date**	08/06/2023	**Page No.:** 2 of 3

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	White or almost white, crystalline powder.
2.	*Solubility	Sparingly soluble in water, freely soluble in ethanol (96 per cent), very slightly soluble in methylene chloride.
3.	*Identification **A.** By Melting point **B.** By IR	 **Result A:** 168°C to 172°C. **Result B:** Not greater than 2°C The Infrared absorption spectrum of sample should be concordant with that of reference spectrum or with the spectrum obtained from Paracetamol RS.
4.	*Related substances (By HPLC) (i) Impurity K (ii) Impurity J (iii) Unspecified impurity (iv) Total impurities	 Not more than 50 ppm Not more than 10 ppm Not more than 0.05% Not more than 0.2%
5.	Sulphated Ash	Not more than 0.1% w/w
6.	*Loss on drying	Not more than 0.5% w/w

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	06/06/2023	07/06/2023	07/06/2023

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	PARACETAMOL BP			
Specification No.	SPEC-RMAP0030-02	**Revision No.**	02	**Item Code.:** RMAP0030
Supersedes	RMASP0030-01	**Effective Date**	08/06/2023	**Page No.:** 3 of 3

S.NO	TEST (s)	SPECIFICATION (s)
7.	*Assay By Titration (On dried basis)	Not less than 99.0% and not more than 101.0% w/w.

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

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-RMAP0030-02	(i) There is no changes in Specification. (ii) Specification number has been changed as per ERP. This changes captured as per change control number.	ST/CC/23/063	08/06/2023

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

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

Safetab Life Science Puducherry-107 QUALITY ASSURANCE

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1. DESCRIPTION: < REFER GAM 001>

White or almost white, crystalline powder.

2. SOLUBILITY: < REFER GAM 002>

100mg of sample + 10mL of Water	Sparingly soluble if the material dissolves.
100mg of sample + 1mL of Ethanol (96%)	Freely soluble if the material dissolves.
10mg of sample + 100mL of methylene chloride	Very slightly soluble if the material dissolves.

3. IDENTIFICATION: < REFER GAM 003>

First identification: B.

Second identification: A.

A. By Melting point:

Determination A:

Determine the melting point of the substance to be examined.

Result A: 168 °C to 172 °C.

Determination B:

Mix equal parts of the substance to be examined and Paracetamol RS and determine the melting point of the mixture.

Result B: The absolute difference between the melting point of the mixture and the value obtained in determination A is not greater than 2°C.

B. By IR:

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

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	06/06/2023	07/06/2023	07/06/2023

4. RELATED SUBSTANCES: (BY HPLC)

Chemicals/Reagents/Standards:

Paracetamol Impurity K	:	Reference standard
Paracetamol Impurity J	:	Reference standard
Potassium dihydrogen phosphate	:	AR grade
Dipotassium hydrogen phosphate	:	AR grade
Purified Water	:	Milli-Q water (or) equivalent
Methanol	:	HPLC grade

Chromatographic Conditions:

Column	:	150mm x 4.6mm, end-capped solid core Octadecylsilyl silica, (5µm).
Column Temperature	:	30°C
Auto sampler temperature	:	5°C
Flow Rate	:	1.5ml/min
Wavelength	:	254nm
Injection volume	:	50µl
Retention time	:	Retention time of Paracetamol peak is at about 4.0 minutes

Mobile phase A:

Dissolve 1.7g of Potassium dihydrogen phosphate and 1.8 g of Dipotassium hydrogen phosphate in water for chromatography and dilute to 1000 mL with the same solvent.

Mobile phase B: Methanol

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	06/06/2023	07/06/2023	07/06/2023

Safetab Life Science QUALITY ASSURANCE Puducherry-607

Gradient program:

Time (min)	Mobile phase A (per cent V/V)	Mobile phase B (per cent V/V)
0 – 1.5	95	5
1.5 – 14.4	95 → 90	5 → 10
14.4 – 28.8	90	10
28.8 – 57.6	90 → 66	10 → 34
57.6 - 60	66	34

Solvent mixture:

A mixture of 15 volumes of Methanol and 85 volumes of water.

Test solution:

Weigh accurately and dissolve about 50.0mg of the substance to be examined in 0.75ml of methanol and dilute to 5.0ml with water.

Reference solution (a):

Dilute 1.0 mL of the test solution to 100.0 mL with the solvent mixture. Dilute 1.0 mL of this solution to 20.0 mL with the solvent mixture.

Reference solution (b):

Dissolve 5.0mg of Paracetamol impurity J RS in 25ml of methanol and dilute to 250.0 mL with the solvent mixture. Dilute 1.0 mL of the solution to 200.0 mL with the solvent mixture.

Reference solution (c):

Weigh accurately about 5.0mg of Paracetamol impurity K RS in the solvent mixture and dilute to 100.0 mL with the solvent mixture. Dilute 1.0 mL of the solution to 10.0 mL with the solvent mixture.

Reference solution (d):

Dilute 1.0 mL of the reference solution (c) to 10.0 mL with the solvent mixture.

Reference solution (e):

Mix 1.0 mL of the reference solution (a) and 1ml of reference solution (c) and dilute to 10.0 mL with the solvent mixture.

Procedure:

Identification of impurities Use the chromatogram obtained with reference solution (b) to identify the peak due to impurity J; use the chromatogram obtained with reference solution (d) to identify the peak due to impurity K.

Relative retention With reference to Paracetamol (retention time = about 4 min): impurity K = about 0.4; impurity J = about 10.1.

System suitability Reference solution (e):

— **Resolution:** minimum 5.0 between the peaks due to impurity K and Paracetamol.

Calculation of percentage contents:

— for impurity J, use the concentration of impurity J in reference solution (b);

— for impurity K, use the concentration of impurity K in reference solution (d);

— for impurities other than J and K, use the concentration of Paracetamol in reference solution (a).

Limits:

— impurity K: maximum 50 ppm;

— impurity J: maximum 10 ppm;

— unspecified impurities: for each impurity, maximum 0.05 per cent;

— total: maximum 0.2 per cent;

— reporting threshold: 0.03 per cent, except for impurities J and K.

Inject 50µl of the above solution as per following sequence.

Injection sequence:

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

Calculations:

Impurity K : (NMT 50ppm)

$$= \frac{AT_K}{AS_K} \times \frac{RS}{100} \times \frac{1}{10} \times \frac{1}{10} \times \frac{5}{WT} \times \frac{P_K}{100} \times 1000 \times 1000$$

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	06/06/2023	07/06/2023	07/06/2023

Where,

AT_K = Area of Impurity K peak in Test solution.

AS_K = Area of the Impurity K peak in the Reference solution (d)

RS = Weight of the Impurity K Reference standard in mg.

WT = Weight of the sample taken in mg.

P = Potency of Impurity K Reference standard in % (as such basis).

Impurity J : (NMT 10ppm)

$$= \frac{AT_J}{AS_J} \times \frac{RS}{250} \times \frac{1}{200} \times \frac{5}{WT} \times \frac{P_J}{100} \times 1000 \times 1000$$

Where,

AT_J = Area of Impurity J peak in Test solution.

AS_J = Area of the Impurity J peak in the Reference solution (b)

RS = Weight of the Impurity J Reference standard in mg.

WT = Weight of the sample taken in mg.

P = Potency of Impurity J Reference standard in % (as such basis).

Unspecified impurity: (NMT 0.05%)

$$= \frac{AT_I}{AS} \times \frac{WT}{5} \times \frac{1}{100} \times \frac{1}{20} \times \frac{5}{WT} \times 100$$

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	06/06/2023	07/06/2023	07/06/2023

Where,

AT_I = Area of Unspecified impurity peak in Test solution.

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

WT = Weight of the sample taken in mg.

Total impurities: (NMT 0.2%)

$$= \frac{AT_T}{AS} \times \frac{WT}{5} \times \frac{1}{100} \times \frac{1}{20} \times \frac{5}{WT} \times 100$$

Where,

AT_T = Area of Total impurities peak in Test solution.

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

WT = Weight of the Test solution in mg.

5. SULPHATED ASH: < REFER GAM 032>

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

6. LOSS ON DRYING: < REFER GAM 026>

Not more than 0.5% w/w, determined on 1.0g of sample by drying in an oven at 105°C.

7. ASSAY: (By Titration)

Weigh accurately about 0.300g of sample in a mixture of 10mL of water and 30mL of dilute sulfuric acid. Boil under a reflux condenser for 1 h, cool and dilute to 100.0mL with water. To 20.0mL of the solution add 40mL of water, 40g of ice, 15mL of dilute hydrochloric acid and 0.1mL of ferroin. Titrate with 0.1M cerium sulfate until a greenish-yellow colour is obtained. Carry out a blank titration

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	06/06/2023	07/06/2023	07/06/2023

Safetab Life Science QUALITY ASSURANCE Puducherry-107

1ml of 0.1M Cerium sulphate is equivalent to 0.00756g of Paracetamol.

Calculation:

$$= \frac{\text{Blank-Titer value} \times \text{Molarity of 0.1M Cerium sulphate} \times 0.00756 \times 100 \times 100 \times 100}{20 \times \text{Sample weight in (g)} \times (100 - \text{Sample LOD}) \times 0.1}$$

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
STP-RMAP0030-02	(i) Related substance test procedure has been changed as per BP 2023 (ii) STP numbering procedure revised as per SOP No. ST/QC/058.	ST/CC/23/084 ST/CC/23/063	08/06/2023

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

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

Safetab Life Science QUALITY ASSURANCE Puducherry-607

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	PHENYLEPHRINE HYDROCHLORIDE BP			
Specification No.	RMASP0031-01	**Revision No.**	01	**Item Code.:** RMAP0031
Supersedes	RMASP0031-00	**Effective Date**	20/02/2023	**Page No.:** 1 of 4

S.NO	RAW MATERIAL GENERAL SPECIFICATION (s)	
1	Molecular formula	$C_9H_{14}CINO_2$
2	Molecular weight	203.7
3	Storage conditions	Protected from light
4	Precautions & Special instructions for sampling	Use hand gloves and nose mask while sampling. Reseal the containers immediately after sampling. Avoid inhaling.
5	Quantity of sample required for analysis	6 g
6	Quantity of reserve sample	12 g
7	Retest period	12 months from the date of release
8	Re-test Parameter	As mentioned in Specification
9	Reference	BP
10	Sampling instruction	Follow the standard operating procedure No.: ST/QC/040.
11	Destructions instructions	Follow the standard operating procedure No.: ST/QC/032.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	16/02/2023	17/02/2023	18/02/2023

	Safetab Life Science Puducherry			MASTER COPY
	RAW MATERIAL SPECIFICATION			
Name of Product	PHENYLEPHRINE HYDROCHLORIDE BP			
Specification No.	RMASP0031-01	**Revision No.**	01	**Item Code.:** RMAP0031
Supersedes	RMASP0031-00	**Effective Date**	20/02/2023	**Page No.:** 2 of 4

S.NO	TEST (s)	SPECIFICATION (s)
1.	*Description	White or almost white, crystalline powder.
2.	*Solubility	Freely soluble in water and in ethanol (96 per cent).
3.	*Identification	
	A. By Specific optical rotation	Between -43° to -47° (dried substance)
	B. By Melting point	Between 171°C to 176°C.
	C. By IR	The Infrared absorption spectrum of sample should be concordant with that of reference spectrum or with the spectrum obtained from Phenylephrine Hydrochloride RS.
	D. By Chemical test	The upper layer remains colourless.
	E. By Chlorides	A curdled, white precipitate is formed
4.	Appearance of solution	Solution S is clear and colourless
5.	Acidity or alkalinity	The solution is yellow. Not more than 0.4 mL of 0.01 M hydrochloric acid is required to change the colour of the indicator to red.
6.	*Specific optical rotation	-43° to -47° (dried substance)

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	16/02/2023	17/02/2023	18/02/2023

S.NO	TEST (s)	SPECIFICATION (s)
7.	*Related substances (By HPLC) (i) Impurity C (ii) Impurity E (iii) Unspecified impurity (iv) Total impurities	 Not more than 0.1% Not more than 0.1% Not more than 0.1% Not more than 0.2%
8.	Sulfates	Maximum 500ppm
9.	Sulfated ash	Not more than 0.1%
10.	*Loss on drying	Not more than 1.0%
11.	*Assay (By Titration) (On dried basis)	Not more than 98.5% and not more than 101.0% w/w

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

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	K.SARAVANAN	M.VIJAYAKUMAR	K.JAYARAJ
Designation	Asst. Manager-QC	AGM-QC	Asst. Manager-QA
Signature			
Date	16/02/2023	17/02/2023	18/02/2023

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
RMASP0031-01	Periodic review.	NA	20/02/2023

**** 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	16/02/2023	17/02/2023	18/02/2023

	Safetab Life Science Puducherry			MASTER COPY
	STANDARD TESTING PROCEDURE			
Name of Product	PHENYLEPHRINE HYDROCHLORIDE BP			
STP No.	RMATP0031-01	**Revision No.**	01	**Item Code.:** RMAP0031
Supersedes	RMATP0031-00	**Effective Date**	20/2/2023	**Page No.:** 1 of 9

1. DESCRIPTION: < REFER GAM 001>

White or almost white, crystalline powder.

2. SOLUBILITY: < REFER GAM 002>

100mg of sample + 1mL of Water	Freely soluble if the material dissolves.
100mg of sample + 1mL of Ethanol (96%)	Freely soluble if the material dissolves.

3. IDENTIFICATION:

First identification: A, C, E

Second identification: A, B, D, E

A. By Specific optical rotation: < REFER GAM 029>

Between -43° to -47° (dried substance)

B. By Melting point: < REFER GAM 028>

Between 171°C to 176°C.

Dissolve 0.3 g in 3 mL of water, add 1 mL of dilute ammonia and initiate crystallisation by scratching the wall of the tube with a glass rod. Wash the crystals with iced water and dry at 105 °C for 2 h.

C. By IR: < REFER GAM 003>

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

D. By Chemical test:

Dissolve about 10 mg in 1 mL of water and add 0.05 mL of a 125 g/L solution of copper sulfate pentahydrate and 1 mL of a 200 g/L solution of sodium hydroxide. A violet colour is produced. Add 1 mL of ether and shake; the upper layer remains colourless.

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	16/02/2023	17/02/2023	18/02/2023

E. By Chlorides: < REFER GAM 003>

Dissolve in 2 mL of water a quantity of the substance to be examined equivalent to about 2 mg of chloride Acidify with dilute nitric acid and add 0.4 mL of silver nitrate solution. Shake and allow to stand. A curdled, white precipitate is formed.

Centrifuge and wash the precipitate with three quantities, each of 1 mL, of water. Carry out this operation rapidly in subdued light, disregarding the fact that the supernatant solution may not become perfectly clear. Suspend the precipitate in 2 mL of water and add 1.5 mL of ammonia. The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.

4. APPEARANCE OF SOLUTION:

Solution S:

Dissolve 2.00 g in carbon dioxide-free water prepared from distilled water and dilute to 100.0 mL with the same solvent.

Solution S is clear and colourless.

5. ACIDITY OR ALKALINITY:

To 10 mL of solution S add 0.1 mL of methyl red solution and 0.2 mL of 0.01 M sodium hydroxide. The solution is yellow. Not more than 0.4 mL of 0.01 M hydrochloric acid is required to change the colour of the indicator to red.

6. SPECIFIC OPTICAL ROTATION: < REFER GAM 029>

Between -43° to -47° (dried substance), determined on solution S.

7. RELATED SUBSTANCES: (BY HPLC)

Chemicals/Reagents/Standards:

Phenylephrine Hydrochloride : Working standard

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Date	16/02/2023	17/02/2023	18/02/2023

Phenylephrine Hydrochloride for peak identification	:	Reference standard
Sodium octanesulfonate monohydrate	:	AR grade
Phosphoric acid	:	AR grade
Purified Water	:	Milli-Q water (or) equivalent
Acetonitrile	:	HPLC grade

Chromatographic Conditions:

Column	:	Purospher STAR RP-18 endcapped, 55mm x 4.0mm, (3.0µm) or equivalent.
Column Temperature	:	45°C
Flow Rate	:	1.5ml/min
Wavelength	:	215nm
Injection volume	:	10µl
Retention time	:	Retention time of Phenylephrine hydrochloride peak is at about 2.8 minutes

Buffer solution pH 2.8:

Dissolve 3.25 g of Sodium octanesulfonate monohydrate in 1000 mL of water by stirring for 30 min and adjust to pH 2.8 with dilute phosphoric acid.

Mobile phase A:

Acetonitrile, buffer solution pH 2.8 (10:90 V/V);

Mobile phase B:

Buffer solution pH 2.8, Acetonitrile(10:90 V/V);

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Gradient program:

Time (min)	Mobile phase A (per cent V/V)	Mobile phase B (per cent V/V)
0 - 3	93	7
3 - 13	93 → 70	7 → 30
13 - 14	70 → 93	30 → 7

Solvent mixture:

Mobile phase B, mobile phase A (20:80 V/V).

Test solution:

Weigh accurately about 50.0 mg of the substance to be examined in the solvent mixture and dilute to 50.0 mL with the solvent mixture.

Reference solution (a):

Dilute 5.0 mL of the test solution to 100.0 mL with the solvent mixture. Dilute 2.0 mL of this solution to 100.0 mL with the solvent mixture.

Reference solution (b):

Dissolve the contents of a vial of phenylephrine hydrochloride for peak identification RS (containing impurities C and E) in 2.0 mL of the solvent mixture.

Relative retention With reference to phenylephrine (retention time = about 2.8 min): impurity C = about 1.3; impurity E = about 3.6.

System suitability:

— **Symmetry factor:** maximum 1.9 for the principal peak in the chromatogram obtained with the test solution;

— **Peak-to-valley ratio:** minimum 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 phenylephrine in the chromatogram obtained with reference solution (b).

Limits:

— **Correction factors:** for the calculation of content, multiply the peak areas of the following impurities by the corresponding correction factor: impurity C = 0.5; impurity E = 0.5;

— **impurities C, E:** for each impurity, not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (0.1 per cent);

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

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

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

Inject 10µl of the above solution as per following sequence.

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Injection sequence:

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

Calculations:

Impurity C: (NMT 0.1%)

$$= \frac{A_{TC}}{A_{SC}} \times \frac{WT}{50} \times \frac{5}{100} \times \frac{2}{100} \times \frac{50}{WT} \times 0.5 \times 100$$

Where,

A_{TC} = Area of Impurity C peak in Test solution.

A_{SC} = Area of the principal peak in the Reference solution (a)

WT = Weight of the sample taken in mg.

Impurity E: (NMT 0.1%)

$$= \frac{A_{TE}}{A_{SE}} \times \frac{WT}{50} \times \frac{5}{100} \times \frac{2}{100} \times \frac{50}{WT} \times 0.5 \times 100$$

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Where,

AT_E = Area of Impurity E peak in Test solution.

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

WT = Weight of the sample taken in mg.

Unspecified impurity: (NMT 0.1%)

$$= \frac{AT_I}{AS_I} \times \frac{WS}{50} \times \frac{5}{100} \times \frac{2}{100} \times \frac{50}{WT} \times 100$$

Where,

AT_I = Area of Unspecified impurity peak in Test solution.

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

WT = Weight of the sample taken in mg.

Total impurities: (NMT 0.2%)

$$= \frac{AT_T}{AS_T} \times \frac{WS}{50} \times \frac{5}{100} \times \frac{2}{100} \times \frac{50}{WT} \times 100$$

Where,

AT_T = Area of All impurities peak in Test solution.

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

WT = Weight of the sample taken in mg.

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Note: Calculate the content of Impurity C and Impurity E areas with multiply the respective correction factor.

8. SULFATES: < REFER GAM 009>

Maximum 500 ppm, determined on solution S.

9. SULPHATED ASH: < REFER GAM 032>

Maximum 0.1%. Determine on 1.0g of sample.

10. LOSS ON DRYING: < REFER GAM 026>

Maximum 1.0 per cent, determined on 1.000 g by drying in an oven at 105 °C.

11. ASSAY: (By Titration)

Weigh accurately and dissolve about 0.150 g in a mixture of 0.5 mL of 0.1 M hydrochloric acid and 80 mL of ethanol (96 per cent). Carry out a potentiometric titration using 0.1M ethanolic sodium hydroxide. Read the volume added between the 2 points of inflexion.

1 mL of 0.1M ethanolic sodium hydroxide is equivalent to 0.02037g of $C_9H_{14}ClNO_2$.

Calculation:

$$= \frac{\text{Titer value x 0.1M ethanolic sodium hydroxide x 0.02037g x100 x 100}}{\text{Sample weight in (g) X (100 – Sample LOD) x 0.1}}$$

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REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
RMATP0031-01	Periodic review.	NA	20/02/2023

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

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