
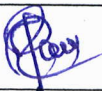


	<b>Safetab Life Science</b> Puducherry			<b>MASTER COPY</b>	
	<b>PRODUCT SPECIFICATION</b>				
					<b>Market</b>
<b>Name of Product</b>	<b>RICHFER CAPSULES</b> (Carbonyl Iron, Folic acid, Cyanocobalamin, Ascorbic acid, Zinc, Alpha Tocopheryl Acetate and Selenium Capsules)				
<b>Specification No.</b>	SPEC-1047-02	<b>Revision No.</b>	02	<b>Product Code:</b> 1047	
<b>Supersedes</b>	SPEC-1047-01	<b>Effective Date:</b>	07/11/2024	<b>Page No.:</b> 1 of 11	

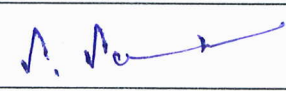

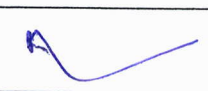
S.NO	GENERAL SPECIFICATION (s)	
1	Pharmacopoeial Reference	In-House
2	Label claim	Each hard gelatin capsule contains: Carbonyl Iron Equivalent to Elemental iron -----100mg Folic Acid BP -----500mcg Cyanocobalamin (Vitamin B12)----- 15mcg (Coated) Ascorbic Acid (coated) ----- 75mg Zinc Sulphate monohydrate BP ----- 61.8 mg (Equivalent to elemental zinc 22.5mg) Alpha Tocopheryl Acetate BP ----- 15IU Sodium selenate Equivalent to Selenium ----- 65mcg
3	Standard packing	3×10's Blister packing
4	Shelf Life	36 Months
5	In-Process Sample Quantity	a) In-process Intermediate – Blend, 50g. d) Intermediate-Filled capsules - 100capsules
6	Finished Product sample quantity	For Microbial contamination Test : 30 capsules For Chemical Analysis : 100 capsules For Control sample : 260 capsules
7	Stability studies sample quantity	For Accelerated study : 300 capsules For Long term study : 1020 capsules For Annual study : 840 capsules
8	Storage condition	Store below 30°C. Protect from light and moisture.
9	Destructions Instructions	Follow the Standard Operating Procedure: ST/QC/032.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	S.SANTHI	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	04/11/24	05/11/2024	06/11/2024


	<b>Safetab Life Science</b> <b>Puducherry</b>		<div style="border: 1px solid black; padding: 5px; text-align: center;">MASTER COPY</div>	
	<b>PRODUCT SPECIFICATION</b>			
			<b>Market</b>	<b>Export</b>
<b>Name of Product</b>	<b>RICHFER CAPSULES</b> (Carbonyl Iron, Folic acid, Cyanocobalamin, Ascorbic acid, Zinc, Alpha Tocopheryl Acetate and Selenium Capsules)			
<b>Specification No.</b>	SPEC-1047-02	<b>Revision No.</b>	02	<b>Product Code:</b> 1047
<b>Supersedes</b>	SPEC-1047-01	<b>Effective Date:</b>	07/11/2024	<b>Page No.:</b> 2 of 11

**RELEASE SPECIFICATION FOR INTERMEDIATE – BLEND**  
**SPECIFICATION CODE: SPEC-1047-BLD**

S.NO	TEST (s)	SPECIFICATION (s)
1.0	Description	Grey colour granular powder
2.0	<b>Assay: Each 500mg blend contains:</b>  a) Carbonyl Iron Equivalent to Elemental iron      100mg  b) Folic Acid BP      500mcg  c) Cyanocobalamin(Vitamin B12) 15mcg (coated)  d) Ascorbic Acid (Coated)      75mg  e) Zinc Sulphate monohydrate BP      61.8 mg (Equivalent to elemental zinc 22.5mg)  f) Alpha Tocopheryl Acetate BP      15IU  g) Sodium selenate Equivalent to Selenium      65mcg	95.0mg to 110.0mg (95.0% to 110.0% of the labeled claim)  Not less than 475.0mcg (Not less than 95.0% of the labeled claim)  Not less than 14.25mcg (Not less than 95.0% of the labeled claim)  Not less than 71.25mg (Not less than 95.0% of the labeled claim)  Not less than 21.3mg (Not less than 95.0% of the labeled claim)  Not less than 14.25IU (Not less than 95.0% of the labeled claim)  Not less than 61.75mcg (Not less than 95.0% of the labeled claim)




Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	S.SANTHI	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	04/11/24	05/11/2024	06/11/2024



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	<b>PRODUCT SPECIFICATION</b>			<b>Market</b>	<b>Export</b>
	<b>Name of Product</b>				<b>Richfer Capsules</b> (Carbonyl Iron, Folic acid, Cyanocobalamin, Ascorbic acid, Zinc, Alpha Tocopheryl Acetate and Selenium Capsules)
<b>Specification No.</b>	SPEC-1047-02	<b>Revision No.</b>	02	<b>Product Code:</b> 1047	
<b>Supersedes</b>	SPEC-1047-01	<b>Effective Date:</b>	07/11/2024	<b>Page No.:</b> 3 of 11	


**RELEASE SPECIFICATION FOR INTERMEDIATE- FILLED CAPSULES**  
**SPECIFICATION CODE: SPEC-1047-FC**

S.NO	TEST (s)	SPECIFICATION (s)
1.0	Description	Red/Red coloured, '0' size GHPL printed hard gelatin capsule filled with Grey colour granular powder.
2.0	<b>Identification</b>  a) Carbonyl Iron (By UV)  b) Folic acid (By HPLC)  c) Cyanocobalamin (By Microbiological Method)  d) Ascorbic acid (By Titration)  e) Zinc sulphate monohydrate (By AAS)  f) Alpha Tocopheryl Acetate (By HPLC)  g) Sodium Selenate (By AAS)	<p>The maximum absorbance of sample solution for Carbonyl Iron is corresponds to that of standard absorbance as obtained in the assay procedure.</p> <p>The retention time of major peak in the chromatogram of the assay preparation should corresponds to that of standard preparation as directed under the assay of Folic acid.</p> <p>Positive to the presence of Cyanocobalamin.</p> <p>Positive to the presence of Ascorbic acid.</p> <p>The maximum absorbance of sample solution for Zinc sulphate monohydrate is corresponds to that of standard absorbance as obtained in the assay procedure.</p> <p>The retention time of major peak in the chromatogram of the assay preparation should corresponds to that of standard preparation as directed under the assay of Alpha Tocopheryl Acetate.</p> <p>The maximum absorbance of sample solution for Sodium Selenate is corresponds to that of standard absorbance as obtained in the assay procedure.</p>

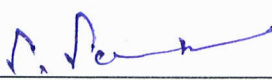


Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	S.SANTHI	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	04/11/24	05/11/2024	06/11/2024


Format No: ST/QC/058:A1



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	<b>PRODUCT SPECIFICATION</b>		<b>Market</b>	<b>Export</b>
<b>Name of Product</b>	<b>RICHFER CAPSULES</b> (Carbonyl Iron, Folic acid, Cyanocobalamin, Ascorbic acid, Zinc, Alpha Tocopheryl Acetate and Selenium Capsules)			
<b>Specification No.</b>	SPEC-1047-02	<b>Revision No.</b>	02	<b>Product Code:</b> 1047
<b>Supersedes</b>	SPEC-1047-01	<b>Effective Date:</b>	07/11/2024	<b>Page No.:</b> 5 of 11


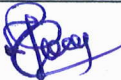

S.NO	TEST (s)	SPECIFICATION (s)
	e) Zinc Sulphate monohydrate BP 61.8 mg (Equivalent to elemental zinc 22.5mg)	Not less than 21.3mg (Not less than 95.0% of the labeled claim)
	f) Alpha Tocopheryl Acetate BP 15IU	Not less than 14.25IU (Not less than 95.0% of the labeled claim)
	g) Sodium selenate Equivalent to Selenium 65mcg	Not less than 61.75mcg (Not less than 95.0% of the labeled claim)

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	S.SANTHI	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	04/11/24	05/11/2024	06/11/2024

	<b>Safetab Life Science</b> Puducherry			<div>MASTER COPY</div>
	<b>PRODUCT SPECIFICATION</b>			
				<b>Market</b>
<b>Name of Product</b>	<b>RICHFER CAPSULES</b> (Carbonyl Iron, Folic acid, Cyanocobalamin, Ascorbic acid, Zinc, Alpha Tocopheryl Acetate and Selenium Capsules)			
<b>Specification No.</b>	SPEC-1047-02	<b>Revision No.</b>	02	<b>Product Code:</b> 1047
<b>Supersedes</b>	SPEC-1047-01	<b>Effective Date:</b>	07/11/2024	<b>Page No.:</b> 6 of 11


**RELEASE SPECIFICATION – FINISHED PRODUCT**  
**SPECIFICATION CODE: SPEC-1047-FP**

S.NO	TEST (s)	SPECIFICATION (s)
1.0	Description	Red/Red coloured, '0' size GHPL printed hard gelatin capsule filled with Grey colour granular powder.
2.0	<b>Identification*</b>  a) Carbonyl Iron (By UV)  b) Folic acid (By HPLC)  c) Cyanocobalamin (By Microbiological Method)  d) Ascorbic acid (By Titration)  e) Zinc sulphate monohydrate (By AAS)  f) Alpha Tocopheryl Acetate (By HPLC)  g) Sodium Selenate (By AAS)	The maximum absorbance of sample solution for Carbonyl Iron is corresponds to that of standard absorbance as obtained in the assay procedure.  The retention time of major peak in the chromatogram of the assay preparation should corresponds to that of standard preparation as directed under the assay of Folic acid.  Positive to the presence of Cyanocobalamin.  Positive to the presence of Ascorbic acid.  The maximum absorbance of sample solution for Zinc sulphate monohydrate is corresponds to that of standard absorbance as obtained in the assay procedure.  The retention time of major peak in the chromatogram of the assay preparation should corresponds to that of standard preparation as directed under the assay of Alpha Tocopheryl Acetate.  The maximum absorbance of sample solution for Sodium Selenate is corresponds to that of standard absorbance as obtained in the assay procedure.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
<b>Name</b>	S.SANTHI	M.VIJAYAKUMAR	S.MARAN
<b>Designation</b>	Asst. Manager-QC	GM-QC	AGM-QA
<b>Signature</b>			
<b>Date</b>	04/11/24	05/11/2024	06/11/2024

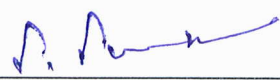







	<b>Safetab Life Science</b> Puducherry			<div>MASTER COPY</div>	
	<b>PRODUCT SPECIFICATION</b>				
				<b>Market</b>	Export
<b>Name of Product</b>	<b>RICHFER CAPSULES</b> (Carbonyl Iron, Folic acid, Cyanocobalamin, Ascorbic acid, Zinc, Alpha Tocopheryl Acetate and Selenium Capsules)				
<b>Specification No.</b>	SPEC-1047-02	<b>Revision No.</b>	02	<b>Product Code:</b> 1047	
<b>Supersedes</b>	SPEC-1047-01	<b>Effective Date:</b>	07/11/2024	<b>Page No.:</b> 8 of 11	

S.NO	TEST (s)	SPECIFICATION (s)
	e) Zinc Sulphate monohydrate BP 61.8 mg(Equivalent to elemental zinc 22.5mg)  f) Alpha Tocopheryl Acetate BP 15IU  g) Sodium selenate Equivalent to Selenium 65mcg	Not less than 21.3mg (Not less than 95.0% of the labeled claim)  Not less than 14.25IU (Not less than 95.0% of the labeled claim)  Not less than 61.75mcg (Not less than 95.0% of the labeled claim)
<b>8.0</b>	<b>Microbial contamination</b>  i) Total Viable aerobic count a) Total aerobic microbial count b) Total yeast and mould count  ii) Escherichia Coli  iii) Salmonella Species  iv) Pseudomonas aeruginosa  v) Staphylococcus aureus	Not more than 1000 cfu/g  Not more than 100 cfu/g  Should be absent/g  Should be absent/10g  Should be absent/g  Should be absent/g

**Note:** \* Marked Test results shall be taken from Filled capsules.




Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
<b>Name</b>	<b>S.SANTHI</b>	<b>M.VIJAYAKUMAR</b>	<b>S.MARAN</b>
<b>Designation</b>	<b>Asst. Manager-QC</b>	<b>GM-QC</b>	<b>AGM-QA</b>
<b>Signature</b>			
<b>Date</b>	04/11/24	05/11/2024	06/11/2024




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	PRODUCT SPECIFICATION			
			Market	Export
Name of Product	RICHFER CAPSULES (Carbonyl Iron, Folic acid, Cyanocobalamin, Ascorbic acid, Zinc, Alpha Tocopheryl Acetate and Selenium Capsules)			
Specification No.	SPEC-1047-02	Revision No.	02	Product Code:1047
Supersedes	SPEC-1047-01	Effective Date:	01/11/2024	Page No.: 9 of 11

**STABILITY SPECIFICATION**  
**SPECIFICATION CODE: SPEC-1047-ST**

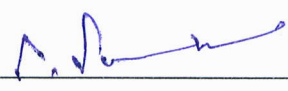


S.NO	TEST (s)	SPECIFICATION (s)
1.0	Description	Red/Red coloured, '0' size GHPL printed hard gelatin capsule filled with Grey colour granular powder.
2.0	Average weight of capsule	596.0mg $\pm$ 5.0% (566.2 – 625.8 mg)
3.0	Average net weight of capsule	500.0mg $\pm$ 5.0% (475.0 – 525.0 mg)
4.0	Disintegration time	Not more than 30 minutes
5.0	<b>Assay: Each hard gelatin capsule contains:</b>  a) Carbonyl Iron Equivalent to Elemental iron 100mg  b) Folic Acid BP 500mcg  c) Cyanocobalamin(Vitamin B12) 15mcg (Coated)  d) Ascorbic Acid (Coated) 75mg	90.0mg to 110.0mg (90.0% to 110.0% of the labeled claim)  Not less than 450.0mcg (Not less than 90.0% of the labeled claim)  Not less than 13.5mcg (Not less than 90.0% of the labeled claim)  Not less than 67.5mg (Not less than 90.0% of the labeled claim)

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
<b>Name</b>	<b>S.SANTHI</b>	<b>M.VIJAYAKUMAR</b>	<b>S.MARAN</b>
<b>Designation</b>	<b>Asst. Manager-QC</b>	<b>GM-QC</b>	<b>AGM-QA</b>
<b>Signature</b>			
<b>Date</b>	04/11/24	05/11/2024	06/11/2024


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	<b>PRODUCT SPECIFICATION</b>			
				<b>Market</b>
<b>Name of Product</b>	<b>RICHFER CAPSULES</b> (Carbonyl Iron, Folic acid, Cyanocobalamin, Ascorbic acid, Zinc, Alpha Tocopheryl Acetate and Selenium Capsules)			
<b>Specification No.</b>	SPEC-1047-02	<b>Revision No.</b>	02	<b>Product Code:</b> 1047
<b>Supersedes</b>	SPEC-1047-01	<b>Effective Date:</b>	07/11/2024	<b>Page No.:</b> 10 of 11

S.NO	TEST (s)	SPECIFICATION (s)
	e) Zinc Sulphate monohydrate BP 61.8 mg(Equivalent to elemental zinc 22.5mg)  f) Alpha Tocopheryl Acetate BP 15IU  g) Sodium selenate Equivalent to Selenium 65mcg	Not less than 20.2mg (Not less than 90.0% of the labeled claim)  Not less than 13.5IU (Not less than 90.0% of the labeled claim)  Not less than 58.5mcg (Not less than 90.0% of the labeled claim)
6.0	<b>Microbial contamination#</b>  i) Total Viable aerobic count a) Total aerobic microbial count b) Total yeast and mould count  ii) Escherichia Coli  iii) Salmonella Species  iv) Pseudomonas aeruginosa  v) Staphylococcus aureus	Not more than 1000 cfu/g  Not more than 100 cfu/g  Should be absent/g  Should be absent/10g  Should be absent/g  Should be absent/g

# Mark test will performed on 6<sup>th</sup> month of Accelerated stability and every 12<sup>th</sup> month of Long term stability.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	S.SANTHI	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	04/11/24	05/11/2024	06/11/2024

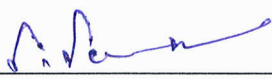
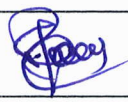




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	<b>PRODUCT SPECIFICATION</b>		<b>Market</b>	Export
<b>Name of Product</b>	<b>RICHFER CAPSULES</b> (Carbonyl Iron, Folic acid, Cyanocobalamin, Ascorbic acid, Zinc, Alpha Tocopheryl Acetate and Selenium Capsules)			
<b>Specification No.</b>	SPEC-1047-02	<b>Revision No.</b>	02	<b>Product Code:</b> 1047
<b>Supersedes</b>	SPEC-1047-01	<b>Effective Date:</b>	07/11/2024	<b>Page No.:</b> 11 of 11

**REVISION HISTORY:**


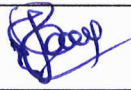

Specification No.	Reason for Review	Change control No.	Effective Date
SPEC-1047-00	Specification number and Format has revised as per SOP No. ST/QC/058.	ST/CC/22/119	18/03/2023
SPEC-1047-01	There is no changes in specification	ST/CC/24/078	22/04/2024
SPEC-1047-02	There is no changes in specification	ST/CC/24/268	07/11/2024

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


Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	S.SANTHI	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	04/11/24	05/11/2024	06/11/2024

	<b>Safetab Life Science</b> Puducherry		<div style="border: 1px solid black; padding: 5px; text-align: center;">MASTER COPY</div>	
	<b>STANDARD TESTING PROCEDURE</b>			
		<b>Market</b>		<b>Export</b>
<b>Name of Product</b>	<b>RICHFER CAPSULES</b> (Carbonyl Iron, Folic acid, Cyanocobalamin, Ascorbic acid, Zinc, Alpha Tocopheryl Acetate and Selenium Capsules)			
<b>STP No.</b>	STP-1047-02	<b>Revision No.</b>	02	<b>Product Code:</b> 1047
<b>Supersedes</b>	STP-1047-01	<b>Effective Date:</b>	01/11/2024	<b>Page No.:</b> 1 of 28

<b>1.0</b>	<b><u>DESCRIPTION:</u></b> (By Visual Inspection)  <b>Blend:</b> Spread about 1 to 2 g of sample on a white surface and note the observation.  <b>Capsules:</b> Take 10 capsules on a white background and note the colour, shape and other observations, remove the content from the capsules and note down of the appearance of the pellets and if any.
<b>2.0</b>	<b><u>IDENTIFICATION:</u></b>  <b>a) Carbonyl Iron (By UV):</b>  The maximum absorbance of sample solution for Carbonyl Iron is corresponds to that of standard absorbance as obtained in the assay procedure.  <b>b) Folic acid (By HPLC):</b>  The retention time of major peak in the chromatogram of the assay preparation should corresponds to that of standard preparation as directed under the assay of Folic acid.  <b>c) Cyanocobalamin (By Microbiological Method):</b>  Positive to the presence of Cyanocobalamin.  <b>d) Ascorbic acid (By Titration):</b>  Positive to the presence of Ascorbic acid.  <b>e) Zinc sulphate monohydrate (By AAS):</b>  The maximum absorbance of sample solution for Zinc sulphate monohydrate is corresponds to that of standard absorbance as obtained in the assay procedure.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	S.SANTHI	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	04/11/24	05/11/2024	06/11/2024



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	<b>STANDARD TESTING PROCEDURE</b>			
			Market	Export
<b>Name of Product</b>	<b>RICHFER CAPSULES</b> (Carbonyl Iron, Folic acid, Cyanocobalamin, Ascorbic acid, Zinc, Alpha Tocopheryl Acetate and Selenium Capsules)			
<b>STP No.</b>	STP-1047-02	<b>Revision No.</b>	02	<b>Product Code:</b> 1047
<b>Supersedes</b>	STP-1047-01	<b>Effective Date:</b>	01/11/2024	<b>Page No.:</b> 2 of 28

**f) Alpha Tocopheryl Acetate (By HPLC):**

The retention time of major peak in the chromatogram of the assay preparation should corresponds to that of standard preparation as directed under the assay of Alpha Tocopheryl Acetate.

**g) Sodium Selenate (By AAS):**

The maximum absorbance of sample solution for Sodium Selenate is corresponds to that of standard absorbance as obtained in the assay procedure.

**3.0 AVERAGE WEIGHT OF CAPSULE:**

Weigh and note down the weight of 20 intact capsules

$$\text{Average weight of filled capsule (in mg)} = \frac{\text{Weight of 20 capsules (g)}}{20} \times 1000$$

**4.0 AVERAGE NET WEIGHT OF CAPSULE:**

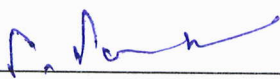


Weigh 20 intact capsules remove the contents from each capsule by suitable means accurately weigh the 20 emptied shells and calculate the net filled content.


$$\text{Average net filled content (in mg)} = \frac{(W1 - W2)}{20} \times 1000$$

Where ,


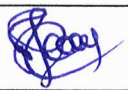

W1= Total weight of 20 intact capsules, in g.

W2= Total weight of 20 empty capsules shells, in g


Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	S.SANTHI	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	04/11/24	05/11/2024	06/11/2024

	<b>Safetab Life Science</b> <b>Puducherry</b>		<div style="border: 1px solid black; padding: 2px; display: inline-block;">MASTER COPY</div>	
	<b>STANDARD TESTING PROCEDURE</b>		<b>Market</b>	<b>Export</b>
<b>Name of Product</b>	<b>RICHFER CAPSULES</b> (Carbonyl Iron, Folic acid, Cyanocobalamin, Ascorbic acid, Zinc, Alpha Tocopheryl Acetate and Selenium Capsules)			
<b>STP No.</b>	STP-1047-02	<b>Revision No.</b>	02	<b>Product Code:</b> 1047
<b>Supersedes</b>	STP-1047-01	<b>Effective Date:</b>	07/11/2024	<b>Page No.:</b> 3 of 28




<b>5.0</b>	<p><b><u>UNIFORMITY OF NET WEIGHT: (Capsules)</u></b></p> <p>Select 20 capsules at random from a particular lot or batch Weigh an intact capsules, Open the capsules without losing any part of the shell and remove the contents as completely as possible Weigh the shell The mass of the content is the difference between the weighing of the intact capsules and emptied capsule shell. Repeat the same procedure for further 19 capsules selected at random.</p> <p>Determine the average mass of the capsules by the following formula</p> $\text{Average mass} = \frac{M_1 + M_2 + M_3 + \dots + M_{20}}{20}$ <p>Where,</p> <p>M = mass of the contents of capsules 1, 2, 3... 20.          20= No. of capsules taken.</p> <p><b>Acceptance criteria:</b></p> <p>The average mass of the capsule should comply with the limits specified in the individual specification monograph. Not more than two of the individual masses deviate from the average mass by more than percentage deviation shown in table and none deviates by more than twice that percentage.</p> <table border="1" style="width: 100%; text-align: center;"> <thead> <tr> <th>Average mass of the capsule content</th> <th>Percentage deviation</th> </tr> </thead> <tbody> <tr> <td>Less than 300 mg</td> <td>± 10</td> </tr> <tr> <td>300 mg or more</td> <td>± 7.5</td> </tr> </tbody> </table>	Average mass of the capsule content	Percentage deviation	Less than 300 mg	± 10	300 mg or more	± 7.5
Average mass of the capsule content	Percentage deviation						
Less than 300 mg	± 10						
300 mg or more	± 7.5						


<b>Particulars</b>	<b>PREPARED BY</b>	<b>REVIEWED BY</b>	<b>APPROVED BY</b>
<b>Name</b>	S.SANTHI	M.VIJAYAKUMAR	S.MARAN
<b>Designation</b>	Asst. Manager-QC	GM-QC	AGM-QA
<b>Signature</b>			
<b>Date</b>	09/11/24	05/11/2024	06/11/2024






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	<b>STANDARD TESTING PROCEDURE</b>			
			Market	Export
<b>Name of Product</b>	<b>RICHFER CAPSULES</b> (Carbonyl Iron, Folic acid, Cyanocobalamin, Ascorbic acid, Zinc, Alpha Tocopheryl Acetate and Selenium Capsules)			
<b>STP No.</b>	STP-1047-02	<b>Revision No.</b>	02	<b>Product Code:</b> 1047
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	<p><b>Calculate the percentage deviation for the highest individual weight of content in capsule as follows:</b></p> <p>Highest individual net weight of capsule (in g)  [----- x100] -100  Average net weight of capsule (in g)</p> <p><b>Calculate the percentage deviation for the lowest individual weight of content in capsule as follows:</b></p> <p>Lowest individual net weight of capsule (in g)  [----- x100] -100  Average net weight of capsule (in g)</p>
<b>7.0</b>	<p><b><u>DISINTEGRATION TIME:</u></b></p> <p><b>For Capsules:</b></p> <p>Introduce one capsule into each tube of the disintegration testing apparatus. Add a disc to each tube suspend the assembly in the beaker containing water maintained at 37°C ± 2°C and operate the apparatus for 30 minutes. Observe all the capsules, if all the capsules are disintegrated completely within 30 minutes, lift the basket from the fluid and note down the time required. If 1 or 2 capsules fail to disintegrate completely, repeat the test on 12 additional capsules. The requirement is met if not fewer than 16 of the total of 18 capsules tested are disintegrated.</p>
<b>8.0</b>	<p><b><u>ASSAY:</u></b></p> <p><b>a) Elemental Iron:</b></p> <p><b>Reference:</b> In-House  <b>Procedure:</b> By UV</p>


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	<p><b>Chemicals/Reagents/Standards:</b></p> <p>           Ferrous ammonium sulphate hexahydrate : AR grade            Sulphuric acid : AR grade            Water : Purified            Sodium metabisulphite : AR grade            2-2, Bipyridyl dye : AR grade            Glacial acetic acid : AR grade            Sodium acetate : AR grade            Acetic acid : AR grade         </p> <p><b>Acetate buffer pH 4.7:</b></p> <p>To 0.3mL glacial acetic acid, add 0.681gms of sodium acetate and add 90ml of water. Adjust the pH to 4.7 with sodium acetate solution or acetic acid as required.</p> <p><b>Sodium metabisulphite solution:</b></p> <p>5.0g of Sodium metabisulphite in 100ml of water (5.0% w/v)</p> <p><b>2-2, Bipyridyl Solution:</b></p> <p>300mg of 2-2, Bipyridyl in 100ml of water. (0.3% w/v)</p> <p><b>Sulphuric acid solution:</b></p> <p>Add 10.0ml of sulphuric acid to about 80ml of water, mix well, cool and make up the volume to 100ml with water (10% v/v).</p> <p><b>Standard preparation:</b></p> <p>Weigh accurately and transfer about 175mg of Ferrous ammonium sulphate hexahydrate AR in to 100ml volumetric flask.</p>
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Add 20ml of Sulphuric acid solution heat on a water bath for about 30 minutes, cool and dilute to 100ml with water. Dilute 5ml of this solution to 100ml with water. **(Concentration:0.0125 mg/ml of Iron)**

**Sample preparation: (For blend)**

Weigh 5g granules and crush to fine powder. Weigh accurately and transfer about equivalent to 25mg of Iron in to 100ml volumetric flask. Add 20ml Sulphuric acid solution and heat on water bath for about 30 minutes, cool and dilute to 100ml with water and filter. Further dilute 5ml of this solution to 100ml with water.

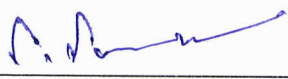


**Sample preparation: (For Capsules)**


Weigh 20 capsules and calculate the average net weight and crush to fine powder. Weigh accurately and transfer about equivalent to 25mg of Iron in to 100ml standard flask. Add 20ml Sulphuric acid solution and heat on water bath for about 30 minutes, cool and dilute to 100ml with water and filter. Dilute 5ml of this solution to 100ml with water. **(Concentration:0.0125 mg/ml of Iron)**

**Procedure:**

Take three 25ml volumetric volumetric flask and mark as standard, sample and reagent blank and add the solutions as given the table.

SOLUTIONS	STANDARD	SAMPLE	REAGENT BLANK
Standard solution	5.0mL	----	----
Sample solution	----	5.0mL	----
Water	----	----	5.0mL
Acetate buffer pH 4.7	5.0mL	5.0mL	5.0mL
Sodium metabisulphite solution	2.5mL	2.5mL	2.5mL
Allow to stand at room temperature for 15 minutes and add the following solution			
2-2, Bipridyl solution	2.5mL	2.5mL	2.5mL

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Shake well, and make up the volume to 25.0mL with water. Measure the absorbance at about 510 nm using reagent blank as blank solution.

**Calculate the assay of Carbonyl Iron Equivalent to Elemental Iron in mg/capsule as follows:**

$$\frac{\text{TABS}}{\text{SABS}} \times \frac{\text{WS}}{100} \times \frac{5}{100} \times \frac{100}{\text{WT}} \times \frac{100}{5} \times \frac{\text{P}}{100} \times \frac{55.845}{392.14} \times \text{ANW}$$

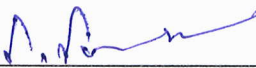


Where,

- TAB = Absorbance of Sample preparation.  
 SAB = Absorbance of Standard preparation.  
 WS = Weight of Ferrous ammonium sulphate hexahydrate.  
 WT = Weight of sample taken in mg.  
 55.845 = Molecular weight of Elemental Iron  
 392.14 = Molecular weight of Ferrous Ammonium sulphate hexahydrate.  
 ANW = Average net weight of the capsule in mg.


**Calculate the assay of Elemental Iron in % as follows:**

$$= \frac{\text{mg/capsule}}{\text{LC}} \times 100$$


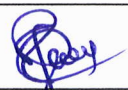

LC = Label claim of Carbonyl Iron equivalent to elemental iron in mg/capsule.


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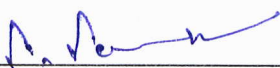


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			<b>Market</b>	Export
<b>Name of Product</b>	<b>RICHFER CAPSULES</b> (Carbonyl Iron, Folic acid, Cyanocobalamin, Ascorbic acid, Zinc, Alpha Tocopheryl Acetate and Selenium Capsules)			
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	<p><b>b) Folic acid:</b></p> <p><b>Reference:</b> In-House</p> <p><b>Procedure:</b> By HPLC</p> <p><b>Chemicals/Reagents/Standards:</b></p> <table style="width: 100%;"> <tr> <td>Folic acid</td> <td>: Working standard</td> </tr> <tr> <td>Potassium dihydrogen orthophosphate</td> <td>: AR grade</td> </tr> <tr> <td>Dipotassium hydrogen orthophosphate</td> <td>: AR grade</td> </tr> <tr> <td>Acetonitrile</td> <td>: HPLC grade</td> </tr> <tr> <td>Purified Water</td> <td>: Milli-Q water (or) equivalent</td> </tr> <tr> <td>Methanol</td> <td>: HPLC grade</td> </tr> <tr> <td>Sodium Hydroxide</td> <td>: AR grade</td> </tr> </table> <p><b>Chromatographic Conditions:</b></p> <table style="width: 100%;"> <tr> <td>Column</td> <td>: Inertsil ODS 3v C18 (250mmx 4.6mm) 5μ or equivalent</td> </tr> <tr> <td>Flow rate</td> <td>: 0.8ml/min</td> </tr> <tr> <td>Wavelength</td> <td>: 280 nm</td> </tr> <tr> <td>Injection Volume</td> <td>: 20 μL</td> </tr> <tr> <td>Column temperature</td> <td>: 40°C</td> </tr> <tr> <td>Run time</td> <td>: 20 minutes</td> </tr> <tr> <td>Retention time</td> <td>: About 12.0 minutes</td> </tr> </table>	Folic acid	: Working standard	Potassium dihydrogen orthophosphate	: AR grade	Dipotassium hydrogen orthophosphate	: AR grade	Acetonitrile	: HPLC grade	Purified Water	: Milli-Q water (or) equivalent	Methanol	: HPLC grade	Sodium Hydroxide	: AR grade	Column	: Inertsil ODS 3v C18 (250mmx 4.6mm) 5μ or equivalent	Flow rate	: 0.8ml/min	Wavelength	: 280 nm	Injection Volume	: 20 μL	Column temperature	: 40°C	Run time	: 20 minutes	Retention time	: About 12.0 minutes
Folic acid	: Working standard																												
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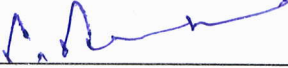


<p><b>Diluent preparation:</b></p> <p>A mixture of 80 volume of water and 20 volume of Acetonitrile.</p> <p><b>Buffer preparation:</b></p> <p>Dissolve 11.0g of Potassium dihydrogen orthophosphate and 6.0g of Dipotassium hydrogen orthophosphate in 1000mL of purified water.</p> <p><b>Mobile phase preparation:</b></p> <p>A mixture of 90 volume of Buffer and 10 volume of Methanol and mix well. Filter through 0.45µ nylon membrane filter and degas.</p> <p><b>Standard preparation:</b></p> <p>Weigh accurately and transfer about 20.0mg of Folic acid working standard into a 100mL volumetric flask. Add 5mL of 1N sodium hydroxide sonicate to dissolve and dilute to volume with diluent. Further dilute 5mL of this solution to 100mL with diluent. Filter the solution through 0.45µ nylon membrane filter. (<b>Concentration:</b> 0.01mg/ml of Folic Acid).</p> <p><b>Test preparation: (blend)</b></p> <p>Weigh 5g granules and crush to fine powder. Weigh accurately and transfer powdered sample equivalent to about 1.0mg of Folic acid into a 100mL volumetric flask. Add 5mL of 1N of sodium hydroxide to disperse the sample and add 60mL of diluent, sonicate for 15 minutes with intermittent shaking (Maintain the bath temperature below 25°C) and dilute to volume with diluent. Filter the solution through 0.45µ nylon membrane filter. (<b>Concentration:</b> 0.01mg/ml of Folic Acid).</p>	
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Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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<b>Designation</b>	<b>Asst. Manager-QC</b>	<b>GM-QC</b>	<b>AGM-QA</b>
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	<p><b>Test preparation: (Capsules)</b></p> <p>Weigh 20 capsules and calculate the average net weight and crush to fine powder. Weigh accurately and transfer powdered sample equivalent to about 1.0mg of Folic acid into a 100mL volumetric flask. Add 5mL of 1N of sodium hydroxide to disperse the sample and add 60mL of diluent, sonicate for 15 minutes with intermittent shaking (Maintain the bath temperature below 25°C) and dilute to volume with diluent. Filter the solution through 0.45µ nylon membrane filter. (<b>Concentration:</b> 0.01mg/ml of Folic Acid).</p> <p><b>Blank preparation:</b></p> <p>Pipette out 5mL of 1N Sodium hydroxide into 100mL volumetric flask and dilute upto volume with diluent.</p> <p><b>Procedure:</b></p> <p>Inject the blank (diluent) in single injection, standard preparation as five replicate injection in to the chromatogram and measure the response of the peak of Folic acid in term of standard area and test in duplicate.</p> <p>The test is not valid unless it meets the system suitability parameters. Calculate the system suitability with respect to the following parameters.</p> <p><b>System suitability:</b></p> <p>Theoretical plate : NLT 2000 for Folic acid peak</p> <p>Tailing factor : NMT 2.0 for Folic acid peak</p> <p>Relative standard deviation : NMT 2.0% for five replicate injections of Folic acid peak.</p> <p>Inject 20µl of the above solution as per following sequence.</p>
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**Injection sequence:**

S. No	Sample Name	No. of injections
1	Blank (Diluent)	1
2	Standard preparation	5
3	Test preparation	2
4	Bracketing standard	1 Each after every 6 sample injection

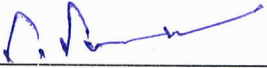


**Calculation:**

**Calculate the assay of Folic acid in mcg/capsule as follows:**


$$= \frac{AT}{AS} \times \frac{WS}{100} \times \frac{5}{100} \times \frac{100}{WT} \times \frac{P}{100} \times 1000 \times ANW$$

Where,




- AT = Average area of Folic acid peak in Test preparation  
 AS = Average area of Folic acid peak in standard preparation.  
 WS = Weight of Folic acid working standard taken in mg  
 WT = Weight of sample taken in mg.  
 P = Potency of Folic acid Working standard (% on as basis).  
 ANW = Average Net Weight of capsule in mg.


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	<p><b>Calculate the assay of Folic acid in % as follows:</b></p> $= \frac{\text{mcg/capsule}}{\text{LC}} \times 100$ <p>LC = Label claim of Folic acid in mcg.</p> <p><b>c) Cyanocobalamin:</b></p> <p><b>Reference:</b> In-House</p> <p><b>Procedure:</b> By Microbiological method</p> <p><b>Chemicals/Reagents/Standards:</b></p> <table style="width: 100%;"> <tr> <td>Cyanocobalamin( Vitamin B12)</td> <td>: Working standard</td> </tr> <tr> <td>Sodium hydroxide</td> <td>: AR grade</td> </tr> <tr> <td>Potassium dihydrogen phosphate</td> <td>: AR grade</td> </tr> <tr> <td>Purified water</td> <td>: Distilled water</td> </tr> </table> <p><b>Test Organism:</b></p> <p>Lactobacillus Leichmannii (ATCC 7830)</p> <p><b>Enriched Culture medium:</b></p> <p>Weigh accurately dextrose 1.0g, peptone 0.75g, yeast extract 0.75g, Potassium dihydrogen phosphate 0.2g, Tomato juice 10mL, polysorbate-80(10%) 1mL, Agar 1.5g, Distilled water 100mL and adjusted to pH 6.8 before adding agar with 50% sodium hydroxide. Make use of these ingredients for preparing the inoculum medium or use a readymade medium. Dispense 3mL of inoculum broth medium in each tube before adding agar. Dispense 5mL of inoculum agar medium in each tube. Plug and autoclave at 15 PSI for 20 minutes. Readymade Hi Media B12 inoculum medium (Hi Media M206) and B12 culture agar (Hi Media M305) can also be used.</p>	Cyanocobalamin( Vitamin B12)	: Working standard	Sodium hydroxide	: AR grade	Potassium dihydrogen phosphate	: AR grade	Purified water	: Distilled water
Cyanocobalamin( Vitamin B12)	: Working standard								
Sodium hydroxide	: AR grade								
Potassium dihydrogen phosphate	: AR grade								
Purified water	: Distilled water								


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			<b>Market</b>	<b>Export</b>
<b>Name of Product</b>	<b>RICHFER CAPSULES</b> (Carbonyl Iron, Folic acid, Cyanocobalamin, Ascorbic acid, Zinc, Alpha Tocopheryl Acetate and Selenium Capsules)			
<b>STP No.</b>	STP-1047-02	<b>Revision No.</b>	02	<b>Product Code:</b> 1047
<b>Supersedes</b>	STP-1047-01	<b>Effective Date:</b>	07/11/2024	<b>Page No.:</b> 13 of 28

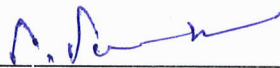


	<p><b>Preparation:</b></p> <p>One day prior to the assay autoclave all the test tubes filling it with water in covered racks. Discard the water after autoclaving and dry heat the test tubes at 140°- 160° for 2 hours. Similarly autoclave the remaining glassware, pipette used for dispensing the medium, cylinder and flask for preparing the assay medium.</p> <p><b>Preparation of test culture for assay:</b></p> <p><b>Inoculum:</b></p> <p>One day prior to assay, transfer cells from the stock culture of <i>L. leichmanni</i> to a sterile tube of inoculum broth. Incubate this culture for 16 - 24 hours at 37°C; centrifuge aseptically. During centrifugation, the cotton is held in place by folding a portion of the cotton over the outside of the tube and fastening with a rubber band. Decant the supernatant and resuspend the cells in a small amount of basal medium and continue to give culture washings for a total of five times. After the last washing has been completed, decant the supernatant and resuspend the cells in 10mL of sterile basal medium solution and make a suspension, which gives a transmittance of about 25%. This suspension is then used for inoculating tubes.</p> <p><b>Preparation of Vitamin B12 Standard:</b></p> <p><b>Standard stock solution of vitamin B12:</b></p> <p>Weigh accurately 50 mg of USP reference standard and transfer to a 500mL volumetric flask. Make the volume to 500mL with 25% ethanol. This solution contains 100 mcg/ml of vitamin B12. Store this solution in the refrigerator.</p> <p><b>Working standard stock solution:</b></p> <p>Dilute 10mL of working stock standard solution to 100mL with distilled water. Take 2mL of this diluted solution and make up the volume to 100mL with distilled water. Dilute 2mL to 100mL using distilled water. Take 1mL of this solution and dilute to 100mL with distilled water. This solution contains 0.04 mmcg/ml of vitamin B12.</p>
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Signature			
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	<p><b>Standard Set (in triplicate):</b></p> <p>Into 36 tubes (19 mm x 150 mm) measure accurately 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0 quantities of the working standard. To these add D/W 4.5, 4.0, 3.5, 3.0, 2.5, 2.0, 1.5, 1.0, 0.5mL, proportionately to make volume to 5mL.</p> <p><b>Preparation of sample:</b></p> <p>Prepare the test solution as described under the individual product, to contain about (0.04 mmcg/ml) of vitamin B12 per mL.</p> <p><b>Richfer capsule:</b></p> <p>Dilute net contents of one capsule to 100mL with-D/W. Dilute 2mL of this to 100mL with D/W. Further pipette 1.0mL and dilute to 100mL with D/W. This is used as test solution.</p> <p><b>Medium used:</b> Vitamin B12 assay Medium (Hi Media No. M036)</p> <p><b>Test solutions (In duplicate):</b></p> <p>Take a test tube rack of 36 tubes. In succeeding block of 6 tubes, measure accurately 1.0, 2.0 and 3.0 of test solution. To each tube of both standard and sample add 5 mL of basal medium and finally water to make volume to 10 ml. Mix the contents well, cover the tubes with metal cover and sterilize by heating at 121 °C (15 PSI) for 8 minutes. Cool the tubes as rapidly as possible by placing them in a shallow tray containing cold water. When all the tubes have achieved room temperature, add aseptically to each tube, except the last triplicate set, one drop of the inoculum from a 2.0 ml pipette. Incubate at 37°C for approximately 18 to 24 hours.</p> <p><b>Readings:</b></p> <p>Set the transmittance of the photoelectric colorimeter to 100 % at 530 nm against the uninoculated blank, which is the solution from the test triplicate set of tubes in the standard set. Shake the solution well in each tube, transfer it to the colorimeter tube and record the optical density reading.</p>
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#### Calculation:

Reject the whole assay if the tubes are obviously contaminated with an extraneous organism; if the inoculated blank tubes (the first triplicate set in the standard tubes) to which no standard has been added, gives transmittance values less than 90%. Plot a graph of the average O.D values against the corresponding levels of vitamin B12 standard per tube. Draw a curve. The O.D. values of the sample when read from the graph will give the corresponding concentration. The concentration is then divided by 1 ml, 2ml, and 3 ml to give the concentration per ml.

An average is taken of those concentrations, which are nearly the same and are then multiplied by the dilution factor. This will give us value of the sample from the graph.

Further calculations done based on sample dilutions taken.

#### Calculation:

$$\text{Vitamin B12 in mcg/capsule} = \frac{\text{Value from graph} \times 100 \times 100 \times 100 \times 1 \times 1}{\text{Weight taken (g)} \times 2 \times 1 \times 1000 \times 1000} \times \text{Net.Weight (g)}$$


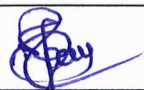

#### d) Ascorbic acid:

**Reference:** In-House


**Procedure:** By Titration

#### Chemicals/Reagents/Standards:

Concentrated Sulphuric acid	: AR grade
Purified Water	: Milli-Q water (or) equivalent
Iodine	: AR grade
Starch	: AR grade

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**Procedure: (Blend)**

Weigh 5g granules and crush to fine powder, weigh accurately about 150 mg equivalent of Ascorbic acid and dissolve as completely as possible, add 15mL of 1M sulphuric acid sonicate for 10minutes to dissolve and add 15 mL of water. Add 1 ml of starch solution. Titrate with 0.05 M iodine until a persistent violet-blue colour is obtained. Carryout a blank titration.

**(Concentration:**

**Procedure: (Capsules)**

Weigh 20 capsules and calculate the average net weight and crush to fine powder. Weigh accurately about 150 mg equivalent of Ascorbic acid and dissolve as completely as possible, add 15mL of 1M sulphuric acid sonicate for 10minutes to dissolve and add 15 mL of water. Add 1 ml of starch solution. Titrate with 0.05 M iodine until a persistent violet-blue colour is obtained. Carryout a blank titration.

1 ml of 0.05M Iodine is equivalent to 8.806 mg of Ascorbic acid.




**Calculate the content of Ascorbic acid in mg/capsule as follows:**


$$= \frac{(\text{Titer value} - \text{Blank}) \times \text{Molarity of 0.05M Iodine} \times 8.806 \times \text{Avg.net weight}}{\text{Sample weight (mg)} \times 0.05}$$

**Calculate the content of Ascorbic acid in % as follows:**

$$= \frac{\text{mg/capsule}}{\text{LC}} \times 100$$

LC = Label claim of Ascorbic acid in mg.

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**e) Zinc:**

**Reference:** In-House

**Procedure:** By AAS

**Chemicals/Reagents/Standards:**

Zinc sulphate monohydrate	:	Working standard
Purified Water	:	Milli-Q water (or) equivalent
Hydrochloric acid	:	AR grade

**Preparation of 0.1N Hydrochloric acid solution:**

Transfer 4.25mL of concentrated Hydrochloric acid solution in to a 500ml volumetric flask containing 200mL of distilled water and mix well and flask volume make up to 500mL with distilled water and mix well.

**Preparation of 1000ppm Zinc standard stock solution:**




Weigh accurately about 884mg of Zinc sulphate hepta hydrate (AR) standard into a clean 200mL volumetric flask and add 4mL of concentrated Hydrochloric acid and mix well to completely dissolve the Zinc sulphate standard. Volume make up to 200mL with distilled water and mix well to get 1000ppm Zinc standard solution.

**Preparation of 20ppm Zinc standard stock solution:**


Pipette out 2mL of 1000ppm Zinc standard stock solution in to a clean 100mL Volumetric flask and volume make up to 100mL with 0.1N Hydrochloric acid and mix well to get 20ppm Zinc standard stock solution.

**Preparation of 1.0 ppm Zinc standard solution:**

Pipette out 5mL of 20ppm Zinc standard stock solution in to a clean 100mL Volumetric flask and volume make up to 100mL with 0.1N Hydrochloric acid and mix well to get 1.0ppm Zinc standard solution.

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**Preparation of Blank solution:**

0.1N Hydrochloric acid solution is use as blank solution.

**Preparation of 1.0 ppm Sample solution: (Blend)**




Weigh 5g granules and crush to fine powder. Weigh accurately powder equivalent to about 2.5mg of elemental Zinc in to a clean 50mL Volumetric flask and add 4mL of concentrated Hydrochloric acid and mix well to completely dissolve and make up to volume with water. Dilute 1mL of the above solution in to a clean 50mL volumetric flask and volume make upto 50mL with 0.1N Hydrochloric acid and mix well. (Sample solution concentration is equivalent to 1ppm of Zinc solution).


**Preparation of 1.0 ppm Sample solution: (Capsules)**

Weigh 20 capsules and calculate the average net weight and crush to fine powder. Weigh accurately powder equivalent to about 2.5mg of elemental Zinc in to a clean 50mL Volumetric flask and add 4mL of concentrated Hydrochloric acid and mix well to completely dissolve and make up to volume with water. Dilute 1mL of the above solution in to a clean 50mL volumetric flask and volume make upto 50mL with 0.1N Hydrochloric acid and mix well. (Sample solution concentration is equivalent to 1ppm of Zinc solution).

**Instrument conditions:**

Recommended parameters	Working conditions
Instrument type	Flame
Concentration unit	mg/L (or) ppm
Instrument mode	Absorbance
Sampling mode	Manual
Calibration mode	Concentration
Wave length (nm)	213.9

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Band pass (nm)	0.2
Calibration algorithm	Segmented curve fit
Flame type	Air/ Acetylene
Air flow and fuel flow	As per default setting of Instrument

**Procedure:**

Set the Instrument zero using blank solution and aspirate the standard solution then blank solution and sample solution.

**Calculation:**

**Calculate the assay of Zinc in mg/capsule as follows:**


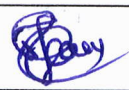

$$= \frac{\text{TAB}}{\text{SAB}} \times \frac{\text{WT}}{200} \times \frac{2}{100} \times \frac{5}{100} \times \frac{50}{\text{WS}} \times \frac{50}{1} \times \frac{\text{P}}{100} \times \frac{65.39}{287.56} \times \text{ANW}$$

**Calculate the assay of Zinc in % as follows:**


$$= \frac{\text{mg/capsule}}{\text{LC}} \times 100$$

Where,

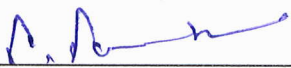


- TAB = Absorbance of Zinc in Test preparation.  
SAB = Absorbance of Zinc in Standard preparation.  
WT = Weight of Zinc sulphate heptahydrate working standard in mg.


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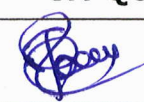

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	WS = Weight of sample taken in mg. P = Potency of Zinc sulphate heptahydrate working standard in ( % on as is basis) LC = Label claim of zinc in mg. 65.39 = Molecular weight of Zinc. 287.56 = Molecular weight of Zinc sulphate heptahydrate. ANW = Average net weight of capsule in mg.
	<b>f) Alpha Tocopherol Acetate:</b> <b>Reference:</b> In-House <b>Procedure:</b> By HPLC <b>Chemicals/Reagents/Standards:</b>  Vitamin E 50% powder (Alpha tocopheryl acetate) : Working standard Methanol : HPLC grade Acetonitrile : HPLC grade Isopropyl alcohol : AR grade Purified water : Milli-Q water (or) equivalent  <b>Chromatographic Conditions:</b>  Column : Water Xterra, 150mmx 4.6mm, 5μ or equivalent Flow rate : 1.0ml/min Wavelength : 268 nm Injection Volume : 20 μL


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	Temperature : 30°C Run time : About 15 minutes Retention time : About 4.0 minutes
	<b>Diluent preparation:</b> A mixture of 25 volume of methanol, 50 volume of Isopropyl alcohol and 25 volume of Acetonitrile.
	<b>Mobile phase preparation:</b> A mixture of 98 volume of Methanol and 2 volume of water and mix well. Filter through 0.45μ nylon membrane filter and degas.
	<b>Standard preparation:</b> Weigh accurately and transfer about 40.0mg of Vitamin E 50% powder working standard into a 100mL volumetric flask. Add 70mL of diluent, sonicate to dissolve and dilute to volume with diluent. Filter through 0.45μ nylon membrane filter and degas. ( <b>Concentration:</b> 0.2IU/ml of Alpha tocopheryl acetate).
	<b>Test preparation: (Blend)</b> Weigh 5g granules and crush to fine powder. Weigh accurately and transfer powdered of sample equivalent to about 20IU of Vitamin E into a 100mL volumetric flask. Add 60mL of diluent to disperse the sample, sonicate for 20 minutes with intermittent shaking (Maintain the bath temperature below 25°C) and dilute to volume with diluent. Filter through 0.45μ nylon membrane filter. ( <b>Concentration:</b> 0.2IU/ml of Alpha tocopheryl acetate).


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	<p><b>Test preparation: (Capsules)</b></p> <p>Weigh 20 capsules and calculate the average net weight and crush to fine powder. Weigh accurately and transfer powdered sample equivalent to about 20IU of Vitamin E into a 100mL volumetric flask. Add 60mL of diluent to disperse the sample, sonicate for 20 minutes with intermittent shaking (Maintain the bath temperature below 25°C) and dilute to volume with diluent. Filter through 0.45µ nylon membrane filter. (<b>Concentration:</b> 0.2IU/ml of Alpha tocopheryl acetate).</p> <p><b>Procedure:</b></p> <p>Inject the blank (Diluent) in single injection, standard preparation as five replicate injection in to the chromatogram and measure the response of the peak of Alpha tocopheryl acetate in term of standard area and test in duplicate. The test is not valid unless it meets the system suitability parameters. Calculate the system suitability with respect to the following parameters.</p> <p><b>System suitability:</b></p> <table style="width: 100%;"> <tr> <td style="width: 40%;">Theoretical plate</td> <td>: NLT 2000 for Alpha tocopheryl acetate peak.</td> </tr> <tr> <td>Tailing factor</td> <td>: NMT 2.0 for Alpha tocopheryl acetate peak.</td> </tr> <tr> <td>Relative standard deviation</td> <td>: NMT 2.0% for five replicate injections of Alpha tocopheryl acetate peak.</td> </tr> </table> <p>Inject 20µl of the above solution as per following sequence.</p>	Theoretical plate	: NLT 2000 for Alpha tocopheryl acetate peak.	Tailing factor	: NMT 2.0 for Alpha tocopheryl acetate peak.	Relative standard deviation	: NMT 2.0% for five replicate injections of Alpha tocopheryl acetate peak.
Theoretical plate	: NLT 2000 for Alpha tocopheryl acetate peak.						
Tailing factor	: NMT 2.0 for Alpha tocopheryl acetate peak.						
Relative standard deviation	: NMT 2.0% for five replicate injections of Alpha tocopheryl acetate peak.						

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**Injection sequence:**

S. No	Sample Name	No. of injections
1	Blank (Diluent)	1
2	Standard preparation	5
3	Test preparation	2
4	(Standard Preparation) Bracketing standard	1 Each after every 6 sample injection




**Calculation:**

**Calculate the assay of Vitamin E acetate in IU/capsule as follows:**


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

Where,


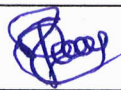

- AT = Average area of Alpha tocopheryl acetate peak in Test preparation  
 AS = Average area of Alpha tocopheryl acetate peak in standard preparation.  
 WS = Weight of Vitamin E 50% powder working standard taken in mg  
 WT = Weight of sample taken in mg.  
 P = Potency of Vitamin E 50% powder Working standard.  
 ANW = Average net weight of capsule in mg.


Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	S.SANTHI	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	04/11/24	05/11/2024	06/11/2024



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	<b>STANDARD TESTING PROCEDURE</b>			
			<b>Market</b>	<b>Export</b>
<b>Name of Product</b>	<b>RICHFER CAPSULES</b> (Carbonyl Iron, Folic acid, Cyanocobalamin, Ascorbic acid, Zinc, Alpha Tocopheryl Acetate and Selenium Capsules)			
<b>STP No.</b>	STP-1047-02	<b>Revision No.</b>	02	<b>Product Code:</b> 1047
<b>Supersedes</b>	STP-1047-01	<b>Effective Date:</b>	01/11/2024	<b>Page No.:</b> 24 of 28

	<p><b>Calculate the assay of Vitamin E acetate in % as follows:</b></p> $= \frac{\text{IU/capsule}}{\text{LC}} \times 100$ <p>LC = Label claim of Vitamin E acetate in IU.</p> <p><b>g) selenium:</b></p> <p><b>Reference:</b> In-House  <b>Procedure:</b> By AAS</p> <p><b>Preparation of 0.1N Nitric acid solution.</b></p> <p>Transfer 3.2ml of concentrated Nitric acid solution in to a 500ml volumetric flask containing 200mL of distilled water and mix well and flask volume make upto 500mL with distilled water and mix well.</p> <p><b>Preparation of 1000ppm Selenium standard stock solution:</b></p> <p>Weigh accurately about 442mg of Sodium selenite anhydrous (AR) standard into a clean 200mL volumetric flask and add 4mL of concentrated Nitric acid and mix well to completely dissolve the Sodium selenite standard. Volume make up to 200mL with distilled water and mix well to get 1000ppm Selenium standard solution.</p> <p><b>Preparation of 5ppm Selenium standard solution:</b></p> <p>Pipette out 1mL of 1000ppm Selenium standard stock solution in to a clean 200mL Volumetric flask and volume make up to 200mL with 0.1N Nitric acid and mix well to get 5ppm Selenium standard solution.</p>
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#### Preparation of Blank solution:

0.1N Nitric acid solution is use as blank solution

#### Preparation of Sample solution: (Blend)




Weigh 5g granules and crush to fine powder. Weigh accurately crushed powder equivalent to about 125mcg of elemental selenium in 25mL Volumetric flask and add 1mL of concentrated Nitric acid and mix well to completely dissolve and volume make up to 25mL with 0.1N Nitric acid and mix well to get 5ppm Selenium sample solution.

#### Preparation of Sample solution: (Capsules)


Weigh 20 capsules and calculate the average net weight and crush to fine powder. Weigh accurately crushed powder equivalent to about 125mcg of elemental selenium in 25mL Volumetric flask and add 1mL of concentrated Nitric acid and mix well to completely dissolve and volume make up to 25mL with 0.1N Nitric acid and mix well to get 5ppm Selenium sample solution.

#### Instrument conditions:

Recommended parameters	Working conditions
Instrument type	Flame
Concentration unit	mg/L (or) ppm
Instrument mode	Absorbance
Sampling mode	Manual
Calibration mode	Concentration
Wave length (nm)	196
Band pass (nm)	0.5

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<b>Designation</b>	<b>Asst. Manager-QC</b>	<b>GM-QC</b>	<b>AGM-QA</b>
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<b>Name of Product</b>	<b>RICHFER CAPSULES</b> (Carbonyl Iron, Folic acid, Cyanocobalamin, Ascorbic acid, Zinc, Alpha Tocopheryl Acetate and Selenium Capsules)			
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<b>Supersedes</b>	STP-1047-01	<b>Effective Date:</b>	07/11/2024	<b>Page No.:</b> 26 of 28

<table border="1"> <tr> <td>Calibration algorithm</td> <td>Segmented curve fit</td> </tr> <tr> <td>Flame type</td> <td>Air/ Acetylene</td> </tr> <tr> <td>Air flow and fuel flow</td> <td>As per default setting of Instrument</td> </tr> </table>	Calibration algorithm	Segmented curve fit	Flame type	Air/ Acetylene	Air flow and fuel flow	As per default setting of Instrument
Calibration algorithm	Segmented curve fit					
Flame type	Air/ Acetylene					
Air flow and fuel flow	As per default setting of Instrument					

**Procedure:**

Set the Instrument zero using blank solution and aspirate the standard solution then blank solution and sample solution.

**Calculation:**

**Calculate the assay of selenium in mcg/capsule as follows:**

$$= \frac{\text{TAB}}{\text{SAB}} \times \frac{\text{WT}}{200} \times \frac{1}{200} \times \frac{25}{\text{WS}} \times \frac{\text{P}}{100} \times \frac{78.96}{172.95} \times \text{ANW}$$

**Calculate the assay of selenium in % as follows:**

$$= \frac{\text{mcg/capsule}}{\text{LC}} \times 100$$


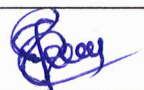

Where,


TAB = Absorbance of Selenium in Test preparation.

SAB = Absorbance of Selenium in Standard preparation.


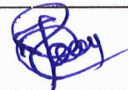

WT = Weight of Sodium selenite anhydrous working standard in mg.

WS = Weight of sample taken in mg.


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	<p>P = Potency of Sodium selenite anhydrous working standard (% on as is basis).</p> <p>LC = Label claim of Selenium in mg.</p> <p>ANW = Average net weight of capsule in mg.</p> <p>78.96 = Molecular weight of Selenium.</p> <p>172.95 = Molecular weight of Sodium selenite anhydrous.</p> <p><b>9.0 MICROBIAL CONTAMINATION:</b></p> <p>Total Viable aerobic count and Pathogen test refer as per the current SOP No: ST/MB/011.</p>
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<b>Supersedes</b>	STP-1047-01	<b>Effective Date:</b>	07/11/2024	<b>Page No.:</b> 28 of 28

<b><u>REVISION HISTORY:</u></b>			
STP No.	Reason for Review	Change control No.	Effective Date
STP-1047-00	(i) STP number and Format has revised as per SOP No. ST/QC/058.  (ii) Ferrous ammonium sulphate Hexahydrate has been used to preparation of standard solution instead of carbonyl iron Working standard.  (iii) 5% w/v Sodium metabisulphite solution has used to the Procedure.	ST/CC/22/119   ST/CC/23/041	18/03/2023
STP-1047-01	Assay of Folic acid and Vitamin E procedure has changed as per Analytical method validation.	ST/CC/24/078	22/04/2024
STP-1047-02	Assay of Folic acid chromatographic condition retention time has been corrected.	ST/CC/24/268	07/11/2024
<b>**END OF THE DOCUMENT**</b>			

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