

	Safetab Life Science		MASTER COPY		
	BATCH MANUFACTURING RECORD		Page No.:	1 of 57	
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

BATCH MANUFACTURING RECORD COVER SHEET:

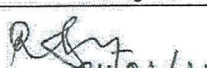
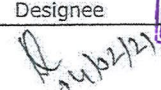
PRODUCT NAME	: RICHFER CAPSULES		
LABEL CLAIM	Each hard Gelatin Capsule contains: Carbonyl Iron Equivalent to Elemental Iron 100mg Folic acid BP 500mcg Cyanocobalamin(coated) (Vitamin B12) 15mcg Ascorbic Acid (coated) 75mg Zinc sulphate Monohydrate BP 61.8mg (Equivalent to Elemental Zinc 22.5mg) Alpha Tocopheryl Acetate BP 15 IU Sodium Selenate Equivalent to Selenium 65mcg Approve colours used in empty hard gelatin capsule. Appropriate overages of Vitamins are added to compensate the loss on storage.		
PACK SIZE	: TP: 3X10's blister pack		
STORAGE CONDITION	: Store in cool and dry place keep away from light and moisture.		
SHELF LIFE	: 36 MONTHS		
CUSTOMER NAME	: GENERIC HEALTHCARE PVT.LTD.		
EFFECTIVE BATCH NUMBER	: GD210207	DATE:	06/02/2021
MANUFACTURING LICENCE No.	: 07 22 1907		
MFG. DATE:	: 11/2021	BMR. No	STBMR:137/01
EXP. DATE:	: 10/2024	Supersedes BMR.No	STBMR:137/00
BMR ISSUED BY/DATE (QA)	: 17/11/21		
BMR CHECKED & RECEIVED BY/DATE (PRODUCTION)	: 17/11/21		
Allotted By: QA Executive Sign/Date: 17/11/21			
DATE OF COMMENCEMENT: 17/11/21		DATE OF COMPLETION: 15/12/21	
This BMR contains 57 Pages + Annexure-1 + ML Additional Pages			
Checked by Competent Staff Sign/Date: 15/12/21			
Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee
Signature with Date	17/11/21	04/12/21	04/12/21

CONTROLLED COPY

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	BATCH MANUFACTURING RECORD			Page No.:	2 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

1.0 LIST OF EQUIPMENTS:

S.No	Name of Equipment	Equipment ID No. to be used
1	Dispensing Booth	ST/SRDB/001
2	Balance -30 Kg Capacity	ST/SRWB/001
3	Balance -620 g Capacity	ST/SRWB/002
4	Balance -150 Kg Capacity	ST/WB/189
5	Balance -100 Kg Capacity	ST/PRWB/002
6	Balance -100 Kg Capacity	ST/WB/205
7	Balance - 220g Capacity	ST/WB/202 or ST/WB/207
8	Vibro Sifter	ST/PRG/006 or ST/PRG/007 or ST/PRG/008
9	Multi mill	ST/PRG/009 or ST/PRG/010
10	Octagonal blender	ST/PRG/015
11	Pharma fill A60	ST/PRCF/011
12	Capsule weighing machine	ST/PRCF/012
13	Capsule polishing machine	ST/PRCF/013
14	Filled capsule sorter	ST/PRCF/014
15	Empty capsule sorter elevator	ST/PRCF/015
16	De dusting unit	ST/PRCF/016
17	Unfilled capsule sorter	ST/PRCF/017
18	De capsulation machine	ST/PRCF/018
19	Disintegration Tester	ST/QADT/002 ST/QADT/003
20	Vernier Caliper	ST/IPV/005

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 20/02/21	 02/02/21	 04/02/21	

	Safetab Life Science			MASTER COPY	
BATCH MANUFACTURING RECORD				Page No.:	3 of 57
Brand Name	RICHER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

2.0 DISPENSING:

2.1 LINE CLEARANCE CHECKS:

S.No	CHECKS	Observation	
		store	IPQA
1	Ensure that all empty containers, labels, used Polybags, hand gloves of previous dispensed Product/ batch are removed from the area.	✓	✓
2	Ensure that all dispensed material of previous product / batch removed from the area.	✓	✓
3	Ensure that the previous batch BMR / documents are removed from the area.	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls, ceiling, pass box, doors and door view panels of man and material entry of dispensing area is clean.	✓	✓
5	Check the cleanliness of the working table, cupboard, washing area and waste bin.	✓	✓
6	Check the cleanliness of the drain points.	✓	✓
7	Ensure that the dispensing booth is cleaned and it's status.	✓	✓
8	Check the cleanliness of the supply and return grill.	✓	✓
9	Check the cleanliness of side wall of the dispensing booth.	✓	✓
10	Check the differential pressure of pre filter, intermediate filter and hepa filter are within the limit	✓	✓
11	Check the cleanliness of the utility line (compressed air, First RO water and purified water).	✓	✓
12	Check the cleanliness of the SS side panel and SS Stool.	✓	✓
13	Ensure that the balances are cleaned and it's calibration status.	✓	✓
14	Check the status board of the area is updated.	✓	✓
15	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓
16	Check the differential pressure of the area should be within the limit.	✓	✓
17	Ensure that dispensing tools or accessories like scoops, spoons are cleaned and labeled with "Clean" label.	✓	✓
18	Check proper gowning procedure followed as per the SOP	✓	✓
19	Ensure the concurrent entries of log book.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (store) sign/date: [Signature] 17/11/21 Verified by (IPQA) sign/date: [Signature] 17/11/21

Equipment	Dispensing Booth	Weighing Balance			AREA
Equipment. ID No.	ST/SRDB/001	ST/SRWB/001 (30.0 Kg)	ST/SRWB/002 (620.0g)	ST/WB/189 (150.0 Kg)	
Previous Product & Batch No.	RICHER - GD211131				
Cleaned By	ngb	ngb	ngb	ngb	ngb
Checked by Stores Sign/Date	[Signature] 17/11/21	[Signature] 17/11/21	[Signature] 17/11/21	[Signature] 17/11/21	[Signature] 17/11/21
Counter checked by IPQA/Sign/Date	[Signature] 17/11/21	[Signature] 17/11/21	[Signature] 17/11/21	[Signature] 17/11/21	[Signature] 17/11/21

2.2 ENVIRONMENTAL CONDITIONS:

	Observation	Stores Sign
Temperature: 23°C to 27°C	25°C	[Signature]
Relative Humidity: 45% to 55 %	52%	[Signature]

2.3 APPROVAL FOR DISPENSING BY IPQA: Sign: [Signature] Date: 17/11/21

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	[Signature] 02/12/21	[Signature] 02/12/21	[Signature] 04/12/21	CONTROLLED COPY

	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page No.:	4 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules	
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO.:	ST/MFC/135/R1	Supersedes MFC No.:	ST/MFC/135/R0	
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024	

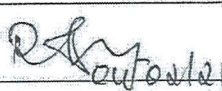
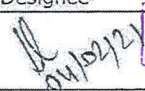
3.0 INDENT OF RAW MATERIALS:

3.1 INDENT OF ACTIVE PHARMACEUTICAL INGREDIENTS:

S.No	Name of the Ingredients	Material Code	Label claim per tablet in mg	Spec	Overages	Total Qty (Kg)	Vendor
1	Carbonyl Iron	RMAC0073	100.000	USP	Nil	45.000	PARAS ORGANICS PVT.LTD
2	Folic Acid	RMAF0018	500.000 mcg	BP	20	0.270	MCCOY DRUGS PVT.LTD
3	Cyanocobalamin	RMAC0066	15mcg	BP	50	10.125gm	HEBEI YUXING PHARMACEUTICAL
4	Ascorbic Acid	RMAA0029	75.000	BP	20	40.500	BAJAJ HEALTHCARE LTD
5	Zinc Sulfate Monohydrate	RMAZ0009	61.800	BP	20	33.372	SHREEJI INDUSTRIES
6	Alpha Tocopheryl Acetate	RMAA0030	15 IU	BP	20	16.200	EMMER CHEM/SHREENATH
7	Sodium Selenate	RMAS0028	65 mcg	IH	25	87.500gm	SNA HEALTHCARE

3.1.1 INDENT OF EXCIPIENTS:

S.No	Name of the Ingredients	Material Code	Unit dose per tablet in mg	Spec	Total Qty (Kg)	Vendor
5	Hydrophobic Colloidal anhydrous silica	RMEC0017	3.000	BP	1.350	WACKER
6	Microcrystalline crystalline cellulose PH 102	RMEM0038	166.022	BP	74.710	DFE
7	Calcium hydrogen phosphate	RMED0015	10.000	BP	4.500	INNOPHOS,INDIA PHOSPHATE
8	Purified Talc	RMET0012	10.000	BP	4.500	NEELKANTH
9	Magnesium stearate	RMEM0033	10.000	BP	4.500	NITIKA

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/02/21	 04/02/21	 04/02/21	

	Safetab Life Science		MASTER COPY		
	BATCH MANUFACTURING RECORD		Page No.:	5 of 57	
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

4.0 CALCULATION:

4.1 Potency calculation for Carbonyl Iron:

Q.C AR.No. for Carbonyl Iron	Mfg Date	Expiry Date	Assay of Carbonyl Iron (%)
mgp/2122/06/b6/00713	05/21	may/26	99.6
mgp/2122/06/b6/00767	05/21	SEP/26	102.5

*The given quantity is based on 100% Assay.
Actual quantity to be added is calculated as:

Actual quantity of Carbonyl Iron = $\frac{100.000 \times 100}{\% \text{ Assay of carbonyl Iron}}$ -----mg/capsule

$$\begin{aligned}
 1) &= \frac{10000}{99.6} = 100.402 \text{ mg/caps}, & 2) &= \frac{10000}{100} = 100 \text{ mg/caps} \\
 &= 20.681 \text{ kgs} & &= 24.402 \text{ kgs} \\
 &= (205981 \text{ nos}) & + & (244019 \text{ nos})
 \end{aligned}$$

*Qty of Carbonyl Iron to be added per batch = 45.083 Kg's

Note: If the assay of Carbonyl Iron is more than 100 %, calculation has to be done only for 100%

Calculation done by(store)/date: S. Viji checked by(production)/date: 17/11/21 Verified by(QA)/date: 05/11/21

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>[Signature]</u> 05/10/21	<u>[Signature]</u> 04/10/21	<u>[Signature]</u> 04/10/21	

	Safetab Life Science			MASTER COPY	
				BATCH MANUFACTURING RECORD	
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	6 of 57
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Batch Size	4,50,000 Capsules
Batch No.:	GD211132	Mfg.Date:	11/2021	Supersedes MFC No:	ST/MFC/135/R0
				Exp.Date:	10/2024

4.2 Potency calculation for Folic Acid:

Q.C AR.No. for Folic Acid	Mfg Date	Expiry Date	Assay of Folic Acid On Anhydrous basis	Water content %
mgp/2122/26/10/21/00796	Jun/21	Jun/26	99.9	7.81
—	—	—	—	—

*The given quantity is based on 100% Assay On Anhydrous basis and without Water content.
Actual quantity to be added is calculated as: Label claim 0.500mg +20% overages

Actual quantity. of Folic Acid = $\frac{0.600 \times 100 \times 100}{\% \text{ Assay on anhydrous basis} \times (100 - \text{water content } \%)}$ mg/capsule

$$= \frac{6000}{9209.781} = 0.651 \text{ mg/caps.}$$

*Qty of Folic Acid to be added per batch = 0.293 Kg's

Note: If the assay of Folic Acid is more than 100 %, calculation has to be done only for 100%

Calculation done by(store)/date: [Signature] 17/11/21 checked by(production)/date: [Signature] 17/11/21 Verified by(QA)/date: [Signature] 17/11/21

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>[Signature]</u> 04/10/21	<u>[Signature]</u> 04/10/21	<u>[Signature]</u> 04/10/21	

	Safetab Life Science		MASTER COPY		
			BATCH MANUFACTURING RECORD		
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	7 of 57
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

4.3 Potency calculation for Cyanocobalamin:

Q.C AR.No. for Cyanocobalamin	Mfg Date	Expiry Date	Assay of Cyanocobalamin on dried basis	LOD %
mep/2122/06/002/00756	5v1/21	5v1/26	97.7	4.23.
—	—	—	—	—

*The given quantity is based on 100% Assay on dried basis and without Loss on drying.
Actual quantity to be added is calculated as:

$$\text{Actual quantity of Cyanocobalamin} = \frac{0.023 \times 100 \times 100}{\% \text{ Assay on dried basis} \times (100 - \text{LOD} \%)} \text{ mg/capsule}$$

$$= \frac{230}{9356.729} = 0.025 \text{ mg/caps.}$$

*Qty of Cyanocobalamin to be added per batch = 11.250 gm's

Note: If the assay of Cyanocobalamin is more than 100 %, calculation has to be done only for 100%

Calculation done by(store)/date: P. V. V. 11/11/21, checked by(production)/date: P. S. S. 04/12/21, Verified by(QA)/date: P. S. S. 04/12/21

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>P. S. S.</u> 04/12/21	<u>P. S. S.</u> 04/12/21	<u>P. S. S.</u> 04/12/21	

	Safetab Life Science			MASTER COPY	
BATCH MANUFACTURING RECORD					
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

4.4 Potency calculation for Alpha Tocopheryl Acetate:

Q.C AR.No. for Alpha Tocopheryl Acetate	Mfg Date	Expiry Date	Assay of Alpha Tocopheryl Acetate (%)
MP/2122/06/00/00719	06/21	SEP/26	95.58
—	—	—	—

*The given quantity is based on 100% Assay.
15IU equivalent to 15mg.

Actual quantity of Alpha Tocopheryl Acetate to be is calculated as: Label claim: 15mg +20%

Actual quantity. of Alpha Tocopheryl Acetate = $\frac{36.000 \times 100}{\% \text{ Assay of Alpha Tocopheryl Acetate}}$ mg/capsule

$$= \frac{3600}{95.58} = 37.665 \text{ mg/caps.}$$

*Qty of Alpha Tocopheryl Acetate to be added per batch = 16.949 Kg's

Note: If the assay of Alpha Tocopheryl Acetate is more than 100 %, calculation has to be done only for 100%

Calculation done by(store)/date: *[Signature]* checked by(production)/date: *[Signature]* Verified by(QA)/date: *[Signature]*

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<i>[Signature]</i> 06/02/21	<i>[Signature]</i> 06/02/21	<i>[Signature]</i> 06/02/21	CONTROLLED COPY

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	BATCH MANUFACTURING RECORD			Page No.:	9 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

4.5 Potency calculation for Zinc sulfate Monohydrate:

Q.C AR.No. for Zinc sulfate Monohydrate	Mfg Date	Expiry Date	Assay of Zinc sulfate Monohydrate (%)
mep/2122/QC/106/00686	1 AUG/21	10/2/26	99.8
—	—	—	—

*The given quantity is based on 100% Assay.

Actual quantity of Zinc sulfate Monohydrate to be is calculated as: Label claim: 61.8mg+20%

Actual quantity. of Zinc sulfate Monohydrate = $\frac{74.160 \times 100}{\% \text{ Assay of Zinc sulfate Monohydrate}}$ mg/capsule

$$= \frac{74.16}{99.8} = 74.309 \text{ mg/caps}$$

*Qty of Zinc sulfate Monohydrate to be added per batch = 33.439 Kg's

Note: If the assay of Zinc sulfate Monohydrate is more than 100 %, calculation has to be done only for 100%

Calculation done by(store)/date: S. V. V. checked by(production)/date: 17/11/21 Verified by(QA)/date: 04/12/21

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>R. V. V.</u> 04/12/21	<u>[Signature]</u> 04/12/21	<u>[Signature]</u> 04/12/21	CONTROLLED COPY

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	BATCH MANUFACTURING RECORD		Page No.:	10 of 57	
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

4.6 Potency calculation for Ascorbic Acid:

Q.C AR.No. for Ascorbic Acid	Mfg Date	Expiry Date	Assay of Ascorbic Acid (%)
mfp/2122/061006/00698	SEP/21	NOV/25	100.2
mfp/2122/061006/00702	SEP/21	NOV/25	99.9

*The given quantity is based on 100% Assay.

Actual quantity of Ascorbic Acid to be is calculated as: Label claim: 75mg+20%

Actual quantity. of Ascorbic Acid = $\frac{90.000 \times 100}{\text{Assay}} \text{ mg/capsule}$

$$\begin{aligned}
 1) &= \frac{9000}{100} = 90 \text{ mg / Capsule} \\
 2) &= \frac{9000}{99.9} = 90.090 \text{ mg / Capsule} \\
 &= 28.888 \text{ Kgs} \quad = 11.624 \text{ Kgs} \\
 &= (320977 \text{ nos}) \quad + (129023 \text{ nos})
 \end{aligned}$$

*Qty of Ascorbic Acid to be added per batch = 40.512 Kg's

Note: If the assay of Ascorbic Acid is more than 100 %, calculation has to be done only for 100%

Calculation done by(store)/date: [Signature] 17/11/21 checked by(production)/date: [Signature] 17/11/21 Verified by(QA)/date: [Signature] 17/11/21

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	CONTROLLED COPY
Signature with Date	<u>[Signature]</u> 04/10/21	<u>[Signature]</u> 04/10/21	<u>[Signature]</u> 04/10/21	

	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page No.:	11 of 57
Brand Name	RICHTER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules	
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO.:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0	
Batch No.:	GD211132	Mfg. Date:	11/2021	Exp. Date:	10/2024	

4.7 Potency calculation for Sodium Selenate:

Q.C AR.No. for Sodium Selenate	Mfg Date	Expiry Date	Assay of Sodium Selenate (%)
mgp/2021/06/02/00921	FEB/21	FEB/24	99.5
—	—	—	—

*The given quantity is based on 100% Assay.
 188.94g/mol molecular weight of Sodium Selenate equivalent to 78.96g/mol molecular weight of selenium.
 So 155.53mcg of sodium Selenate equivalent to 65mcg of Selenium

Actual quantity of Sodium Selenate to be is calculated as: Label claim: 155.53mg+20%

$$0.19441 \times 100$$

Actual quantity. of Sodium Selenate = -----mg/capsule

% Assay of Sodium Selenate

$$= \frac{19.441}{99.5} = 0.195 \text{ mg/caps.}$$

*Qty of Sodium Selenate to be added per batch = **87.750 gm's**

Note: If the assay of Sodium Selenate is more than 100 %, calculation has to be done only for 100%

Quantity of Microcrystalline cellulose PH 102 varies based on assay content of Folic acid, carbonyl Iron, Alpha Tocopheryl acetate, Cyanocobalamin, Zinc sulfate monohydrate, Ascorbic Acid, Sodium Selenate for fill weight constant

4.7.1 Calculation for Quantity of Microcrystalline cellulose PH 102 to be dispensed

**Actual quantity of Microcrystalline cellulose PH 102 to be dispensed
 = [Std. qty. of Folic acid+ Std. qty. of Carbonyl Iron + Std. qty. of Alpha Tocopheryl acetate + Std. qty. of Cyanocobalamin + Std. qty. of Zinc sulfate monohydrate + Std. qty. of Ascorbic Acid + Std. qty. of Sodium Selenate + Std. qty. of Microcrystalline cellulose PH 102] - [Actual qty. of Folic acid + Actual qty. of Carbonyl Iron + Actual qty. of Alpha Tocopheryl acetate + Actual qty. of Cyanocobalamin+ Actual qty. of Zinc sulfate monohydrate + Actual qty. of Ascorbic Acid+ Actual qty. of Sodium Selenate].

$$= [0.270+45.000+16.200+10.125\text{gm}+33.372+40.500+87.500\text{gm}+74.710]-$$

$$[0.293 + 45.083 + 16.949 + 11.250 \text{ gm} + 33.439 + 40.512 + 87.750 \text{ gm}]$$

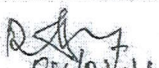
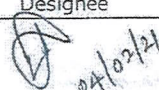
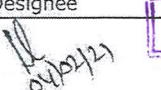
$$= \frac{73.665}{73.775} \text{ Kg}$$

*Qty of Microcrystalline cellulose PH 102 to be added per batch = **73.665 Kg's**

Calculation done by(store)/date:

checked by(production)/date:

Verified by(QA)/date:

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	CONTROLLED COPY
Signature with Date	 24/02/21	 24/02/21	 24/02/21	



Safetab Life Science

MASTER COPY

BATCH MANUFACTURING RECORD

Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	12 of 57
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC No:	ST/MFC/135/R1	Batch Size	4,50,000 Capsules
Batch No.:	GD211132	Mfg.Date:	11/2021	Supersedes MFC No:	ST/MFC/135/R0
				Exp.Date:	10/2024

5.0 DISPENSING OF RAW MATERIALS AGAINST RAW MATERIAL INDENT:

Dispensing Started at Date 17/11/21 Time 17.05

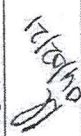
S.No	Name of the Ingredients	Actual Qty. per batch (Kg)	A.R No:	Gross Weight (Kg)	Tare Weight (Kg)	Net Weight (Kg)	Weighted By Stores	Checked by stores	Verified by IPQA
1	Carbonyl Iron USP	*	MSP/2122/06/06/00713	20.881	0.200	20.681	ng	ng	ng
			MSP/2122/06/06/00767	94.602	0.200	24.402	ng	ng	ng
2	Folic Acid BP	**	MSP/2122/06/06/00796	0.313	0.020	0.293	ng	ng	ng
3	Cyanocobalamin BP	***	MSP/2122/06/06/00756			11.250	ng	ng	ng
4	Ascorbic Acid BP	****	MSP/2122/06/06/00698	28.300	3.300	25.000	ng	ng	ng
			MSP/2122/06/06/00762	3.928	0.010	3.888	ng	ng	ng
				11.824	0.200	11.624	ng	ng	ng

Designation	Prepared by:	Checked by:	Approved by:
Signature with Date	QA Executive / Designee	Production Head / Designee	QA Head / Designee
	<u>R. S. Sufia</u>	<u>17/11/21</u>	<u>17/11/21</u>

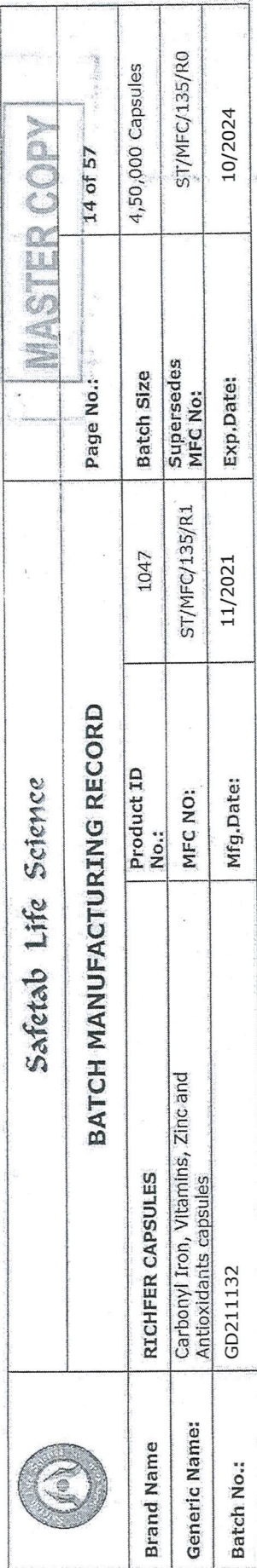
CONTROLLED COPY

	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD					
	Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
	Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg. Date:	11/2021	Exp. Date:	10/2024	Page No.: 13 of 57

S.No	Name of the Ingredients	Actual Qty. per batch(Kg)	A.R. No:	Gross Weight (Kg)	Tare Weight(Kg)	Net Weight(Kg)	Weighted By Stores	Checked by stores	Verified by IPQA
5	Zinc Sulfate Monohydrate BP	*****	MSP/2122/06100686	25.200	0.200	25.000	neg	dyf	dyf
			MSP/2122/06100686	8.639	0.200	8.439	neg	dyf	dyf
				-	-	-	-	-	-
				-	-	-	-	-	-
6	Vitamin E Acetate 50% granules BP	*****	MSP/2122/06100719	17.199	0.250	16.949	neg	dyf	dyf
				-	-	-	-	-	-
				-	-	-	-	-	-
7	Sodium Selenate IHS	*****	MSP/2021/06100921	95.750	8.000 gms	87.750 gms	neg	dyf	dyf
				-	-	-	-	-	-
				-	-	-	-	-	-
8	Hydrophobic Colloidal anhydrous silica BP	1.350	MSP/2122/06100615	1.450	0.100	1.350	neg	dyf	dyf
				-	-	-	-	-	-
				-	-	-	-	-	-

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee
Signature with Date	 24/10/21	 24/10/21	 24/10/21

CONTROLLED COPY



S.No	Name of the Ingredients	Actual Qty. per batch(kg)	A.R. No:	Gross Weight (Kg)	Tare Weight(Kg)	Net Weight(Kg)	Weighted By Stores	Checked by stores	Checked by IPQA
9	Microcrystalline crystalline cellulose PH 102 BP	#	MSP/2122/061062/00670	25.250	0.250	25.000	vg	vg	vg
			MSP/2122/061062/00670	25.250	0.250	25.000	vg	vg	vg
			MSP/2122/061062/00670	24.025	0.250	23.775	vg	vg	vg
			-	-	-	-	-	-	-
10	Calcium hydrogen phosphate BP	4.500	MSP/2122/061062/00579	4.600	0.100	4.500	vg	vg	vg
			-	-	-	-	-	-	-
			-	-	-	-	-	-	-
			-	-	-	-	-	-	-
11	Purified Talc BP	4.500	MSP/2122/061062/00594	4.600	0.100	4.500	vg	vg	vg
			-	-	-	-	-	-	-
			-	-	-	-	-	-	-
			-	-	-	-	-	-	-
12	Magnesium stearate BP	4.500	MSP/2122/061062/00504	4.600	0.100	4.500	vg	vg	vg
			-	-	-	-	-	-	-
			-	-	-	-	-	-	-
			-	-	-	-	-	-	-

Dispensing Completed at Date 17/11/21 Time 18.10

```
[*,**,**,*]**,*# refer calculation]
```

	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee
Designation			
Signature with Date	<i>[Signature]</i> 17/10/2011	<i>[Signature]</i> 17/10/2011	<i>[Signature]</i> 17/10/2011

CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	15 of 57
Brand Name	RICHTER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC No.:	ST/MFC/135/R1	Supersedes MFC No.:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

6.0 DISPENSING:

6.1 LINE CLEARANCE CHECKS:

S.No	CHECKS	Observation	
		store	IPQA
1	Ensure that all empty containers, labels, used Polybags, hand gloves of previous dispensed Product/ batch are removed from the area.	✓	✓
2	Ensure that all dispensed material of previous product / batch removed from the area.	✓	✓
3	Ensure that the previous batch BMR / documents are removed from the area.	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls, ceiling, pass box, doors and door view panels of man and material entry of dispensing area is clean.	✓	✓
5	Check the cleanliness of the working table, cupboard, washing area and waste bin.	✓	✓
6	Check the cleanliness of the drain points.	✓	✓
7	Ensure that the dispensing booth is cleaned and it's status.	✓	✓
8	Check the cleanliness of the supply and return grill.	✓	✓
9	Check the cleanliness of side wall of the dispensing booth.	✓	✓
10	Check the differential pressure of pre filter, intermediate filter and hepa filter are within the limit	✓	✓
11	Check the cleanliness of the utility line (compressed air, First RO water and purified water).	✓	✓
12	Check the cleanliness of the SS side panel and SS Stool.	✓	✓
13	Ensure that the balances are cleaned and it's calibration status.	✓	✓
14	Check the status board of the area is updated.	✓	✓
15	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓
16	Check the differential pressure of the area should be within the limit.	✓	✓
17	Ensure that dispensing tools or accessories like scoops, spoons are cleaned and labeled with "Clean" label.	✓	✓
18	Check proper gowning procedure followed as per the SOP	✓	✓
19	Ensure the concurrent entries of log book.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (store) sign/date: Pnt 02/12/21

Verified by (IPQA) sign/date: Pnt 02/12/21

Equipment	Dispensing Booth	Weighing Balance			AREA
Equipment. ID No.	ST/SRDB/001	ST/SRWB/001 (30.0 Kg)	ST/SRWB/002 (620.0g)	ST/WB/189 (150.0 Kg)	
Previous Product & Batch No.	NOVASTAT ASP 20 S2110650412				
Cleaned By	Rh	Rh	Rh	Rh	Rh
Checked by Stores Sign/Date	Pnt 02/12/21	Pnt 02/12/21	Pnt 02/12/21	Pnt 02/12/21	Pnt 02/12/21
Counter checked by IPQA/Sign/Date	Pnt 02/12/21	Pnt 02/12/21	Pnt 02/12/21	Pnt 02/12/21	Pnt 02/12/21

6.2 ENVIRONMENTAL CONDITIONS:

	Observation	Stores Sign
Temperature: 23°C to 27°C	23.5°C	Pnt
Relative Humidity: 45% to 55 %	53%	Pnt

6.3 APPROVAL FOR DISPENSING BY IPQA: Sign: Pnt

Date: 02/12/21

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>Pnt 02/12/21</u>	<u>Pnt 02/12/21</u>	<u>Pnt 02/12/21</u>	CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	16 of 57
Brand Name	RICHTER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO.:	ST/MFG/135/R1	Supersedes MFC No.:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

6.4 INDENT OF CAPSULE:

S.No	Name of the Ingredients	Material Code	Spec	Overages	Total Qty (NO's)	Vendor
1	"0" Size Red/Red hard gelatin capsule(GHPL Printed)	RMER0012	IHS	NIL	454500	ERAWAT PHARMA

6.4.1 DISPENSING OF EMPTY HARD GELATIN CAPSULE AGAINST CAPSULE:

Dispensing Started at Date 03/12/21 Time 15:20

S. No	Name of the Ingredients	Actual Qty. per batch (NO'S)	A.R No:	Gross Weight (Kg)	Tare Weight (Kg)	Net Weight (Kg)	Weighed By Stores	Checked by stores	Verified by IPQA
1	"0" Size Red/Red hard gelatin capsule(GHPL Printed) IHS	454500	mSP/2021/024/02R/01072	10.000	0.400	9.600	ph	ph	ph
			mSP/2021/024/02R/01072	10.000	0.400	9.600	ph	ph	ph
			mSP/2021/024/02R/01072	10.000	0.400	9.600	ph	ph	ph
			mSP/2021/024/02R/01072	10.000	0.400	9.600	ph	ph	ph
			mSP/2021/024/02R/01072	5.800	0.400	5.400	ph	ph	ph

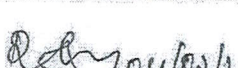
	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<i>[Signature]</i> 04/12/21	<i>[Signature]</i> 04/12/21	<i>[Signature]</i> 04/12/21	

	Safetab Life Science		MASTER COPY		
	BATCH MANUFACTURING RECORD		Page No.:	17 of 57	
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

7.0 VERIFICATION OF DISPENSED MATERIALS:

S.No	Name of the Ingredients	Gross weight in Kg	A.R.No.	Checked by Production Sign/Date	Checked by IPQA Sign/Date
1	Carbonyl Iron USP	20.88	mep/2122/ben/ben/100213	E. S. S. S. S.	18/11/21
		21.60	mep/2122/ben/ben/100262	E. S. S. S. S.	18/11/21
		NA	NA	NA	NA
2	Folic Acid BP	0.31	mep/2122/ben/ben/100286	E. S. S. S. S.	18/11/21
		NA	NA	NA	NA
		NA	NA	NA	NA
3	Cyanocobalamin BP	11.26	mep/2122/ben/ben/100256	E. S. S. S. S.	18/11/21
		NA	NA	NA	NA
		NA	NA	NA	NA
4	Ascorbic Acid BP	28.30	mep/2122/ben/ben/100678	E. S. S. S. S.	18/11/21
		3.92	mep/2122/ben/ben/100692	E. S. S. S. S.	18/11/21
		11.82	mep/2122/ben/ben/100712	E. S. S. S. S.	18/11/21
5	Zinc Sulfate Monohydrate BP	26.20	mep/2122/ben/ben/100686	E. S. S. S. S.	18/11/21
		2.54	mep/2122/ben/ben/100686	E. S. S. S. S.	18/11/21
		NA	NA	NA	NA
6	Vitamin E Acetate 50% granules BP	17.17	mep/2122/ben/ben/100219	E. S. S. S. S.	18/11/21
		NA	NA	NA	NA
		NA	NA	NA	NA
7	Sodium Selenate IHS	95.25	mep/2122/ben/ben/100212	E. S. S. S. S.	18/11/21
		NA	NA	NA	NA
		NA	NA	NA	NA
8	Hydrophobic Colloidal anhydrous silica BP	1.26	mep/2122/ben/ben/100616	E. S. S. S. S.	18/11/21
		NA	NA	NA	NA
		NA	NA	NA	NA
9	Microcrystalline crystalline cellulose PH 102 BP	26.25	mep/2122/ben/ben/100270	E. S. S. S. S.	18/11/21
		26.25	mep/2122/ben/ben/100670	E. S. S. S. S.	18/11/21
		21.02	mep/2122/ben/ben/100270	E. S. S. S. S.	18/11/21
10	Calcium hydrogen phosphate BP	11.60	mep/2122/ben/ben/100279	E. S. S. S. S.	18/11/21
		NA	NA	NA	NA
		NA	NA	NA	NA
11	Purified Talc BP	11.60	mep/2122/ben/ben/100279	E. S. S. S. S.	18/11/21
		NA	NA	NA	NA
		NA	NA	NA	NA
12	Magnesium stearate BP	11.60	mep/2122/ben/ben/100279	E. S. S. S. S.	18/11/21
		NA	NA	NA	NA
		NA	NA	NA	NA

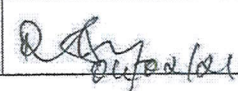
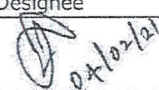
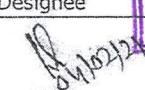
Note: Check the weight of the dispensed material, if found satisfactory, then proceeds to next stage, if any discrepancy inform to QA head for further instruction

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 07/10/21	 07/10/21	 07/10/21	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	18 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO.:	ST/MFC/135/R1	Supersedes MFC No.:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

8.0 VERIFICATION OF DISPENSED EMPTY CAPSULE SHELLS:

S.No	Name of the Ingredients	Gross weight in Kg	A.R.No.	Checked by Production Sign/Date	Checked by IPQA Sign/Date
1	"0" Size Red/Red hard gelatin capsule(GHPL Printed) IHS	10.00	MSP/2021 /Jan/Dec /01072	M. Kyoshty	N.M. 03/12/21
		10.00	MSP/2021 /Jan/Dec /01072	M. Kyoshty	N.M. 03/12/21
		10.00	MSP/2021 /Jan/Dec /01072	M. Kyoshty	N.M. 03/12/21
		10.00	MSP/2021 /Jan/Dec /01072	M. Kyoshty	N.M. 03/12/21
		5.80	MSP/2021 /Jan/Dec /01072	M. Kyoshty	N.M. 03/12/21
				M. Kyoshty	No

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/10/21	 04/10/21	 04/10/21	

	Safetab Life Science			MASTER COPY	
				BATCH MANUFACTURING RECORD	
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	19 of 57
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

9.0 GRANULATION:

9.1 LINE CLEARANCE CHECKS:

S.No	Check	Observation			
		Production		IPQA	
		I	II	I	II
1	Ensure that all empty containers, labels, used polybags, hand gloves of previous Product/ batch are removed from the area.	✓	✓	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓	✓	✓
3	Ensure that the previous batch BMR/documents are removed from the area.	✓	✓	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls ceiling, tube light fixture, supply grills, riser grills, filters and electrical fixtures are clean.	✓	✓	✓	✓
5	Check the cleanliness of the doors, door view panel, SOP stand and compressed air filter outer surface.	✓	✓	✓	✓
6	Check for absence of previous batch/product from area below machine and inside the vessel.	✓	✓	✓	✓
7	Check whether the equipment body of Sifter, RMG, FBD and Multimill, Utensils are clean.	✓	✓	✓	✓
8	Ensure that the balances are cleaned and it's calibration status.	✓	✓	✓	✓
9	Check whether the Equipments/ Instruments to be used are within calibration/preventive maintenance due date.	✓	NA	✓	✓
10	Check the cleanliness of the utility line (compressed air, First RO water and purified water).	✓	✓	✓	✓
11	Check the cleanliness of the drain points.	✓	✓	✓	✓
12	Check the status board of the area is updated.	✓	✓	✓	✓
13	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓	✓	✓
14	Check the differential pressure of the area should be within the limit	✓	✓	✓	✓
15	Ensure the concurrent entries of log book.	✓	✓	✓	✓

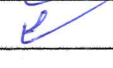
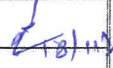
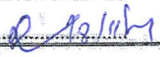
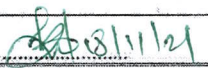
Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (Production) sign/date: <i>[Signature]</i> 18/11/21		DAY I: <i>[Signature]</i> 18/11/21	DAY II: — NA —
Verified by (IPQA) sign/date: <i>[Signature]</i> 18/11/21		DAY I: <i>[Signature]</i> 18/11/21	DAY II: — NA —
Equipment	Vibro sifter	Multimill	Weighing Balance
Equipment ID No:	ST/PRN/006		ST/PRN/006 07/01
Previous Product:	Richfer capsules		
Batch No.	GD211132		
Cleaned by/date:	<i>[Signature]</i> 18/11/21		<i>[Signature]</i> 18/11/21
Checked by/date:	Production: <i>[Signature]</i> 18/11/21	IPQA: <i>[Signature]</i> 18/11/21	

	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	<i>[Signature]</i> 04/12/21	<i>[Signature]</i> 04/12/21	<i>[Signature]</i> 04/12/21

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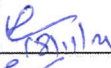
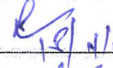
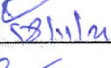
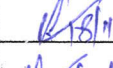
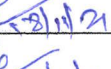
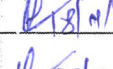
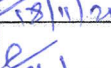
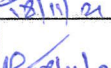
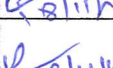
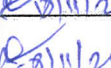
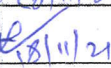
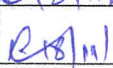
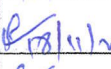
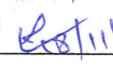
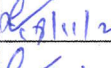
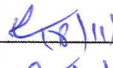
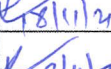
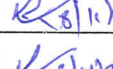
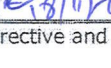
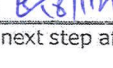
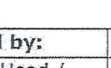
	Safetab Life Science		MASTER COPY		
	BATCH MANUFACTURING RECORD		Page No.:	20 of 57	
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

9.2 ENVIRONMENTAL CONDITIONS	Date: 18/11/21	Time: 10:30	Date:	Time:
	Observation	Production Sign	Observation	Production Sign
Temperature: 23°C to 27°C	2h.1c			
Relative Humidity: 45% to 55 %	57.1			
9.3 APPROVAL FOR SIFTING:				
Production Sign/Date: 		IPQA Sign/Date: 		

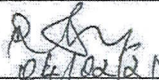
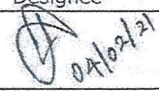
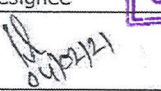
9.4 SIFTING INSTRUCTIONS:

S. NO	PROCESS INSTRUCTIONS
1	Check the cleanliness of the Vibro sifter.
2	Use hand gloves while handling the materials.
3	Use Sodium vapor lamp throughout the process.
4	Carryout the sifting operation as per current version of SOP.
5	Check the integrity of sieve before and after sifting and record in the BMR.
6	Collect sifted materials in cleaned containers in polythene bag.

9.5 SIFTING RECORD:

S. No	Name of Ingredient	Mesh size of sieve	Integrity checked before use	Checked By Production/ Date	Verified by IPQA/ date	Integrity checked after use	Checked By Production/ Date	Verified by IPQA/ date
1	Carbonyl Iron USP	30#	OK/ Not-OK		18/11/21	OK/ Not-OK		18/11/21
2	Folic Acid BP	30#	OK/ Not-OK		18/11/21	OK/ Not-OK		18/11/21
3	Cyanocobalamin BP	30#	OK/ Not-OK		18/11/21	OK/ Not-OK		18/11/21
4	Ascorbic Acid BP	30#	OK/ Not-OK		18/11/21	OK/ Not-OK		18/11/21
5	Zinc Sulfate Monohydrate BP	30#	OK/ Not-OK		18/11/21	OK/ Not-OK		18/11/21
6	Vitamin E Acetate 50% granules BP	30#	OK/ Not-OK		18/11/21	OK/ Not-OK		18/11/21
7	Sodium Selenate IHS	30#	OK/ Not-OK		18/11/21	OK/ Not-OK		18/11/21
8	Hydrophobic Colloidal anhydrous silica PB	30#	OK/ Not-OK		18/11/21	OK/ Not-OK		18/11/21
9	Microcrystalline crystalline cellulose PH 102 BP	30#	OK/ Not-OK		18/11/21	OK/ Not-OK		18/11/21
10	Calcium hydrogen phosphate BP	30#	OK/ Not-OK		18/11/21	OK/ Not-OK		18/11/21
11	Purified Talc BP	30#	OK/ Not-OK		18/11/21	OK/ Not-OK		18/11/21
12	Magnesium stearate BP	60#	OK/ Not-OK		18/11/21	OK/ Not-OK		18/11/21

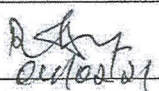
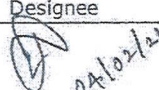
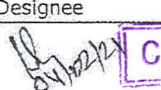
Note: If any discrepancy found, Initiate the deviation for corrective and preventive action and proceed to next step after QA approval.
*Document the sieve integrity asv.

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/10/21	 04/10/21	 04/10/21	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	21 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO.:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

9.6 SIFTING PROCESS:

Step No	Process Instructions	Date : 18/11/24		Done By	Checked by/Date
		Time			
		Started	Completed		
9.7.1	Sift 50.00 Kg of Microcrystalline cellulose PH 102, 0.31 Kg of Folic Acid, 33.44 Kg of Zinc Sulfate Monohydrate, and 15.95 Kg of Vitamin E Acetate 50% granules BP through 30#.	11:10	11:30	Pia	R 18/11/24
9.7.2	Sift 6.50 Kg of Calcium hydrogen Phosphate, 11.26 Kg of Cyanocobalamin (Coated) through 30#.	11:35	11:55	Pia	R 18/11/24
9.7.3	Sift 22.22 Kg of Microcrystalline crystalline cellulose PH 102, 45.08 Kg of Carbonyl Iron, 60.51 Kg of Ascorbic Acid, 87.25 Kg of Sodium Selenate through 30#.	12:00	12:15	Pia	R 18/11/24
9.7.4	Sift 6.50 Kg of Talc, 1.35 Kg of Hydrophobic colloidal anhydrous silica through 30#.	12:18	12:35	Pia	R 18/11/24
9.7.5	Sift 6.50 Kg of Magnesium Stearate Through 60#.	12:36	12:46	Pia	R 18/11/24

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date		 04/10/24	 04/10/24	CONTROLLED COPY

	Safetab Life Science		MASTER COPY		
BATCH MANUFACTURING RECORD			Page No.:	22 of 57	
Brand Name	RICHTER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

10.0 BLENDING AND LUBRICATION:

10.1 LINE CLEARANCE CHECKS:

S.No	Checks	Observation	
		production	IPQA
1	Ensure that all empty containers, used polybags, labels, hand gloves of previous Product/ batch are removed from the area.	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓
3	Ensure that the previous batch BMR / documents are removed from the area.	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls ceiling, tube light fixture, supply grills, riser grills, filters and electrical fixtures are clean.	✓	✓
5	Check the cleanliness of the doors, door view panel and SOP stand.	✓	✓
6	Check the cleanliness of the utility line (compressed air, First RO water and purified water).	✓	✓
7	Check the cleanliness of the drain points.	✓	✓
8	Check for absence of previous batch/product from area below machine and inside machine by opening the guards of Octagonal blender.	✓	✓
9	Check whether the machine body and control panel of octagonal blender is clean.	✓	✓
10	Ensure that the balances are cleaned and it's calibration status.	✓	✓
11	Check whether the Equipments/ Instruments to be used are within calibration/preventive maintenance due date.	✓	✓
12	Check the status board of the area is updated with cleaned label.	✓	✓
13	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓
14	Check the differential pressure of the area should be within the limit.	✓	✓
15	Ensure the concurrent entries of log book.	✓	✓
16	Check the functioning and cleaning of return riser.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

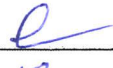
Checked by (production) sign/date: [Signature] 19/11/21

Verified by (IPQA) sign/date: [Signature] 19/11/21

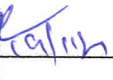
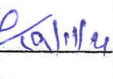
Equipment	Octagonal blender		
Code No			
Previous product	ST/PR-1015		
Batch No	Richter capsules		
Cleaned by:	GD 211131		
Checked by:	[Signature]		
	Production: <u>[Signature]</u>	IPQA: <u>[Signature]</u>	

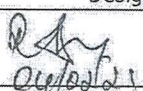
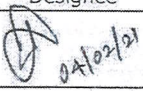
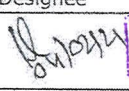
Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	CONTROLLED COPY
Signature with Date	<u>[Signature]</u> 04/12/21	<u>[Signature]</u> 04/12/21	<u>[Signature]</u> 04/12/21	

	Safetab Life Science			MASTER COPY	
BATCH MANUFACTURING RECORD				Page No.:	23 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

10.2 ENVIRONMENTAL CONDITIONS:	Date: 19/11/21	Time: 12:55
	Observation	Production Sign
Temperature: 23°C to 27°C	23.6	
Relative Humidity: 45% to 55 %	51.7	
10.3 APPROVAL FOR BLENDING AND LUBRICATION:		
Production Sign/Date: 		IPQA Sign/Date: 

10.4 BLENDING AND LUBRICATION INSTRUCTION:

Step No.	Process Instructions	Date: 19/11/21		Done by	Checked by/Date
		Time			
		Started	Completed		
1	Use hand gloves, nose mask while handling the materials.				
2	Operate the Octagonal Blender as per the current version of the SOP.				
3	Load the sifted materials (Step No: 9.7.1, 9.7.2, 9.7.3, 9.7.4) into octagonal blender.	13:00	13:15	cineth	
4	Mix for 30 minutes.	13:18	13:48	cineth	
5	Add the sifted Magnesium Stearate distribute / sprinkle over the blended material.	13:50	13:55	cineth	
6	Mix for 5 minutes.	13:56	14:01	cineth	
7	Unload the final blend into suitable containers lined with double polythene bag container with proper label.	14:02	14:15	cineth	
8	Record the weight in below mentioned table.	14:17	14:20	cineth	

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date				

	Safetab Life Science			MASTER COPY	
BATCH MANUFACTURING RECORD				Page No.:	24 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

10.5 WEIGHING OF FINAL BLEND: Date: 19/11/24

Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg
1	41.40	2.70	38.70	16			
2	40.87	2.70	38.17	17			
3	42.15	2.50	39.65	18			
4	37.76	2.50	35.26	19			
5	40.05	2.50	37.55	20			
6	37.67	2.50	35.17	21			
7				22			
8				23			
9				24			
10				25			
11				26			
12				27			
13				28			
14				29			
15				30			

Total weight of Lubricated granules: 224.50 kg

Weighed by: V. S. Raman

Checked sign by/date: 19/11/24

Intimate IPQA to draw the sample.

Sample withdrawn by IPQA

Production Sign: [Signature] Date: 19/11/24

IPQA Sign: [Signature] Date: 19/11/24

Send Test request form for lubricated granules to QC department.

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	CONTROLLED COPY
Signature with Date	[Signature] 24/12/24	[Signature] 24/12/24	[Signature] 24/12/24	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	25 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO.:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

10.6 RECONCILIATION:

1.0	Theoretical weight of blend	:	225.000 Kg
2.0	Actual weight of blend	:	224.50 Kg
3.0	Manufacturing Loss (1.0 - 6.0)	:	0.40 Kg
4.0	In-process samples		
	A IPQA Samples	:	Kg
	B QC Samples	:	0.05 Kg
	C Validation Samples	:	0.05 Kg
5.0	Total samples: (A + B + C)	:	0.10 Kg
6.0	Total: (2.0 + 5.0)	:	224.60 Kg
7.0	% Yield = $\frac{6.0}{1.0} \times 100$ (Limit- NLT 99.00%)	:	99.82 %

Reconciliation done by Production sign/Date: 19/11/21 Checked by IPQA sign/Date: 19/11/21

If yield is out of limit, raise deviation and inform to QA. After QA, investigation and approval proceed to the next stage.

Total rejects destroyed: 0.40 Kg's (Rejected materials should be destroyed in the presence of QA)

Done by Production sign/Date: 19/11/21 Checked by IPQA sign/Date: 19/11/21

10.7 BLENDED GRANULES RELEASED FOR CAPSULE FILLING:

Reconciliation checked and blended granules released for Capsule Filling.

Production sign/Date: 19/11/21 IPQA sign/Date: 19/11/21

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>19/11/21</u>	<u>19/11/21</u>	<u>19/11/21</u>	CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
BATCH MANUFACTURING RECORD				Page No.:	26 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO.:	ST/MFC/135/R1	Supersedes MFC No.:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

11.0 CAPSULE FILLING:

11.1 LINE CLEARANCE CHECKS:

S.No	Checks	Observation	
		Production	IPQA
1	Ensure that all empty containers, labels, used polybags, labels, hand gloves of previous Product/ batch are removed from the area.	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓
3	Ensure that the previous batch BMR / documents are removed from the area.	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls, ceiling, windows, tube light fixture, supply grills, riser grills, filters and electrical fixtures are clean.	✓	✓
5	Check the cleanliness of the doors, door/window view panel, SOP stand and compressed air filter outer surface.	✓	✓
6	Ensure that the balances are cleaned and it's calibration status.	✓	✓
7	Check whether the Equipments/ Instruments to be used are within calibration/preventive maintenance due date.	✓	✓
8	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓
9	Check the status board of the area is updated with cleaned label.	✓	✓
10	Check the differential pressure of the area should be within the limit.	✓	✓
11	Ensure the concurrent entries of log book.	✓	✓
12	Check the functioning and cleaning of return riser	✓	✓
13	Check the Release Status of product blend / granules/ pallets/ tablets.	✓	✓
14	Ensure that the Polythene bag of dust bin replaced with new bag.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (Production) sign/date: S.M. 03/12/21

Verified by (IPQA) sign/date: N.M. 03/12/21

Checked By: Production, Sign: [Signature]								
Equipment	Pharmas 11 Abo	CWM	CPM	FCS	ELSE	DDU	ULS	Area
Equipment ID No:	ST/PAC/101	ST/PAC/102	ST/PAC/103	ST/PAC/104	ST/PAC/105	ST/PAC/106	ST/PAC/107	
Previous product	Richfer capsule							
Batch No.	4D211131							

11.2 ENVIRONMENTAL CONDITIONS

	Date: 03/12/21		Date: 04/12/21	
	Observation	Production Sign	Observation	Production Sign
Temperature: 23°C to 27°C	24°C	S.M.	24.3°C	✓
Relative Humidity: 45% to 55 %	53%	S.M.	51%	✓

11.3 APPROVAL FOR CAPSULE FILING:

Production executive Sign: S.M. Date: 03/12/2021

Product Changeover Line clearance IPQA Sign: N.M. Date: 03/12/21

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	CONTROLLED COPY
Signature with Date	<u>[Signature]</u> 04/12/21	<u>[Signature]</u> 04/12/21	<u>[Signature]</u> 04/12/21	

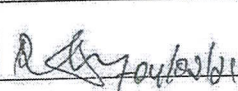
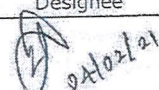
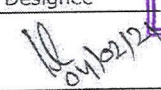
	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	27 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg. Date:	11/2021	Exp. Date:	10/2024

11.4 PROCESS INSTRUCTIONS:

S. No	Process Instructions	Start Time	End Time	Done by	Checked by / Date
1	Check the cleanliness of area and equipment.				
2	Set the filling machine with the required change parts.	07:25	07:40	Dinakaran	S. P. 23/12/21
3	Transfer the granules to capsule filling room.	07:45	08:00	Dinakaran	S. P. 23/12/21
4	Operate the capsule filling machine as per the current version of the SOP.	08:05	08:20	Dinakaran	S. P. 23/12/21
5	Collect the initially filled capsules and check for appearance, group weight, weight variation, lock length and disintegration time.	08:25	08:40	Dinakaran	S. P. 23/12/21
6	Get the setting certified from production executive and IPQA after compliance with the 'Filling parameters'.				
7	Carry out the in-process checks as per the frequency mentioned in the following table.				
8	Collect the filled capsule in double polythene bag lined containers with proper label.	09:10	09:50	Packagerepam	Dinakaran
9	Check and record the weight of the filled capsules.				

11.5 CAPSULE FILLING SPECIFICATION / PARAMETERS:

S. No	Parameter	Limits	No. of Capsules to be checked from each side	Frequency	
				Production	IPQA
1	Description	Red/Red '0' size GHPL printed on both body and cap Hard gelatin capsule Filled with Pale Green colour granular powder.	20	Every 30 min	Every 1 hrs
2	Weight of empty capsules(B)	95mg	20	Initial	Initial
3	Net fill weight (C)	500 mg $\pm$ 3.0% (Limit: 485.000 mg to 515.000 mg)	20	Every 2hrs	Every 4hrs
4	Weight of filled capsule A = B + C	595mg $\pm$ 3.0% (Limit: 577.150 mg to 612.850 mg)	20	Every 30 min	Every 1 hrs
5	Weight of 20 filled Capsules(D)=20x A	11.900g $\pm$ 3% (Limit: 11.543g to 12.257g)	20	Every 30 min	Every 1 hrs
6	Uniformity of weight	$\pm$ 5% of average weight (565.250mg to 624.750mg)	20	Every 2hrs	Every 4hrs
7	Locking length	21.40mm $\pm$ 0.4mm (Limit: 21.00mm - 21.80mm)	5	Every 1 hrs	Every 2 hrs
8	Disintegration Time	NMT 30 minutes in 37°C $\pm$ 2°C	6	Every 2hrs	Every 4hrs

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date				

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	28 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC No.:	ST/MFC/135/R1	Supersedes MFC No.:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg. Date:	11/2021	Exp. Date:	10/2024

11.5.1 MACHINE SETTING FOR FILLING:

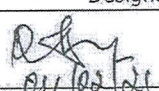
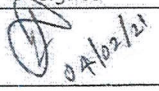
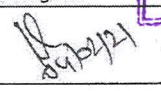
S.No.	Weight of Filled capsules in mg	Weight of Empty capsules in mg	Net weight in mg	Lock Length in mm
1	595	95	500	21.35
2	598	96	502	21.32
3	586	98	488	21.34
4	602	98	505	21.32
5	595	95	500	21.36
6	608	96	512	21.30
7	588	98	490	21.27
8	592	98	495	21.32
9	593	95	498	21.35
10	596	96	500	21.30
11	600	98	502	21.36
12	598	98	500	21.35
13	590	95	495	21.30
14	594	96	498	21.37
15	592	98	500	21.30
16	605	95	510	21.32
17	596	96	500	21.30
18	600	98	502	21.36
19	598	98	500	21.34
20	600	96	504	21.35

Parameters	Instrument used	Observation	Limits
Appearance	Visual	Complies	Red/Red 'O' size GHPL printed on both body and cap Hard gelatin capsule Filled with Pale Green colour granular powder.
Group weight of 20 capsules	Balance	11.902 gm	11.900g $\pm$ 3% (Limit: 11.543g to 12.257g)
Average weight	Balance	595 mg	595mg $\pm$ 3.0% (Limit: 577.150 mg to 612.850 mg)
Lock Length	Vernier	21.32 mm	21.40mm $\pm$ 0.4mm (Limit: 21.00mm - 21.80mm)
Uniformity of mass	Balance	586 mg to 608 mg	$\pm$ 5% of average weight (565.250mg to 624.750mg)
Disintegration Time	Disintegration Tester	03 minutes 42 sec	NMT 30 minutes in 37°C $\pm$ 2°C

M/C set up checked by (Production): S.M. Date: 03/12/2024

Initial Setting capsules Destroyed by : Sign : S.M. Date: 03/12/2024

M/C set up and initial setting capsule destruction checked by IPQA: Sign : N.M. Date: 03/12/2024

	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	 04/12/24	 04/12/24	 04/12/24

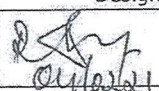
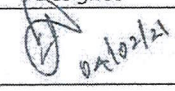
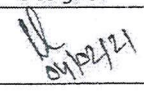
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	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	29 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

11.6 IN-PROCESS CHECKS BY PRODUCTION (EVERY 30 MINUTES)

DATE	TIME	HEG Capsules Size: 10 Color: Cap: Red, Body: Red Printing: GHPL printed on both body and cap Group Weight: 11.900 $\pm$ 3 % Limit: 11.543 gm to 12.257gm Average Weight: 595 mg $\pm$ 3 % Limit: 577.150mg - 612.850mg Lock Length: 21.40mm $\pm$ 0.4mm Limit: 21.00mm to 21.80mm				Checked by Production
		Appearance *	Weight of 20 caps in g	Average weight in mg	Lock Length in mm	
03/12/21	09:15	Complies	11.920	595	21.32	S.M
03/12/21	09:45	Complies	11.912	596	21.30	S.M
03/12/21	10:15	Complies	11.944	598	21.35	S.M
03/12/21	10:45	Complies	11.902	595	21.36	S.M
MFC Stopped at 11:00 to 11:10 due to Tea break						
03/12/21	11:20	Complies	11.962	598	21.34	S.M
03/12/21	11:55	Complies	11.980	599	21.35	S.M
03/12/21	12:30	Complies	11.962	598	21.32	S.M
03/12/21	13:00	Complies	11.920	596	21.34	S.M
03/12/21	13:35	Complies	11.904	595	21.36	S.M
03/12/21	14:10	Complies	11.982	599	21.19	M.B
03/12/21	14:40	Complies	11.924	596	21.27	M.B
03/12/21	15:15	Complies	12.026	601	21.34	M.B
03/12/21	15:45	Complies	11.942	597	21.32	M.B
MFC Stopped at 16:00 to 16:10 due to Tea break						
03/12/21	16:20	Complies	11.925	596	21.41	M.B
03/12/21	16:50	Complies	11.982	599	21.28	M.B
03/12/21	17:30	Complies	12.014	600	21.34	M.B
03/12/21	18:00	Complies	12.024	601	21.19	M.B
03/12/21	18:35	Complies	11.944	597	21.27	M.B
03/12/21	19:05	Complies	11.965	598	21.41	M.B
MFC Stopped at 19:30 to 20:00 due to Dinner break						
03/12/21	20:30	Complies	11.924	596	21.36	M.B
03/12/21	21:05	Complies	12.011	600	21.29	M.B
03/12/21	21:35	Complies	11.962	598	21.35	M.B
03/12/21	22:26	Complies	11.965	597	21.22	A
03/12/21	22:50	Complies	12.001	600	21.28	A

* If appearance are satisfactory document as complies.

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	CONTROLLED COPY
Signature with Date				



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11.6A IN-PROCESS CHECKS BY PRODUCTION (EVERY 30 MINUTES)

* If appearance are satisfactory document as complies.

* wrong Entry 104/124

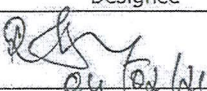
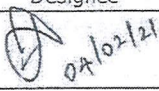
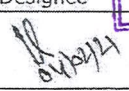
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	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page No.:	31 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules	
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0	
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024	

11.7 IN-PROCESS CHECKS BY IPQA (EVERY 1 HOUR):

DATE	TIME	HEG Capsules Size: '0' Color: Cap: Red, Body: Red Printing: GHPL printed on both body and cap Group Weight: 11.900 $\pm$ 3 % Limit: 11.543 gm to 12.257gm Average Weight: 595 mg $\pm$ 3 % Limit: 577.150mg - 612.850mg Lock Length: 21.40mm $\pm$ 0.4mm Limit: 21.00mm to 21.80mm				Checked by IPQA
		Appearance*	Weight of 20 caps in g	Average weight in mg	Lock Length in mm	
03/12/21	09:25	Complies	12.012	600	21.36	N.M
03/12/21	10:30	Complies	11.947	597	21.31	N.M
— M/C stopped at 11:00 to 11:10 due to tea break —						
03/12/21	11:35	Complies	11.987	599	21.37	N.M
03/12/21	12:35	Complies	11.907	595	21.32	N.M
03/12/21	13:40	Complies	11.924	596	21.36	N.M
03/12/21	14:40	Complies	11.946	597	21.32	OK
03/12/21	15:40	Complies	11.928	596	21.35	OK
— M/C stopped at 16:00 to 16:10 for tea break —						
03/12/21	16:50	Complies	11.932	596	21.28	OK
03/12/21	17:50	Complies	11.967	598	21.34	OK
03/12/21	18:30	Complies	11.723	596	21.37	OK
— M/C stopped at 19:50 to 20:00 for Dinner —						
03/12/21	20:20	Complies	11.928	596	21.36	OK
03/12/21	21:20	Complies	11.947	597	21.32	OK
03/12/21	22:20	Complies	11.962	598	21.28	OK
03/12/21	23:20	Complies	11.907	595	21.33	OK
— M/C stopped at 00:00 to 00:10 due to tea break —						
04/12/21	00:20	Complies	11.986	599	21.25	OK
— Validation samples taken from 00:30 to 00:45 —						
— Machine stopped at 00:50 due to Batch Completed —						

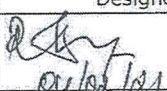
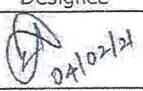
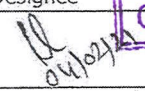
* If appearance are satisfactory document as complies.

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	CONTROLLED COPY
Signature with Date	 04/12/21	 04/12/21	 04/12/21	

	Safetab Life Science		MASTER COPY		
	BATCH MANUFACTURING RECORD			Page No.:	33 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

11.8 IN-PROCESS CHECKS FREQUENCY: EVERY 2 HOUR BY PRODUCTION:

Date: 03/12/24		Time: 09:25											
Weight of 20 capsules : 11.904 gm		Average weight of capsule : 595 mg											
	A	B	C		A	B	C		A	B	C		
1	590	95	495	8	596	98	498	15	592	97	495		
2	594	96	498	9	596	97	499	16	593	95	498		
3	597	97	500	10	595	95	500	17	596	96	500		
4	600	95	505	11	598	96	502	18	599	97	502		
5	603	96	507	12	597	97	500	19	602	95	507		
6	597	97	500	13	604	95	507	20	597	97	500		
7	597	95	502	14	596	96	500						
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight												± 5% of average weight (565.250mg to 624.750mg)	
Min. fill weight 0.495 g 98.80%													
Max. fill weight 0.507 g 101.19%													
Average fill weight of 20 Capsules: 0.501 g													
Disintegration Time : 03 minutes 46 sec										(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by: S.M. (Production)													
Date: 03/12/24		Time: 11:30											
Weight of 20 capsules : 11.944 gm		Average weight of capsule : 597 mg											
	A	B	C		A	B	C		A	B	C		
1	594	96	498	8	595	95	500	15	593	95	498		
2	593	97	502	9	592	96	496	16	596	96	500		
3	595	95	500	10	595	97	498	17	599	97	502		
4	592	96	496	11	595	95	500	18	595	95	500		
5	595	97	498	12	598	96	502	19	602	96	506		
6	595	95	500	13	598	97	500	20	598	98	500		
7	598	96	502	14	593	97	496						
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight												± 5% of average weight (565.250mg to 624.750mg)	
Min. fill weight 0.496 g 99.02%													
Max. fill weight 0.506 g 102.99%													
Average fill weight of 20 Capsules: 0.501 g													
Disintegration Time : 03 minutes 44 sec										(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by: S.M. (Production)													

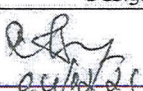
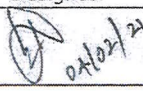
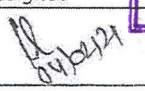
	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	 04/12/24	 04/12/24	 04/12/24

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	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page No.:	34 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules	
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0	
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024	

11.8A IN-PROCESS CHECKS FREQUENCY: EVERY 2 HOUR BY PRODUCTION:

Date: 03/12/21		Time: 13:30					
Weight of 20 capsules : 11.920 gm				Average weight of capsule : 596 mg			
	A	B	C		A	B	C
1	590	95	495	8	596	96	500
2	594	96	498	9	599	97	502
3	597	97	500	10	590	95	495
4	595	95	502	11	594	96	498
5	596	96	500	12	598	98	500
6	592	97	495	13	599	97	502
7	593	95	498	14	602	96	506
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight				± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight 0.494 g 98.82%							
Max. fill weight 0.506 g 101.20%							
Average fill weight of 20 Capsules: 0.596 g							
Disintegration Time : 03 minutes 46 sec				(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by: S.M. (Production)							
Date: 03/12/21		Time: 15:35					
Weight of 20 capsules : 11.982 g				Average weight of capsule : 599 mg			
	A	B	C		A	B	C
1	598	99	499	8	601	99	502
2	592	96	496	9	597	97	500
3	602	98	504	10	592	96	496
4	608	99	509	11	597	98	499
5	595	97	498	12	597	99	498
6	593	96	497	13	604	97	507
7	607	98	509	14	605	96	509
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight				± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight 0.496 g 98.80%							
Max. fill weight 0.509 g 101.39%							
Average fill weight of 20 Capsules: 0.592 g							
Disintegration Time : 03 minutes 51 sec				(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by: M.Sy (Production)							

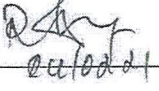
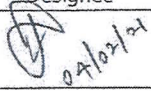
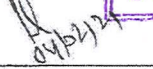
Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee
Signature with Date			

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	Safetab Life Science			MASTER COPY	
BATCH MANUFACTURING RECORD				Page No.:	35 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC No.:	ST/MFC/135/R1	Supersedes MFC No.:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg. Date:	11/2021	Exp. Date:	10/2024

11.8B IN-PROCESS CHECKS FREQUENCY: EVERY 2 HOUR BY PRODUCTION:

Date: 03/12/21 Time: 17:40											
Weight of 20 capsules : 11.964 g						Average weight of capsule : 598 mg					
	A	B	C		A	B	C		A	B	C
1	597	98	499	8	597	97	500	15	604	98	506
2	591	96	495	9	596	98	498	16	597	97	500
3	597	99	498	10	598	96	502	17	596	98	498
4	597	97	500	11	597	97	500	18	594	99	495
5	604	98	506	12	603	99	504	19	596	97	499
6	598	96	502	13	595	98	497	20	604	98	506
7	600	99	501	14	591	96	495				
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight								± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight 0.495 g 99.00%											
Max. fill weight 0.506 g 101.20%											
Average fill weight of 20 Capsules: 0.500 g											
Disintegration Time : 04 mins 41 sec								(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by: H. B. (Production)											
Date: 03/12/21 Time: 20:35											
Weight of 20 capsules : 11.922 g						Average weight of capsule : 596 mg					
	A	B	C		A	B	C		A	B	C
1	598	99	499	8	594	96	498	15	596	98	498
2	591	97	494	9	593	99	494	16	598	96	502
3	598	98	500	10	599	97	502	17	599	99	500
4	600	96	504	11	602	98	504	18	596	97	499
5	597	99	498	12	596	96	500	19	602	98	504
6	599	97	502	13	598	99	499	20	597	96	501
7	598	98	500	14	591	97	494				
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight								± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight 0.494 g 98.99%											
Max. fill weight 0.504 g 101.00%											
Average fill weight of 20 Capsules: 0.499 g											
Disintegration Time : 04 mins 50 sec								(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by: H. B. (Production)											

	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	 24/10/21	 04/12/21	 04/12/21

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	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD					
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules	
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0	
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024	

11.8C IN-PROCESS CHECKS FREQUENCY: EVERY 2 HOUR BY PRODUCTION:

Date: <u>03/12/21</u>		Time: <u>22:35</u>	
Weight of 20 capsules : <u>11.963</u>			
Average weight of capsule : <u>598</u>			
	A	B	C
1	<u>600</u>	<u>99</u>	<u>501</u>
2	<u>600</u>	<u>96</u>	<u>504</u>
3	<u>596</u>	<u>97</u>	<u>599</u>
4	<u>592</u>	<u>97</u>	<u>599</u>
5	<u>602</u>	<u>96</u>	<u>506</u>
6	<u>592</u>	<u>98</u>	<u>594</u>
7	<u>603</u>	<u>99</u>	<u>504</u>
8	<u>601</u>	<u>99</u>	<u>502</u>
9	<u>598</u>	<u>97</u>	<u>501</u>
10	<u>594</u>	<u>96</u>	<u>598</u>
11	<u>601</u>	<u>96</u>	<u>505</u>
12	<u>598</u>	<u>99</u>	<u>599</u>
13	<u>599</u>	<u>97</u>	<u>502</u>
14	<u>602</u>	<u>98</u>	<u>504</u>
15	<u>595</u>	<u>99</u>	<u>596</u>
16	<u>599</u>	<u>98</u>	<u>501</u>
17	<u>592</u>	<u>97</u>	<u>595</u>
18	<u>600</u>	<u>97</u>	<u>503</u>
19	<u>595</u>	<u>98</u>	<u>597</u>
20	<u>602</u>	<u>99</u>	<u>503</u>
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight ± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight <u>0.194</u> g <u>99.21</u> %			
Max. fill weight <u>0.506</u> g <u>101.21</u> %			
Average fill weight of 20 Capsules: <u>0.500</u> g			
Disintegration Time : <u>04 min 48 sec</u> (Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by: <u>A</u> (Production)			
Date: <u>03/12/21</u>		Time: <u>22:35</u>	
Weight of 20 capsules : <u>11.963</u>			
Average weight of capsule : <u>598</u>			
	A	B	C
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight ± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight g %			
Max. fill weight g %			
Average fill weight of 20 Capsules: g			
Disintegration Time : (Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by: (Production)			

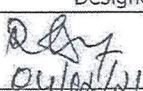
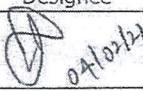
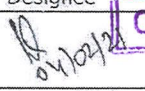
Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee
Signature with Date	<u>[Signature]</u> <u>04/12/21</u>	<u>[Signature]</u> <u>04/12/21</u>	<u>[Signature]</u> <u>04/12/21</u>

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	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page No.:	37 of 57
Brand Name	RICHFER CAPSULES		Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules		MFC NO.:	ST/MFC/135/R1	Supersedes MFC No.:	ST/MFC/135/R0
Batch No.:	GD211132		Mfg.Date:	11/2021	Exp.Date:	10/2024

11.8D IN-PROCESS CHECKS FREQUENCY: EVERY 2 HOUR BY PRODUCTION:

Date:.....		Time:.....					
Weight of 20 capsules :				Average weight of capsule :			
	A	B	C		A	B	C
1			8				15
2			9				16
3			10				17
4			11				18
5			12				19
6			13				20
7			14				
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight				± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight g.....%							
Max. fill weight g.....%							
Average fill weight of 20 Capsules:.....g							
Disintegration Time :				(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by:(Production)							
Date:.....		Time:.....					
Weight of 20 capsules :				Average weight of capsule :			
	A	B	C		A	B	C
1			8				15
2			9				16
3			10				17
4			11				18
5			12				19
6			13				20
7			14				
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight				± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight g.....%							
Max. fill weight g.....%							
Average fill weight of 20 Capsules:.....g							
Disintegration Time :				(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by:(Production)							

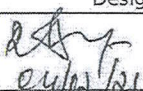
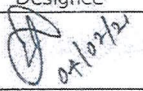
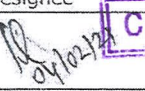
	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	 04/10/21	 04/10/21	 04/10/21

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	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	38 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO.:	ST/MFC/135/R1	Supersedes MFC No.:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

11.8E IN-PROCESS CHECKS FREQUENCY: EVERY 2 HOUR BY PRODUCTION:

Date:..... Time:.....											
Weight of 20 capsules :								Average weight of capsule :			
	A	B	C		A	B	C		A	B	C
1				8				15			
2				9				16			
3				10				17			
4				11				18			
5				12				19			
6				13				20			
7				14							
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight								± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight g.....%											
Max. fill weight g%											
Average fill weight of 20 Capsules:.....g											
Disintegration Time :								(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by:(Production)											
Date:..... Time:.....											
Weight of 20 capsules :								Average weight of capsule :			
	A	B	C		A	B	C		A	B	C
1				8				15			
2				9				16			
3				10				17			
4				11				18			
5				12				19			
6				13				20			
7				14							
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight								± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight g.....%											
Max. fill weight g%											
Average fill weight of 20 Capsules:.....g											
Disintegration Time :								(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by:(Production)											

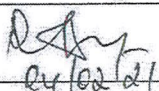
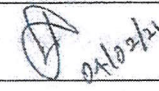
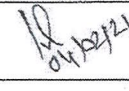
	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	 04/12/21	 04/12/21	 04/12/21

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	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page No.:	39 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules	
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC No.:	ST/MFC/135/R1	Supersedes MFC No.:	ST/MFC/135/R0	
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024	

11.8F IN-PROCESS CHECKS FREQUENCY: EVERY 2 HOUR BY PRODUCTION:

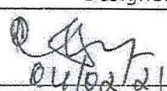
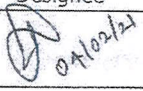
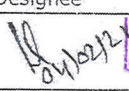
Date:..... Time:.....											
Weight of 20 capsules :								Average weight of capsule :			
	A	B	C		A	B	C		A	B	C
1				8				15			
2				9				16			
3				10				17			
4				11				18			
5				12				19			
6				13				20			
7				14							
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight								± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight g.....%											
Max. fill weight g%											
Average fill weight of 20 Capsules:.....g											
Disintegration Time :								(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by:(Production)											
Date:..... Time:.....											
Weight of 20 capsules :								Average weight of capsule :			
	A	B	C		A	B	C		A	B	C
1				8				15			
2				9				16			
3				10				17			
4				11				18			
5				12				19			
6				13				20			
7				14							
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight								± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight g.....%											
Max. fill weight g%											
Average fill weight of 20 Capsules:.....g											
Disintegration Time :								(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by:(Production)											

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/02/21	 04/02/21	 04/02/21	

	Safetab Life Science		MASTER COPY		
	BATCH MANUFACTURING RECORD		Page No.:	40 of 57	
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO.:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

11.8G IN-PROCESS CHECKS FREQUENCY: EVERY 2 HOUR BY PRODUCTION:

Date:..... Time:.....												
Weight of 20 capsules :						Average weight of capsule :						
	A	B	C			A	B	C		A	B	C
1				8					15			
2				9					16			
3				10					17			
4				11					18			
5				12					19			
6				13					20			
7				14								
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight						± 5% of average weight (565.250mg to 624.750mg)						
Min. fill weight g.....%												
Max. fill weight g%												
Average fill weight of 20 Capsules:.....g												
Disintegration Time :						(Limit: NMT 30 minutes at 37°C ± 2°C)						
Checked by:(Production)												
Date:..... Time:.....												
Weight of 20 capsules :						Average weight of capsule :						
	A	B	C			A	B	C		A	B	C
1				8					15			
2				9					16			
3				10					17			
4				11					18			
5				12					19			
6				13					20			
7				14								
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight						± 5% of average weight (565.250mg to 624.750mg)						
Min. fill weight g.....%												
Max. fill weight g%												
Average fill weight of 20 Capsules:.....g												
Disintegration Time :						(Limit: NMT 30 minutes at 37°C ± 2°C)						
Checked by:(Production)												

	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	 04/10/21	 04/10/21	 04/10/21

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	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	41 of 57
Brand Name	RICHER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

11.9 IN-PROCESS CHECKS FREQUENCY: EVERY 4 HOUR BY IPQA:

Date: <u>03/12/21</u> Time: <u>09:30</u>											
Weight of 20 capsules : <u>12.0128</u>						Average weight of capsule : <u>600mg</u>					
	A	B	C		A	B	C		A	B	C
1	599	96	503	8	597	96	501	15	600	98	502
2	599	98	501	9	600	95	505	16	600	94	506
3	598	96	502	10	596	98	498	17	596	96	500
4	593	97	496	11	600	97	503	18	599	97	502
5	600	95	505	12	603	96	507	19	600	95	505
6	600	98	502	13	598	97	501	20	595	94	501
7	602	94	508	14	598	95	503				
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight ± 5% of average weight (565.250mg to 624.750mg)											
Min. fill weight <u>0.496</u> g <u>98.80</u> %											
Max. fill weight <u>0.508</u> g <u>101.19</u> %											
Average fill weight of 20 Capsules: <u>0.502</u> g											
Disintegration Time : <u>04 min 10 sec</u>						(Limit: NMT 30 minutes at 37°C ± 2°C)					
Checked by: <u>N (m)</u> (IPQA)											
Date: <u>03/12/21</u> Time: <u>13:25</u>											
Weight of 20 capsules : <u>11.9348</u>						Average weight of capsule : <u>596mg</u>					
	A	B	C		A	B	C		A	B	C
1	596	98	498	8	598	97	501	15	592	97	495
2	598	96	502	9	593	95	498	16	593	96	497
3	600	95	505	10	599	96	503	17	594	95	499
4	592	97	495	11	602	96	506	18	599	97	502
5	594	96	498	12	600	98	502	19	600	95	505
6	599	97	502	13	596	96	500	20	600	97	503
7	598	98	500	14	596	98	498				
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight ± 5% of average weight (565.250mg to 624.750mg)											
Min. fill weight <u>0.495</u> g <u>99.00</u> %											
Max. fill weight <u>0.506</u> g <u>101.20</u> %											
Average fill weight of 20 Capsules: <u>0.500</u> g											
Disintegration Time : <u>03 min 57 sec</u>						(Limit: NMT 30 minutes at 37°C ± 2°C)					
Checked by: <u>N (m)</u> (IPQA)											

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	CONTROLLED COPY
Signature with Date	<u>[Signature]</u> 04/12/21	<u>[Signature]</u> 04/12/21	<u>[Signature]</u> 04/12/21	

	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page No.:	42 of 57
Brand Name	RICHFER CAPSULES		Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules		MFC NO.:	ST/MFC/135/R1	Supersedes MFC No.:	ST/MFC/135/R0
Batch No.:	GD211132		Mfg.Date:	11/2021	Exp.Date:	10/2024

11.9A IN-PROCESS CHECKS FREQUENCY: EVERY 4 HOUR BY IPQA:

Date: 03/12/21		Time: 17:35						
Weight of 20 capsules : 11.769g				Average weight of capsule : 598mg				
	A	B	C		A	B	C	
1	593	96	497	8	594	95	499	
2	596	95	501	9	590	96	499	
3	596	96	500	10	599	97	502	
4	596	95	501	11	596	96	500	
5	599	96	503	12	596	95	501	
6	597	95	502	13	599	96	503	
7	593	96	497	14	603	97	506	
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight								± 5% of average weight (565.250mg to 624.750mg)
Min. fill weight 0.494 g 98.80%								
Max. fill weight 0.506 g 101.20%								
Average fill weight of 20 Capsules: 0.500 g								
Disintegration Time : 03 mins 25 sec				(Limit: NMT 30 minutes at 37°C ± 2°C)				
Checked by:  (IPQA)								
Date: 03/12/21		Time: 21:35						
Weight of 20 capsules : 11.948g				Average weight of capsule : 597mg				
	A	B	C		A	B	C	
1	599	96	503	8	594	97	497	
2	596	97	499	9	591	95	496	
3	597	96	501	10	595	96	499	
4	599	95	504	11	597	95	502	
5	596	96	500	12	596	96	500	
6	596	95	501	13	596	95	501	
7	602	96	506	14	603	97	506	
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight								± 5% of average weight (565.250mg to 624.750mg)
Min. fill weight 0.496 g 99.00%								
Max. fill weight 0.506 g 101.00%								
Average fill weight of 20 Capsules: 0.501 g								
Disintegration Time : 03 mins 32 sec				(Limit: NMT 30 minutes at 37°C ± 2°C)				
Checked by:  (IPQA)								

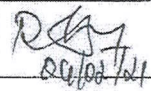
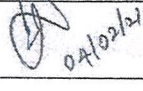
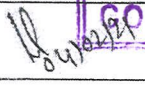
Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee
Signature with Date	 04/12/21	 04/12/21	 04/12/21

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	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page No.:	43 of 57
Brand Name	RICHFER CAPSULES		Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules		MFC No.:	ST/MFC/135/RT	Supersedes MFC No.:	ST/MFC/135/R0
Batch No.:	GD211132		Mfg.Date:	11/2021	Exp.Date:	10/2024

11.9B IN-PROCESS CHECKS FREQUENCY: EVERY 4 HOUR BY IPQA:

Date:.....		Time:.....					
Weight of 20 capsules :				Average weight of capsule :			
	A	B	C		A	B	C
1			8				15
2			9				16
3			10				17
4			11				18
5			12				19
6			13				20
7			14				
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight				± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight g.....%							
Max. fill weight g%							
Average fill weight of 20 Capsules:.....g							
Disintegration Time :				(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by:(IPQA)							
Date:.....		Time:.....					
Weight of 20 capsules :				Average weight of capsule :			
	A	B	C		A	B	C
1			8				15
2			9				16
3			10				17
4			11				18
5			12				19
6			13				20
7			14				
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight				± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight g.....%							
Max. fill weight g%							
Average fill weight of 20 Capsules:.....g							
Disintegration Time :				(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by:(IPQA)							

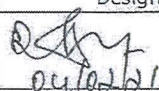
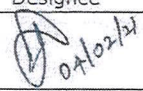
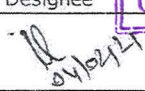
	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	 04/02/21	 04/02/21	 04/02/21

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	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	44 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

11.9C IN-PROCESS CHECKS FREQUENCY: EVERY 4 HOUR BY IPQA:

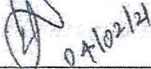
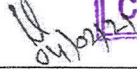
Date:..... Time:.....												
Weight of 20 capsules :						Average weight of capsule :						
	A	B	C			A	B	C		A	B	C
1				8					15			
2				9					16			
3				10					17			
4				11					18			
5				12					19			
6				13					20			
7				14								
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight									± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight g.....%												
Max. fill weight g.....%												
Average fill weight of 20 Capsules:.....g												
Disintegration Time :						(Limit: NMT 30 minutes at 37°C ± 2°C)						
Checked by:(IPQA)												
Date:..... Time:.....												
Weight of 20 capsules :						Average weight of capsule :						
	A	B	C			A	B	C		A	B	C
1				8					15			
2				9					16			
3				10					17			
4				11					18			
5				12					19			
6				13					20			
7				14								
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight									± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight g.....%												
Max. fill weight g.....%												
Average fill weight of 20 Capsules:.....g												
Disintegration Time :						(Limit: NMT 30 minutes at 37°C ± 2°C)						
Checked by:(IPQA)												

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 24/02/21	 04/02/21	 04/02/21	

	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD					
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	45 of 57	
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Batch Size	4,50,000 Capsules	
Batch No.:	GD211132	Mfg.Date:	11/2021	Supersedes MFC No:	ST/MFC/135/R0	
		Exp.Date:	10/2024			

11.9D IN-PROCESS CHECKS FREQUENCY: EVERY 4 HOUR BY IPQA:

Date: Time:											
Weight of 20 capsules :						Average weight of capsule :					
	A	B	C		A	B	C		A	B	C
1				8				15			
2				9				16			
3				10				17			
4				11				18			
5				12				19			
6				13				20			
7				14							
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight								± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight g.....%											
Max. fill weight g.....%											
Average fill weight of 20 Capsules:.....g											
Disintegration Time :						(Limit: NMT 30 minutes at 37°C ± 2°C)					
Checked by:(IPQA)											
Date: Time:											
Weight of 20 capsules :						Average weight of capsule :					
	A	B	C		A	B	C		A	B	C
1				8				15			
2				9				16			
3				10				17			
4				11				18			
5				12				19			
6				13				20			
7				14							
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight								± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight g.....%											
Max. fill weight g.....%											
Average fill weight of 20 Capsules:.....g											
Disintegration Time :						(Limit: NMT 30 minutes at 37°C ± 2°C)					
Checked by:(IPQA)											

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/02/21	 04/02/21	 04/02/21	

	Safetab Life Science		MASTER COPY		
	BATCH MANUFACTURING RECORD		Page No.:	46 of 57	
Brand Name	RICHER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC No.:	ST/MFC/135/R1	Supersedes MFC No.:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg. Date:	11/2021	Exp. Date:	10/2024

12.0 WEIGHING RECORD OF FILLED CAPSULES:

Cont. No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by	Cont. No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by
1	11.12	1.80	9.32	Dinakaran	S.M.	26	11.91	1.80	10.02	Pachayappa	P
2	10.84	1.80	9.04	Dinakaran	S.M.	27	11.57	1.80	9.77	Pachayappa	P
3	11.08	1.80	9.28	Dinakaran	S.M.	28	10.87	1.80	9.07	Pachayappa	P
4	11.39	1.80	9.51	Dinakaran	S.M.	29	11.62	1.80	9.82	Pachayappa	P
5	11.50	1.80	9.70	Dinakaran	S.M.	30					
6	10.64	1.80	8.84	Dinakaran	S.M.	31					
7	11.01	1.80	9.21	Dinakaran	S.M.	32					
8	11.12	1.80	9.32	Dinakaran	S.M.	33					
9	11.98	1.80	10.18	Dinakaran	S.M.	34					
10	10.39	1.80	8.59	Dinakaran	S.M.	35					
11	11.84	1.80	10.04	Labshu	M.G	36					
12	11.20	1.80	9.40	Labshu	M.G	37					
13	11.74	1.80	9.94	Labshu	M.G	38					
14	11.22	1.80	9.42	Labshu	M.G	39					
15	11.79	1.80	9.99	Labshu	M.G	40					
16	11.72	1.80	9.92	Labshu	M.G	41					
17	10.88	1.80	9.08	Labshu	M.G	42					
18	11.08	1.80	9.28	Labshu	M.G	43					
19	11.02	1.80	9.22	Labshu	M.G	44					
20	11.47	1.80	9.67	Labshu	M.G	45					
21	10.72	1.80	8.92	Labshu	M.G	46					
22	9.43	1.80	7.63	Labshu	M.G	47					
23	11.07	1.80	9.27	Pachayappa	P	48					
24	11.67	1.80	9.87	Pachayappa	P	49					
25	11.50	1.80	9.70	Pachayappa	P	50					
Total weight of Filled capsules:										265.87	kg

Intimate IPQA to draw the sample		Sample withdrawn by IPQA.	
Production Sign: <i>[Signature]</i>	Date: 04/12/21	IPQA Sign: <i>[Signature]</i>	Date: 04/12/21
Send Test request form for analysis of filled capsules to QC department.			

Designation	Prepared by:	Checked by:	Approved by:
	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	<i>[Signature]</i> 04/12/21	<i>[Signature]</i> 04/12/21	<i>[Signature]</i> 04/12/21

CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	47 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

12.1 RECONCILIATION:

Average weight of capsule: mg

1.0	Theoretical weight of Filled capsules	:	267.75 Kg	450000 No's
2.0	Actual weight of Filled capsules	:	265.87 Kg	446840 No's
3.0	Capsule filling Loss (1.0 - 6.0)	:	0.95 Kg	1597 No's
4.0	In-process samples			
	A IPQA Samples	:	0.63 Kg	1060 No's
	B QC Samples	:	0.06 Kg	100 No's
	C Validation Samples	:	0.24 Kg	400 No's
5.0	Total samples: (A + B + C)	:	0.93 Kg	1560 No's
6.0	Total: (5.0 + 2.0)	:	266.80 Kg	448403 No's
7.0	% Yield = $\frac{6.0}{1.0} \times 100$ (Limit: NLT 97.00 %)	:	99.64	%

Reconciliation done by Production sign/Date: 20/12/21

Checked by IPQA sign/Date: 20/12/21

If yield is out of limit, raise deviation and inform to QA. After QA, investigation and approval proceed to the next stage.

Total rejects destroyed: 0.95 Kg Rejected materials shall be destroyed in the presence of QA

Done by Production sign/Date: 20/12/21 Checked By IPQA sign/Date: 20/12/21

12.2 CAPSULES RELEASED FOR INSPECTION:

Production Sign/Date: 20/12/21

IPQA Sign/Date: 20/12/21

	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	CONTROLLED COPY
Designation				
Signature with Date	<u>[Signature]</u> 20/12/21	<u>[Signature]</u> 20/12/21	<u>[Signature]</u> 20/12/21	

	Safetab Life Science			MASTER COPY	
				BATCH MANUFACTURING RECORD	
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	48 of 57
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

13.0 CAPSULE INSPECTION:

13.1 LINE CLEARANCE CHECKS:

S.No	Checks	Observation	
		production	IPQA
1	Check whether empty containers, polythene bags and documents of previous batch/product are removed from the area.	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓
3	Check the absence of tablets of previous batch/product in the container and surrounding area.	✓	✓
4	Check the area (floor, wall, ceiling, door, windows) are clean.	✓	✓
5	Check whether the tube light fixture, supply grills, riser grills, filters and electrical fixtures are clean.	✓	✓
6	Check whether the daily records are updated and signed.	✓	✓
7	Check the environmental condition and record in BMR.	✓	✓
8	Check whether area and equipment status board is updated.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (Production) sign/date: S. R. 03/12/21

Verified by (IPQA) sign/date: C. R. 03/12/21

ENVIRONMENTAL CONDITIONS:	Date: <u>02/12/2021</u>		Date:	
	Observation	Production Sign	Observation	Production Sign
Temperature: 23°C to 27°C	<u>24°C</u>	<u>S. R.</u>		
Relative Humidity: 45% to 55 %	<u>53%</u>	<u>S. R.</u>		

13.2 APPROVAL FOR INSPECTION:

Production Sign/Date: S. R. 03/12/2021

IPQA Sign./Date: C. R. 03/12/21

S. No	Process Instructions
1	Carry out visual inspection of capsules on capsule manual inspection area.
2	Collect inspected capsules in containers lined with polythene bags. Weigh the containers and record the weight.
3	Intimate In-process Quality Assurance.

13.3 CAPSULES VISUAL INSPECTION RECORD:

Date	Container No		Time		Total Quantity Rejected	Capsule Inspection Done by/Date	Checked by/Date
	From	To	Started	Completed			
<u>03/12/21</u>	<u>01</u>	<u>09</u>	<u>09:20</u>	<u>10:50</u>	<u>0.52</u>	<u>S. R. 03/12/21</u>	<u>S. R. 03/12/21</u>
<u>1</u>							

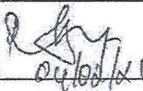
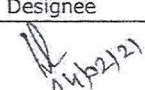
Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee
Signature with Date	<u>S. R. 03/12/21</u>	<u>C. R. 03/12/21</u>	<u>C. R. 03/12/21</u>

CONTROLLED COPY

	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page No.:	49 of 57
Brand Name	RICHER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules	
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO.:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0	
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024	

13.4 WEIGHING RECORD OF INSPECTED CAPSULES:

Cont. No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by	Cont. No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by
1	11.10	1.80	9.30	Shamila	S.R.	26	11.80	1.80	10.00	Silambar	A
2	10.82	1.80	9.02	Shamila	S.R.	27	11.55	1.80	9.75	Silambar	A
3	11.02	1.80	9.22	Shamila	S.R.	28	10.85	1.80	9.05	Silambar	A
4	11.38	1.80	9.50	Shamila	S.R.	29	10.62	1.80	8.82	Silambar	A
5	11.49	1.80	9.69	Shamila	S.M.	30					
6	10.62	1.80	8.82	Shamila	S.M.	31					
7	10.99	1.80	9.19	Shamila	S.M.	32					
8	11.15	1.80	9.35	Shamila	S.M.	33					
9	11.96	1.80	10.16	Shamila	S.M.	34					
10	10.39	1.80	8.59	Shamila	S.M.	35					
11	11.82	1.80	10.02	Seetha	M.G.	36					
12	11.18	1.80	9.38	Seetha	M.G.	37					
13	11.73	1.80	9.93	Seetha	M.G.	38					
14	11.20	1.80	9.40	Seetha	M.G.	39					
15	11.77	1.80	9.97	Seetha	M.G.	40					
16	11.70	1.80	9.90	Seetha	M.G.	41					
17	10.86	1.80	9.06	Seetha	M.G.	42					
18	11.06	1.80	9.26	Seetha	M.G.	43					
19	11.00	1.80	9.20	Seetha	M.G.	44					
20	11.05	1.80	9.25	Seetha	M.G.	45					
21	10.70	1.80	8.90	Seetha	M.G.	46					
22	9.41	1.80	7.61	Seetha	M.G.	47					
23	11.05	1.80	09.25	Silambar	A	48					
24	11.45	1.80	09.65	Silambar	A	49					
25	11.63	1.80	9.83	Silambar	A	50					
Total weight of Filled capsules:										96535	kg

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/02/21	 04/02/21	 04/02/21	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	50 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

13.5 RECONCILIATION: (INSPECTION OF CAPSULES)

1.0	Theoretical weight of capsules	:	267.75 kg	450000 No's
2.0	Capsules transferred for Inspection	:	265.87 kg	446840 No's
3.0	Rejected Capsules	:	240 0.52 kg	874 No's
4.0	Total weight of good Capsules	:	265.35 kg	445966 No's
5.0	$\% \text{ Yield} = \frac{4.0}{1.0} \times 100$ (Limit- NLT 96.50%)* * Tentative limit	:	99.10 %	

Reconciliation done by Production sign/Date: 12/12/21 Checked by IPQA sign/Date: 12/12/21

Total rejects destroyed: 0.52 Kg. Rejected materials should be destroyed in the presence of QA.

Done by Packing sign/Date: 12/12/21 Checked by IPQA sign/Date: 12/12/21

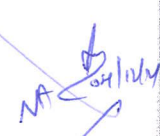
Haroon Entry

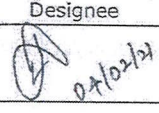
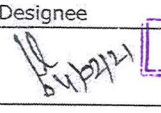
14.0 RELEASE FOR PACKING:
BMR reviewed by IPQA Sign/Date : <u>12/12/21</u>
BMR Released for packing by QA Head Sign/Date: <u>12/12/21</u>

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>12/12/21</u>	<u>12/12/21</u>	<u>12/12/21</u>	CONTROLLED COPY

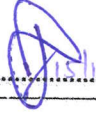
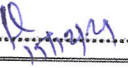
	Safetab Life Science		MASTER COPY		
	BATCH MANUFACTURING RECORD		Page No.:	51 of 57	
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

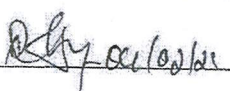
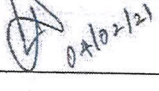
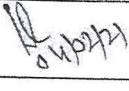
15.0 PROCESS HISTORY

NA 

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/10/21	 04/10/21	 04/10/21	

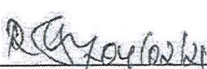
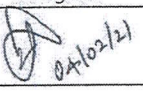
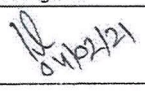
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Brand Name	RICHER CAPSULES	Product ID No.:	1047	Page No.:	52 of 57
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Batch Size	4,50,000 Capsules
Batch No.:	GD211132	Mfg.Date:	11/2021	Supersedes MFC No:	ST/MFC/135/R0
				Exp.Date:	10/2024

16.0 Following the BMR records in additional attached.		Checked by Production Head	Reviewed by QA Head
1	Raw Materials dispensed labels	✓	✓
2	Granulation stage analytical report	✓	✓
3	Filled capsule analytical report	✓	✓
Note: Tick mark (✓) if Complies and (X) if Does not comply. This Batch Manufacturing reviewed on date: 15/12/21 Production Head sign./date:  15/12/21 This Batch Manufacturing Record received, reviewed and batch is released for packing on date: 15/12/21 Reviewed by QA Head:  15/12/21			

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/12/21	 04/12/21	 04/12/21	

	Safetab Life Science			MASTER COPY	
BATCH MANUFACTURING RECORD				Page No.:	53 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO.:	ST/MFC/135/R1	Supersedes MFC No.:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

17.0 ABBREVIATIONS					
S.No.	Short Form	Abbreviation	S.No.	Short Form	Abbreviation
1	BP	British Pharmacopeia	19	A.R.No.	Analytical Report Number
2	API	Active Pharmaceutical Ingredients	20	IPQA	In Process Quality Assurance
3	BMR	Batch Manufacturing Record	21	L	Lakhs
4	MFG	Manufacturing	22	TRF	Test Request Form
5	EXP	Expiry	23	SOP	Standard Operating Procedure
6	QA	Quality Assurance	24	mm	Millimeter
7	Kg	Kilogram	25	NLT	Not Less Than
8	g	Gram	26	NMT	Not More Than
9	lts	Liters	27	Tab	Tablet
10	Min	Minutes	28	RHS	Right Hand Side
11	Hrs	Hours	29	LHS	Left Hand Side
12	M/C	Machine	30	Std	Standard
13	Prod	Production	31	Avg	Average
14	B.No	Batch number	32	rpm	Rotation Per Minute
15	mg	Milligram	33	No's	Numbers
16	Qty	Quantity	34	Sign	Signature
17	QC	Quality Control	35		
18	LOD	Loss On Drying	36		

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/02/21	 04/02/21	 04/02/21	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD				
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

BMR COPY/QUALITY CONTROL COPY

18.0 TEST REQUEST FORM FOR LUBRICATED GRANULES:

From: Manufacturing Department		To: Q.A. Department	
To be filled by production		To be filled by IPQA	
Date of Mfg.: 11/2021 Date of exp.: 10/2024		Quantity Sampled: 50 gm	
Test Request for: Content		Sampled by: D. G. M. on date: 19/11/24	
TRF raised by: [Signature] on date: 19/11/24		No. of containers: 06	
		Sample received by: [Signature] on date: 19/11/24	
To be filled by QC			
TRF received on: 19/11/2021			
Sample tested on: 19/11/2021			
Test Results		Limits	
Each 100mg of Granule contains - Ascorbic acid! - 84.25mg (112.4%), Carbonyl Iron! - 103.02mg (103.0%), Folic acid! - 550.48mg (110.1%), Vitamin E! - 19.27 IU (128.5%), Selenium! - 77.36mg (118.0%), Zinc! - 25.86mg (114.5%), Cyanocobalamin! - 21.7mg (144.7%),			
Analytical Reference no.: GK/01234/2021		Space for QC Approval (Stamping and Signing)	
Analysed By: [Signature] on: 20/11/2021		APPROVED Sign: [Signature] Date: 20/11/24	

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	[Signature] 20/11/24	[Signature] 20/11/24	[Signature] 20/11/24	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	55 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC No.:	ST/MFC/135/R1	Supersedes MFC No.:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg. Date:	11/2021	Exp. Date:	10/2024

BMR COPY/QUALITY CONTROL COPY

19.0 TEST REQUEST FORM FOR FILLED CAPSULES:

From: Manufacturing Department		To: Q.A. Department	
To be filled by production		To be filled by IPQA	
Date of Mfg.: 11/2021		Quantity Sampled : 100 caps	
Date of exp.: 10/2024		Sampled by: [Signature] on date: 04/12/21	
Test Request for: Content		No. of containers: 23	
TRF raised by: [Signature] on date: 04/12/21		Sample received by: [Signature] on date: 04/12/21	
To be filled by QC			
TRF received on: 04/12/2021			
Sample tested on: 15/12/2021			
Test Results			
Each hard gelatin capsule contains: Carbonyl Iron $\Rightarrow$ 101.59 mg (101.6%) Folic acid $\Rightarrow$ 562.27 mcg (112.5%) Cyanocobalamin $\Rightarrow$ 22.8 mcg (148.0%) Ascorbic acid $\Rightarrow$ 87.42 mg (116.6%) Zinc Sulphate mono hydrate eq. zinc $\Rightarrow$ 23.36 mg (112.7%) Alpha Tocopheryl Acetate 50% $\Rightarrow$ 18.70 IU (124.7%) Sodium Selenate eq. Selenium $\Rightarrow$ 75.17 mcg (115.6%)			
Analytical Reference no.: SFP/L/01661/2021		Space for QC Approval (Stamping and Signing)	
Analysed By: K. Sam on: 15/12/2021		APPROVED Sign: [Signature] Date: 15/12/21	

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee
Signature with Date	[Signature] 04/12/21	[Signature] 04/12/21	[Signature] 04/12/21

CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
BATCH MANUFACTURING RECORD				Page No.:	56 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC No.:	ST/MFC/135/R1	Supersedes MFC No.:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg. Date:	11/2021	Exp. Date:	10/2024

20.0 BATCH MANUFACTURING RECORD REVIEW CHECK LIST		
S.No. No.	CHECK POINTS	Status
1	The entire Page no: <u>1</u> to <u>57</u> are available, verified and found correct.	✓ Yes / No
2	Batch numbers available in all pages verified and are correct.	✓ Yes / No
3	Manufacturing and expiry is correctly allotted verified.	✓ Yes / No
4	Dispensing carried out on calibrated balance verified.	✓ Yes / No
5	Dispensing Cards attached.	✓ Yes / No
6	Line clearance is taken prior to all dispensing and manufacturing activities.	✓ Yes / No
7	Dispensing is carried out as per indent of raw materials are correct.	✓ Yes / No
8	Environmental conditions comply during all the manufacturing steps.	✓ Yes / No
9	All wrong entries if any have been strike out and signed and verified.	✓ Yes / No
10	Actual equipment used is as specified and verified.	✓ Yes / No
11	Blend, Compressed Tablet container labels are attached.	✓ Yes / No
12	Lubrication, Compression and Inspection reconciliation is filled and variance is within acceptance limit.	✓ Yes / No
13	If any deviation and change control raised related to this batch attached with Batch record.	Yes / No / NA
Note:	If any abnormalities noticed during batch manufacturing record review it should be brought to the notice of QA Head.	

Batch Manufacturing Record reviewed by IPQA Sign/Date: 15/12/21

QA Head Sign/Date: 15/12/21

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>[Signature]</u> <u>04/12/21</u>	<u>[Signature]</u> <u>04/12/21</u>	<u>[Signature]</u> <u>04/12/21</u>	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	57 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211132	Mfg.Date:	11/2021	Exp.Date:	10/2024

21.0 REVISION HISTORY:

Revision No.	Date of Revision	Changes Made	Effective Date
00	--	1. New product introduced refer change control No: ST/CC/20/076.	03.12.2020
01	04/02/21	1. Yield limit fixed based on trend sate refer changer control no: ST/CC/21/010.	06/02/21

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	