

	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.:	GD211131	Mfg. Date:	11/2021	Exp. Date:	10/2024

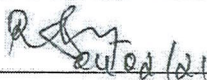
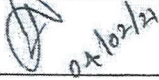
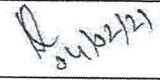
BATCH MANUFACTURING RECORD COVER SHEET:

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/NOV 1	BMR. No	STBMR:137/01		
EXP. DATE:	: 10/NOV 4	Supersedes BMR.No	STBMR:137/00		
BMR ISSUED BY/DATE (QA)	: 25/11/21				
BMR CHECKED & RECEIVED BY/DATE (PRODUCTION)	: 11/11/21				
Allotted By: QA Executive Sign/Date: 25/11/21					
DATE OF COMMENCEMENT: 12/11/21		DATE OF COMPLETION: 13/12/21			
This BMR contains 57 Pages + Annexure-1 + Nil Additional Pages					
Checked by Competent Staff Sign/Date: 13/12/21					
Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee		
Signature with Date	25/11/21	13/12/21	13/12/21	CONTROLLED COPY	

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				BATCH MANUFACTURING RECORD	
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	2 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.:	GD211131	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	 24/12/21	 24/12/21	 24/12/21	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	3 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.:	GD211131	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.	ARABVA.L - ARH21021				
Cleaned By	<i>ngn</i>	<i>ngn</i>	<i>ngn</i>	<i>ngn</i>	<i>ngn</i>
Checked by Stores Sign/Date	<i>[Signature]</i> 17/11/21	<i>[Signature]</i> 17/11/21	<i>[Signature]</i> 17/11/21	<i>[Signature]</i> 17/11/21	<i>[Signature]</i> 17/11/21
Counter checked by IPQA/Sign/Date	<i>[Signature]</i> 17/11/21	<i>[Signature]</i> 17/11/21	<i>[Signature]</i> 17/11/21	<i>[Signature]</i> 17/11/21	<i>[Signature]</i> 17/11/21

2.2 ENVIRONMENTAL CONDITIONS:

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

2.3 APPROVAL FOR DISPENSING BY IPQA: Sign: *[Signature]*

Date: 17/11/21

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

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	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.:	GD211131	Mfg.Date:	11/2021	Exp.Date:	10/2024	

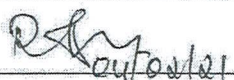
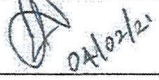
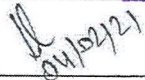
3.0 INDENT OF RAW MATERIALS:

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	 04/05/21	 04/05/21	 04/05/21	

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				BATCH MANUFACTURING RECORD	
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	5 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.:	GD211131	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/QA/602/00713	06/21	may/26	99.6
-	-	-	-

*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

$$= \frac{10000 \cdot 87}{99.6} = 100.402 \text{ mg/Caps.}$$

*Qty of Carbonyl Iron to be added per batch = 45.181 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: [Signature] checked by(production)/date: [Signature] Verified by(QA)/date: [Signature]

* Wrong Entry [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> 06/02/21	<u>[Signature]</u> 04/02/21	<u>[Signature]</u> 04/02/21	

	Safetab Life Science		MASTER COPY		
	BATCH MANUFACTURING RECORD		Page No.:	6 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.:	GD211131	Mfg.Date:	11/2021	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/2122/000100796	JUL/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 = $0.600 \times 100 \times 100$ -----mg/capsule

% Assay on anhydrous basis X (100 – water content %)

$$= \frac{6000}{9209.781} \times 0.651 = 651.481 \text{ mg / 1000}$$

*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: **Q. V. J.** checked by(production)/date: **Q. V. J.** Verified by(QA)/date: **Q. V. J.**

* wrong Entry mg 17/11/21

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

	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.:	GD211131	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 %
mg/212269/00756	Jul/21	Jul/26	97.7	4.23
—	—	—	—	—

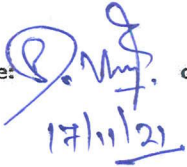
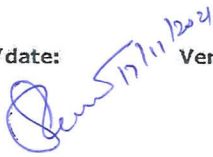
*The given quantity is based on 100% Assay on dried basis and without Loss on drying.
Actual quantity to be added is calculated as:

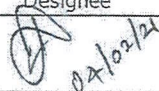
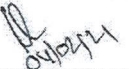
$$\text{Actual quantity. of Cyanocobalamin} = \frac{0.023 \times 100 \times 100}{\% \text{ Assay on dried basis} \times (100 - \text{LOD} \%)} \text{ mg/capsule}$$

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

*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:  17/11/21 checked by(production)/date:  17/11/21 Verified by(QA)/date:  17/11/21

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 02/10/21	 02/10/21	 02/10/21	

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	BATCH MANUFACTURING RECORD		Page No.:	8 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.:	GD211131	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 (%)
mgp/2122/06/002/00719	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:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>[Signature]</u> 06/02/21	<u>[Signature]</u> 06/02/21	<u>[Signature]</u> 06/02/21	

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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.:	GD211131	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 (%)
MSP/2122/QA/02/00686	AUG/21	JUL/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 = 74.160×100 -----mg/capsule

% Assay of Zinc sulfate Monohydrate

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

*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:

[Signature]
17/11/21

checked by(production)/date:

[Signature]
17/11/2021

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	<i>[Signature]</i> 04/02/21	<i>[Signature]</i> 04/02/21	<i>[Signature]</i> 04/02/21	

	Safetab Life Science		MASTER COPY		
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.:	GD211131	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 (%)
mgp/2122/QA/has/00698	SEP/21	AUG/25	100.2
—	—	—	—

*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 = $\frac{90.000 \times 100}{\text{---}} \text{mg/capsule}$

% Assay of Ascorbic Acid

$$= \frac{9000}{100} = 90 \text{ mg/Caps.}$$

*Qty of Ascorbic Acid to be added per batch = 40.500 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: Q. Mg. checked by(production)/date: 17/11/21 Verified by(QA)/date: 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>Q. Mg.</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	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.:	GD211131	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/2021/26/1002/00921	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%

Actual quantity. of Sodium Selenate = 0.19441×100 -----mg/capsule

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

*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].

$$= [0.270+45.000+16.200+10.125\text{gm}+33.372+40.500+87.500\text{gm}+74.710] - [0.293 + 45.118 + 16.949 + 11.250\text{gm} + 33.439 + 40.500 + 87.750\text{gm}]$$

$$= 73.676 \text{ Kg}$$

*Qty of Microcrystalline cellulose PH 102 to be added per batch = 73.676 Kg's

Calculation done by(store)/date: D. V. K. checked by(production)/date: Can Verified by(QA)/date: 17/11/21

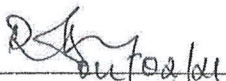
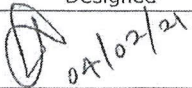
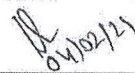
	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>[Signature]</u> 20/10/21	<u>[Signature]</u> 04/02/21	<u>[Signature]</u> 04/02/21	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	12 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.:	GD211131	Mfg.Date:	11/2021	Exp.Date:	10/2024

5.0 DISPENSING OF RAW MATERIALS AGAINST RAW MATERIAL INDENT:

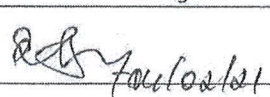
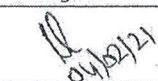
 Dispensing Started at Date 17/11/21 Time 16.00.

S.No	Name of the Ingredients	Actual Qty. per batch(Kg)	A.R No:	Gross Weight (Kg)	Tare Weight(Kg)	Net Weight(Kg)	Weighed By Stores	Checked by stores	Verified by IPQA
1	Carbonyl Iron USP	*	msp/2122/061062/00713	25.200	0.200	25.000	gh	gh	gh
			msp/2122/061062/00713	20.381	0.200	20.181	gh	gh	gh
			-	-	-	-	-	-	-
			-	-	-	-	-	-	-
2	Folic Acid BP	**	msp/2122/061062/00796	0.313	0.020	0.293	gh	gh	gh
			-	-	-	-	-	-	-
			-	-	-	-	-	-	-
3	Cyanocobalamin BP	***	msp/2122/061062/00756	-	-	11.250 gm	gh	gh	gh
			-	-	-	-	-	-	-
			-	-	-	-	-	-	-
4	Ascorbic Acid BP	****	msp/2122/061062/00698	28.300	3.300	25.000	gh	gh	gh
			msp/2122/061062/00698	15.700	0.200	15.500	gh	gh	gh
			-	-	-	-	-	-	-
			-	-	-	-	-	-	-

	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.:	13 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.:	GD211131	Mfg.Date:	11/2021	Exp.Date:	10/2024

S.No	Name of the Ingredients	Actual Qty. per batch(Kg)	A.R No:	Gross Weight (Kg)	Tare Weight(Kg)	Net Weight(Kg)	Weighed By Stores	Checked by stores	Verified by IPQA
5	Zinc Sulfate Monohydrate BP	*****	msl/2122/061002/00686	25.200	0.200	25.000	ngl	Inf	Pa
			msl/2122/061002/00686	8.639	0.200	8.439	ngl	Inf	Pa
			—	—	—	—	—	—	—
			—	—	—	—	—	—	—
6	Vitamin E Acetate 50% granules BP	*****	msl/2122/061002/00719	17.199	0.250	16.949	ngl	Inf	Pa
			—	—	—	—	—	—	—
			—	—	—	—	—	—	—
7	Sodium Selenate IHS	*****	msl/2021/061002/00921	95.750gms	8.000gms	87.750gms	ngl	Inf	Pa
			—	—	—	—	—	—	—
			—	—	—	—	—	—	—
8	Hydrophobic Colloidal anhydrous silica BP	1.350	msl/2122/061002/00615	1.450	0.100	1.350	ngl	Inf	Pa
			—	—	—	—	—	—	—
			—	—	—	—	—	—	—

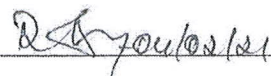
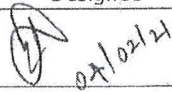
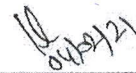
	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/02/21	 04/02/21	 04/02/21	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	14 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.:	GD211131	Mfg.Date:	11/2021	Exp.Date:	10/2024

S.No	Name of the Ingredients	Actual Qty. per batch(Kg)	A.R No:	Gross Weight (Kg)	Tare Weight(Kg)	Net Weight(Kg)	Weighed By Stores	Checked by stores	Checked by IPQA
9	Microcrystalline crystalline cellulose PH 102 BP	#	mfp/2122/00100670	25.250	0.250	25.000	ngb	dyf	Pa
			mfp/2122/00100670	25.250	0.250	25.000	ngb	dyf	Pa
			mfp/2122/00100670	23.939	0.250	23.689	ngb	dyf	Pa
				-	-	-	-	-	-
10	Calcium hydrogen phosphate BP	4.500	mfp/2122/00100479	4.600	0.100	4.500	ngb	dyf	Pa
				-	-	-	-	-	-
				-	-	-	-	-	-
11	Purified Talc BP	4.500	mfp/2122/00100494	4.600	0.100	4.500	ngb	dyf	Pa
				-	-	-	-	-	-
				-	-	-	-	-	-
12	Magnesium stearate BP	4.500	mfp/2122/00100504	4.600	0.100	4.500	ngb	dyf	Pa
				-	-	-	-	-	-

Dispensing Completed at Date 17/11/21 Time 17:00

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

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

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	15 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.:	GD211131	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: *mlr 02/12/21*

Verified by (IPQA) sign/date: *ch 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.	<i>RICHFER GD 211125</i>				
Cleaned By	<i>Ragn</i>	<i>Ragn</i>	<i>Ragn</i>	<i>Ragn</i>	<i>Ragn</i>
Checked by Stores Sign/Date	<i>mlr 02/12/21</i>	<i>mlr 02/12/21</i>	<i>mlr 02/12/21</i>	<i>mlr 02/12/21</i>	<i>mlr 02/12/21</i>
Counter checked by IPQA/Sign/Date	<i>ch 02/12/21</i>	<i>ch 02/12/21</i>	<i>ch 02/12/21</i>	<i>ch 02/12/21</i>	<i>ch 02/12/21</i>

6.2 ENVIRONMENTAL CONDITIONS:

Temperature: 23°C to 27°C	Observation	Stores Sign
	<i>25°C</i>	<i>mlr</i>
Relative Humidity: 45% to 55 %	Observation	Stores Sign
	<i>52 %</i>	<i>mlr</i>

6.3 APPROVAL FOR DISPENSING BY IPQA: Sign: *ch* Date: *02/12/21*

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	
Signature with Date	<i>Ragn 04/05/21</i>	<i>04/02/21</i>	<i>04/02/21</i>	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	16 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/MFG/135/R1	Supersedes MFC No.:	ST/MFC/135/R0
Batch No.:	GD211131	Mfg.Date:	11/2021	Exp.Date:	10/2024

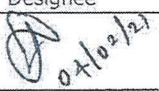
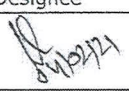
6.4 INDENT OF CAPSULE:

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 02/12/21 Time 13:00

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/2021/066/0CR/01072	10.000	0.400	9.600	Ragn	Mbr	che
			MSP/2021/066/0CR/01072	10.000	0.400	9.600	Ragn	Mbr	che
			MSP/2021/066/0CR/01072	10.000	0.400	9.600	Ragn	Mbr	che
			MSP/2021/066/0CR/01072	10.000	0.400	9.600	Ragn	Mbr	che
			MSP/2021/066/0CR/01072	4.900	0.400	4.500	Ragn	Mbr	che
			-	-	-	-	-	-	-
			-	-	-	-	-	-	-

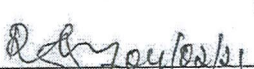
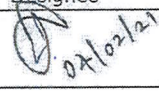
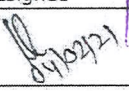
	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/12/21	 04/12/21	 04/12/21	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	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.:	GD211131	Mfg.Date:	11/2021	Exp.Date:	10/2024

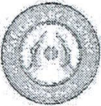
7.0 VERIFICATION OF DISPENSED MATERIALS:

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	25.20	msp/2122/ben/aer/00713	18/11/21	G 18/11/21
		20.38	msp/2122/ben/aer/00713	18/11/21	G 18/11/21
		NA	NA	NA	NA
2	Folic Acid BP	0.31	msp/2122/ben/aer/00716	18/11/21	G 18/11/21
		NA	NA	NA	NA
		NA	NA	NA	NA
3	Cyanocobalamin BP	20gms	msp/2122/ben/aer/00756	18/11/21	G 18/11/21
		NA	NA	NA	NA
		NA	NA	NA	NA
4	Ascorbic Acid BP	28.30	msp/2122/ben/aer/00698	18/11/21	G 18/11/21
		15.70	msp/2122/ben/aer/00698	18/11/21	G 18/11/21
		NA	NA	NA	NA
5	Zinc Sulfate Monohydrate BP	25.20	msp/2122/ben/aer/00686	18/11/21	G 18/11/21
		8.64	msp/2122/ben/aer/00686	18/11/21	G 18/11/21
		NA	NA	NA	NA
6	Vitamin E Acetate 50% granules BP	17.20	msp/2122/ben/aer/00719	18/11/21	G 18/11/21
		NA	NA	NA	NA
		NA	NA	NA	NA
7	Sodium Selenate IHS	0.10	msp/2122/ben/aer/00901	18/11/21	G 18/11/21
		NA	NA	NA	NA
		NA	NA	NA	NA
8	Hydrophobic Colloidal anhydrous silica BP	1.45	msp/2122/ben/aer/00615	18/11/21	G 18/11/21
		NA	NA	NA	NA
		NA	NA	NA	NA
9	Microcrystalline crystalline cellulose PH 102 BP	25.25	msp/2122/ben/aer/00670	18/11/21	G 18/11/21
		25.25	msp/2122/ben/aer/00670	18/11/21	G 18/11/21
		25.25	msp/2122/ben/aer/00670	18/11/21	G 18/11/21
10	Calcium hydrogen phosphate BP	4.60	msp/2122/ben/aer/00479	18/11/21	G 18/11/21
		NA	NA	NA	NA
		NA	NA	NA	NA
11	Purified Talc BP	4.60	msp/2122/ben/aer/00494	18/11/21	G 18/11/21
		NA	NA	NA	NA
		NA	NA	NA	NA
12	Magnesium stearate BP	4.60	msp/2122/ben/aer/00504	18/11/21	G 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

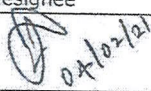
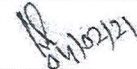
	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date				CONTROLLED COPY

② wing Enay 18/11/21

	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.:	GD211131	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/Dec/Dec/01072	1st Joshi	Gro21/21
		10.00	MSP/2021/Dec/Dec/01072	1st Joshi	Gro21/21
		10.00	MSP/2021/Dec/Dec/01072	1st Joshi	Gro21/21
		10.00	MSP/2021/Dec/Dec/01072	1st Joshi	Gro21/21
		4.90	MSP/2021/Dec/Dec/01072	1st Joshi	Gro21/21
					NA 1st Joshi

	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.:	19 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.:	GD211131	Mfg.Date:	11/2021	Exp.Date:	10/2024

9.0 GRANULATION:

9.1 LINE CLEARANCE CHECKS:

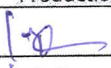
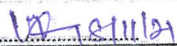
S.No	Check	Observation			
		Production		IPQA	
		I	II	I	II
1	Ensure that all empty containers, labels, used polybags, hand gloves of previous Product/ batch are removed from the area.	✓	✓	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓	✓	✓
3	Ensure that 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: <u>14/11/21</u>	DAY I: <u>14/11/21</u>	DAY II: <u>—</u>		
Verified by (IPQA) sign/date: <u>18/11/21</u>	DAY I: <u>18/11/21</u>	DAY II: <u>—</u>		
Equipment	Vibro sifter	Multimill	Weighing Balance	Area
Equipment ID No:	<u>ST/PRW/006</u>	<u>—</u>	<u>ST/PRW/003</u>	<u>ST/PRG/0101</u>
Previous Product:	<u>Novastat Asp 20</u>			
Batch No.	<u>Q211065031</u>			
Cleaned by/date:	<u>Kalavaran</u>	<u>Kalavaran</u>	<u>Kalavaran</u>	<u>Kalavaran</u>
Checked by/date:	Production: <u>14/11/21</u>	IPQA: <u>CX</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> <u>04/12/21</u>	<u>[Signature]</u> <u>04/12/21</u>	<u>[Signature]</u> <u>04/12/21</u>	

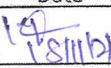
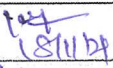
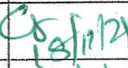
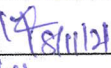
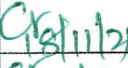
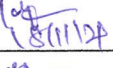
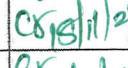
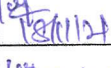
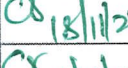
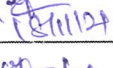
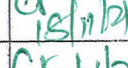
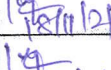
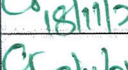
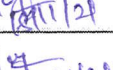
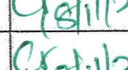
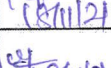
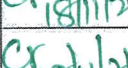
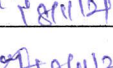
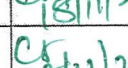
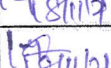
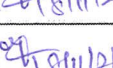
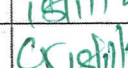
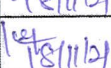
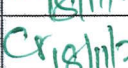
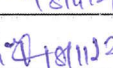
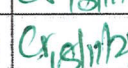
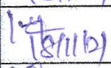
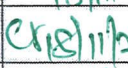
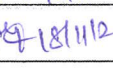
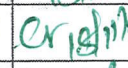
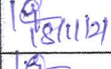
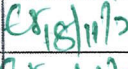
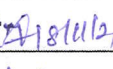
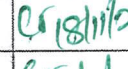
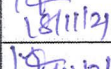
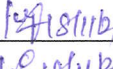
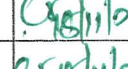
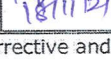
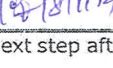
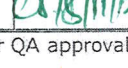
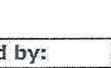
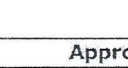
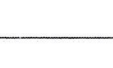
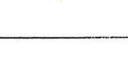
	Safetab Life Science		MASTER COPY		
	BATCH MANUFACTURING RECORD		Page No.:	20 of 57	
Brand Name	RICHER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211131	Mfg.Date:	11/2021	Exp.Date:	10/2024

9.2 ENVIRONMENTAL CONDITIONS	Date: 18/11/24	Time: 09:00	Date:	Time:
	Observation	Production Sign	Observation	Production Sign
Temperature: 23°C to 27°C	25.1°C			
Relative Humidity: 45% to 55 %	53%			
9.3 APPROVAL FOR SIFTING:				
Production Sign/Date:  18/11/24		IPQA Sign/Date:  18/11/24		

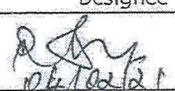
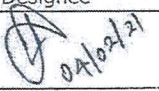
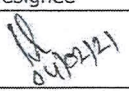
9.4 SIFTING INSTRUCTIONS:

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	 18/11/24	 18/11/24	OK/ Not OK	 18/11/24	 18/11/24
2	Folic Acid BP	30#	OK/ Not OK	 18/11/24	 18/11/24	OK/ Not OK	 18/11/24	 18/11/24
3	Cyanocobalamin BP	30#	OK/ Not OK	 18/11/24	 18/11/24	OK/ Not OK	 18/11/24	 18/11/24
4	Ascorbic Acid BP	30#	OK/ Not OK	 18/11/24	 18/11/24	OK/ Not OK	 18/11/24	 18/11/24
5	Zinc Sulfate Monohydrate BP	30#	OK/ Not OK	 18/11/24	 18/11/24	OK/ Not OK	 18/11/24	 18/11/24
6	Vitamin E Acetate 50% granules BP	30#	OK/ Not OK	 18/11/24	 18/11/24	OK/ Not OK	 18/11/24	 18/11/24
7	Sodium Selenate IHS	30#	OK/ Not OK	 18/11/24	 18/11/24	OK/ Not OK	 18/11/24	 18/11/24
8	Hydrophobic Colloidal anhydrous silica PB	30#	OK/ Not OK	 18/11/24	 18/11/24	OK/ Not OK	 18/11/24	 18/11/24
9	Microcrystalline crystalline cellulose PH 102 BP	30#	OK/ Not OK	 18/11/24	 18/11/24	OK/ Not OK	 18/11/24	 18/11/24
10	Calcium hydrogen phosphate BP	30#	OK/ Not OK	 18/11/24	 18/11/24	OK/ Not OK	 18/11/24	 18/11/24
11	Purified Talc BP	30#	OK/ Not OK	 18/11/24	 18/11/24	OK/ Not OK	 18/11/24	 18/11/24
12	Magnesium stearate BP	60#	OK/ Not OK	 18/11/24	 18/11/24	OK/ Not OK	 18/11/24	 18/11/24

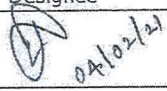
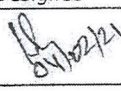
Note: If any discrepancy found, Initiate the deviation for corrective and preventive action and proceed to next step after QA approval.
*Document the sieve integrity as√.

	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	 04/10/24	CONTROLLED COPY

	Safetab Life Science		MASTER COPY		
			BATCH MANUFACTURING RECORD		
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	21 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.:	GD211131	Mfg.Date:	11/2021	Exp.Date:	10/2024

9.6 SIFTING PROCESS:

SIFTING PROCESS:					
Step No	Process Instructions	Date : 18/11/21		Done By	Checked by/Date
		Time			
		Started	Completed		
9.7.1	Sift 50.00 Kg of Microcrystalline cellulose PH 102, 0.29 Kg of Folic Acid, 33.44 Kg of Zinc Sulfate Monohydrate, and 16.95 Kg of Vitamin E Acetate 50% granules BP through 30#.	04:02	04:12	Kaleiraman	18/11/21
9.7.2	Sift 4.50 Kg of Calcium hydrogen Phosphate, 0.01 Kg of Cyanocobalamin (Coated) through 30#.	04:13	04:25	Kaleiraman	18/11/21
9.7.3	Sift 23.69 Kg of Microcrystalline crystalline cellulose PH 102 , 15.18 Kg of Carbonyl Iron , 10.00 Kg of Ascorbic Acid, 0.90 Kg of Sodium Seienate through 30#.	04:26	04:38	Kaleiraman	18/11/21
9.7.4	Sift 4.50 Kg of Talc, 1.35 Kg of Hydrophobic colloidal anhydrous silica through 30#.	04:39	04:49	Kaleiraman	18/11/21
9.7.5	Sift 4.50 Kg of Magnesium Stearate Through 60#.	04:50	05:00	Kaleiraman	18/11/21

	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	

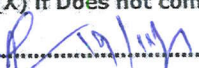
	Safetab Life Science		MASTER COPY		
BATCH MANUFACTURING RECORD			Page No.:	22 of 57	
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211131	Mfg.Date:	11/2021	Exp.Date:	10/2024

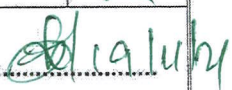
10.0 BLENDING AND LUBRICATION:

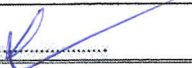
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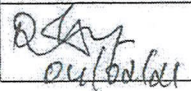
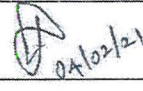
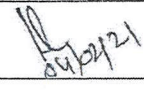
S.No	Checks	Observation	
		production	IPQA
1	Ensure that all empty containers, used polybags, labels, hand gloves of previous Product/ batch are removed from the area.	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓
3	Ensure that the previous batch BMR / 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

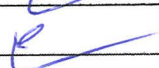
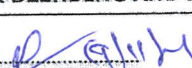
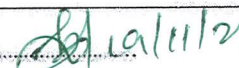
Checked by (production) sign/date: 

Verified by (IPQA)sign/date: 

Equipment	Octagonal blender	
Code No	ST/PAU/015	
Previous product	Albiglam pcp	
Batch No	S2111101K	
Cleaned by:	Pindh, ponarise	
Checked by:	Production: 	IPQA: 

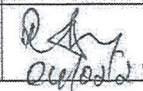
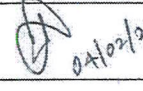
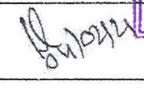
	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/02/21	 04/02/21	 04/02/21	

	Safetab Life Science			MASTER COPY	
				BATCH MANUFACTURING RECORD	
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.:	GD211131	Mfg.Date:	11/2021	Exp.Date:	10/2024

10.2 ENVIRONMENTAL CONDITIONS:	Date: 19/11/21	Time: 11:00
	Observation	Production Sign
Temperature: 23°C to 27°C	25.2°C	
Relative Humidity: 45% to 55 %	51%	
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.	11:02	11:15	inath	
4	Mix for 30 minutes.	11:18	11:48	inath	
5	Add the sifted Magnesium Stearate distribute / sprinkle over the blended material.	11:50	11:52	inath	
6	Mix for 5 minutes.	11:53	11:58	inath	
7	Unload the final blend into suitable containers lined with double polythene bag container with proper label.	12:00	12:10	inath	
8	Record the weight in below mentioned table.	12:12	12:16	inath	

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
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.:	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.:	GD211131	Mfg.Date:	11/2021	Exp.Date:	10/2024	

10.5 WEIGHING OF FINAL BLEND: Date: 19/11/21

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 ✓	38.56	2.71	35.85	16			
2 ✓	18.22	2.84	15.38	17			
3 ✓	15.20	3.07	12.13	18			
4 ✓	38.27	2.69	35.58	19			
5 ✓	37.33	3.00	34.33	20			
6 ✓	31.60	2.60	29.00	21			
7				22			
8				23			
9				24			
10				25			
11				26			
12				27			
13				28			
14				29			
15				30			

Total weight of Lubricated granules: 222.62 kg

Weighed by: P. N. Oth

Checked sign by/date: P. N. Oth

Intimate IPQA to draw the sample.

Sample withdrawn by IPQA

Production Sign: P. N. Oth Date: 19/11/21

IPQA Sign: P. N. Oth Date: 19/11/21

Send Test request form for lubricated granules to QC department.

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	P. N. Oth 19/11/21	P. N. Oth 19/11/21	P. N. Oth 19/11/21	

	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.:	GD211131	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	:	225.67 Kg
3.0	Manufacturing Loss (1.0 - 6.0)	:	0.08 Kg
4.0	In-process samples		
	A IPQA Samples	:	1.18 Kg
	B QC Samples	:	0.05 Kg
	C Validation Samples	:	0.20 Kg
5.0	Total samples: (A + B + C)	:	0.25 Kg
6.0	Total: (2.0 + 5.0)	:	225.92 Kg
7.0	% Yield = $\frac{6.0}{1.0} \times 100$ (Limit- NLT 99.00%)	:	99.96 %

Reconciliation done by Production sign/Date: *[Signature]* 19/11/21 Checked by IPQA sign/Date: *[Signature]* 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: *0.08* Kg's (Rejected materials should be destroyed in the presence of QA)

Done by Production sign/Date: *[Signature]* 19/11/21 Checked by IPQA sign/Date: *[Signature]* 19/11/21

10.7 BLENDED GRANULES RELEASED FOR CAPSULE FILLING:

Reconciliation checked and blended granules released for Capsule Filling.

Production sign/Date: *[Signature]* 02/12/21 IPQA sign/Date: *[Signature]* 02/12/21

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

	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.:	GD211131	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: M.S.G. 02/12/21 Verified by (IPQA) sign/date: C. 02/12/21

Checked by (Production) Sign: <u>XXXXXXXXXXXXXXXXXXXX</u>								
Equipment	<u>Pharmatol</u> <u>ABO</u>	<u>CWM</u>	<u>CPM</u>	<u>FCS</u>	<u>ECSE</u>	<u>DDU</u>	<u>UCS</u>	Area
Equipment ID No:	<u>ST/PRC/101</u>	<u>ST/PRC/102</u>	<u>ST/PRC/103</u>	<u>ST/PRC/104</u>	<u>ST/PRC/105</u>	<u>ST/PRC/106</u>	<u>ST/PRC/107</u>	
Previous product	<u>Richfer Capsules</u>							
Batch No.	<u>FD21113</u> <u>GD211125</u>							

11.2 ENVIRONMENTAL CONDITIONS	Date: <u>02/12/21</u>		Date: <u>03/12/21</u>	
	Observation	Production Sign	Observation	Production Sign
Temperature: 23°C to 27°C	<u>24.3°C</u>	<u>M.S.G.</u>	<u>24.2°C</u>	<u>✓</u>
Relative Humidity: 45% to 55 %	<u>53.1%</u>	<u>M.S.G.</u>	<u>51.1%</u>	<u>✓</u>

11.3 APPROVAL FOR CAPSULE FILING:	
Production executive Sign..... <u>M.S.G.</u> Date: <u>02/12/21</u>	
Product Changeover Line clearance IPQA Sign.: <u>C.</u> Date: <u>02/12/21</u>	

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

CONTROLLED COPY

* wrong Entry M.S.G. 02/12/21

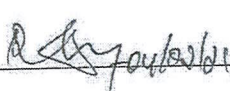
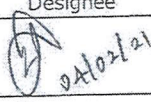
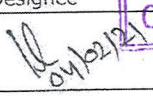
	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	27 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO.:	ST/MFC/135/R1	Supersedes MFC No.:	ST/MFC/135/R0
Batch No.:	GD211131	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.	14:20	14:30	Labeshu	M-8 02/10/21
3	Transfer the granules to capsule filling room.	14:40	14:50	Labeshu	M-8 02/10/21
4	Operate the capsule filling machine as per the current version of the SOP.	15:00	15:05	Labeshu	M-8 02/10/21
5	Collect the initially filled capsules and check for appearance, group weight, weight variation, lock length and disintegration time.	15:05	15:15	Labeshu	M-8 02/10/21
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.	15:25	05:30	Pachayappa	Labeshu
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

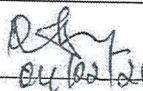
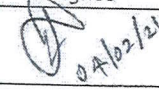
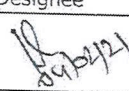
	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/10/21	 04/10/21	 04/10/21	

	Safetab Life Science		MASTER COPY		
					BATCH MANUFACTURING RECORD
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	28 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.:	GD211131	Mfg.Date:	11/2021	Supersedes MFC No:	ST/MFC/135/R0
				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	591	96	495	21.16
2	598	99	499	21.35
3	587	97	489	21.42
4	592	98	494	21.37
5	598	96	502	21.30
6	604	99	505	21.29
7	606	97	509	21.24
8	605	98	507	21.35
9	594	96	498	21.41
10	603	99	504	21.37
11	598	97	501	21.30
12	598	98	500	21.28
13	593	96	497	21.35
14	597	99	498	21.26
15	600	97	503	21.41
16	598	98	500	21.37
17	594	96	498	21.36
18	595	99	496	21.25
19	599	97	502	21.24
20	599	98	501	21.18

Parameters	Instrument used	Observation	Limits
Appearance	Visual	Complies	Red/Red '0' size GHPL printed on both body and cap Hard gelatin capsule Filled with Pale Green colour granular powder.
Group weight of 20 capsules	Balance	11.920 g	11.900g $\pm$ 3% (Limit: 11.543g to 12.257g)
Average weight	Balance	596 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	587 - 605 mg	+5% of average weight (565.250mg to 624.750mg)
Disintegration Time	Disintegration Tester	04 minutes 46 sec	NMT 30 minutes in 37°C $\pm$ 2°C
M/C set up checked by (Production): H.S. Date: 02/10/21			
Initial Setting capsules Destroyed by : Sign: H.S. Date: 02/10/21			
M/C set up and initial setting capsule destruction checked by IPQA: Sign: G. Date: 02/10/21			

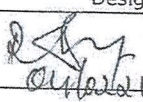
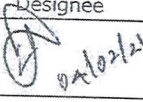
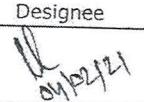
	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/10/21	 04/10/21	 04/10/21	CONTROLLED COPY

	Safetab Life Science		MASTER COPY		
			BATCH MANUFACTURING RECORD		
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	29 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.:	GD211131	Mfg.Date:	11/2021	Supersedes MFC No:	ST/MFC/135/R0
				Exp.Date:	10/2024

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

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 Production
		Appearance *	Weight of 20 caps in g	Average weight in mg	Lock Length in mm	
02/12/21	15:35	Complies	11.962	598	21.16	M.B
+ MFC Stopped at 16:00 to 16:10 due to Tea break-1						
02/12/21	16:20	Complies	12.010	600	21.24	M.B
02/12/21	16:50	Complies	11.907	595	21.32	M.B
02/12/21	17:30	Complies	12.024	601	21.41	M.B
02/12/21	18:05	Complies	11.922	596	21.30	M.B
02/12/21	18:35	Complies	11.985	599	21.28	M.B
02/12/21	19:10	Complies	12.042	602	21.37	M.B
+ MFC Stopped at 19:30 to 20:00 due to Dinner break-1						
02/12/21	20:20	Complies	12.012	600	21.35	M.B
02/12/21	20:50	Complies	11.942	597	21.42	M.B
02/12/21	21:30	Complies	12.024	601	21.31	M.B
02/12/21	22:10	Complies	11.924	596	21.29	A
02/12/21	22:40	Complies	11.962	598	21.32	A
02/12/21	23:10	Complies	12.006	600	21.35	A
02/12/21	23:40	Complies	11.944	597	21.30	A
+ MFC Stopped at 00:00 to 00:10 due to Tea break-1						
03/12/21	00:20	Complies	11.982	599	21.28	A
03/12/21	00:50	Complies	12.022	601	21.40	A
03/12/21	01:20	Complies	11.942	597	21.36	A
03/12/21	01:50	Complies	11.986	599	21.32	A
03/12/21	02:20	Complies	11.903	595	21.39	A
03/12/21	02:50	Complies	11.942	597	21.27	A
03/12/21	03:20	Complies	12.001	600	21.32	A
03/12/21	03:50	Complies	11.9248	596	21.29	A
+ MFC Stopped at 04:00 to 04:10 due to Tea break-1						
03/12/21	04:20	Complies	11.945	597	21.36	A

* If appearance are satisfactory document as complies.

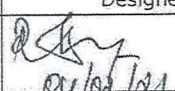
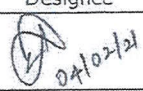
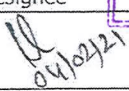
Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	CONTROLLED COPY
Signature with Date	 02/12/21	 02/12/21	 02/12/21	

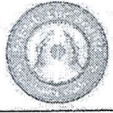
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BATCH MANUFACTURING RECORD					
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	33 of 57
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO.:	ST/MFC/135/R1	Supersedes MFC No.:	ST/MFC/135/R0
Batch No.:	GD211131	Mfg.Date:	11/2021	Exp.Date:	10/2024

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

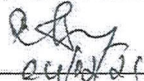
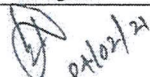
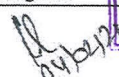
Date: 02/12/21 Time: 15:45											
Weight of 20 capsules : 11.942 g						Average weight of capsule : 597 mg					
	A	B	C		A	B	C		A	B	C
1	595	99	496	8	596	96	500	15	594	98	496
2	588	97	491	9	603	99	504	16	595	96	499
3	596	96	500	10	594	97	497	17	601	99	502
4	602	98	504	11	600	98	502	18	601	97	504
5	597	99	498	12	596	96	500	19	598	98	500
6	593	97	496	13	590	99	491	20	594	96	498
7	593	98	495	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 0.491 g 98.79 %											
Max. fill weight 0.504 g 101.40 %											
Average fill weight of 20 Capsules: 0.497 g											
Disintegration Time : 04 mins 41 sec								(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by: M. R. (Production)											
Date: 02/12/21 Time: 17:50											
Weight of 20 capsules : 11.982 g						Average weight of capsule : 599 mg					
	A	B	C		A	B	C		A	B	C
1	597	98	499	8	595	97	498	15	599	99	500
2	596	96	500	9	597	98	499	16	595	97	498
3	593	99	494	10	590	96	494	17	600	98	502
4	599	97	502	11	604	99	505	18	603	96	507
5	598	98	500	12	598	97	501	19	600	99	501
6	603	96	507	13	605	98	507	20	603	97	506
7	601	99	502	14	598	96	502				
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 0.507 g 101.40 %											
Average fill weight of 20 Capsules: 0.500 g											
Disintegration Time : 04 mins 44 sec								(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by: M. R. (Production)											

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

	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.:	GD211131	Mfg.Date:	11/2021	Exp.Date:	10/2024

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

Date: 02/12/21		Time: 20:30					
Weight of 20 capsules : 11.9628				Average weight of capsule : 598mg			
	A	B	C		A	B	C
1	596	97	499	8	595	97	498
2	592	96	496	9	594	98	496
3	601	99	502	10	604	99	505
4	602	97	505	11	597	97	500
5	598	98	500	12	597	96	501
6	594	96	498	13	595	98	497
7	603	99	504	14	595	99	496
				15	597	97	500
				16	603	98	505
				17	597	96	501
				18	597	99	498
				19	599	97	502
				20	597	98	499
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 99.20%							
Max. fill weight 0.605 g 101.00%							
Average fill weight of 20 Capsules: 0.500 g							
Disintegration Time : 04 mins 26 sec				(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by: H.Sy (Production)							
Date: 02/12/21		Time: 22:30					
Weight of 20 capsules : 11.8679 gm				Average weight of capsule : 593			
	A	B	C		A	B	C
1	597	96	501	8	600	98	502
2	598	97	496	9	605	99	506
3	600	98	502	10	595	97	498
4	601	96	505	11	600	98	502
5	592	97	495	12	595	96	499
6	598	98	500	13	598	97	501
7	602	99	502	14	602	97	505
				15	599	97	502
				16	592	96	496
				17	600	97	503
				18	595	98	497
				19	602	98	504
				20	601	99	502
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 99.81%							
Max. fill weight 0.606 g 100.99%							
Average fill weight of 20 Capsules: 0.501 g							
Disintegration Time : 04 min 32 sec				(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by: (Production)							

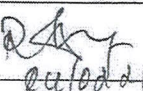
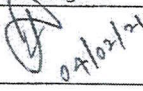
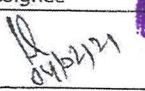
	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	 02/12/21	 02/12/21	 02/12/21

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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.:	GD211131	Mfg. Date:	11/2021	Exp. Date:	10/2024

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

Date: 08/12/21 Time: 00:30											
Weight of 20 capsules : 11.942						Average weight of capsule : 597					
	A	B	C		A	B	C		A	B	C
1	597	96	501	8	597	98	499	15	603	98	505
2	599	97	502	9	604	99	505	16	601	99	502
3	598	97	500	10	600	98	502	17	594	97	497
4	596	98	498	11	595	99	496	18	599	98	501
5	597	97	500	12	597	97	500	19	598	99	499
6	596	97	499	13	597	96	501	20	600	97	503
7	601	99	502	14	601	97	504				
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 99.01 %											
Max. fill weight 0.505 g 100.79 %											
Average fill weight of 20 Capsules: 0.501 g											
Disintegration Time : 04 min 18 sec						(Limit: NMT 30 minutes at 37°C ± 2°C)					
Checked by: A (Production)											
Date: 08/12/21 Time: 02:40											
Weight of 20 capsules : 11.955						Average weight of capsule : 598					
	A	B	C		A	B	C		A	B	C
1	598	97	501	8	598	99	499	15	595	97	498
2	596	96	500	9	598	96	502	16	600	98	502
3	596	99	497	10	593	97	496	17	594	99	495
4	600	98	502	11	599	98	501	18	599	99	500
5	598	98	500	12	597	98	499	19	597	98	499
6	598	97	496	13	602	97	505	20	601	97	504
7	602	98	504	14	599	96	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 0.495 g 99.00 %											
Max. fill weight 0.505 g 101.00 %											
Average fill weight of 20 Capsules: 0.500 g											
Disintegration Time : 04 min 32 sec						(Limit: NMT 30 minutes at 37°C ± 2°C)					
Checked by: A (Production)											

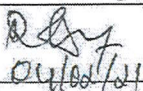
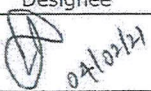
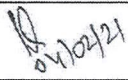
	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 24/12/21	 04/12/21	 04/12/21	CONTROLLED COPY

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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.:	GD211131		Mfg.Date:	11/2021	Exp.Date:	10/2024

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

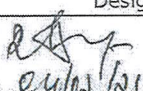
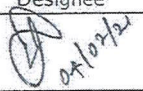
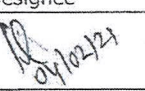
Date:..... Time:.....												
Weight of 20 capsules :						Average weight of capsule :						
	A	B	C			A	B	C		A	B	C
1				8					15			
2				9					16			
3				10					17			
4				11					18			
5				12					19			
6				13					20			
7				14								
A : Weight of filled capsule, B: weight of empty capsule, C: 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:	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.:	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.:	GD211131		Mfg.Date:	11/2021	Exp.Date:	10/2024

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

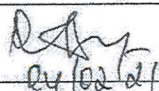
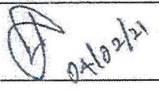
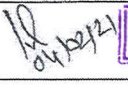
Date:..... Time:.....												
Weight of 20 capsules :						Average weight of capsule :						
	A	B	C			A	B	C		A	B	C
1				8					15			
2				9					16			
3				10					17			
4				11					18			
5				12					19			
6				13					20			
7				14								
A : Weight of filled capsule, B: weight of empty capsule, C: 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:	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.:	39 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.:	GD211131	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)												

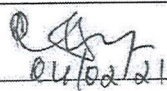
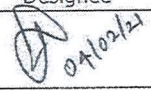
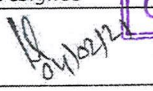
	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	 24/10/21	 24/10/21	 24/10/21

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	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.:	GD211131	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
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)							

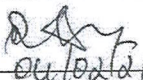
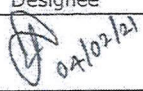
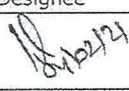
	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	 04/10/21	 04/10/21	 04/10/21

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	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page No.:	41 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.:	GD211131		Mfg. Date:	11/2021	Exp. Date:	10/2024

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

Date: 02/12/21 Time: 15:55											
Weight of 20 capsules: 11.922 g						Average weight of capsule: 596 mg					
	A	B	C		A	B	C		A	B	C
1	598	97	501	8	600	95	505	15	601	95	506
2	596	96	500	9	601	96	505	16	597	94	503
3	597	95	502	10	598	95	503	17	598	96	502
4	599	96	503	11	599	96	503	18	599	95	504
5	598	95	503	12	597	95	502	19	595	96	499
6	595	94	501	13	595	96	499	20	594	95	499
7	596	96	500	14	596	94	502				
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 499.99.20%											
Max. fill weight 506 g 100.59%											
Average fill weight of 20 Capsules: 503 g											
Disintegration Time: 04 min 26 sec								(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by: G (IPQA)											
Date: 02/12/21 Time: 20:00											
Weight of 20 capsules: 11.982 g						Average weight of capsule: 599 mg					
	A	B	C		A	B	C		A	B	C
1	599	95	504	8	595	95	500	15	596	95	501
2	595	94	501	9	596	95	501	16	595	94	499
3	596	95	501	10	595	96	499	17	599	96	503
4	599	96	503	11	596	95	501	18	601	94	507
5	595	95	500	12	595	94	501	19	600	96	504
6	595	96	499	13	596	96	500	20	602	95	501
7	596	95	501	14	592	95	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 497.99.00%											
Max. fill weight 507 g 100.99%											
Average fill weight of 20 Capsules: 502 g											
Disintegration Time: 04 min 25 sec								(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by: G (IPQA)											

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 02/12/21	 04/12/21	 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.:	GD211131		Mfg. Date:	11/2021	Exp. Date:	10/2024

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

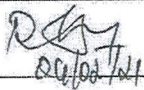
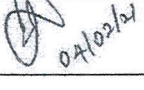
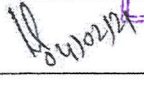
Date: 03/12/21 Time: 00:15											
Weight of 20 capsules : 11.964 g						Average weight of capsule : 598 mg					
	A	B	C		A	B	C		A	B	C
1	599	96	503	8	593	95	498	15	601	96	505
2	595	95	500	9	596	96	500	16	598	97	501
3	598	96	502	10	601	95	506	17	596	96	500
4	596	96	500	11	599	96	503	18	600	97	503
5	595	97	498	12	595	95	500	19	595	95	500
6	495	96	499	13	598	96	502	20	595	96	499
7	599	96	503	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 0.498 g 99.20%											
Max. fill weight 0.506 g 100.79%											
Average fill weight of 20 Capsules: 0.502 g											
Disintegration Time : 04 min 56 sec								(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by: [Signature] (IPQA)											
Date: 03/12/21 Time: 04:15											
Weight of 20 capsules : 11.903 g						Average weight of capsule : 595 mg					
	A	B	C		A	B	C		A	B	C
1	595	95	500	8	595	95	500	15	597	97	500
2	598	96	502	9	599	96	503	16	592	96	496
3	594	96	498	10	597	96	501	17	594	97	497
4	597	95	502	11	593	95	498	18	597	96	501
5	592	96	496	12	599	96	503	19	498	95	503
6	595	95	500	13	596	96	500	20	594	96	498
7	593	96	497	14	598	97	501				
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 99.39%											
Max. fill weight 0.503 g 100.80%											
Average fill weight of 20 Capsules: 0.499 g											
Disintegration Time : 04 min 25 sec								(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by: [Signature] (IPQA)											

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	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.:	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/R1	Supersedes MFC No.:	ST/MFC/135/R0
Batch No.:	GD211131		Mfg. Date:	11/2021	Exp. Date:	10/2024

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

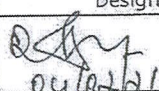
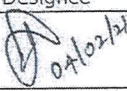
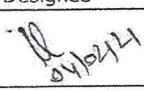
Date:..... Time:.....											
Weight of 20 capsules :				Average weight of capsule :							
	A	B	C		A	B	C		A	B	C
1				8				15			
2				9				16			
3				10				17			
4				11				18			
5				12				19			
6				13				20			
7				14							
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight								± 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	CONTROLLED COPY
Signature with Date	 04/02/21	 04/02/21	 04/02/21	

	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.:	GD211131	Mfg.Date:	11/2021	Exp.Date:	10/2024	

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

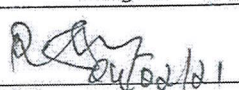
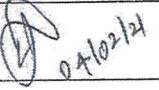
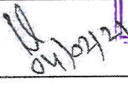
Date:..... Time:.....												
Weight of 20 capsules :						Average weight of capsule :						
	A	B	C			A	B	C		A	B	C
1				8					15			
2				9					16			
3				10					17			
4				11					18			
5				12					19			
6				13					20			
7				14								
A : Weight of filled capsule, B: weight of empty capsule, C: 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:	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.:	45 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.:	GD211131	Mfg.Date:	11/2021	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
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

CONTROLLED COPY

	Safetab Life Science		MASTER COPY		
	BATCH MANUFACTURING RECORD		Page No.:	46 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.:	GD211131	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	11.55	1.80	9.75	Labsh	M.G	26	11.85	1.80	10.05	Pachayappa	A
2	11.58	1.80	9.78	Labsh	M.G	27	8.85	1.80	7.05	Pachayappa	A
3	12.02	1.80	10.22	Labsh	M.G	28					
4	11.12	1.80	9.32	Labsh	M.G	29					
5	11.91	1.80	10.11	Labsh	M.G	30					
6	11.70	1.80	9.90	Labsh	M.G	31					
7	11.99	1.80	10.19	Labsh	M.G	32					
8	11.29	1.80	9.49	Labsh	M.G	33					
9	11.96	1.80	10.16	Labsh	M.G	34					
10	11.79	1.80	9.99	Labsh	M.G	35					
11	11.62	1.80	9.82	Pachayappa	A	36					
12	11.32	1.80	9.52	Pachayappa	A	37					
13	12.29	1.80	10.49	Pachayappa	A	38					
14	12.25	1.80	10.45	Pachayappa	A	39					
15	11.55	1.80	9.75	Pachayappa	A	40					
16	12.68	1.80	10.88	Pachayappa	A	41					
17	12.32	1.80	10.52	Pachayappa	A	42					
18	12.23	1.80	10.43	Pachayappa	A	43					
19	11.85	1.80	10.05	Pachayappa	A	44					
20	12.12	1.80	10.32	Pachayappa	A	45					
21	11.85	1.80	10.05	Pachayappa	A	46					
22	11.53	1.80	9.73	Pachayappa	A	47					
23	11.89	1.80	10.09	Pachayappa	A	48					
24	11.89	1.80	10.09	Pachayappa	A	49					
25	06.30	1.80	06.50	Pachayappa	A	50					
Total weight of Filled capsules:										264.30	kg

Intimate IPQA to draw the sample	Sample withdrawn by IPQA.
Production Sign: <i>A</i> Date: 03/12/21	IPQA Sign: <i>[Signature]</i> Date: 03/12/21
Send Test request form for analysis of filled capsules to QC department.	

	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.:	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.:	GD211131	Mfg.Date:	11/2021	Exp.Date:	10/2024

12.1 RECONCILIATION:

Average weight of capsule: 595 mg

1.0	Theoretical weight of Filled capsules	:	<u>267.75</u> Kg	450000 No's
2.0	Actual weight of Filled capsules	:	<u>264.30</u> Kg	<u>444201</u> No's
3.0	Capsule filling Loss (1.0 - 6.0)	:	<u>2.66</u> Kg	<u>4470</u> No's
4.0	In-process samples			
	A IPQA Samples	:	<u>0.57</u> Kg	<u>960</u> No's
	B QC Samples	:	<u>0.105</u> Kg	<u>100</u> No's
	C Validation Samples	:	<u>0.17</u> Kg	<u>300</u> No's
5.0	Total samples: (A + B + C)	:	<u>0.79</u> Kg	<u>1360</u> No's
6.0	Total: (5.0 + 2.0)	:	<u>265.09</u> Kg	<u>445529</u> No's
7.0	% Yield = $\frac{6.0}{1.0} \times 100$ (Limit: NLT 97.00 %)	:	<u>99.00</u> %	%

Reconciliation done by Production sign/Date: Ar 03/12/21

Checked by IPQA sign/Date: Ar 03/12/21

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: 2.66 Kg Rejected materials shall be destroyed in the presence of QA

Done by Production sign/Date: Ar 03/12/21 Checked By IPQA sign/Date: Ar 03/12/21

12.2 CAPSULES RELEASED FOR INSPECTION:

Production Sign/Date: H. Say 02/12/21

IPQA Sign/Date: Ar 02/12/21

	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>02/12/21</u>	<u>[Signature]</u> <u>02/12/21</u>	<u>[Signature]</u> <u>02/12/21</u>	

	Safetab Life Science			MASTER COPY	
				Page No.: 48 of 57	
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.:	GD211131	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: M-8/02/12/21

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

ENVIRONMENTAL CONDITIONS:	Date: 02/12/21		Date: 03/12/21	
	Observation	Production Sign	Observation	Production Sign
Temperature: 23°C to 27°C	24.3°C	M-8	24°C	M
Relative Humidity: 45% to 55 %	53.1%	M-8	52%	M

13.2 APPROVAL FOR INSPECTION:

Production Sign/Date: M-8/11/21

IPQA Sign./Date: Cx-02/12/21

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			
02/12/21	01	10	15:45	12:00	0.34	Kalaimani 02/12/21	M-8 02/12/21
03/12/2021	11	27	00:15	05:30	0.30	Parthiv 03/12/21	M 03/12/2021

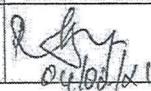
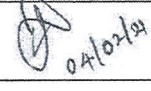
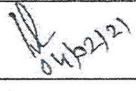
Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee
Signature with Date	<u>[Signature]</u> 04/02/21	<u>[Signature]</u> 04/02/21	<u>[Signature]</u> 04/02/21

CONTROLLED COPY

	Safetab Life Science		MASTER COPY		
	BATCH MANUFACTURING RECORD		Page No.:	49 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.:	GD211131	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	11.53	1.80	9.73	Kalaimi	M.G	26	11.80	1.80	10.00	Silambu	Ar
2	11.56	1.80	9.76	Kalaimi	M.G	27	8.80	1.80	07.00	Silambu	Ar
3	12.00	1.80	10.20	Kalaimi	M.G	28					
4	11.10	1.80	9.30	Kalaimi	M.G	29					
5	11.90	1.80	10.10	Kalaimi	M.G	30					
6	11.68	1.80	9.88	Kalaimi	M.G	31					
7	11.97	1.80	10.17	Kalaimi	M.G	32					
8	11.27	1.80	9.47	Kalaimi	M.G	33					
9	11.95	1.80	10.15	Kalaimi	M.G	34					
10	11.77	1.80	9.97	Kalaimi	M.G	35					
11	11.40	1.80	09.60	Silambu	Ar	36					
12	11.30	1.80	09.50	Silambu	Ar	37					
13	12.26	1.80	10.46	Silambu	Ar	38					
14	12.23	1.80	10.43	Silambu	Ar	39					
15	11.53	1.80	09.73	Silambu	Ar	40					
16	12.45	1.80	10.65	Silambu	Ar	41					
17	12.30	1.80	10.50	Silambu	Ar	42					
18	12.20	1.80	10.40	Silambu	Ar	43					
19	11.82	1.80	10.02	Silambu	Ar	44					
20	12.11	1.80	10.31	Silambu	Ar	45					
21	11.82	1.80	10.02	Silambu	Ar	46					
22	11.50	1.80	09.70	Silambu	Ar	47					
23	11.86	1.80	10.06	Silambu	Ar	48					
24	11.86	1.80	10.06	Silambu	Ar	49					
25	08.29	1.80	06.49	Silambu	Ar	50					
Total weight of Filled capsules:										262.66	kg

	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.:	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.:	GD211131	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	:	264.30 kg	444201 No's
3.0	Rejected Capsules	:	0.64 kg	1075 No's
4.0	Total weight of good Capsules	:	263.66 kg	443126 No's
5.0	$\% \text{ Yield} = \frac{4.0}{1.0} \times 100$ (Limit- NLT 96.50%)* *Tentative limit	:	98.47 %	

Reconciliation done by Production sign/Date: Ar 03/12/21 Checked by IPQA sign/Date: Cr 03/12/21

Total rejects destroyed: 0.64 Kg. Rejected materials should be destroyed in the presence of QA.

Done by Packing sign/Date: Ar 03/12/21 Checked by IPQA sign/Date: Cr 03/12/21

14.0 RELEASE FOR PACKING:

BMR reviewed by IPQA Sign/Date : 13/12/21

BMR Released for packing by QA Head Sign/Date: 13/12/21

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>Ar 03/12/21</u>	<u>Ar 03/12/21</u>	<u>Cr 03/12/21</u>	

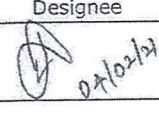
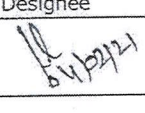
	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD				
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	51 of 57
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Batch Size	4,50,000 Capsules
Batch No.:	GD211131	Mfg.Date:	11/2021	Supersedes MFC No:	ST/MFC/135/R0
				Exp.Date:	10/2024

15.0 PROCESS HISTORY



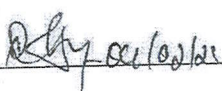
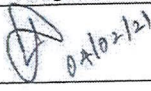
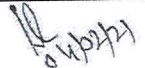
S. Ri

02/12/24

	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	

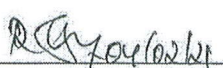
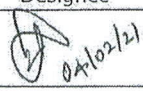
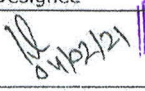
	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	52 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211131	Mfg.Date:	11/2021	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.....13/12/21		Production Head sign./date.....  13/12/21	
This Batch Manufacturing Record received, reviewed and batch is released for packing on date.....13/12/21		Reviewed by QA Head.....  13/12/21	

	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	CONTROLLED COPY
Designation				
Signature with Date	 01/10/21	 01/10/21	 01/10/21	

	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.:	GD211131	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	 04/10/21	 04/10/21	 04/10/21	

	Safetab Life Science			MASTER COPY	
BATCH MANUFACTURING RECORD				Page No.:	54 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.:	GD211131	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 gms	
Test Request for: content		Sampled by: [Signature] on date: 19/11/21	
TRF raised by: [Signature] on date: 19/11/21		No. of containers: 06	
To be filled by QC		Sample received by: [Signature] on date: 15/11/21	
TRF received on: 19/11/2021			
Sample tested on: 19/11/2021			
Test Results		Limits	
Each 1000mg of Granules contains:- Ascorbic acid:- 86.45mg (115.3%) Folic acid:- 554.20mg (118.8%) Vitamin E:- 19.11 mg (127.4%) Carbonyl Iron:- 103.02mg (103.0%) Selenium:- 98.11 mg (120.17%) Zinc:- 25.73mg (114.34%) Cyanocobalamin:- 20.7mg (138.0%)			
Analytical Reference no: GK/01236/2021		Space for QC Approval (Stamping and Signing)	
Analysed By: K.J.M. on: 3/11/2021		APPROVED Sign: [Signature] Date: 30/11/21	

	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	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.:	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.:	GD211131	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 Date of exp.: 10/2024		Quantity Sampled: 100 caps	
Test Request for: Content		Sampled by: [Signature] on date: 03/12/21	
TRF raised by: [Signature] on date: 03/12/21		No. of containers: 27	
		Sample received by: [Signature] on date: 03/12/21	
To be filled by QC			
TRF received on: 03/12/21			
Sample tested on: 03/12/21			
Test Results			
Each Capsule contains Carbonyl Iron equivalent Elemental Iron - 98.12mg (92.1%) Folic acid - 590.54mg (112.7%) Cyanocobalamin - 21.0mg (140.0%) Ascorbic acid - 88.90mg (112.5%) Zinc - 25.64mg (113.9%) Vitamin E 50% - 19.11IU (127.4%) Selenium - 76.10mcg (117.1%)			
Analytical Reference no.: SFPL/101652/21		Space for QC Approval (Stamping and Signing)	
Analysed By: [Signature] on: 13/12/21		APPROVED Sign: [Signature] Date: 13/12/21	

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

	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.:	GD211131	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: 13/12/21

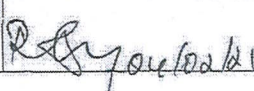
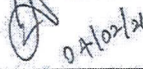
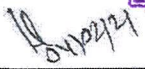
QA Head Sign/Date: 13/12/21

	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.:	GD211131	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	 04/02/21	 04/02/21	 04/02/21	