

	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.:	GD211133	Mfg.Date:	11/2021	Exp.Date:	10/2024

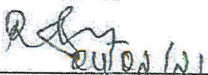
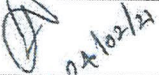
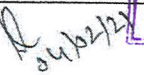
BATCH MANUFACTURING RECORD COVER SHEET:

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

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	BATCH MANUFACTURING RECORD			Page No.:	2 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211133	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:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 24/10/21	 24/10/21	 24/10/21	

	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.:	GD211133	Mfg.Date:	11/2021	Exp.Date:	10/2024

2.C 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.	RICHFER - GD211132				
Cleaned By	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</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> 17/11/21	<i>[Signature]</i> 17/11/21	<i>[Signature]</i> 17/11/21	CONTROLLED COPY

	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page No.:	4 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules	
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO.:	ST/MFC/135/R1	Supersedes MFC No.:	ST/MFC/135/R0	
Batch No.:	GD211133	Mfg.Date:	11/2021	Exp.Date:	10/2024	

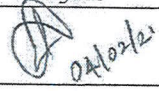
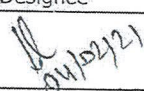
3.0 INDENT OF RAW MATERIALS:

3.1 INDENT OF ACTIVE PHARMACEUTICAL INGREDIENTS:

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

3.1.1 INDENT OF EXCIPIENTS:

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

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

	Safetab Life Science			MASTER COPY	
				BATCH MANUFACTURING RECORD	
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	Batch Size	4,50,000 Capsules
Batch No.:	GD211133	Mfg.Date:	11/2021	Supersedes MFC No:	ST/MFC/135/R0
				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 (%)
msp/2122/02/02/00767	09/21	SEP/26	102.5
—	—	—	—

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

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

$$= \frac{10000}{100} = 100 \text{ mg / Caps.}$$

*Qty of Carbonyl Iron to be added per batch = 45,000 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] 17/11/21 checked by(production)/date: [Signature] 17/11/21 Verified by(QA)/date: [Signature] 17/11/21

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

	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.:	GD211133	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/2122/00/000796	Jun/21	Jun/26	99.9	7.81
—	—	—	—	—

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

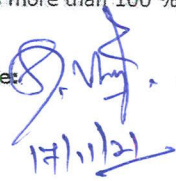
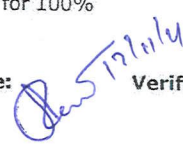
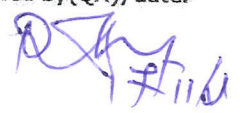
Actual quantity. of Folic Acid = $\frac{0.600 \times 100 \times 100}{\text{---mg/capsule}}$

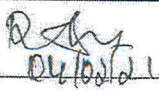
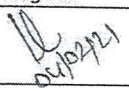
% Assay on anhydrous basis X (100 - water content %)

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

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

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

Calculation done by(store)/date:  checked by(production)/date:  Verified by(QA)/date: 

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	CONTROLLED COPY
Signature with Date	 04/08/21	 04/07/21	 04/07/21	

	Safetab Life Science			MASTER COPY		
BATCH MANUFACTURING RECORD					Page No.:	7 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.:	GD211133	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 %
mp/2122/00100756	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: [Signature] 17/11/21 checked by(production)/date: [Signature] 17/11/21 Verified by(QA)/date: [Signature] 17/11/21

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

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BATCH MANUFACTURING RECORD					
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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.:	GD211133	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 (%)
MSP/2122/0610(R) 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]
17/11/21

checked by(production)/date:

[Signature]
17/11/21

Verified by(QA)/date:

[Signature]
17/11/21

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

	Safetab Life Science			MASTER COPY	
BATCH MANUFACTURING RECORD					
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	9 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.:	GD211133	Mfg.Date:	11/2021	Supersedes MFC No:	ST/MFC/135/R0
				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/2122/06/02/00686	AUG/21	JUN/26	99.8
MSP/2122/06/02/00770	JUN/20	JUN/25	100.0

*The given quantity is based on 100% Assay.

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

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

% Assay of Zinc sulfate Monohydrate

$$1) = \frac{7416}{99.8} = 74.309 \text{ mg/capsule}, 2) = \frac{7416}{100} = 74.160 \text{ mg/capsule}$$

$$= 14.411 \text{ kgs} \quad = 18.990 \text{ kgs}$$

$$(193933 \text{ nos}) \quad + (256067 \text{ nos})$$

*Qty of Zinc sulfate Monohydrate to be added per batch = 33.40 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: Q. V. J. 17/11/21, checked by(production)/date: Q. S. J. 17/11/21, Verified by(QA)/date: Q. S. J. 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>Q. V. J.</u> 17/11/21	<u>Q. S. J.</u> 04/10/21	<u>Q. S. J.</u> 04/10/21	

	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.:	GD211133	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/00762	SEP/21	Aug/25	99.9
-	-	-	-

*The given quantity is based on 100% Assay.

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

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

$$= \frac{9000}{99.9} = 90.090 \text{ mg/caps.}$$

*Qty of Ascorbic Acid to be added per batch = 40.541 Kg's

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

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

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

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	11 of 57
Brand Name	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.:	GD211133	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 (%)
MSP/2021/06/06/00921	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 = $\frac{0.19441 \times 100}{\% \text{ Assay of Sodium Selenate}}$ 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+10.125gm+33.372+40.500+87.500gm+74.710]-

[0.292 + 45.000 + 16.949 + 11.250 + 33.401 + 40.541 + 87.750 gm]
 = 73.867 Kg

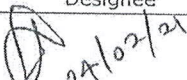
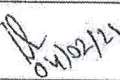
*Qty of Microcrystalline cellulose PH 102 to be added per batch = 73.867 Kg's

Calculation done by(store)/date: Q. M. 17/11/21 checked by(production)/date: Q. M. 17/11/21 Verified by(QA)/date: Q. M. 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. M. 17/11/21</u>	<u>Q. M. 17/11/21</u>	<u>Q. M. 17/11/21</u>	

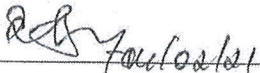
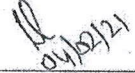
	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	12 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211133	Mfg.Date:	11/2021	Exp.Date:	10/2024

5.0 DISPENSING OF RAW MATERIALS AGAINST RAW MATERIAL INDENT:									
Dispensing Started at Date <u>17/11/21</u> Time <u>18:15</u>									
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/QA/QC/00767	25.200	0.200	25.000	ngl	ngl	ngl
			MSP/2122/QA/QC/00767	20.200	0.200	20.000	ngl	ngl	ngl
			-	-	-	-	-	-	-
			-	-	-	-	-	-	-
2	Folic Acid BP	**	MSP/2122/QA/QC/00796	0.3137	0.020	0.293	ngl	ngl	ngl
			-	-	-	-	-	-	-
			-	-	-	-	-	-	-
3	Cyanocobalamin BP	***	MSP/2122/QA/QC/00756	-	-	11.250	ngl	ngl	ngl
			-	-	-	-	-	-	-
			-	-	-	-	-	-	-
4	Ascorbic Acid BP	****	MSP/2122/QA/QC/00762	28.300	3.300	25.000	ngl	ngl	ngl
			MSP/2122/QA/QC/00762	15.741	0.200	15.541	ngl	ngl	ngl
			-	-	-	-	-	-	-
			-	-	-	-	-	-	-

	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	

	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.:	GD211133	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	*****	rgp/2122/00100686	14.611	0.200	14.411	rgp	inf.	Pa
			rgp/2122/00100770	19.190	0.200	18.990	rgp	inf	Pa
			-	-	-	-	-	-	-
			-	-	-	-	-	-	-
6	Vitamin E Acetate 50% granules BP	*****	rgp/2122/00100719	17.199	0.250	16.949	rgp	inf	Pa
			-	-	-	-	-	-	-
			-	-	-	-	-	-	-
7	Sodium Selenate IHS	*****	rgp/2021/00100921	95.750 gms	8.000 gms	87.750 gms	rgp	inf	Pa
			-	-	-	-	-	-	-
			-	-	-	-	-	-	-
8	Hydrophobic Colloidal anhydrous silica BP	1.350	rgp/2122/00100615	1.450	0.100	1.350	rgp	inf	Pa
			-	-	-	-	-	-	-
			-	-	-	-	-	-	-

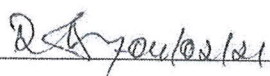
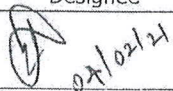
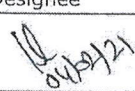
Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	CONTROLLED COPY
Signature with Date	 04/02/21	 04/02/21	 04/02/21	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	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.:	GD211133	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/2122/0610/00670	25.250	0.250	25.000	yes	yes	yes
			mfp/2122/0610/00670	25.250	0.250	25.000	yes	yes	yes
			mfp/2122/0610/00670	24.117	0.250	23.867	yes	yes	yes
			-	-	-	-	-	-	-
10	Calcium hydrogen phosphate BP	4.500	mfp/2122/0610/00479	4.600	0.100	4.500	yes	yes	yes
			-	-	-	-	-	-	-
			-	-	-	-	-	-	-
11	Purified Talc BP	4.500	mfp/2122/0610/00494	4.600	0.100	4.500	yes	yes	yes
			-	-	-	-	-	-	-
			-	-	-	-	-	-	-
12	Magnesium stearate BP	4.500	mfp/2122/0610/00504	4.600	0.100	4.500	yes	yes	yes
			-	-	-	-	-	-	-

Dispensing Completed at Date 17/11/21 Time 19.15

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

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

	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.:	GD211133	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: *[Signature]* 02/10/21

Verified by (IPQA) sign/date: *[Signature]* 02/10/21

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.	Richter - 60211132				
Cleaned By	Rsh	Rsh	Rsh	Rsh	Rsh
Checked by Stores Sign/Date	Pnt 02/10/21	Pnt 02/10/21	Pnt 02/10/21	Pnt 02/10/21	Pnt 02/10/21
Counter checked by IPQA/Sign/Date	Jy 02/10/21	Jy 02/10/21	Jy 02/10/21	Jy 02/10/21	Jy 02/10/21

6.2 ENVIRONMENTAL CONDITIONS:

	Observation	Stores Sign
Temperature: 23°C to 27°C	23.6° C	<i>[Signature]</i>
Relative Humidity: 45% to 55 %	53 %	<i>[Signature]</i>

6.3 APPROVAL FOR DISPENSING BY IPQA: Sign: *[Signature]* Date: 02/10/21

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

	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/MFC/135/R1	Supersedes MFC No.:	ST/MFC/135/R0
Batch No.:	GD211133	Mfg.Date:	11/2021	Exp.Date:	10/2024

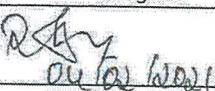
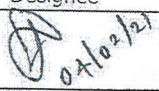
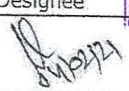
6.4 INDENT OF CAPSULE:

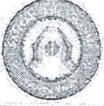
S.No	Name of the Ingredients	Material Code	Spec	Overages	Total Qty (NO's)	Vendor
1	"0" Size Red/Red hard gelatin capsule(GHPL Printed)	RMER0012	IHS	NIL	454500	ERAWAT PHARMA

6.4.1 DISPENSING OF EMPTY HARD GELATIN CAPSULE AGAINST CAPSULE:

Dispensing Started at Date 01/12/21 Time 15.00

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/2021/2M/2CR 01072	10.000	0.400	9.600	nl	nt	nl
			MSP/2021/2M/2CR 01072	10.000	0.400	9.600	nl	nt	nl
			MSP/2021/2M/2CR 01072	10.000	0.400	9.600	nl	nt	nl
			MSP/2021/2M/2CR 01072	10.000	0.400	9.600	nl	nt	nl
			MSP/2021/2M/2CR 01072	5.800	0.400	5.400	nl	nt	nl

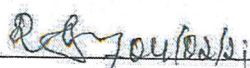
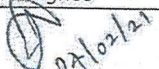
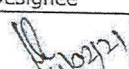
	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 01/12/21	 01/12/21	 01/12/21	

	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.:	GD211133	Mfg.Date:	11/2021	Exp.Date:	10/2024

7.0 VERIFICATION OF DISPENSED MATERIALS:

S.No	Name of the Ingredients	Gross weight in Kg	A.R.No.	Checked by Production Sign/Date	Checked by IPQA Sign/Date
1	Carbonyl Iron USP	20.20	msp/2122/den/2021/00762	E. S. L. H.	18/11/21
		20.20	msp/2122/den/2021/00762	E. S. L. H.	18/11/21
		1	na	na	na
2	Folic Acid BP	0.31	msp/2122/den/2021/00796	E. S. L. H.	18/11/21
		1	na	na	na
		1	na	na	na
3	Cyanocobalamin BP	11.26g	msp/2122/den/2021/00766	E. S. L. H.	18/11/21
		1	na	na	na
		1	na	na	na
4	Ascorbic Acid BP	20.30	msp/2122/den/2021/00762	E. S. L. H.	18/11/21
		10.7h	msp/2122/den/2021/00762	E. S. L. H.	18/11/21
		1	na	na	na
5	Zinc Sulfate Monohydrate BP	1h.61	msp/2122/den/2021/00766	E. S. L. H.	18/11/21
		19.19	msp/2122/den/2021/00766	E. S. L. H.	18/11/21
		1	na	na	na
6	Vitamin E Acetate 50% granules BP	17.19	msp/2122/den/2021/00719	E. S. L. H.	18/11/21
		1	na	na	na
		1	na	na	na
7	Sodium Selenate IHS	95.76g	msp/2122/den/2021/00791	E. S. L. H.	18/11/21
		1	na	na	na
		1	na	na	na
8	Hydrophobic Colloidal anhydrous silica BP	1.45	msp/2122/den/2021/00615	E. S. L. H.	18/11/21
		1	na	na	na
		1	na	na	na
9	Microcrystalline crystalline cellulose PH 102 BP	25.25	msp/2122/den/2021/00670	E. S. L. H.	18/11/21
		25.25	msp/2122/den/2021/00670	E. S. L. H.	18/11/21
		25.11	msp/2122/den/2021/00670	E. S. L. H.	18/11/21
10	Calcium hydrogen phosphate BP	h.60	msp/2122/den/2021/00679	E. S. L. H.	18/11/21
		1	na	na	na
		1	na	na	na
11	Purified Talc BP	h.60	msp/2122/den/2021/00681	E. S. L. H.	18/11/21
		1	na	na	na
		1	na	na	na
12	Magnesium stearate BP	h.60	msp/2122/den/2021/00681	E. S. L. H.	18/11/21
		1	na	na	na
		1	na	na	na

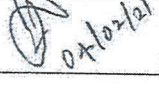
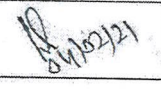
Note: Check the weight of the dispensed material, if found satisfactory, then proceeds to next stage, if any discrepancy inform to QA head for further instruction

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

	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.:	GD211133	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/2021/01/10/01072	A 04/12/21	A 04/12/21
		10.00	MSP/2021/01/10/01072	A 04/12/21	A 04/12/21
		10.00	MSP/2021/01/10/01072	A 04/12/21	A 04/12/21
		10.00	MSP/2021/01/10/01072	A 04/12/21	A 04/12/21
		5.80	MSP/2021/01/10/01072	A 04/12/21	A 04/12/21

	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.:	19 of 57
Brand Name	RICHTER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules		
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO.:	ST/MFC/135/R1	Supersedes MFC No.:	ST/MFC/135/R0		
Batch No.:	GD211133	Mfg.Date:	11/2021	Exp.Date:	10/2024		

9.0 GRANULATION:

9.1 LINE CLEARANCE CHECKS:

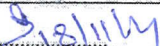
S.No	Check	Observation			
		Production		IPQA	
		I	II	I	II
1	Ensure that all empty containers, labels, used polybags, hand gloves of previous Product/ batch are removed from the area.	✓	NA	✓	NA
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	NA	✓	NA
3	Ensure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

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

Checked by (Production) sign/date: <i>[Signature]</i> 18/11/21	DAY I: <i>[Signature]</i>	DAY II: <i>NA</i>		
Verified by (IPQA) sign/date: <i>[Signature]</i> 18/11/21	DAY I: <i>[Signature]</i>	DAY II: <i>NA</i>		
Equipment	Vibro sifter	Multimill	Weighing Balance	Area
Equipment ID No:	ST/PRV/006		ST/PRV/003	C101
Previous Product:	Richter capsules			
Batch No.	GD211133			
Cleaned by/date:	<i>[Signature]</i> 18/11/21		<i>[Signature]</i> 18/11/21	<i>[Signature]</i> 18/11/21
Checked by/date:	Production: <i>[Signature]</i>	IPQA: <i>[Signature]</i>		

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	CONTROLLED COPY
Signature with Date	<i>[Signature]</i> 18/11/21	<i>[Signature]</i> 18/11/21	<i>[Signature]</i> 18/11/21	

	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.:	GD211133	Mfg. Date:	11/2021	Exp. Date:	10/2024	

9.2 ENVIRONMENTAL CONDITIONS	Date: 18/11/24	Time: 13:10	Date:	Time:
	Observation	Production Sign	Observation	Production Sign
Temperature: 23°C to 27°C	25.1c			
Relative Humidity: 45% to 55 %	51.5			
9.3 APPROVAL FOR SIFTING:				
Production Sign/Date:  18/11/24		IPQA Sign/Date:  18/11/24		

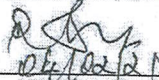
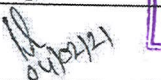
9.4 SIFTING INSTRUCTIONS:

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

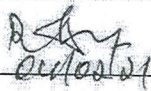
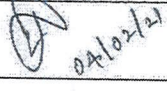
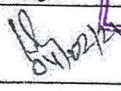
Note: If any discrepancy found, Initiate the deviation for corrective and preventive action and proceed to next step after QA approval.
 *Document the sieve integrity asv.

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

	Safetab Life Science				MASTER COPY	
Brand Name	RICHTER 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	Batch Size	4,50,000 Capsules	
Batch No.:	GD211133	Mfg.Date:	11/2021	Supersedes MFC No:	ST/MFC/135/R0	
				Exp.Date:	10/2024	

9.6 SIFTING PROCESS:

Step No	Process Instructions	Date : 18/11/24		Done By	Checked by/Date
		Time			
		Started	Completed		
9.7.1	Sift 50.00 Kg of Microcrystalline cellulose PH 102, 3.2 Kg of Folic Acid, 23.22 Kg of Zinc Sulfate Monohydrate, and 19.28 Kg of Vitamin E Acetate 50% granules BP through 30#.	13:15	13:35	Puja	Puja 18/11/24
9.7.2	Sift 1.50 Kg of Calcium hydrogen Phosphate, 11.25 Kg of Cyanocobalamin (Coated) through 30#.	13:38	13:50	Puja	Puja 18/11/24
9.7.3	Sift 23.22 Kg of Microcrystalline crystalline cellulose PH 102, 15.033 Kg of Carbonyl Iron, 10.512 Kg of Ascorbic Acid, 37.25 Kg of Sodium Selenate through 30#.	13:52	14:20	veerani	g. deep 18/11/24
9.7.4	Sift 1.50 Kg of Talc, 1.35 Kg of Hydrophobic colloidal anhydrous silica through 30#.	14:23	14:33	veerani	g. deep 18/11/24
9.7.5	Sift 1.50 Kg of Magnesium Stearate Through 60#.	14:40	14:45	veerani	g. deep 18/11/24

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

	Safetab Life Science			MASTER COPY	
BATCH MANUFACTURING RECORD					
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	22 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.:	GD211133	Mfg.Date:	11/2021	Supersedes MFC No:	ST/MFC/135/R0
				Exp.Date:	10/2024

10.0 BLENDING AND LUBRICATION:

10.1 LINE CLEARANCE CHECKS:

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

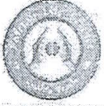
Note: Tick mark (✓) if Complies and (X) if Does not comply

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

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

Equipment	Octagonal blender	
Code No	ST IPRG/015	
Previous product	Richter Capsules	
Batch No	GD 211132	
Cleaned by:	Neeraj arai	
Checked by:	Production: <u>19/11/21</u>	IPQA: <u>19/11/21</u>

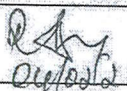
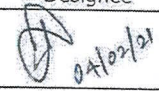
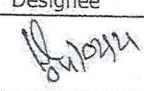
Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	CONTROLLED COPY
Signature with Date	<u>19/11/21</u>	<u>19/11/21</u>	<u>19/11/21</u>	

	Safetab Life Science		MASTER COPY		
			BATCH MANUFACTURING RECORD		
Brand Name	RICHTER CAPSULES	Product ID No.:	1047	Page No.:	23 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.:	GD211133	Mfg.Date:	11/2021	Supersedes MFC No:	ST/MFC/135/R0
				Exp.Date:	10/2024

10.2 ENVIRONMENTAL CONDITIONS:	Date: 19/11/24	Time: 14:45
	Observation	Production Sign
Temperature: 23°C to 27°C	23.6°C	
Relative Humidity: 45% to 55%	53%	
10.3 APPROVAL FOR BLENDING AND LUBRICATION:		
Production Sign/Date: 19/11/24		IPQA Sign/Date: 19/11/24

10.4 BLENDING AND LUBRICATION INSTRUCTION:

Step No.	Process Instructions	Date: 19/11/24		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.	14:50	15:00	Veeramani	19/11/24
4	Mix for 30 minutes.	15:10	15:40	Veeramani	19/11/24
5	Add the sifted Magnesium Stearate distribute / sprinkle over the blended material.	15:41	15:47	Veeramani	19/11/24
6	Mix for 5 minutes.	15:50	15:55	Veeramani	19/11/24
7	Unload the final blend into suitable containers lined with double polythene bag container with proper label.	15:57	16:10	Veeramani	19/11/24
8	Record the weight in below mentioned table.	16:12	16:17	Veeramani	19/11/24

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 06/12/21	 04/12/21	 06/12/21	

	Safetab Life Science		MASTER COPY		
BATCH MANUFACTURING RECORD					
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	24 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.:	GD211133	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	43.36	3.13	40.23	16			
2	38.92	2.56	36.36	17			
3	44.57	3.32	41.25	18			
4	38.39	2.83	35.56	19			
5	36.11	2.66	33.45	20			
6	40.52	2.77	37.75	21			
7				22			
8				23			
9				24			
10				25			
11				26			
12				27			
13				28			
14				29			
15				30			

Total weight of Lubricated granules: 224.60 kg

Weighed by: Veeramani

Checked sign by/date: 19/11/21

Intimate IPQA to draw the sample.

Sample withdrawn by IPQA

Production Sign: [Signature] Date: 19/11/21

IPQA Sign: [Signature] Date: 19/11/21

Send Test request form for lubricated granules to QC department.

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	CONTROLLED COPY
Signature with Date	<u>[Signature]</u> 06/10/21	<u>[Signature]</u> 04/10/21	<u>[Signature]</u> 04/10/21	

	Safetab Life Science		MASTER COPY		
BATCH MANUFACTURING RECORD					
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	25 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.:	GD211133	Mfg.Date:	11/2021	Supersedes MFC No:	ST/MFC/135/R0
				Exp.Date:	10/2024

10.6 RECONCILIATION:

1.0	Theoretical weight of blend	:	225.000 Kg
2.0	Actual weight of blend	:	224.60 Kg
3.0	Manufacturing Loss (1.0 - 6.0)	:	0.30 Kg
4.0	In-process samples		
	A IPQA Samples	:	- Kg
	B QC Samples	:	0.05 Kg
	C Validation Samples	:	0.05 Kg
5.0	Total samples: (A + B + C)	:	0.10 Kg
6.0	Total: (2.0 + 5.0)	:	224.70 Kg
7.0	% Yield = $\frac{6.0}{1.0} \times 100$ (Limit- NLT 99.00%)	:	99.87 %

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

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

Total rejects destroyed: 0.30 Kg's (Rejected materials should be destroyed in the presence of QA)

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

10.7 BLENDED GRANULES RELEASED FOR CAPSULE FILLING:

Reconciliation checked and blended granules released for Capsule Filling.

Production sign/Date: 19/11/21

IPQA sign/Date: 19/11/21

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

	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page No.:	26 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.:	GD211133	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: Pharmaji 04/12/24

Verified by (IPQA) sign/date: Pharmaji 04/12/24

Equipment	Pharmaji	Cum	CPM	FLS	ECSE	DDU	U2	Area
Equipment ID No:	ST/PRCF/11	ST/PRCF/12	ST/PRCF/13	ST/PRCF/14	ST/PRCF/15	ST/PRCF/16	ST/PRCF/17	
Previous product	Richfer Capsule							
Batch No.	GD 211132							

11.2 ENVIRONMENTAL CONDITIONS

	Date: 04/12/24		Date:	
	Observation	Production Sign	Observation	Production Sign
Temperature: 23°C to 27°C	24.38	✓	✓	✓
Relative Humidity: 45% to 55 %	51%	✓	✓	✓

11.3 APPROVAL FOR CAPSULE FILING:

Production executive Sign: Pharmaji Date: 04/12/24

Product Changeover Line clearance IPQA Sign: Pharmaji Date: 04/12/24

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

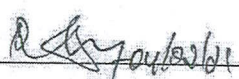
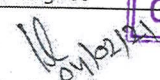
	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page No.:	27 of 57
Brand Name	RICHTER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules	
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO.:	ST/MFC/135/R1	Supersedes MFC No.:	ST/MFC/135/R0	
Batch No.:	GD211133	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.	02:25	02:30	Pachayyapran	Asulin
3	Transfer the granules to capsule filling room.	02:30	23:35	Pachayyapran	Asulin
4	Operate the capsule filling machine as per the current version of the SOP.	02:35	02:40	Pachayyapran	Asulin
5	Collect the initially filled capsules and check for appearance, group weight, weight variation, lock length and disintegration time.	02:40	02:50	Pachayyapran	Asulin
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.	03:00	03:10	Pachayyapran	Asulin
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	 04/02/21	 04/02/21	 04/02/21	

	Safetab Life Science		MASTER COPY		
BATCH MANUFACTURING RECORD					
Brand Name	RICHER 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	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211133	Mfg.Date:	11/2021	Exp.Date:	10/2024

11.5.1 MACHINE SETTING FOR FILLING:

S.No.	Weight of Filled capsules in mg	Weight of Empty capsules in mg	Net weight in mg	Lock Length in mm
1	601	96	505	21.36
2	599	99	500	21.22
3	602	98	504	21.19
4	605	98	507	21.35
5	604	97	507	21.22
6	594	97	497	21.26
7	602	96	506	21.27
8	600	95	505	21.28
9	596	96	500	21.22
10	603	96	507	21.18
11	599	97	502	21.32
12	602	97	505	21.30
13	595	96	499	21.27
14	601	95	506	21.21
15	600	96	504	21.18
16	597	96	501	21.32
17	604	97	507	21.19
18	596	98	498	21.22
19	601	96	505	21.27
20	603	97	506	21.23

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	11.903	11.900g $\pm$ 3% (Limit: 11.543g to 12.257g)
Average weight	Balance	595	595mg $\pm$ 3.0% (Limit: 577.150 mg to 612.850 mg)
Lock Length	Vernier	21.26 mm	21.40mm $\pm$ 0.4mm (Limit: 21.00mm - 21.80mm)
Uniformity of mass	Balance	594 - 605	$\pm$ 5% of average weight (565.250mg to 624.750mg)
Disintegration Time	Disintegration Tester	04 min 32 sec	NMT 30 minutes in 37°C $\pm$ 2°C
M/C set up checked by (Production): <u>R</u> Date: <u>04/12/21</u>			
Initial Setting capsules Destroyed by : Sign : <u>R</u> Date: <u>04/12/21</u>			
M/C set up and initial setting capsule destruction checked by IPQA: Sign : <u>af</u> Date: <u>04/12/21</u>			

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

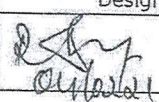
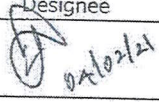
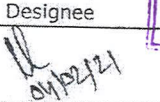
CONTROLLED COPY

	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.:	GD211133	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: 10 Color: Cap: Red, Body: Red Printing: GHPL printed on both body and cap Group Weight: 11.900 $\pm$ 3 % Limit: 11.543 gm to 12.257gm Average Weight: 595 mg $\pm$ 3 % Limit: 577.150mg - 612.850mg Lock Length: 21.40mm $\pm$ 0.4mm Limit: 21.00mm to 21.80mm				Checked by Production
		Appearance *	Weight of 20 caps in g	Average weight in mg	Lock Length in mm	
04/12/24	08:20	Complies	11.924	596	21.32	A
04/12/24	08:50	Complies	11.903	595	21.25	A
M/C Stopped at 09:00 to 09:10 due to Tea break						
04/12/24	09:20	Complies	11.984	599	21.28	A
04/12/24	09:50	Complies	11.923	596	21.19	A
04/12/24	10:20	Complies	12.024	601	21.23	A
M/C Stopped at 10:30 due to shift closed						
04/12/24	08:10	Complies	11.900	596	21.25	S.R.
04/12/24	08:45	Complies	11.900	595	21.24	S.R.
04/12/24	08:15	Complies	11.962	598	21.23	S.R.
M/C Stopped at 08:45 to 09:00 due to Break						
04/12/24	09:10	Complies	11.924	596	21.29	S.R.
04/12/24	09:45	Complies	11.904	595	21.35	S.R.
04/12/24	10:15	Complies	11.922	596	21.32	S.R.
04/12/24	10:45	Complies	12.009	600	21.30	S.R.
M/C Stopped at 11:00 to 11:10 due to Tea break						
04/12/24	11:20	Complies	11.944	597	21.32	S.R.
04/12/24	11:55	Complies	11.906	595	21.34	S.R.
04/12/24	12:25	Complies	11.964	598	21.30	S.R.
04/12/24	13:00	Complies	11.986	599	21.37	S.R.
04/12/24	13:30	Complies	12.006	600	21.29	S.R.
04/12/24	14:10	Complies	11.965	598	21.31	M.B.
04/12/24	14:40	Complies	11.987	599	21.41	M.B.
04/12/24	15:15	Complies	12.026	601	21.35	M.B.
04/12/24	15:45	Complies	12.012	600	21.27	M.B.
M/C Stopped at 16:00 to 16:10 due to Tea break						
04/12/24	16:20	Complies	12.004	600	21.26	M.B.

* If appearance are satisfactory document as complies.

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



Page No.: 30 of 57

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Product ID
No.:

1047

Batch Size

4,50,000 Capsules

MFC NO:

ST/MFC/135/R1

Supersedes
MFC No:

ST/MFC/135/R0

Mfg.Date:

11/2021

Exp.Date:

10/2024

[illegible]

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	CONTROLLED COPY
Signature with Date	 02/10/24	 02/10/24	 02/10/24	

CONTROLLED COPY

* allong Entry M. G.
04/12/21



Page No.:

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	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	



MASTER COPY

BATCH MANUFACTURING RECORD

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

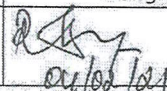
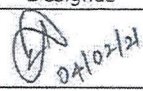
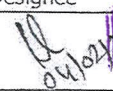
* If appearance are satisfactory document as complies.

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 01/05/21	 24/02/21	 01/05/21	CONTROLLED COPY

	Safetab Life Science			MASTER COPY	
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	Batch Size	4,50,000 Capsules
Batch No.:	GD211133	Mfg.Date:	11/2021	Supersedes MFC No:	ST/MFC/135/R0
				Exp.Date:	10/2024

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

Date: 04/12/21 Time: 08:30											
Weight of 20 capsules : 11.962						Average weight of capsule : 598					
	A	B	C		A	B	C		A	B	C
1	600	99	501	8	599	97	502	15	595	96	499
2	598	96	502	9	599	98	501	16	599	97	502
3	593	97	496	10	598	98	500	17	598	97	501
4	601	98	503	11	598	99	499	18	594	97	497
5	597	98	499	12	605	98	507	19	602	98	504
6	595	99	496	13	594	96	498	20	601	98	501
7	602	96	506	14	598	95	503				
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight								± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight 0.496 g 98.81%											
Max. fill weight 0.507 g 100.99%											
Average fill weight of 20 Capsules: 0.502 g											
Disintegration Time : 06 min 26 sec						(Limit: NMT 30 minutes at 37°C ± 2°C)					
Checked by: (Production)											
Date: 04/12/21 Time: 09:20											
Weight of 20 capsules : 11.920 gm						Average weight of capsule : 596 mg					
	A	B	C		A	B	C		A	B	C
1	590	95	495	8	590	95	495	15	594	95	499
2	594	96	498	9	594	96	498	16	596	96	500
3	592	92	500	10	592	97	500	17	598	97	501
4	599	95	502	11	600	98	502	18	595	95	500
5	596	96	500	12	596	96	500	19	602	96	506
6	593	98	495	13	598	98	500	20	603	98	505
7	598	97	498	14	595	97	498				
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight								± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight 0.495 g 95.00%											
Max. fill weight 0.506 g 101.20%											
Average fill weight of 20 Capsules: 0.500 g											
Disintegration Time : 03 minutes 52 sec						(Limit: NMT 30 minutes at 37°C ± 2°C)					
Checked by: S.M (Production)											

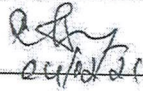
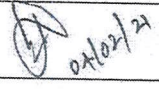
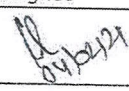
Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee
Signature with Date	 04/12/21	 04/12/21	 04/12/21

CONTROLLED COPY

	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.:	GD211133		Mfg.Date:	11/2021	Exp.Date:	10/2024

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

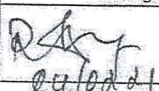
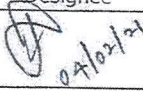
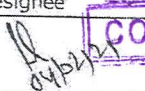
Date: 04.12.2024 Time: 09:25											
Weight of 20 capsules : 11.960 gm						Average weight of capsule : 598 mg					
	A	B	C		A	B	C		A	B	C
1	592	95	498	8	592	96	496	15	598	96	502
2	594	96	498	9	596	97	499	16	598	98	500
3	598	97	500	10	595	95	500	17	599	97	502
4	598	95	502	11	598	96	502	18	591	95	496
5	596	96	500	12	598	97	500	19	594	96	498
6	595	97	498	13	602	95	507	20	597	98	499
7	594	95	499	14	596	96	500				
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight								± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight 0.496 g 99.22%											
Max. fill weight 0.507 g 101.19%											
Average fill weight of 20 Capsules: 0.501 g											
Disintegration Time : 03 minutes 42 sec								(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by: S.M. (Production)											
Date: 04.12.2024 Time: 11:25											
Weight of 20 capsules : 11.920 gm						Average weight of capsule : 596 mg					
	A	B	C		A	B	C		A	B	C
1	591	96	495	8	596	96	500	15	594	96	498
2	596	97	498	9	593	98	495	16	596	97	499
3	596	97	499	10	595	97	498	17	595	97	500
4	595	95	500	11	595	95	500	18	597	96	501
5	597	96	501	12	597	96	501	19	597	97	500
6	597	97	500	13	597	97	500	20	590	95	495
7	597	95	502	14	590	95	495				
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight								± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight 0.495 g 99.22%											
Max. fill weight 0.506 g 101.12%											
Average fill weight of 20 Capsules: 0.500 g											
Disintegration Time : 03 minutes 44 sec								(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by: S.K. (Production)											

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

	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.:	GD211133	Mfg.Date:	11/2021	Exp.Date:	10/2024

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

Date: 04/12/24		Time: 12:25	
Weight of 20 capsules : 11.940 gm			
Average weight of capsule : 597 mg			
	A	B	C
1	591	95	496
2	594	96	497
3	592	97	500
4	600	98	502
5	592	97	500
6	593	98	495
7	592	99	498
8	596	96	500
9	599	98	501
10	605	97	508
11	595	95	500
12	591	96	495
13	596	98	497
14	592	97	500
15	596	95	501
16	596	96	500
17	606	98	508
18	592	97	500
19	590	95	495
20	594	96	498
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight			
± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight 0.495 g 99.00 %			
Max. fill weight 0.508 g 101.60 %			
Average fill weight of 20 Capsules: 0.500 g			
Disintegration Time : 03 minutes 49 sec		(Limit: NMT 30 minutes at 37°C ± 2°C)	
Checked by: S.M. (Production)			
Date: 04/12/24		Time: 15:35	
Weight of 20 capsules : 11.982 g			
Average weight of capsule : 599 mg			
	A	B	C
1	597	96	501
2	597	99	498
3	591	97	494
4	605	98	507
5	598	96	502
6	597	99	498
7	594	97	497
8	592	98	494
9	603	96	507
10	599	99	500
11	595	97	498
12	599	98	501
13	593	96	497
14	593	99	494
15	599	97	502
16	603	96	507
17	592	98	494
18	599	99	500
19	601	97	504
20	600	98	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 47 sec		(Limit: NMT 30 minutes at 37°C ± 2°C)	
Checked by: M.G. (Production)			

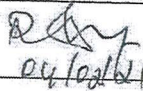
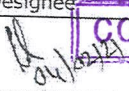
Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee
Signature with Date	 24/12/24	 04/12/24	 04/12/24

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	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD					
Brand Name	RICHFER CAPSULES		Product ID No.:	1047	Page No.:	36 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.:	GD211133		Mfg.Date:	11/2021	Supersedes MFC No:	ST/MFC/135/R0
					Exp.Date:	10/2024

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

Date: 04/10/21 Time: 20:30											
Weight of 20 capsules: 11.889 g						Average weight of capsule: 594 mg					
	A	B	C		A	B	C		A	B	C
1	594	96	498	8	599	97	502	15	597	96	501
2	594	98	496	9	603	98	505	16	597	99	498
3	600	99	501	10	596	96	500	17	601	97	504
4	597	97	500	11	595	99	496	18	599	98	501
5	600	96	504	12	596	97	499	19	593	96	497
6	597	98	499	13	601	96	505	20	598	99	499
7	597	99	498	14	598	98	500				
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight ± 5% of average weight (565.250mg to 624.750mg)											
Min. fill weight 0.496 g 99.20 %											
Max. fill weight 0.606 g 101.00 %											
Average fill weight of 20 Capsules: 0.500 g											
Disintegration Time: 04 min 51 sec								(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by: M.F. (Production)											
Date: 04/12/21 Time: 22:35											
Weight of 20 capsules: 11.927 g						Average weight of capsule: 596 mg					
	A	B	C		A	B	C		A	B	C
1	597	97	500	8	598	99	499	15	597	99	498
2	597	98	499	9	596	98	498	16	598	97	501
3	595	98	497	10	603	99	504	17	600	97	503
4	600	99	501	11	596	96	500	18	603	98	505
5	596	96	500	12	598	97	501	19	600	99	501
6	596	97	499	13	603	99	504	20	598	98	500
7	603	98	505	14	604	98	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 0.497 g 99.21 %											
Max. fill weight 0.606 g 100.99 %											
Average fill weight of 20 Capsules: 0.501 g											
Disintegration Time: 04 min 49 sec								(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by: A (Production)											

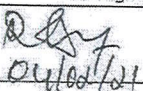
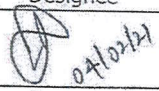
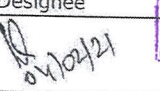
Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee
Signature with Date	 04/10/21	 04/10/21	 04/10/21

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	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page No.:	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.:	GD211133	Mfg. Date:	11/2021	Exp. Date:	10/2024	

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

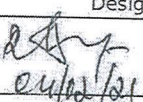
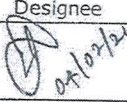
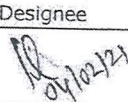
Date:..... Time:.....											
Weight of 20 capsules :				Average weight of capsule :							
	A	B	C		A	B	C		A	B	C
1				8				15			
2				9				16			
3				10				17			
4				11				18			
5				12				19			
6				13				20			
7				14							
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight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

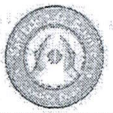
	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/10/21	 04/10/21	 04/10/21	

	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page No.:	38 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.:	GD211133	Mfg.Date:	11/2021	Exp.Date:	10/2024	

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

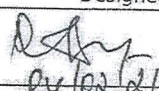
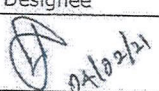
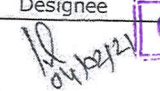
Date:..... Time:.....												
Weight of 20 capsules :						Average weight of capsule :						
	A	B	C			A	B	C		A	B	C
1				8					15			
2				9					16			
3				10					17			
4				11					18			
5				12					19			
6				13					20			
7				14								
A : Weight of filled capsule, B: weight of empty capsule, C: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

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

	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD					
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	39 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.:	GD211133	Mfg.Date:	11/2021	Supersedes MFC No:	ST/MFC/135/R0	
				Exp.Date:	10/2024	

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

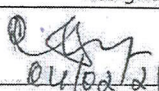
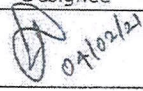
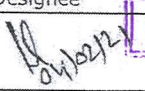
Date:..... Time:.....											
Weight of 20 capsules :						Average weight of capsule :					
	A	B	C		A	B	C		A	B	C
1				8				15			
2				9				16			
3				10				17			
4				11				18			
5				12				19			
6				13				20			
7				14							
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight								± 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	 24/02/21	 24/02/21	 24/02/21	

	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD				Page No.:	40 of 57
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules	
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0	
Batch No.:	GD211133	Mfg.Date:	11/2021	Exp.Date:	10/2024	

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

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

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

	Safetab Life Science			MASTER COPY	
BATCH MANUFACTURING RECORD					
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	41 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.:	GD211133	Mfg.Date:	11/2021	Supersedes MFC No:	ST/MFC/135/R0
				Exp.Date:	10/2024

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

Date: 04/12/21 Time: 03:35											
Weight of 20 capsules : 11.9278						Average weight of capsule : 596 mg					
	A	B	C		A	B	C		A	B	C
1	598	96	502	8	597	95	502	15	593	96	497
2	595	95	500	9	595	96	499	16	599	97	502
3	599	96	503	10	600	95	505	17	596	96	500
4	593	96	497	11	598	95	503	18	594	95	499
5	596	95	501	12	595	95	500	19	596	95	501
6	597	97	500	13	594	96	498	20	596	96	500
7	599	96	503	14	601	96	505				
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 0.497 g 99.20 %											
Max. fill weight 0.505 g 100.79 %											
Average fill weight of 20 Capsules: 0.501 g											
Disintegration Time : 04 min 36 sec						(Limit: NMT 30 minutes at 37°C ± 2°C)					
Checked by: [Signature] (IPQA)											
Date: 04/12/21 Time: 07:05											
Weight of 20 capsules : 11.8678						Average weight of capsule : 593 mg					
	A	B	C		A	B	C		A	B	C
1	595	97	498	8	600	94	506	15	593	94	499
2	597	95	502	9	595	94	501	16	599	96	503
3	601	96	498	10	593	95	498	17	595	94	501
4	597	97	500	11	597	94	503	18	593	96	497
5	592	95	497	12	600	94	506	19	597	95	502
6	598	95	503	13	595	94	501	20	599	95	504
7	597	96	501	14	593	95	498				
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight ± 5% of average weight (565.250mg to 624.750mg)											
Min. fill weight 0.495 g 99.19 %											
Max. fill weight 0.506 g 101.40 %											
Average fill weight of 20 Capsules: 0.499 g											
Disintegration Time : 04 min 30 sec						(Limit: NMT 30 minutes at 37°C ± 2°C)					
Checked by: [Signature] (IPQA)											

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee	CONTROLLED COPY
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.:	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.:	GD211133	Mfg.Date:	11/2021	Exp.Date:	10/2024

11. 9A IN-PROCESS CHECKS FREQUENCY: EVERY 4 HOUR BY IPQA:

Date: 04/12/21 Time: 11:35											
Weight of 20 capsules : 11.948g						Average weight of capsule : 597mg					
	A	B	C		A	B	C		A	B	C
1	598	95	503	8	599	97	502	15	599	95	504
2	597	96	501	9	598	95	503	16	593	96	497
3	592	94	498	10	593	96	497	17	598	97	501
4	595	95	500	11	590	95	495	18	598	95	503
5	598	96	502	12	595	96	499	19	600	96	504
6	596	95	501	13	595	95	500	20	591	95	496
7	603	96	507	14	597	96	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 0.495 g 98.80 %											
Max. fill weight 0.507 g 101.20 %											
Average fill weight of 20 Capsules: 0.501 g											
Disintegration Time : 03 mins 41 sec						(Limit: NMT 30 minutes at 37°C ± 2°C)					
Checked by: [Signature] (IPQA)											
Date: 04/12/21 Time: 15:35											
Weight of 20 capsules : 11.951g						Average weight of capsule : 597mg					
	A	B	C		A	B	C		A	B	C
1	597	96	501	8	597	95	502	15	601	95	506
2	594	95	499	9	596	96	500	16	598	96	502
3	595	95	500	10	594	97	497	17	595	95	500
4	598	96	502	11	592	96	496	18	598	96	502
5	596	96	500	12	594	95	499	19	593	95	498
6	598	97	501	13	597	95	502	20	595	96	499
7	602	96	506	14	596	96	500				
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight ± 5% of average weight (565.250mg to 624.750mg)											
Min. fill weight 0.496 g 99.00 %											
Max. fill weight 0.506 g 100.98 %											
Average fill weight of 20 Capsules: 0.501 g											
Disintegration Time : 03 mins 45 sec						(Limit: NMT 30 minutes at 37°C ± 2°C)					
Checked by: [Signature] (IPQA)											

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

	Safetab Life Science			MASTER COPY	
				BATCH MANUFACTURING RECORD	
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	43 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.:	GD211133	Mfg.Date:	11/2021	Supersedes MFC No:	ST/MFC/135/R0
				Exp.Date:	10/2024

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

Date: 04/12/21 Time: 20:30											
Weight of 20 capsules : 11.907g						Average weight of capsule : 595.35mg					
	A	B	C		A	B	C		A	B	C
1	593	96	497	8	595	96	499	15	593	95	498
2	597	95	502	9	597	95	502	16	593	96	497
3	596	96	500	10	596	96	500	17	589	95	494
4	593	99	501	11	596	95	501	18	594	95	499
5	598	95	503	12	600	99	506	19	598	96	502
6	594	96	498	13	597	95	502	20	601	95	506
7	589	95	494	14	598	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 0.499 g 99.8 %											
Max. fill weight 0.506 g 101.2 %											
Average fill weight of 20 Capsules: 0.500 g											
Disintegration Time : 03 Mins 36s								(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by: [Signature] (IPQA)											
Date: Time:											
Weight of 20 capsules :						Average weight of capsule :					
	A	B	C		A	B	C		A	B	C
1				8				15			
2				9				16			
3				10				17			
4				11				18			
5				12				19			
6				13				20			
7				14							
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight								± 5% of average weight (565.250mg to 624.750mg)			
Min. fill weight g %											
Max. fill weight g %											
Average fill weight of 20 Capsules: g											
Disintegration Time :								(Limit: NMT 30 minutes at 37°C ± 2°C)			
Checked by: (IPQA)											

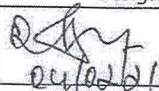
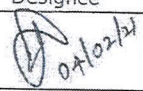
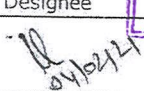
	Prepared by:	Checked by:	Approved by:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	[Signature] 04/12/21	[Signature] 04/12/21	[Signature] 04/12/21

CONTROLLED COPY

	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.:	GD211133		Mfg.Date:	11/2021	Exp.Date:	10/2024

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

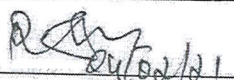
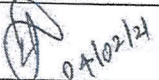
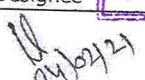
Date:..... Time:.....											
Weight of 20 capsules :						Average weight of capsule :					
	A	B	C		A	B	C		A	B	C
1				8				15			
2				9				16			
3				10				17			
4				11				18			
5				12				19			
6				13				20			
7				14							
A : Weight of filled capsule, B: weight of empty capsule, C: Fill weight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

	Prepared by:	Checked by:	Approved by:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 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.:	GD211133	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					
Brand Name	RICHFER CAPSULES		Product ID No.:	1047	Page No.:	46 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.:	GD211133		Mfg.Date:	11/2021	Supersedes MFC No:	ST/MFC/135/R0
					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	12.27	1.80	10.47	Pachayapa	P	26	11.32	1.80	9.52	Pachayapa	P
2	11.02	1.80	9.22	Pachayapa	P	27	10.57	1.80	8.77	Pachayapa	P
3	12.63	1.80	10.73	Pachayapa	P	28	6.10	1.80	4.30	Pachayapa	P
4	11.93	1.80	10.13	Pachayapa	P	29					
5	12.62	1.80	10.82	Pachayapa	P	30					
6	11.98	1.80	10.18	Dinakaran	S.M.	31					
7	12.88	1.80	11.08	Dinakaran	S.M.	32					
8	11.01	1.80	9.21	Dinakaran	S.M.	33					
9	11.20	1.80	9.40	Dinakaran	S.M.	34					
10	11.82	1.80	10.02	Dinakaran	S.M.	35					
11	11.43	1.80	9.63	Dinakaran	S.M.	36					
12	11.16	1.80	9.36	Dinakaran	S.M.	37					
13	11.34	1.80	9.54	Dinakaran	S.M.	38					
14	11.62	1.80	9.82	Dinakaran	M.P.	39					
15	11.45	1.80	9.65	Dinakaran	M.P.	40					
16	11.17	1.80	9.37	Dinakaran	M.P.	41					
17	12.12	1.80	10.32	Dinakaran	M.P.	42					
18	11.23	1.80	9.43	Dinakaran	M.P.	43					
19	10.87	1.80	9.07	Dinakaran	M.P.	44					
20	11.35	1.80	9.55	Dinakaran	M.P.	45					
21	10.15	1.80	8.35	Pachayapa	P	46					
22	11.72	1.80	9.92	Pachayapa	P	47					
23	10.85	1.80	9.05	Pachayapa	P	48					
24	11.67	1.80	9.87	Pachayapa	P	49					
25	11.57	1.80	9.77	Pachayapa	P	50					
						Total weight of Filled capsules:		265.94 kg			

Intimate IPQA to draw the sample		Sample withdrawn by IPQA.	
Production Sign: <i>[Signature]</i>	Date: <i>04/12/24</i>	IPQA Sign: <i>[Signature]</i>	Date: <i>04/12/24</i>
Send Test request form for analysis of filled capsules to QC department.			

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee
Signature with Date	<i>[Signature]</i> 04/12/24	<i>[Signature]</i> 04/12/24	<i>[Signature]</i> 04/12/24

CONTROLLED COPY

	Safetab Life Science		MASTER COPY		
					BATCH MANUFACTURING RECORD
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	47 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.:	GD211133	Mfg.Date:	11/2021	Exp.Date:	10/2024

12.1 RECONCILIATION:

Average weight of capsule: mg

1.0	Theoretical weight of Filled capsules	:	267.75 Kg	450000 No's
2.0	Actual weight of Filled capsules	:	265.94 Kg	44958 No's
3.0	Capsule filling Loss (1.0 - 6.0)	:	0.86 Kg	1645 No's
4.0	In-process samples			
	A IPQA Samples	:	0.66 Kg	1120 No's
	B QC Samples	:	0.06 Kg	100 No's
	C Validation Samples	:	0.23 Kg	400 No's
5.0	Total samples: (A + B + C)	:	0.95 Kg	1620 No's
6.0	Total: (5.0 + 2.0)	:	266.89 Kg	448555 No's
7.0	% Yield = $\frac{6.0}{1.0} \times 100$ (Limit: NLT 97.00 %)	:	99.67	%

Reconciliation done by Production sign/Date: 04/12/21

Checked by IPQA sign/Date: 04/12/21

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

Total rejects destroyed: 0.86 Kg Rejected materials shall be destroyed in the presence of QA

Done by Production sign/Date: 04/12/21 Checked By IPQA sign/Date: 04/12/21

12.2 CAPSULES RELEASED FOR INSPECTION:

Production Sign/Date: 04/12/21

IPQA Sign/Date: 04/12/21

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

	Safetab Life Science			MASTER COPY	
				BATCH MANUFACTURING RECORD	
		Page No.:		48 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.:	GD211133	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: *Adulal*

Verified by (IPQA) sign/date: *Adulal*

ENVIRONMENTAL CONDITIONS:	Date: <i>04/12/21</i>		Date:	
	Observation	Production Sign	Observation	Production Sign
Temperature: 23°C to 27°C	<i>26.20C</i>	<i>A</i>	<i>✓</i>	
Relative Humidity: 45% to 55 %	<i>51%</i>	<i>A</i>	<i>✓</i>	

13.2 APPROVAL FOR INSPECTION:

Production Sign/Date: *Adulal*

IPQA Sign./Date: *Adulal*

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			
<i>04/12/21</i>	<i>01</i>	<i>85</i>	<i>03:30</i>	<i>22:10</i>	<i>0.57</i>	<i>Adulal</i>	<i>Adulal</i>

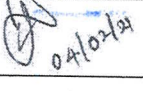
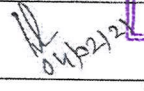
Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved by: QA Head / Designee
Signature with Date	<i>Adulal</i>	<i>Adulal</i>	<i>Adulal</i>

CONTROLLED COPY

	Safetab Life Science		MASTER COPY		
			BATCH MANUFACTURING RECORD		
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	49 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.:	GD211133	Mfg.Date:	11/2021	Supersedes MFC No:	ST/MFC/135/R0
				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	12.25	1.80	10.45	Silambu	P	26	11.30	1.80	9.50	Silambu	P
2	11.00	1.80	9.20	Silambu	P	27	10.55	1.80	8.75	Silambu	P
3	12.50	1.80	10.70	Silambu	P	28	6.08	1.80	4.28	Silambu	P
4	11.81	1.80	10.01	Silambu	P	29					
5	12.60	1.80	10.80	Silambu	P	30					
6	11.97	1.80	10.17	vanthini	S.P.	31					
7	10.85	1.80	9.05	vanthini	S.P.	32					
8	10.99	1.80	9.19	vanthini	S.P.	33					
9	11.18	1.80	9.38	vanthini	S.P.	34					
10	11.50	1.80	9.70	vanthini	S.P.	35					
11	11.41	1.80	9.61	vanthini	S.P.	36					
12	11.14	1.80	9.34	vanthini	S.P.	37					
13	11.32	1.80	9.52	vanthini	S.P.	38					
14	11.60	1.80	9.80	Manjaul	M.P.	39					
15	11.15	1.80	9.35	Manjaul	M.P.	40					
16	11.43	1.80	9.63	Manjaul	M.P.	41					
17	12.10	1.80	10.30	Manjaul	M.P.	42					
18	11.21	1.80	9.41	Manjaul	M.P.	43					
19	10.85	1.80	9.05	Manjaul	M.P.	44					
20	11.33	1.80	9.53	Manjaul	M.P.	45					
21	12.12	1.80	10.32	manjaul	P	46					
22	11.71	1.80	9.91	manjaul	P	47					
23	10.82	1.80	9.02	manjaul	P	48					
24	11.65	1.80	9.85	Silambu	P	49					
25	11.35	1.80	9.55	Silambu	P	50					
Total weight of Filled capsules:										965.87	kg

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

	Safetab Life Science			MASTER COPY	
BATCH MANUFACTURING RECORD				Page No.:	50 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.:	GD211133	Mfg.Date:	11/2021	Exp.Date:	10/2024

13.5 RECONCILIATION: (INSPECTION OF CAPSULES)

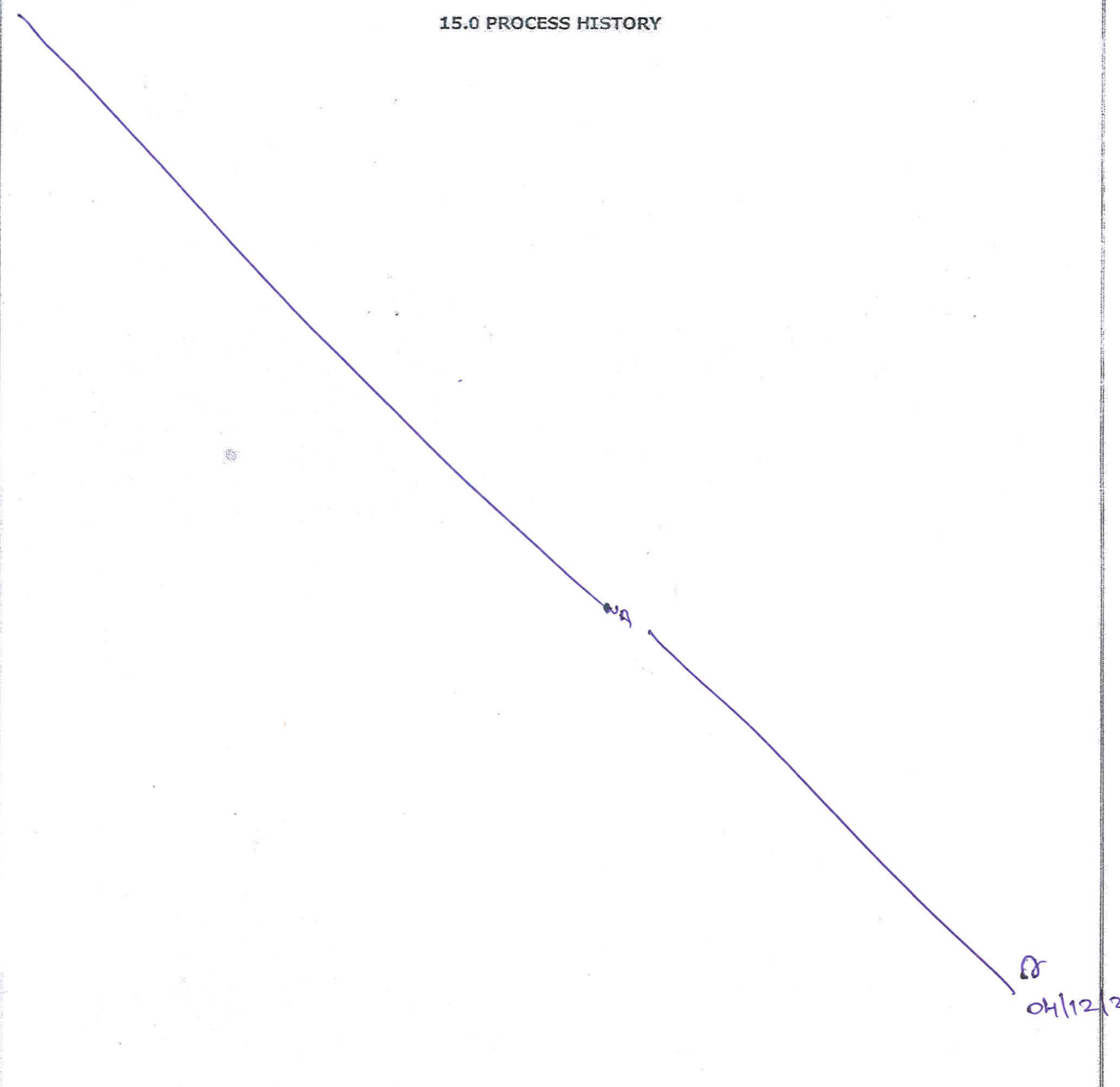
1.0	Theoretical weight of capsules	:	267.75 kg	450000 No's
2.0	Capsules transferred for Inspection	:	265.94 kg	446958 No's
3.0	Rejected Capsules	:	0.57 kg	958 No's
4.0	Total weight of good Capsules	:	265.37 kg	446000 No's
5.0	$\% \text{ Yield} = \frac{4.0}{1.0} \times 100$ (Limit- NLT 96.50%)* *Tentative limit	:	99.11 %	
Reconciliation done by Production sign/Date: <u>[Signature]</u> / <u>12/12/21</u> Checked by IPQA sign/Date: <u>[Signature]</u> / <u>12/12/21</u>				
Total rejects destroyed: <u>0.57</u> Kg. Rejected materials should be destroyed in the presence of QA.				
Done by Packing sign/Date: <u>[Signature]</u> / <u>12/12/21</u> Checked by IPQA sign/Date: <u>[Signature]</u> / <u>12/12/21</u>				

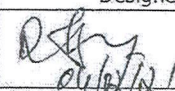
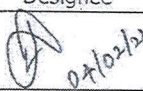
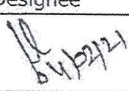
14.0 RELEASE FOR PACKING:
BMR reviewed by IPQA Sign/Date : <u>[Signature]</u> / <u>15/12/21</u>
BMR Released for packing by QA Head Sign/Date: <u>[Signature]</u> / <u>15/12/21</u>

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

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	51 of 57
Brand Name	RICHTER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Supersedes MFC No:	ST/MFC/135/R0
Batch No.:	GD211133	Mfg.Date:	11/2021	Exp.Date:	10/2024

15.0 PROCESS HISTORY



	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	

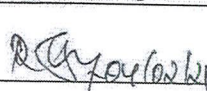
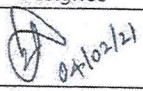
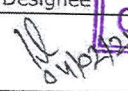
	Safetab Life Science				MASTER COPY	
	BATCH MANUFACTURING RECORD					
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	52 of 57	
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC NO:	ST/MFC/135/R1	Batch Size	4,50,000 Capsules	
Batch No.:	GD211133	Mfg.Date:	11/2021	Supersedes MFC No:	ST/MFC/135/R0	
				Exp.Date:	10/2024	

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

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

	Safetab Life Science		MASTER COPY		
	BATCH MANUFACTURING RECORD		Page No.:	53 of 57	
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Batch Size	4,50,000 Capsules
Generic Name:	Carbonyl Iron, Vitamins, Zinc and Antioxidants capsules	MFC No.:	ST/MFC/135/R1	Supersedes MFC No.:	ST/MFC/135/R0
Batch No.:	GD211133	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:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date		 04/02/21		CONTROLLED COPY

	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.:	GD211133	Mfg.Date:	11/2021	Exp.Date:	10/2024

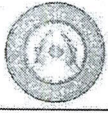
BMR COPY/QUALITY CONTROL COPY

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.: <u>11/2021</u> Date of exp: <u>10/2024</u>		Quantity Sampled: <u>50 gm</u>	
Test Request for: <u>Content</u>		Sampled by: <u>P. G. M. S.</u> on date: <u>19/11/24</u>	
TRF raised by: <u>[Signature]</u> on date: <u>19/11/24</u>		No. of containers: <u>06</u>	
To be filled by QC		Sample received by: <u>[Signature]</u> on date: <u>20/11/24</u>	
TRF received on: <u>20/11/2024</u>			
Sample tested on: <u>20/11/2024</u>			
Test Results		Limits	
<u>Each 1000g of Granules contains:-</u> <u>Carbonyl Iron:- 98.4600g (98.5%)</u> <u>Ascorbic acid:- 89.2700g (116.4%)</u> <u>Vitamin E:- 19.45 IU (129.7%)</u> <u>Selenic acid:- 78.8300g (121.28%)</u> <u>Zinc:- 26.000g (115.54%)</u> <u>Folic acid:- 581.4300g (116.3%)</u> <u>Cyanocobalamin:- 21.2000g (142.7%)</u>			
Analytical Reference no.: <u>GV/0124/1/2024</u>		Space for QC Approval (Stamping and Signing)	
Analysed By: <u>K. S. M.</u> on: <u>20/11/2024</u>		APPROVED Sign: <u>[Signature]</u> Date: <u>20/11/24</u>	

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

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.:	GD211133	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.: <u>11/2021</u> Date of exp: <u>10/2024</u>		Quantity Sampled : <u>100 caps</u>	
Test Request for : <u>Content</u>		Sampled by : <u>Er</u> on date: <u>04/12/21</u>	
TRF raised by: <u>M. G</u> on date: <u>04/12/21</u>		No. of containers : <u>28</u>	
		Sample received by: <u>[Signature]</u> on date: <u>15/12/21</u>	
To be filled by QC			
TRF received on : <u>05/12/2021</u>			
Sample tested on : <u>05/12/2021</u>			
Test Results			
Each hard gelatin capsule contains : Carbonyl Iron ⇒ 99.05 mg (99.1%) Folic acid ⇒ 571.97 mcg (114.4%) Cyanocobalamin ⇒ 21.3 mcg (142.0%) Ascorbic acid ⇒ 88.74 mg (118.3%) Zinc Sulphate monohydrate eq. Zinc ⇒ 25.68 mg (114.2%) Alpha Tocopheryl Acetate 50% ⇒ 18.87 IU (125.8%) Sodium Selenate eq. to Selenium ⇒ 77.09 mcg (118.6%)			
Analytical Reference no.: <u>SFP/L/01673/2021</u>		Space for QC Approval (Stamping and Signing) APPROVED <u>[Signature]</u> Sign..... Date <u>15/12/21</u>	
Analysed By : <u>[Signature]</u> on : <u>15/12/2021</u>			

	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.:	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/RI	Supersedes MFC No:	ST/MFC/135/RO
Batch No.:	GD211133	Mfg.Date:	11/2021	Exp.Date:	10/2024

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

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

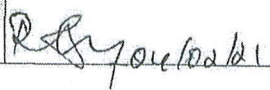
QA Head Sign/Date: 15/12/21

	Prepared by:	Checked by:	Approved by:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>15/12/21</u>	<u>15/12/21</u>	<u>15/12/21</u>	

	Safetab Life Science		MASTER COPY		
					BATCH MANUFACTURING RECORD
Brand Name	RICHFER CAPSULES	Product ID No.:	1047	Page No.:	57 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.:	GD211133	Mfg.Date:	11/2021	Supersedes MFC No:	ST/MFC/135/R0
				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	