



ACCELERATED STABILITY REPORT

Safetab Life Science

Product Name: RICHFER CAPSULES
Strength: Carbonyl Iron 100mg + Folic acid 500mcg + Cyanocobalamin 15mcg + Ascorbic acid 75mg + Zinc 22.5mg + Alpha Tocopheryl Acetate 15IU + Selenium 65mcg
Batch No: GD201201
Mfg. Date: Dec-20
Exp.Date: Nov-23

Pack : Blister packing (3 x 10 's)
Study Started on : 31/12/2020
Study Completed on : 28/06/2021
Reason for study : New Product

Tests	Specifications	Initial	3 Months	6 Months
Condition>>	NA	NA	40 ± 2°C & 75 ± 5% RH	40 ± 2°C & 75 ± 5% RH
Description	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.
Average weight of capsule	596.0mg ±5.0% (566.2 – 625.8 mg)	597.1mg	606.6mg	615.9mg
Average net weight of capsule	500.0mg ±5.0% (475.0 – 525.0 mg)	501.3mg	510.4mg	518.1mg
Disintegration Time	Not more than 30 minutes	05 Minutes 09 Seconds	05 Minutes 22 Seconds	06 Minutes 33 Seconds
Assay: Each hard gelatin capsule contains:				
a) Carbonyl Iron Equivalent to Elemental iron 100mg	90.0% to 110.0% of the labeled claim I.e. 90.0mg to 110.0mg	100.20mg (100.2%)	100.44mg (100.4%)	99.49mg (99.5%)
b) Folic Acid BP 500mcg	Not less than 90.0% of the labeled claim I.e. 450.0mcg	535.17mcg (107.0%)	537.70mcg (107.5%)	521.48mcg (104.3%)
c) Cyanocobalamin BP 15mcg	Not less than 90.0% of the labeled claim I.e. 13.5mcg	22.1mcg (147.3%)	18.2mcg (121.3%)	15.3mcg (102.0%)
d) Ascorbic Acid BP 75mg	Not less than 90.0% of the labeled claim I.e. 67.5mg	87.06mg (116.1%)	86.6mg (115.5%)	86.01mg (114.7%)
e) Zinc Sulphate monohydrate BP 61.8 mg (Equivalent to elemental zinc 22.5mg)	Not less than 90.0% of the labeled claim I.e. 20.25mg	26.11mg (116.0%)	25.95mg (115.4%)	25.64mg (114.0%)
f) Alpha Tocopheryl Acetate Concentrate 50% BP 15IU	Not less than 90.0% of the labeled claim I.e. 13.5IU	18.31IU (122.1%)	17.89IU (119.2%)	18.29IU (121.9%)
g) Sodium selenate Equivalent to Selenium 65mcg	Not less than 90.0% of the labeled claim I.e. 58.5mcg	77.07mcg (118.6%)	76.46mcg (117.6%)	74.95mcg (115.3%)
Microbiological parameters:				
1.Total Viable aerobic count				
a) Total aerobic microbial count	Not more than 1000 cfu/g	30cfu/g		50cfu/g
b) Total yeast and mould count	Not more than 100 cfu/g	Found absent/g		Found absent/g
2. Pseudomonas aeruginosa	Should be absent/g	Found absent/g	NA	Found absent/g
3. Salmonella Species	Should be absent/10g	Found absent/10g		Found absent/10g
4. Escherichia Coli	Should be absent/g	Found absent/g		Found absent/g
5. Staphylococcus aureus	Should be absent/g	Found absent/g		Found absent/g
Remarks		Pass	Pass	Pass

Conclusion: The above referred batch meets the acceptance criteria when stored at above mentioned condition for 6 months.

Particulars	Prepared By	Checked By	Approved By
Name	C.ALBIN JOSE	M. VIJAYAKUMAR	K. JAYARAJ
Designation	Asst. Manager - QC	AGM - QC	Asst. Manager - QA
Signature			
Date	25/04/23	25/04/23	26/04/2023



ACCELERATED STABILITY REPORT

Safetab Life Science

Product Name: RICHFER CAPSULES
Strength: Carbonyl Iron 100mg + Folic acid 500mcg + Cyanocobalamin 15mcg + Ascorbic acid 75mg + Zinc 22.5mg + Alpha Tocopheryl Acetate 15IU + Selenium 65mcg
Batch No: GD201209
Mfg. Date: Dec-20
Exp.Date: Nov-23

Pack : Blister packing (3 x 10 's)
Study Started on : 06/01/2021
Study Completed on : 06/07/2021
Reason for study : New Product

Tests	Specifications	Initial	3 Months	6 Months
Condition>>	NA	NA	40 ± 2°C & 75 ± 5% RH	40 ± 2°C & 75 ± 5% RH
Description	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.
Average weight of capsule	596.0mg ±5.0% (566.2 – 625.8 mg)	592.9mg	610.8mg	612.4mg
Average net weight of capsule	500.0mg ±5.0% (475.0 – 525.0 mg)	497.2mg	515.7mg	515.8mg
Disintegration Time	Not more than 30 minutes	05 Minutes 07 Seconds	05 Minutes 22 Seconds	05 Minutes 23 Seconds
Assay: Each hard gelatin capsule contains:				
a) Carbonyl Iron Equivalent to Elemental iron 100mg	90.0% to 110.0% of the labeled claim I.e. 90.0mg to 110.0mg	99.54mg (99.5%)	98.66mg (98.7%)	96.54mg (96.5%)
b) Folic Acid BP 500mcg	Not less than 90.0% of the labeled claim I.e. 450.0mcg	567.33mcg (113.5%)	598.23mcg (119.6%)	508.73mcg (101.7%)
c) Cyanocobalamin BP 15mcg	Not less than 90.0% of the labeled claim I.e. 13.5mcg	23.0mcg (153.3%)	17.92mcg (119.5%)	15.81mcg (105.4%)
d) Ascorbic Acid BP 75mg	Not less than 90.0% of the labeled claim I.e. 67.5mg	87.96mg (117.3%)	87.8mg (117.1%)	85.15mg (113.5%)
e) Zinc Sulphate monohydrate BP 61.8 mg (Equivalent to elemental zinc 22.5mg)	Not less than 90.0% of the labeled claim I.e. 20.25mg	25.71mg (114.3%)	24.89mg (110.6%)	24.48mg (108.8%)
f) Alpha Tocopheryl Acetate Concentrate 50% BP 15IU	Not less than 90.0% of the labeled claim I.e. 13.5IU	18.53IU (123.6%)	18.48IU (123.2%)	17.89IU (119.3%)
g) Sodium selenate Equivalent to Selenium 65mcg	Not less than 90.0% of the labeled claim I.e. 58.5mcg	76.41mcg (117.6%)	75.49mcg (116.1%)	73.41mcg (112.9%)
Microbiological parameters:				
1.Total Viable aerobic count				
a) Total aerobic microbial count	Not more than 1000 cfu/g	150cfu/g		10cfu/g
b) Total yeast and mould count	Not more than 100 cfu/g	Found absent/g		Found absent/g
2. Pseudomonas aeruginosa	Should be absent/g	Found absent/g	NA	Found absent/g
3. Salmonella Species	Should be absent/10g	Found absent/10g		Found absent/10g
4. Escherichia Coli	Should be absent/g	Found absent/g		Found absent/g
5. Staphylococcus aureus	Should be absent/g	Found absent/g		Found absent/g
Remarks		Pass	Pass	Pass

Conclusion: The above referred batch meets the acceptance criteria when stored at above mentioned condition for 6 months.

Particulars	Prepared By	Checked By	Approved By
Name	C.ALBIN JOSE	M. VIJAYAKUMAR	K. JAYARAJ
Designation	Asst. Manager - QC	AGM - QC	Asst. Manager - QA
Signature			
Date	26/04/23	26/04/23	26/04/2023



ACCELERATED STABILITY REPORT

Safetab Life Science

Product Name: RICHFER CAPSULES
Strength: Carbonyl Iron 100mg + Folic acid 500mcg + Cyanocobalamin 15mcg + Ascorbic acid 75mg + Zinc 22.5mg + Alpha Tocopheryl Acetate 15IU + Selenium 65mcg
Batch No: GD201210
Mfg. Date: Dec-20
Exp.Date: Nov-23

Pack : Blister packing (3 x 10 's)
Study Started on : 07/01/2021
Study Completed on : 07/07/2021
Reason for study : New Product

Tests	Specifications	Initial	3 Months	6 Months
Condition>>	NA	NA	40 ± 2°C & 75 ± 5% RH	40 ± 2°C & 75 ± 5% RH
Description	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.
Average weight of capsule	596.0mg ±5.0% (566.2 – 625.8 mg)	597.0mg	613.3mg	618.4mg
Average net weight of capsule	500.0mg ±5.0% (475.0 – 525.0 mg)	501.2mg	517.9mg	519.5mg
Disintegration Time	Not more than 30 minutes	05 Minutes 33 Seconds	04 Minutes 45 Seconds	06 Minutes 01 Seconds
Assay: Each hard gelatin capsule contains:				
a) Carbonyl Iron Equivalent to Elemental iron 100mg	90.0% to 110.0% of the labeled claim I.e. 90.0mg to 110.0mg	101.46mg (101.5%)	101.99mg (102.0%)	97.23mg (97.2%)
b) Folic Acid BP 500mcg	Not less than 90.0% of the labeled claim I.e. 450.0mcg	599.54mcg (119.9%)	629.26mcg (125.9%)	495.89mcg (99.2%)
c) Cyanocobalamin BP 15mcg	Not less than 90.0% of the labeled claim I.e. 13.5mcg	23.12mcg (154.7%)	18.45mcg (123.0%)	16.1mcg (107.3%)
d) Ascorbic Acid BP 75mg	Not less than 90.0% of the labeled claim I.e. 67.5mg	88.20mg (117.6%)	87.7mg (116.9%)	86.21mg (114.9%)
e) Zinc Sulphate monohydrate BP 61.8 mg (Equivalent to elemental zinc 22.5mg)	Not less than 90.0% of the labeled claim I.e. 20.25mg	26.23mg (116.6%)	25.37mg (112.8%)	25.09mg (111.5%)
f) Alpha Tocopheryl Acetate Concentrate 50% BP 15IU	Not less than 90.0% of the labeled claim I.e. 13.5IU	19.14IU (127.6%)	18.26IU (121.7%)	18.33IU (122.2%)
g) Sodium selenate Equivalent to Selenium 65mcg	Not less than 90.0% of the labeled claim I.e. 58.5mcg	77.06mcg (118.6%)	74.87mcg (115.2%)	73.99mcg (113.8%)
Microbiological parameters:				
1.Total Viable aerobic count				
a) Total aerobic microbial count	Not more than 1000 cfu/g	20cfu/g		20cfu/g
b) Total yeast and mould count	Not more than 100 cfu/g	Found absent/g		Found absent/g
2. Pseudomonas aeruginosa	Should be absent/g	Found absent/g	NA	Found absent/g
3. Salmonella Species	Should be absent/10g	Found absent/10g		Found absent/10g
4. Escherichia Coli	Should be absent/g	Found absent/g		Found absent/g
5. Staphylococcus aureus	Should be absent/g	Found absent/g		Found absent/g
Remarks		Pass	Pass	Pass

Conclusion: The above referred batch meets the acceptance criteria when stored at above mentioned condition for 6 months.

Particulars	Prepared By	Checked By	Approved By
Name	C.ALBIN JOSE	M. VIJAYAKUMAR	K. JAYARAJ
Designation	Asst. Manager - QC	AGM - QC	Asst. Manager - QA
Signature			
Date	25/04/23	25/04/23	26/04/2023



LONGTERM STABILITY REPORT

Safetab Life Science

Product Name: RICHFER CAPSULES
Strength: Carbonyl Iron 100mg + Folic acid 500mcg + Cyanocobalamin 15mcg + Ascorbic acid 75mg + Zinc 22.5mg + Alpha Tocopheryl Acetate 15IU + Selenium 65mcg
Batch No: GD201201
Mfg. Date: Dec-20
Exp.Date: Nov-23

Pack : Blister packing (3 x 10 's)
Study Started on : 31/12/2020
Study Completed on : Ongoing
Reason for study : New Product

Tests	Specifications	Initial	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months
Condition>>>	NA	NA	30 ± 2°C & 75 ± 5% RH	30 ± 2°C & 75 ± 5% RH	30 ± 2°C & 75 ± 5% RH	30 ± 2°C & 75 ± 5% RH	30 ± 2°C & 75 ± 5% RH	30 ± 2°C & 75 ± 5% RH	-
Description	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	-
Average weight of capsule	596.0mg ±5.0% (566.2 – 625.8 mg)	597.1mg	597.5mg	602.0mg	610.4mg	609.4mg	606.0mg	616.9mg	-
Average net weight of capsule	500.0mg ±5.0% (475.0 – 525.0 mg)	501.3mg	501.7mg	505.3mg	514.4mg	511.9mg	509.2mg	520.5mg	-
Disintegration Time	Not more than 30 minutes	05 Minutes 09 Seconds	04 Minutes 39 Seconds	05 Minutes 58 Seconds	06 Minutes 01 Seconds	05 Minutes 37 Seconds	06 Minutes 02 Seconds	05 Minutes 59 Seconds	-
Assay: Each hard gelatin capsule contains:									
a) Carbonyl Iron Equivalent to Elemental iron 100mg	90.0% to 110.0% of the labeled claim I.e. 90.0mg to 110.0mg	100.20mg (100.2%)	98.74mg (98.7%)	96.98mg (97.0%)	99.10mg (99.1%)	101.00mg (101.0%)	100.38mg (100.4%)	106.25mg (106.3%)	-
b) Folic Acid BP 500mcg	Not less than 90.0% of the labeled claim I.e. 450.0mcg	535.17mcg (107.0%)	562.78mcg (112.6%)	610.15mcg (122.0%)	549.68mcg (109.9%)	567.75mcg (113.5%)	575.73mcg (115.1%)	580.52mcg (116.1%)	-
c) Cyanocobalamin BP 15mcg	Not less than 90.0% of the labeled claim I.e. 13.5mcg	22.1mcg (147.3%)	20.0mcg (133.3%)	18.0mcg (120.0%)	19.6mcg (130.3%)	19.0mcg (126.7%)	18.3mcg (122.3%)	17.36mcg (115.7%)	-
d) Ascorbic Acid BP 75mg	Not less than 90.0% of the labeled claim I.e. 67.5mg	87.06mg (116.1%)	86.94mg (115.9%)	87.06mg (116.1%)	83.08mg (110.8%)	85.41mg (113.8%)	79.84mg (106.5%)	75.46mg (100.6%)	-
e) Zinc Sulphate monohydrate BP 61.8 mg (Equivalent to elemental zinc 22.5mg)	Not less than 90.0% of the labeled claim I.e. 20.25mg	26.11mg (116.0%)	25.60mg (113.8%)	25.34mg (112.6%)	24.82mg (110.3%)	24.05mg (106.9%)	23.99mg (106.6%)	23.83mg (105.9%)	-
f) Alpha Tocopheryl Acetate Concentrate 50% BP 15IU	Not less than 90.0% of the labeled claim I.e. 13.5IU	18.31IU (122.1%)	18.29IU (122.0%)	18.67IU (124.5%)	18.35IU (122.3%)	18.21IU (121.4%)	18.26IU (121.8%)	18.41IU (122.7%)	-
g) Sodium selenate Equivalent to Selenium 65mcg	Not less than 90.0% of the labeled claim I.e. 58.5mcg	77.07mcg (118.6%)	75.66mcg (116.4%)	74.77mcg (115.0%)	73.38mcg (112.9%)	71.27mcg (109.6%)	70.99mcg (109.2%)	70.99mcg (109.2%)	-
Microbiological parameters:									
1.Total Viable aerobic count									
a) Total aerobic microbial count	Not more than 1000 cfu/g	30cfu/g							
b) Total yeast and mould count	Not more than 100 cfu/g	Found absent							
2. Pseudomonas aeruginosa	Should be absent/g	Found absent							
3. Salmonella Species	Should be absent/10g	Found absent							
4. Escherichia Coli	Should be absent/g	Found absent							
5. Staphylococcus aureus	Should be absent/g	Found absent							
Remarks		Pass	Pass	Pass	Pass	Pass	Pass	Pass	-

Conclusion: The above referred batch meets the acceptance criteria when stored at above mentioned condition for 24 months.

Particulars	Prepared By	Checked By	Approved By
Name	C.ALBIN JOSE	M. VIJAYAKUMAR	K. JAYARAJ
Designation	Asst. Manager - QC	AGM - QC	Asst. Manager - QA
Signature			
Date	26/04/23	25/04/23	26/04/2023



LONGTERM STABILITY REPORT

Safetab Life Science

Product Name: RICHFER CAPSULES
Strength: Carbonyl Iron 100mg + Folic acid 500mcg + Cyanocobalamin 15mcg + Ascorbic acid 75mg + Zinc 22.5mg + Alpha Tocopheryl Acetate 15IU + Selenium 65mcg
Batch No: GD201209
Mfg. Date: Dec-20
Exp.Date: Nov-23

Pack: Blister packing (3 x 10 's)
Study Started on: 06/01/2021
Study Completed on: Ongoing
Reason for study: New Product

Tests	Specifications	Initial	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months
Condition>>	NA	NA	30 ± 2°C & 75 ± 5% RH	30 ± 2°C & 75 ± 5% RH	30 ± 2°C & 75 ± 5% RH	30 ± 2°C & 75 ± 5% RH	30 ± 2°C & 75 ± 5% RH	30 ± 2°C & 75 ± 5% RH	-
Description	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	-
Average weight of capsule	596.0mg ±5.0% (566.2 – 625.8 mg)	592.9mg	605.0mg	600.0mg	610.4mg	608.3mg	608.9mg	619.3mg	-
Average net weight of capsule	500.0mg ±5.0% (475.0 – 525.0 mg)	497.2mg	508.6mg	502.5mg	514.4mg	513.1mg	512.5mg	522.1mg	-
Disintegration Time	Not more than 30 minutes	05 Minutes 07 Seconds	04 Minutes 39 Seconds	05 Minutes 45 Seconds	06 Minutes 01 Seconds	05 Minutes 14 Seconds	05 Minutes 49 Seconds	07 Minutes 50 Seconds	-
Assay: Each hard gelatin capsule contains:									
a) Carbonyl Iron Equivalent to Elemental iron 100mg	90.0% to 110.0% of the labeled claim I.e. 90.0mg to 110.0mg	99.54mg (99.5%)	100.05mg (100.0%)	94.12mg (94.1%)	99.10mg (99.1%)	101.22mg (101.2%)	98.52mg (98.5%)	106.52mg (106.5%)	-
b) Folic Acid BP 500mcg	Not less than 90.0% of the labeled claim I.e. 450.0mcg	567.33mcg (113.5%)	543.13mcg (108.6%)	551.08mcg (110.2%)	549.68mcg (109.9%)	583.21mcg (116.6%)	563.72mcg (112.7%)	586.54mcg (117.3%)	-
c) Cyanocobalamin BP 15mcg	Not less than 90.0% of the labeled claim I.e. 13.5mcg	23.0mcg (153.3%)	21.9mcg (145.9%)	21.0mcg (139.8%)	20.3mcg (135.5%)	19.5mcg (130.1%)	18.8mcg (125.4%)	17.06mcg (113.7%)	-
d) Ascorbic Acid BP 75mg	Not less than 90.0% of the labeled claim I.e. 67.5mg	87.96mg (117.3%)	87.9mg (117.3%)	86.99mg (115.9%)	83.25mg (111.0%)	86.45mg (115.3%)	88.68mg (118.2%)	75.91mg (101.2%)	-
e) Zinc Sulphate monohydrate BP 61.8 mg (Equivalent to elemental zinc 22.5mg)	Not less than 90.0% of the labeled claim I.e. 20.25mg	25.71mg (114.3%)	25.12mg (111.6%)	24.76mg (110.0%)	24.34mg (108.2%)	23.30mg (103.6%)	23.25mg (108.4%)	23.20mg (103.1%)	-
f) Alpha Tocopheryl Acetate Concentrate 50% BP 15IU	Not less than 90.0% of the labeled claim I.e. 13.5IU	18.53IU (123.6%)	18.26IU (121.7%)	17.50IU (116.7%)	18.31IU (122.1%)	18.27IU (121.8%)	18.06IU (120.4%)	17.95IU (119.6%)	-
g) Sodium selenate Equivalent to Selenium 65mcg	Not less than 90.0% of the labeled claim I.e. 58.5mcg	76.41mcg (117.6%)	75.24mcg (115.8%)	74.08mcg (114.0%)	71.75mcg (110.4%)	70.60mcg (108.6%)	70.49mcg (108.4%)	62.18mcg (95.7%)	-
Microbiological parameters:									
1. Total Viable aerobic count									
a) Total aerobic microbial count	Not more than 1000 cfu/g	150cfu/g				20cfu/g		20cfu/g	
b) Total yeast and mould count	Not more than 100 cfu/g	Found absent				Less than 10cfu/gm		Less than 10cfu/gm	
2. Pseudomonas aeruginosa	Should be absent/g	Found absent	NA	NA	NA	Found absent	NA	Found absent	-
3. Salmonella Species	Should be absent/10g	Found absent				Found absent		Found absent	
4. Escherichia Coli	Should be absent/g	Found absent				Found absent		Found absent	
5. Staphylococcus aureus	Should be absent/g	Found absent				Found absent		Found absent	
Remarks		Pass	Pass	Pass	Pass	Pass	Pass	Pass	-

Conclusion: The above referred batch meets the acceptance criteria when stored at above mentioned condition for 24 months.

Particulars	Prepared By	Checked By	Approved By
Name	C.ALBIN JOSE	M. VIJAYAKUMAR	K. JAYARAJ
Designation	Asst. Manager - QC	AGM - QC	Asst. Manager - QA
Signature			
Date	25/01/23	25/01/23	26/04/2023



Safetab Life Science

LONGTERM STABILITY REPORT

Product Name: RICHFER CAPSULES
Strength: Carbonyl Iron 100mg + Folic acid 500mcg + Cyanocobalamin 15mcg + Ascorbic acid 75mg + Zinc 22.5mg + Alpha Tocopheryl Acetate 15IU + Selenium 65mcg
Batch No: GD201210
Mfg. Date: Dec-20
Exp.Date: Nov-23

Pack: Blister packing (3 x 10 's)
Study Started on: 07/01/2021
Study Completed on: Ongoing
Reason for study: New Product

Tests	Specifications	Initial	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months
Condition>>	NA	NA	30 ± 2°C & 75 ± 5% RH	30 ± 2°C & 75 ± 5% RH	30 ± 2°C & 75 ± 5% RH	30 ± 2°C & 75 ± 5% RH	30 ± 2°C & 75 ± 5% RH	30 ± 2°C & 75 ± 5% RH	-
Description	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	Red/Red coloured, '0' size hard gelatin capsule filled with Grey colour granular powder.	-
Average weight of capsule	596.0mg ±5.0% (566.2 – 625.8 mg)	597.0mg	606.0mg	603.3mg	607.1mg	609.5mg	612.9mg	618.3mg	-
Average net weight of capsule	500.0mg ±5.0% (475.0 – 525.0 mg)	501.2mg	510.4mg	507.0mg	510.9mg	514.1mg	516.9mg	521.2mg	-
Disintegration Time	Not more than 30 minutes	05 Minutes 33 Seconds	05 Minutes 16 Seconds	05 Minutes 58 Seconds	05 Minutes 37 Seconds	05 Minutes 25 Seconds	05 Minutes 40 Seconds	07 Minutes 59 Seconds	-
Assay: Each hard gelatin capsule contains:									
a) Carbonyl Iron Equivalent to Elemental iron 100mg	90.0% to 110.0% of the labeled claim I.e. 90.0mg to 110.0mg	101.46mg (101.5%)	100.45mg (100.5%)	99.72mg (99.7%)	98.43mg (98.4%)	104.75mg (104.7%)	99.47mg (99.5%)	106.36mg (106.4%)	-
b) Folic Acid BP 500mcg	Not less than 90.0% of the labeled claim I.e. 450.0mcg	599.54mcg (119.9%)	554.69mcg (110.9%)	556.83mcg (111.4%)	549.66mcg (109.9%)	529.52mcg (105.9%)	553.19mcg (110.6%)	595.94mcg (119.2%)	-
c) Cyanocobalamin BP 15mcg	Not less than 90.0% of the labeled claim I.e. 13.5mcg	23.12mcg (154.7%)	21.9mcg (146.1%)	21.0mcg (140.2%)	20.3mcg (135.4%)	19.4mcg (129.6%)	18.5mcg (123.5%)	17.20mcg (114.7%)	-
d) Ascorbic Acid BP 75mg	Not less than 90.0% of the labeled claim I.e. 67.5mg	88.20mg (117.6%)	86.9mg (115.9%)	87.35mg (116.5%)	82.72mg (110.3%)	89.32mg (119.1%)	84.32mg (112.4%)	76.02mg (101.4%)	-
e) Zinc Sulphate monohydrate BP 61.8 mg (Equivalent to elemental zinc 22.5mg)	Not less than 90.0% of the labeled claim I.e. 20.25mg	26.23mg (116.6%)	25.37mg (112.8%)	25.11mg (111.6%)	25.01mg (111.2%)	24.03mg (106.8%)	23.93mg (106.4%)	23.88mg (106.2%)	-
f) Alpha Tocopheryl Acetate Concentrate 50% BP 15IU	Not less than 90.0% of the labeled claim I.e. 13.5IU	19.14IU (127.6%)	18.44IU (122.9%)	18.39IU (122.6%)	18.38IU (122.5%)	18.43IU (122.8%)	18.39IU (122.6%)	17.64IU (117.6%)	-
g) Sodium selenate Equivalent to Selenium 65mcg	Not less than 90.0% of the labeled claim I.e. 58.5mcg	77.06mcg (118.6%)	75.71mcg (116.5%)	75.66mcg (114.9%)	73.87mcg (113.6%)	71.98mcg (110.8%)	71.79mcg (110.5%)	64.54mcg (99.3%)	-
Microbiological parameters:									
1.Total Viable aerobic count	Not more than 1000 cfu/g Not more than 100 cfu/g Should be absent/g Should be absent/10g Should be absent/g Should be absent/g	20cfu/g	NA	NA	NA	40cfu/g Less than 10cfu/gm Found absent Found absent Found absent Found absent	NA	40cfu/g Less than 10cfu/gm Found absent Found absent Found absent Found absent	-
a) Total aerobic microbial count		Found absent							
b) Total yeast and mould count		Found absent							
2. Pseudomonas aeruginosa		Found absent							
3. Salmonella Species		Found absent							
4. Escherichia Coli		Found absent							
5. Staphylococcus aureus		Found absent							
Remarks		Pass	Pass	Pass	Pass	Pass	Pass	Pass	-

Conclusion: The above referred batch meets the acceptance criteria when stored at above mentioned condition for 24 months.

Particulars	Prepared By	Checked By	Approved By
Name	C.ALBIN JOSE	M. VIJAYAKUMAR	K. JAYARAJ
Designation	Asst. Manager - QC	AGM - QC	Asst. Manager - QA
Signature			
Date	25/04/23	25/04/23	26/04/2023