



Safetab Life Science

ACCELERATED STABILITY REPORT

Product Name: GENFORTE
Strength: Ibuprofen 400mg + Paracetamol 500mg
Batch No: GD200305
Mfg. Date: Mar-20
Exp.Date: Feb-23

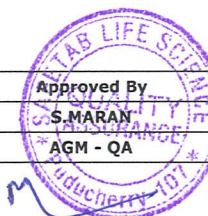
Pack: Bilster packing (1 x 10's Tablets)
Study Started on: 20/04/2020
Study Completed on: 20/10/2020
Reason for study: New Product

Tests	Specifications	Initial	3 Months	6 Months
Condition>>	NA	NA	40 ± 2°C & 75 ± 5% RH	40 ± 2°C & 75 ± 5% RH
Description	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.
Average weight of tablet	1040.0 mg ± 3 % (1008.8 mg to 1071.2 mg)	1041.7mg	1038.0mg	1037.8mg
Disintegration Time	Not more than 15 minutes	01 Minutes 15 Seconds	01 Minutes 55 Seconds	05 Minutes 13 Seconds
Dissolution: (i) Ibuprofen BP	Not less than 80% of the stated amount of Ibuprofen dissolved in 60 Minutes.	Min: 99.4%; Max: 101.0%; Avg: 100.1%	Min: 97.6%; Max: 99.8%; Avg: 98.6%	Min: 98.4%; Max: 101.5%; Avg: 99.6%
(ii) Paracetamol BP	Not less than 80% of the stated amount of Paracetamol dissolved in 60 Minutes.	Min: 99.2%; Max: 102.5%; Avg: 101.0%	Min: 99.2%; Max: 101.8%; Avg: 100.6%	Min: 98.7%; Max: 101.2%; Avg: 99.8%
Related substances: i) Single maximum unknown impurity	Not more than 0.20%	0.05%	0.05%	0.02%
ii) Total impurities	Not more than 0.50%	0.10%	0.09%	0.05%
Assay: Each uncoated tablet contains: Ibuprofen BP 400mg	90.0% to 110.0% of the labeled claim I.e. 360.0mg to 440.0mg	393.21mg (98.3%)	389.57mg (97.4%)	387.68mg (96.9%)
Paracetamol BP 500mg	90.0% to 110.0% of the labeled claim I.e. 450.0mg to 550.0mg	500.42mg (100.1%)	500.32mg (100.1%)	494.21mg (98.8%)
Microbial contamination: (i) Total Viable aerobic count a) Total aerobic microbial count b) Total yeast and mould count ii) Esherichia Coli iii) Salmonella Species iv) Pseudomonas aeruginosa v) Staphylococcus aureus	Not more than 1000 cfu/g Not more than 100 cfu/g Should be absent/g Should be absent/10g Should be absent/g Should be absent/g	70cfu/g Found absent/g Found absent/g Found absent/10g Found absent/g Found absent/g	NA	30cfu/g Found absent/g Found absent/g Found absent/10g Found absent/g Found absent/g
Remarks		Pass	Pass	Pass

NA : Not applicable

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	K.SARAVANAN	M. VIJAYAKUMAR	S.MARAN
Designation	Dy. Manager - QC	GM - QC	AGM - QA
Signature			
Date	06/02/2024	08/02/24	08/02/24





Safetab Life Science

ACCELERATED STABILITY REPORT

Product Name: GENFORTE
Strength: Ibuprofen 400mg + Paracetamol 500mg
Batch No: GD200306
Mfg. Date: Mar-20
Exp. Date: Feb-23

Pack : Bilster packing (1 x 10's Tablets)
Study Started on : 29/04/2020
Study Completed on : 29/10/2020
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	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.
Average weight of tablet	1040.0 mg ± 3 % (1008.8 mg to 1071.2 mg)	1043.2mg	1043.4mg	1030.4mg
Disintegration Time	Not more than 15 minutes	01 Minutes 05 Seconds	06 Minutes 06 Seconds	07 Minutes 54 Seconds
Dissolution: (i) Ibuprofen BP	Not less than 80% of the stated amount of Ibuprofen dissolved in 60 Minutes.	Min: 99.1%; Max: 100.8%; Avg: 100.0%	Min: 97.5%; Max: 100.6%; Avg: 99.2%	Min: 98.2%; Max: 100.6%; Avg: 99.5%
(ii) Paracetamol BP	Not less than 80% of the stated amount of Paracetamol dissolved in 60 Minutes.	Min: 100.1%; Max: 102.2%; Avg: 100.9%	Min: 98.9%; Max: 101.4%; Avg: 100.4%	Min: 98.3%; Max: 100.1%; Avg: 99.1%
Related substances: i) Single maximum unknown impurity	Not more than 0.20%	0.05%	0.06%	0.04%
ii) Total impurities	Not more than 0.50%	0.09%	0.06%	0.06%
Assay: Each uncoated tablet contains: Ibuprofen BP 400mg	90.0% to 110.0% of the labeled claim I.e. 360.0mg to 440.0mg	394.07mg (98.5%)	388.25mg (97.1%)	385.36mg (96.3%)
Paracetamol BP 500mg	90.0% to 110.0% of the labeled claim I.e. 450.0mg to 550.0mg	505.54mg (101.1%)	497.79mg (99.6%)	485.50mg (97.1%)
Microbial contamination: (i) Total Viable aerobic count a) Total aerobic microbial count b) Total yeast and mould count ii) Esherichia Coli iii) Salmonella Species iv) Pseudomonas aeruginosa v) Staphylococcus aureus	Not more than 1000 cfu/g Not more than 100 cfu/g Should be absent/g Should be absent/10g Should be absent/g Should be absent/g	70cfu/g Found absent/g Found absent/g Found absent/10g Found absent/g Found absent/g	NA	60cfu/g Found absent/g Found absent/g Found absent/10g Found absent/g Found absent/g
Remarks		Pass	Pass	Pass

NA : Not applicable

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	K.SARAVANAN	M. VIJAYAKUMAR	S.MARAN
Designation	Dy. Manager - QC	GM - QC	AGM - QA
Signature			
Date	06/02/2024	08/02/24	08/02/24



Safetab Life Science

ACCELERATED STABILITY REPORT

Product Name: GENFORTE
Strength: Ibuprofen 400mg + Paracetamol 500mg
Batch No: GD200307
Mfg. Date: Mar-20
Exp. Date: Feb-23

Pack: Bilster packing (1 x 10's Tablets)
Study Started on: 05/05/2020
Study Completed on: 05/11/2020
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	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.
Average weight of tablet	1040.0 mg ± 3 % (1008.8 mg to 1071.2 mg)	1041.8mg	1042.2mg	1041.8mg
Disintegration Time	Not more than 15 minutes	01 Minutes 18 Seconds	07 Minutes 01 Seconds	04 Minutes 53 Seconds
Dissolution: (i) Ibuprofen BP	Not less than 80% of the stated amount of Ibuprofen dissolved in 60 Minutes.	Min: 100.3%; Max: 101.5%; Avg: 100.9%	Min: 99.6%; Max: 103.2%; Avg: 101.1%	Min: 99.1%; Max: 100.1%; Avg: 99.6%
(ii) Paracetamol BP	Not less than 80% of the stated amount of Paracetamol dissolved in 60 Minutes.	Min: 101.0%; Max: 110.9%; Avg: 104.0%	Min: 98.6%; Max: 103.5%; Avg: 101.8%	Min: 98.8%; Max: 100.5%; Avg: 99.6%
Related substances: i) Single maximum unknown impurity	Not more than 0.20%	0.05%	0.04%	0.02%
ii) Total impurities	Not more than 0.50%	0.10%	0.05%	0.03%
Assay: Each uncoated tablet contains: Ibuprofen BP 400mg	90.0% to 110.0% of the labeled claim I.e. 360.0mg to 440.0mg	392.46mg (98.1%)	395.15mg (98.8%)	389.62mg (97.4%)
Paracetamol BP 500mg	90.0% to 110.0% of the labeled claim I.e. 450.0mg to 550.0mg	502.67mg (100.5%)	500.81mg (100.2%)	494.54mg (98.9%)
Microbial contamination: (i) Total Viable aerobic count a) Total aerobic microbial count b) Total yeast and mould count ii) Esherichia Coli iii) Salmonella Species iv) Pseudomonas aeruginosa v) Staphylococcus aureus	Not more than 1000 cfu/g Not more than 100 cfu/g Should be absent/g Should be absent/10g Should be absent/g Should be absent/g	75cfu/g Found absent/g Found absent/g Found absent/10g Found absent/g Found absent/g	NA	30cfu/g Found absent/g Found absent/g Found absent/10g Found absent/g Found absent/g
Remarks		Pass	Pass	Pass

NA : Not applicable

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	K.SARAVANAN	M. VIJAYAKUMAR	S.MARAN
Designation	Dy. Manager - QC	GM - QC	AGM - QA
Signature			
Date	06/02/2024	08/02/24	08/02/24



Safetab Life Science

LONGTERM STABILITY REPORT

Product Name: GENFORTE
Strength: Ibuprofen 400mg + Paracetamol 500mg
Batch No: GD200305
Mfg. Date: Mar-20
Exp.Date: Feb-23

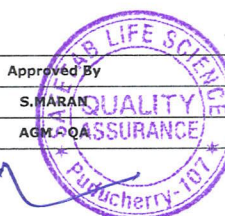
Pack : Bilster packing (1 x 10's Tablets)
Study Started on : 20/04/2020
Study Completed on : 20/04/2023
Reason for study : New Product

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	30 ± 2°C & 75 ± 5% RH
Description	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.
Average weight of tablet	1040.0 mg ± 3 % (1008.8 mg to 1071.2 mg)	1041.7mg	1046.3mg	1040.9mg	1038.7mg	1039.0mg	1046.3mg	1041.7mg	1045.8mg
Disintegration Time	Not more than 15 minutes	01 Minutes 15 Seconds	01 Minutes 39 Seconds	02 Minutes 16 Seconds	02 Minutes 50 Seconds	02 Minutes 12 Seconds	02 Minutes 29 Seconds	02 Minutes 40 Seconds	01 Minutes 37 Seconds
Dissolution: (i) Ibuprofen BP	Not less than 80% of the stated amount of Ibuprofen dissolved in 60 Minutes.	Min: 99.4%; Max: 101.0%; Avg: 100.1%	Min: 97.1%; Max: 99.8%; Avg: 98.3%	Min: 97.5%; Max: 100.1%; Avg: 98.5%	Min: 100.3%; Max: 103.1%; Avg: 101.5%	Min: 102.7%; Max: 108.3%; Avg: 105.5%	Min: 97.2%; Max: 99.1%; Avg: 98.2%	Min: 98.6%; Max: 101.5%; Avg: 99.8%	Min: 99.3%; Max: 104.5%; Avg: 101.9%
(ii) Paracetamol BP	Not less than 80% of the stated amount of Paracetamol dissolved in 60 Minutes.	Min: 99.2%; Max: 102.5%; Avg: 101.0%	Min: 98.1%; Max: 100.7%; Avg: 99.2%	Min: 98.1%; Max: 99.8%; Avg: 98.9%	Min: 99.6%; Max: 102.2%; Avg: 100.8%	Min: 98.8%; Max: 104.6%; Avg: 101.7%	Min: 96.4%; Max: 100.6%; Avg: 98.8%	Min: 100.0%; Max: 102.1%; Avg: 100.8%	Min: 98.5%; Max: 103.2%; Avg: 101.2%
Related substances: i) Single maximum unknown impurity ii) Total impurities	Not more than 0.20% Not more than 0.50%	0.05% 0.10%	0.06% 0.09%	0.03% 0.08%	0.04% 0.06%	0.04% 0.08%	0.06% 0.06%	0.05% 0.12%	0.06% 0.09%
Assay: Each uncoated tablet contains: Ibuprofen BP 400mg	90.0% to 110.0% of the labeled claim I.e. 360.0mg to 440.0mg	393.21mg (98.3%)	394.24mg (98.6%)	389.77mg (97.4%)	393.58mg (98.4%)	394.77mg (98.7%)	394.86mg (98.7%)	390.49mg (97.6%)	397.78mg (99.4%)
Paracetamol BP 500mg	90.0% to 110.0% of the labeled claim I.e. 450.0mg to 550.0mg	500.42mg (100.1%)	500.22mg (100.0%)	505.53mg (101.1%)	491.29mg (98.3%)	505.55mg (101.1%)	501.17mg (100.2%)	503.46mg (100.7%)	507.66mg (101.5%)
Microbial contamination: (i) Total Viable aerobic count a) Total aerobic microbial count b) Total yeast and mould count ii) Esherichia Coli iii) Salmonella Species iv) Pseudomonas aeruginosa v) Staphylococcus aureus	Not more than 1000 cfu/g Not more than 100 cfu/g Should be absent/g Should be absent/10g Should be absent/g Should be absent/g	70cfu/g Found absent/g Found absent/g Found absent/10g Found absent/g Found absent/g	NA NA NA NA NA NA	NA NA NA NA NA NA	NA NA NA NA NA NA	30cfu/g Found absent/g Found absent/10g Found absent/g Found absent/g	NA NA NA NA NA NA	40cfu/g Less than 10cfu/g Found absent/g Found absent/10g Found absent/g Found absent/g	20cfu/g <10cfu/g Found absent/g Found absent/10g Found absent/g Found absent/g
Remarks		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

NA : Not applicable

Conclusion: The above referred batch meets the acceptance criteria when stored at above mentioned condition for 36 months.

Particulars	Prepared By	Checked By	Approved By
Name	K.SARAVANAN	M. VIJAYAKUMAR	S.MARAN
Designation	Dy. Manager - QC	GM - QC	AGM - QA
Signature			
Date	06/02/2024	08/02/24	08/02/24





Safetab Life Science

LONGTERM STABILITY REPORT

Product Name: GENFORTE
Strength: Ibuprofen 400mg + Paracetamol 500mg
Batch No: GD200306
Mfg. Date: Mar-20
Exp.Date: Feb-23

Pack : Bilster packing (1 x 10's Tablets)
Study Started on : 29/04/2020
Study Completed on : 29/04/2023
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	30 ± 2°C & 75 ± 5% RH
Description	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.
Average weight of tablet	1040.0 mg ± 3 % (1008.8 mg to 1071.2 mg)	1043.2mg	1042.5mg	1041.6mg	1036.9mg	1040.2mg	1042.8mg	1040.3mg	1047.2mg
Disintegration Time	Not more than 15 minutes	01 Minutes 05 Seconds	05 Minutes 10 Seconds	02 Minutes 37 Seconds	02 Minutes 12 Seconds	02 Minutes 14 Seconds	02 Minutes 31 Seconds	01 Minutes 45 Seconds	02 Minutes 08Seconds
Dissolution: (i) Ibuprofen BP	Not less than 80% of the stated amount of Ibuprofen dissolved in 60 Minutes.	Min: 99.1%; Max: 100.8%; Avg: 100.0%	Min: 99.6%; Max: 101.5%; Avg: 100.1%	Min: 97.4%; Max: 102.0%; Avg: 99.5%	Min: 102.0%; Max: 105.9%; Avg: 103.2%	Min: 98.7%; Max: 103.8%; Avg: 100.5%	Min: 97.8%; Max: 100.0%; Avg: 99.0%	Min: 93.7%; Max: 99.3%; Avg: 97.4%	Min: 99.6%; Max: 101.1%; Avg: 100.4%
(ii) Paracetamol BP	Not less than 80% of the stated amount of Paracetamol dissolved in 60 Minutes.	Min: 100.1%; Max: 102.2%; Avg: 100.9%	Min: 100.6%; Max: 102.1%; Avg: 101.1%	Min: 97.9%; Max: 101.7%; Avg: 100.1%	Min: 100.0%; Max: 104.1%; Avg: 101.8%	Min: 99.8%; Max: 115.4%; Avg: 104.6%	Min: 98.5%; Max: 101.2%; Avg: 99.6%	Min: 96.0%; Max: 100.8%; Avg: 99.3%	Min: 98.8%; Max: 101.4%; Avg: 99.8%
Related substances: i) Single maximum unknown impurity ii) Total impurities	Not more than 0.20% Not more than 0.50%	0.05% 0.09%	0.09% 0.10%	0.04% 0.07%	0.07% 0.10%	0.07% 0.22%	0.06% 0.10%	0.03% 0.11%	0.04% 0.08%
Assay: Each uncoated tablet contains: Ibuprofen BP 400mg	90.0% to 110.0% of the labeled claim I.e. 360.0mg to 440.0mg	394.07mg (98.5%)	394.12mg (98.5%)	385.55mg (96.4%)	383.69mg (95.9%)	388.06mg (97.0%)	392.55mg (98.1%)	392.61mg (98.2%)	403.26mg (100.8%)
Paracetamol BP 500mg	90.0% to 110.0% of the labeled claim I.e. 450.0mg to 550.0mg	505.54mg (101.1%)	502.61mg (100.5%)	488.37mg (97.7%)	485.53mg (97.1%)	512.48mg (102.5%)	501.09mg (100.2%)	519.39mg (103.9%)	515.69mg (103.1%)
Microbial contamination: (i) Total Viable aerobic count a) Total aerobic microbial count b) Total yeast and mould count ii) Esherichia Coli iii) Salmonella Species iv) Pseudomonas aeruginosa v) Staphylococcus aureus	Not more than 1000 cfu/g Not more than 100 cfu/g Should be absent/g Should be absent/10g Should be absent/g Should be absent/g	70cfu/g Found absent/g Found absent/g Found absent/10g Found absent/g Found absent/g	NA NA NA NA NA NA	NA NA NA NA NA NA	NA NA NA NA NA NA	85cfu/g Found absent/g Found absent/g Found absent/10g Found absent/g Found absent/g	NA NA NA NA NA NA	120cfu/g Less than 10cfu/g Found absent/g Found absent/10g Found absent/g Found absent/g	20cfu/g Less than 10cfu/g Found absent/g Found absent/10g Found absent/g Found absent/g
Remarks		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

NA : Not applicable

Conclusion: The above referred batch meets the acceptance criteria when stored at above mentioned condition for 36 months.

Particulars	Prepared By	Checked By	Approved By
Name	K.SARAVANAN	M. VIJAYAKUMAR	S. MARAN
Designation	Dy. Manager - QC	GM - QC	AGM - QA
Signature			
Date	06/02/2024	08/02/24	08/02/24



Safetab Life Science

LONGTERM STABILITY REPORT

Product Name: GENFORTE
Strength: Ibuprofen 400mg + Paracetamol 500mg
Batch No: GD200307
Mfg. Date: Mar-20
Exp.Date: Feb-23

Pack : Bilster packing (1 x 10's Tablets)
Study Started on : 05/05/2020
Study Completed on : 05/05/2023
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	30 ± 2°C & 75 ± 5% RH
Description	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.
Average weight of tablet	1040.0 mg ± 3 % (1008.8 mg to 1071.2 mg)	1041.8mg	1046.2mg	1041.3mg	1044.0mg	1036.7mg	1046.8mg	1051.5mg	1048.7mg
Disintegration Time	Not more than 15 minutes	01 Minutes 18 Seconds	01 Minutes 47 Seconds	01 Minutes 27 Seconds	02 Minutes 47 Seconds	02 Minutes 23 Seconds	02 Minutes 18 Seconds	03 Minutes 00 Seconds	01 Minutes 58 Seconds
Dissolution: (i) Ibuprofen BP	Not less than 80% of the stated amount of Ibuprofen dissolved in 60 Minutes.	Min: 100.3%; Max: 101.5%; Avg: 100.9%	Min: 95.5%; Max: 101.6%; Avg: 99.2%	Min: 99.5%; Max: 100.8%; Avg: 100.1%	Min: 101.2%; Max: 105.4%; Avg: 102.3%	Min: 98.8%; Max: 103.0%; Avg: 100.7%	Min: 98.2%; Max: 100.3%; Avg: 99.6%	Min: 100.3%; Max: 101.2%; Avg: 100.8%	Min: 101.1%; Max: 108.0%; Avg: 104.1%
(ii) Paracetamol BP	Not less than 80% of the stated amount of Paracetamol dissolved in 60 Minutes.	Min: 101.0%; Max: 110.9%; Avg: 104.0%	Min: 97.6%; Max: 103.2%; Avg: 101.3%	Min: 99.2%; Max: 100.8%; Avg: 100.0%	Min: 100.7%; Max: 104.1%; Avg: 101.9%	Min: 102.6%; Max: 107.1%; Avg: 104.7%	Min: 99.6%; Max: 101.8%; Avg: 101.1%	Min: 98.7%; Max: 101.4%; Avg: 100.4%	Min: 100.0%; Max: 107.0%; Avg: 103.3%
Related substances: i) Single maximum unknown impurity ii) Total impurities	Not more than 0.20% Not more than 0.50%	0.05% 0.10%	0.06% 0.07%	0.03% 0.04%	0.09% 0.11%	0.04% 0.08%	0.03% 0.05%	0.03% 0.10%	0.12% 0.29%
Assay: Each uncoated tablet contains: Ibuprofen BP 400mg	90.0% to 110.0% of the labeled claim I.e. 360.0mg to 440.0mg	392.46mg (98.1%)	385.67mg (96.4%)	391.03mg (97.8%)	391.51mg (97.9%)	393.30mg (98.3%)	399.58mg (99.9%)	394.82mg (98.7%)	405.88mg (101.5%)
Paracetamol BP 500mg	90.0% to 110.0% of the labeled claim I.e. 450.0mg to 550.0mg	502.67mg (100.5%)	492.89mg (98.6%)	496.80mg (99.4%)	503.06mg (100.6%)	508.76mg (101.8%)	497.73mg (99.5%)	508.16mg (101.6%)	524.70mg (104.9%)
Microbial contamination: (i) Total Viable aerobic count a) Total aerobic microbial count b) Total yeast and mould count ii) Escherichia Coli iii) Salmonella Species iv) Pseudomonas aeruginosa v) Staphylococcus aureus	Not more than 1000 cfu/g Not more than 100 cfu/g Should be absent/g Should be absent/10g Should be absent/g Should be absent/g	75cfu/g Found absent/g Found absent/g Found absent/10g Found absent/g Found absent/g	NA	NA	NA	80cfu/g Found absent/g Found absent/g Found absent/10g Found absent/g Found absent/g	NA	10cfu/g Less than 10cfu/g Found absent/g Found absent/10g Found absent/g Found absent/g	20cfu/g Less than 10cfu/g Found absent/g Found absent/10g Found absent/g Found absent/g
Remarks		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

NA : Not applicable

Conclusion: The above referred batch meets the acceptance criteria when stored at above mentioned condition for 36 months.

Particulars	Prepared By	Checked By	Approved By
Name	K.SARAVANAN	M. VIJAYAKUMAR	S. MARAN
Designation	Dy. Manager - QC	GM - QC	AGM - QA
Signature			
Date	06/02/2023	08/02/23	08/02/23

