	Safetab Life Science Puducherry			MASTER COPY
	PRODUCT SPECIFICATION			**Market** Export
Name of Product	**GENFORTE** (Ibuprofen and Paracetamol Tablets)			
Specification No.	SPEC-977-00	**Revision No.**	00	**Product Code:**977
Supersedes	FGSTSG031-01	**Effective Date:**	21/08/2024	**Page No.:** 1 of 10

S.NO	GENERAL SPECIFICATION (s)	
1	Pharmacopoeial Reference	In-House
2	Label claim	Each uncoated tablet contains: Ibuprofen BP ---------- 400mg Paracetamol BP ---------- 500mg
3	Standard packing	10×10's Blister Packing
4	Shelf Life	36 Months
5	In-Process Sample Quantity	a) In-process Intermediate – Blend, 50g. b) Intermediate compressed tablets –100 tablets
6	Finished Product sample quantity	For Microbial contamination Test : 20 Tablets For Chemical Analysis : 100 Tablets For Control sample : 240 Tablets
7	Stability studies sample quantity	For Accelerated study : 170 tablets For Long term study : 580 tablets For Annual study : 480 tablets
8	Storage condition	Store in cool and dry place. Protect from light and moisture.
9	Destructions Instructions	Follow the Standard Operating Procedure: ST/QC/032.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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Date	17/08/24	19/08/2024	20/08/2024

RELEASE SPECIFICATION FOR INTERMEDIATE – BLEND
SPECIFICATION CODE: SPEC-977-BLD

S.NO	TEST (s)	SPECIFICATION (s)
1.0	Description	Light Orange colour granular powder.
2.0	**Assay: Each 1040mg of blend contains:**	
	Ibuprofen BP 400mg	380.0mg to 440.0mg (95.0% to 110.0% of the labeled claim)
	Paracetamol BP 500mg	475.0mg to 550.0mg (95.0% to 110.0% of the labeled claim)

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RELEASE SPECIFICATION FOR INTERMEDIATE – COMPRESSED TABLETS
SPECIFICATION CODE: SPEC-977-COM

S.NO	TEST (s)	SPECIFICATION (s)
1.0	Description	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.
2.0	**Identification**	
	a) Ibuprofen (By HPLC)	The retention time of the one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Ibuprofen in the standard preparation as obtained in the assay.
	b) Paracetamol (By HPLC)	The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Paracetamol in the standard preparation as obtained in assay.
3.0	Average weight of tablet	1040.0 mg ± 3 % (1008.8 mg to 1071.2 mg)
4.0	Uniformity of weight	Not more than 2 of the individual weights deviate from the average weight by more than ±5% and none deviate by more than ±10.0%.
5.0	**Dimension:**	
	Length	19.30mm ± 0.20mm(19.10mm to 19.50mm)
	Width	9.0mm ± 0.20mm(8.80mm to 9.20mm)
6.0	Thickness	7.70mm±0.30mm (7.40mm to 8.00mm)

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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Signature			
Date	17/08/24	19/08/2024	20/08/2024

S.NO	TEST (s)	SPECIFICATION (s)
7.0	Hardness	150N – 300N
8.0	Disintegration time	Not more than 15 minutes
9.0	Friability	Not more than 1.0%
10.0	**Dissolution (By HPLC)**	
	(i) Ibuprofen BP	Not less than 80% of the stated amount of Ibuprofen dissolved in 60 Minutes.
	(ii) Paracetamol BP	Not less than 80% of the stated amount of Paracetamol dissolved in 60 Minutes.
11.0	**Related Substances: (By HPLC)**	
	(i) Single maximum unknown impurity	Not more than 0.20%
	(ii) Total impurities	Not more than 0.50%
12.0	**Assay: Each uncoated tablet contains:**	
	Ibuprofen BP 400mg	380.0mg to 440.0mg (95.0% to 110.0% of the labeled claim)
	Paracetamol BP 500mg	475.0mg to 550.0mg (95.0% to 110.0% of the labeled claim)

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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RELEASE SPECIFICATION – FINISHED PRODUCT
SPECIFICATION CODE: SPEC-977-FP

S.NO	TEST (s)	SPECIFICATION (s)
1.0	Description	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.
2.0	**Identification***	
	b) Ibuprofen (By HPLC)	The retention time of the one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Ibuprofen in the standard preparation as obtained in the assay.
	b) Paracetamol (By HPLC)	The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Paracetamol in the standard preparation as obtained in assay.
3.0	Average weight of tablet	1040.0 mg ± 3 % (1008.8 mg to 1071.2 mg)
4.0	Uniformity of weight	Not more than 2 of the individual weights deviate from the average weight by more than ±5% and none deviate by more than ±10.0%.
5.0	**Dimension*:**	
	Length	19.30mm ± 0.20mm(19.10mm to 19.50mm)
	Width	9.0mm ± 0.20mm(8.80mm to 9.20mm)
6.0	Thickness*	7.70mm±0.30mm (7.40mm to 8.00mm)

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	17/08/24	19/08/2024	20/08/2024

S.NO	TEST (s)	SPECIFICATION (s)
7.0	Hardness*	150N – 300N
8.0	Disintegration time	Not more than 15 minutes
9.0	Friability*	Not more than 1.0%
10.0	**Dissolution (By HPLC)***	
	(i) Ibuprofen BP	Not less than 80% of the stated amount of Ibuprofen dissolved in 60 Minutes.
	(ii) Paracetamol BP	Not less than 80% of the stated amount of Paracetamol dissolved in 60 Minutes.
11.0	**Related Substances: (By HPLC)***	
	(i) Single maximum unknown impurity	Not more than 0.20%
	(ii) Total impurities	Not more than 0.50%
12.0	**Assay: Each uncoated tablet contains*:**	
	Ibuprofen BP 400mg	380.0mg to 440.0mg (95.0% to 110.0% of the labeled claim)
	Paracetamol BP 500mg	475.0mg to 550.0mg (95.0% to 110.0% of the labeled claim)

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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S.NO	TEST (s)	SPECIFICATION (s)
13.0	**Microbial contamination:**	
	i) Total Viable aerobic count	
	a) Total aerobic microbial count	Not more than 1000 cfu/g
	b) Total yeast and mould count	Not more than 100 cfu/g
	ii) Escherichia Coli	Should be absent/g
	iii) Salmonella Species	Should be absent/10g
	iv) Pseudomonas aeruginosa	Should be absent/g
	v) Staphylococcus aureus	Should be absent/g

Note: * Marked Test results shall be taken from compressed tablets.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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STABILITY SPECIFICATION
SPECIFICATION CODE: SPEC-977-ST

S.NO	TEST (s)	SPECIFICATION (s)
1.0	Description	Light Orange coloured Oval shaped biconvex uncoated tablets with half break line on one side and plain on other side.
2.0	Average weight of tablet	1040.0 mg ± 3 % (1008.8 mg to 1071.2 mg)
3.0	**Dissolution (By HPLC)** (i) Ibuprofen BP (ii) Paracetamol BP	 Not less than 80% of the stated amount of Ibuprofen dissolved in 60 Minutes. Not less than 80% of the stated amount of Paracetamol dissolved in 60 Minutes.
4.0	**Related Substances: (By HPLC)** (i) Single maximum unknown impurity (ii) Total impurities	 Not more than 0.20% Not more than 0.50%
5.0	**Assay: Each uncoated tablet contains:** Ibuprofen BP 400mg Paracetamol BP 500mg	 360.0mg to 440.0mg (90.0% to 110.0% of the labeled claim) 450.0mg to 550.0mg (90.0% to 110.0% of the labeled claim)

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	PRODUCT SPECIFICATION			Market: Export
Name of Product	**GENFORTE** (Ibuprofen and Paracetamol Tablets)			
Specification No.	SPEC-977-00	**Revision No.**	00	**Product Code:**977
Supersedes	FGSTSG031-01	**Effective Date:**	21/08/2024	**Page No.:** 9 of 10

S.NO	TEST (s)	SPECIFICATION (s)
6.0	**Microbial contamination#**	
	i)Total viable aerobic count	
	a) Total aerobic microbial count	Not more than 1000 cfu/g
	b) Total yeast and mould count	Not more than 100 cfu/g
	ii) Escherichia coli	Should be absent/g
	iii) Salmonella Species	Should be absent/10g
	iv) Pseudomonas aeruginosa	Should be absent/g
	v) Staphylococcus aureus	Should be absent/g

Mark test will performed on 6th month of Accelerated stability and every 12th month of Long term stability.

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	PRODUCT SPECIFICATION			Market: Export
Name of Product	**GENFORTE** (Ibuprofen and Paracetamol Tablets)			
Specification No.	SPEC-977-00	**Revision No.**	00	**Product Code:**977
Supersedes	FGSTSG031-01	**Effective Date:**	21/08/2024	**Page No.:** 10 of 10

REVISION HISTORY:

Specification No.	Reason for Review	Change control No.	Effective Date
FGSTSG031-00	New specification prepared.	NA	14-03-2020
FGSTSG031-01	(i) Market detail incorporated as per SOP. (ii) Thickness and Hardness limit has revised. This changes captured as per change control number ST/CC/21/173. (iii) Specification format revised as per SOP No. ST/QC/058 for better clarity.	ST/CC/21/173	04-12-2021
SPEC-977-00	Specification format and numbering system has revised as per Sop No: ST/QC/058.	ST/CC/23/063	21/08/2024

**** END OF THE DOCUMENT ****

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	STANDARD TESTING PROCEDURE			**Market** Export
Name of Product	**GENFORTE** (Ibuprofen and Paracetamol Tablets)			
STP No.	STP-977-00	**Revision No.**	00	**Product Code:**977
Supersedes	FGTTSG031-01	**Effective Date:**	21/08/2024	**Page No.:** 1 of 16

1.0 **DESCRIPTION:** (By Visual Inspection)

Blend: Spread about 1 to 2 g of sample on a white surface and note the observation.

Tablets: Take 10 tablets on a white background and note the colour, shape, coated or uncoated, embossing and other observations, if any.

2.0 **IDENTIFICATION: (By HPLC)**

a) Ibuprofen (By HPLC):

The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Ibuprofen in the standard preparation as obtained in assay.

b) Paracetamol (by HPLC):

The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Paracetamol in the standard preparation as obtained in assay.

3.0 **AVERAGE WEIGHT OF TABLET:**

Weigh and note down the weight of 20 tablets.

$$\text{Average weight of tablet (in mg)} = \frac{\text{Weight of 20 tablets (g)}}{20} \times 1000$$

4.0 **UNIFORMITY OF WEIGHT:**

Weigh 20 tablets selected at random and determine the individual weight.

Acceptance criteria:

The average mass of the tablets should comply with the limits specified in the individual specification / monograph.

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Not more than two of the individual masses deviate from the average mass by more than percentage deviation shown in table and none deviate by more than twice that percentage.

Average mass of the tablet	Percentage deviation
80mg or Less than 80mg	± 10
More than 80 mg but Less than 250 mg	± 7.5
250 mg or more	± 5

Calculate the percentage deviation for highest individual weight of tablet as follows:

$$\left[\frac{\text{Highest individual weight of tablet (in g)}}{\text{Average weight of tablet (in g)}} \times 100\right] - 100$$

Calculate the percentage deviation for lowest individual weight of tablet as follows:

$$\left[\frac{\text{Lowest individual weight of tablet (in g)}}{\text{Average weight of tablet (in g)}} \times 100\right] - 100$$

5.0 LENGTH, WIDTH AND THICKNESS:

Select randomly 10 tablets and measure the Length, Width and thickness using a suitable Vernier caliper. Record the values. Calculate the average thickness of the tablets as follows:

Average thickness (in mm) = Total thickness of 10 tablets (in mm)/10

Average Length (in mm) = Total Length of 10 tablets (in mm)/10

Average Width (in mm) = Total Width of 10 tablets (in mm)/10

Report the average, minimum and maximum values.

6.0 HARDNESS:

Select randomly 10 tablets and check the hardness using a suitable Hardness tester. Record the values. Calculate the average hardness of the tablets as follows:

Average hardness (in N) = Total hardness of 10 tablets (in N)/10.

7.0 DISINTEGRATION TIME:

Introduce one tablet into each tube of the disintegration testing apparatus. Add a disc to each tube suspend the assembly in the beaker containing water maintained at 37°C ± 2°C and operate the apparatus for 15 minutes. Observe all the tablets, if all the tablets are disintegrated completely within 15 minutes, lift the basket from the fluid and note down the time required. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets. The requirement is met if not fewer than 16 of the total of 18 tablets tested are disintegrated.

8.0 FRIABILITY:

Weigh 10 tablets and note down the mass in gram up to four decimals (a). Placed weighed tablets in friability test apparatus and operate the friability test apparatus for 100 rotations. After completion of the test collect the tablets from sample collector carefully. Remove broken particles, chipped pieces (if any) by means of gentle brushing. Weigh the tablet and record the mass in gram up to four decimals (b).

$$\% \text{ of Friability} = \frac{\text{Initial Weight(a) - Final weight (b)}}{\text{Initial Weight (a)}} \times 100$$

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9.0 **DISSOLUTION:**

Reference: In House
Procedure: By HPLC

Chemicals/Reagents/Standards:

Ibuprofen	:	Working standard
Paracetamol	:	Working standard
Potassium Di-hydrogen orthophosphate	:	AR grade
Sodium hydroxide	:	AR grade
Orthophosphoric acid	:	AR grade
Methanol	:	HPLC grade
Water	:	Purified

Dissolution parameters:

Apparatus	:	Apparatus No.2 (Paddle)
Volume	:	900 mL
Dissolution medium	:	Phosphate buffer pH 7.2
Speed	:	100 rpm
Temperature	:	37.0±0.5°C
Time	:	60 minutes

Preparation of Dissolution medium:

Weigh accurately about 6.80 g of potassium Di-hydrogen orthophosphate in 1000 ml of water. Adjust pH to 7.2±0.05 with sodium hydroxide solution.

Preparation of Mobile phase:

Prepare a degassed mixture of water, Methanol and Orthophosphoric acid in the ratio 247:750:3 v/v/v.

Chromatographic Conditions:

Column	:	Kromasil C8 (250 mm X 4.6 mm), 5µm
Wave length	:	221 nm
Column Temperature	:	30°C
Flow Rate	:	1.0 mL/min
Injection Volume	:	10 µL
Run time	:	15 Minutes
Retention time	:	About 2.9 minutes for Paracetamol, about 10.1 minutes for Ibuprofen

Preparation of Blank Solution:

Dilute 10 mL of dissolution medium to 50 mL with mobile phase.

Preparation of Standard solution:

Weigh accurately and transfer about 55 mg of Paracetamol working standard and 44 mg of Ibuprofen working standard into a 100 mL volumetric flask. Add 50 mL of dissolution medium and sonicate to dissolve. Make up to volume with dissolution medium and mix. Further dilute 10 ml of above solution into 50 ml with mobile phase and mix. (**Concenatration:**0.110mg/ml of Paracetamol, 0.088mg/ml of Ibuprofen)

Test preparation:

Set the dissolution parameters and place one tablet into each vessel individually containing 900 ml of dissolution medium, immediately start the apparatus. At the end of specified time withdraw the sample from midway zone of vessels. Further dilute 10 ml of above solution into 50 ml with mobile phase and mix. Filter through 0.45µ PVDF filter. (**Concenatration:**0.111mg/ml of Paracetamol, 0.089mg/ml of Ibuprofen)

Procedure:

Inject the solutions as mentioned below and measure the responses of the peaks due to Ibuprofen and Paracetamol.

Injection sequence:

S. No	Sample Name	No. of injections
1	Blank Solution	1
2	Standard preparation	5
3	Test preparation	6
4	Bracketing standard	1 Each after every 6 sample injection

System suitability:

1) The Resolution between the peaks corresponding to Paracetamol and Ibuprofen obtained with standard solution should not be less than 2.0

2) The tailing factor for the peak of Paracetamol and Ibuprofen obtained with standard solution should not more than 2.0.

3) The column efficiency for the peak of Paracetamol and Ibuprofen obtained in the chromatogram of Standard solution should not less than 2000

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4) The % RSD for the retention time of Paracetamol and Ibuprofen peak obtained with the replicate injections of standard solution should not more than 1.00

5) The % RSD for the peak area response of Paracetamol and Ibuprofen peak obtained with the replicate injections of standard solution should not more than 2.00

6) The % RSD for the retention time of Paracetamol and Ibuprofen peak obtained with the replicate injections of standard solution and bracketing standard solution should not more than 1.00

7) The % RSD for the peak area response of Paracetamol and Ibuprofen peak obtained with the replicate injections of standard solution and bracketing standard solution should not more than 2.00.

Calculations:

Calculate % drug release of Ibuprofen as follows:

$$= \frac{AT}{AS} \times \frac{WS}{100} \times \frac{10}{50} \times \frac{900}{1} \times \frac{50}{10} \times \frac{P}{100} \times \frac{100}{LC}$$

Where,

AT = Area of peak due to Ibuprofen in test preparation.

AS = Average area of peak due to Ibuprofen in standard preparation.

WS = Weight of Ibuprofen working standard in mg.

P = Potency of Ibuprofen working standard in % on as such basis.

LC = Label claim of Ibuprofen in mg.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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Calculate % drug release of Paracetamol as follows:

$$= \frac{AT}{AS} \times \frac{WS}{100} \times \frac{10}{50} \times \frac{900}{1} \times \frac{50}{10} \times \frac{P}{100} \times \frac{100}{LC}$$

Where,

AT	=	Area of peak due to Paracetamol in test preparation.
AS	=	Average area of peak due to Paracetamol in standard preparation.
WS	=	Weight of Paracetamol working standard in mg.
P	=	Potency of Paracetamol working standard in % on as such basis.
LC	=	Label claim of Paracetamol in mg.

10.0 **RELATED SUBSTANCES:**

Reference: In House
Procedure: By HPLC

Note: For reagents, Mobile phase, Chromatographic conditions proceed as directed in dissolution test, except run time.

Run Time: 30 minutes for standard solution 45 minutes for Blank, Placebo and Sample Solutions.

Preparation of Diluent:

Use mobile phase as diluent.

Preparation of Placebo solution:

Weigh accurately and transfer about 35 mg of Plain Placebo into 200ml volumetric flask. Add 50 mL of diluent and sonicate for 10 minutes with intermittent shaking.

Make up to volume with diluent and mix. Filter through 0.45µ PVDF filter.

Preparation of Standard low load solution:

Weigh accurately and transfer about 50 mg of Ibuprofen working standard into a 200 mL volumetric flask. Add about 100 mL of diluent and sonicate to dissolve. Make up to volume with diluent and mix. Dilute 10 ml of above solution to 100 ml with diluent and mix. Further dilute to 10 ml of above solution into 100 ml with diluent and mix. (**Concentration:** 0.0025mg/ml of Ibuprofen)

Test preparation:

Preparation of sample solution:

Weigh accurately 20 tablets and make powder by using morter and pestle. Weigh and transfer sample powder equivalent to 50 mg of Ibuprofen, into a 100 ml volumetric flask. Add about 70 ml of diluent and hand shake to dissolve, dilute up to the volume with diluent and mix. Filter through 0.45µ PVDF filter. (**Concentration:** 0.500mg/ml of Ibuprofen)

Inject 10µl of the above solution (blank, standard, placebo and sample) as per following sequence and measure the area due to any unknown impurity peak.

Note: Prepare sample solutions freshly, inject immediately.

Injection sequence:

S. No	Sample Name	No. of injections
1	Blank (Diluent)	1
2	Standard low load solution	5
3	Placebo Preparation	1
4	Test preparation	1
5	Bracketing standard	1

System suitability requirement:

1) The tailing factor for the peak of Ibuprofen obtained with standard low load solution should not more than 2.0.

2) The theoretical plates for the peak of Ibuprofen obtained with the chromatogram of standard low load solution should not less than 2000.

3) The % RSD for the retention time of Ibuprofen peak obtained with the replicate injections of standard low load solution should not more than 1.0

4) The % RSD for the peak area response of Ibuprofen peak obtained with the replicate injections of standard low load solution should not more than 5.0

5) The % RSD for the retention time of Ibuprofen peak obtained with the replicate injections of standard low load solution and bracketing standard low load solution should not more than 1.0

6) The % RSD for the peak area response of Ibuprofen peak obtained with the replicate injections of standard low load solution and bracketing standard low load solution should not more than 5.0

Calculations:

Single maximum unknown impurity:

$$= \frac{AT_I}{AS} \times \frac{WS}{200} \times \frac{10}{100} \times \frac{10}{100} \times \frac{100}{WT} \times AW \times \frac{P}{100} \times \frac{100}{400}$$

Where,

ATI = Area of peak due to Single maximum unknown impurity in test preparation.

AS = Average area of peak due to Ibuprofen in standard preparation.

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WS = Weight of Ibuprofen working standard in mg.

WT = Weight of sample taken in mg.

AW = Average weight of tablet in mg.

P = Potency of Ibuprofen working standard in % on as such basis.

Total impurities:

$$= \frac{AT_T}{AS} \times \frac{WS}{200} \times \frac{10}{100} \times \frac{10}{100} \times \frac{100}{WT} \times AW \times \frac{P}{100} \times \frac{100}{400}$$

Where,

AT_T = Area of peak due to Total impurity in test preparation.

AS = Average area of peak due to Ibuprofen in standard preparation.

WS = Weight of Ibuprofen working standard in mg.

WT = Weight of sample taken in mg.

AW = Average weight of tablet in mg.

P = Potency of Ibuprofen working standard in % on as such basis.

11.0 ASSAY: (BY HPLC)

Note: For reagents, Mobile phase, Chromatographic conditions proceed as directed in dissolution test.

Preparation of Diluent:

Use mobile phase as diluent.

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Preparation of Standard solution:

Weigh accurately and transfer about 125 mg of Paracetamol working standard and 100 mg of Ibuprofen working standard into a 100 mL volumetric flask. Add 50 ml of diluent and sonicate to dissolve. Make up to volume with diluent and mix. Further dilute to 5 ml of above solution into 50 ml with diluent and mix. (**Concentration:**0.125mg/ml of Paracetamol and 0.100mg/ml of Ibuprofen)

Test preparation: (For blend)

Weigh 20g of sample and make powder by using mortar and pestle. Weigh and transfer sample powder equivalent to 100 mg of Ibuprofen into a 100 ml volumetric flask. Add about 70 ml of diluent and sonicate for 10 minutes with intermittent shaking, dilute up to the volume with diluent and mix. Further dilute 5 ml of above solution into 50 ml with diluent and mix. Filter through 0.45µ PVDF filter. (**Concentration:** 0.125mg/ml of Paracetamol and 0.100mg/ml of Ibuprofen)

Test preparation: (For tablets)

Weigh accurately 20 tablets and make powder by using mortar and pestle. Weigh and transfer sample powder equivalent to 100 mg of Ibuprofen into a 100 ml volumetric flask. Add about 70 ml of diluent and sonicate for 10 minutes with intermittent shaking, dilute up to the volume with diluent and mix. Further dilute 5 ml of above solution into 50 ml with diluent and mix. Filter through 0.45µ PVDF filter. (**Concentration:** 0.125mg/ml of Paracetamol and 0.100mg/ml of Ibuprofen)

Injection sequence:

S. No	Sample Name	No. of injections
1	Blank (Diluent)	1
2	Standard solution	5
3	Test preparation	2
4	Bracketing standard	1 Each after every 6 sample injection

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	S.SANTHI	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	17/08/24	19/08/2024	20/08/2024

System suitability:

1) The Resolution between the peaks corresponding to Paracetamol and Ibuprofen obtained with standard solution should not be less than 2.0

2) The tailing factor for the peak of Paracetamol and Ibuprofen obtained with standard solution should not more than 2.0.

3) The column efficiency for the peak of Paracetamol and Ibuprofen obtained in the chromatogram of Standard solution should not less than 2000

4) The % RSD for the retention time of Paracetamol and Ibuprofen peak obtained with the replicate injections of standard solution should not more than 1.00

5) The % RSD for the peak area response of Paracetamol and Ibuprofen peak obtained with the replicate injections of standard solution should not more than 2.00

6) The % RSD for the retention time of Paracetamol and Ibuprofen peak obtained with the replicate injections of standard solution and bracketing standard solution should not more than 1.00

7) The % RSD for the peak area response of Paracetamol and Ibuprofen peak obtained with the replicate injections of standard solution and bracketing standard solution should not more than 2.00

Calculations:

Calculate the assay of Ibuprofen in mg/tablet as follows:

$$= \frac{AT}{AS} \times \frac{WS}{100} \times \frac{5}{50} \times \frac{100}{WT} \times \frac{50}{5} \times \frac{P}{100} \times AW$$

Where,

AT = Average area of peak due to Ibuprofen in test preparation.

AS = Average area of peak due to Ibuprofen in standard preparation.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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WS = Weight of Ibuprofen working standard in mg.

WT = Weight of sample taken in mg.

AW = Average weight of tablet in mg.

P = Potency of Ibuprofen working standard in % on as such basis.

Calculate the assay of Ibuprofen in % as follows:

$$= \frac{\text{mg/tablet}}{\text{LC}} \times 100$$

LC = Label claim of Ibuprofen in mg.

Calculate the assay of Paracetamol in mg/tablet as follows:

$$= \frac{AT}{AS} \times \frac{WS}{100} \times \frac{5}{50} \times \frac{100}{WT} \times \frac{50}{5} \times \frac{P}{100} \times AW$$

Where,

AT = Average area of peak due to Paracetamol in test preparation.

AS = Average area of peak due to Paracetamol in standard preparation.

WS = Weight of Paracetamol working standard in mg.

WT = Weight of sample taken in mg.

AW = Average weight of tablet in mg.

P = Potency of Paracetamol working standard in % on as such basis.

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Calculate the assay of Paracetamol in % as follows:

$$= \frac{\text{mg/tablet}}{\text{LC}} \times 100$$

LC = Label claim of Paracetamol in mg.

12.0 MICROBIAL CONTAMINATION:

Total Viable aerobic count and Pathogen test refer as per the current SOP No: ST/MB/011.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	17/08/24	19/08/2024	20/08/2024

REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
FGTTSG031-00	New specification prepared.	NA	14-03-2020
FGTTSG031-01	(i) Market detail incorporated as per SOP. (iii) STP format revised as per SOP No. ST/QC/058 for better clarity.	ST/CC/21/173	04-12-2021
STP-977-00	(i) Related substances testing procedure has been changed as based on Analytical method validation. (ii) STP format and numbering system has revised as per Sop No: ST/QC/058.	ST/CC/24/096 ST/CC/23/063	21/08/2024

****END OF THE DOCUMENT****

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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