





	<b>Safetab Life Science</b> <b>Puducherry</b>			
	<b>PRODUCT SPECIFICATION</b>			<b>Market</b>
<b>Name of Product</b>	<b>LITACOLD FLU</b> (Chlorphenamine Maleate, Phenylephrine Hydrochloride, Caffeine and Paracetamol Tablets)			
<b>Specification No.</b>	SPEC-978-00	<b>Revision No.</b>	00	<b>Product Code:</b> 978
<b>Supersedes</b>	FGSTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 1 of 12

S.NO	GENERAL SPECIFICATION (s)	
1	Pharmacopoeial Reference	In-House
2	Label claim	Each Uncoated tablet contains:  Chlorphenamine Maleate BP ----- 2mg Phenylephrine Hydrochloride BP ----- 5mg Caffeine (Anhydrous) BP ----- 30mg Paracetamol BP ----- 500mg
3	Standard packing	1×4's Strip 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 : 200 tablets For Long term study : 580 tablets For Annual study : 470 tablets
8	Storage condition	Store below 30°C. Protect from light.
9	Destructions Instructions	Follow the Standard Operating Procedure: ST/QC/032.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	S.SANTHI	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	04/05/24	06/05/2024	07/05/2024




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	<b>Safetab Life Science</b> <b>Puducherry</b>			
	<b>PRODUCT SPECIFICATION</b>			<b>Market</b>
<b>Name of Product</b>	<b>LITACOLD FLU</b> (Chlorphenamine Maleate, Phenylephrine Hydrochloride, Caffeine and Paracetamol Tablets)			
<b>Specification No.</b>	SPEC-978-00	<b>Revision No.</b>	00	<b>Product Code:</b> 978
<b>Supersedes</b>	FGSTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 2 of 12



**RELEASE SPECIFICATION FOR INTERMEDIATE – BLEND**  
**SPECIFICATION CODE: SPEC-978-BLD**

S.NO	TEST (s)	SPECIFICATION (s)
1.0	Description	Light yellow coloured granular powder.
2.0	<b>Assay: Each 635mg of blend contains:</b>  <div> Chlorphenamine Maleate BP      2mg  Phenylephrine Hydrochloride BP      5mg  Caffeine (Anhydrous) BP      30mg  Paracetamol BP      500mg </div>	1.9mg to 2.2mg (95.0% to 110.0% of the labeled claim)  4.75mg to 5.50mg (95.0% to 110.0% of the labeled claim)  28.5mg to 33.0mg (95.0% to 110.0% of the labeled claim)  475.0mg to 550.0mg (95.0% to 110.0% of the labeled claim)

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	S.SANTHI	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	04/05/24	06/05/2024	07/05/2024




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	<b>PRODUCT SPECIFICATION</b>			<b>Market</b>
<b>Name of Product</b>	<b>LITACOLD FLU</b> (Chlorphenamine Maleate, Phenylephrine Hydrochloride, Caffeine and Paracetamol Tablets)			
<b>Specification No.</b>	SPEC-978-00	<b>Revision No.</b>	00	<b>Product Code:</b> 978
<b>Supersedes</b>	FGSTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 3 of 12



**RELEASE SPECIFICATION FOR INTERMEDIATE – COMPRESSED TABLETS**  
**SPECIFICATION CODE: SPEC-978-COM**

S.NO	TEST (s)	SPECIFICATION (s)
1.0	Description	Light yellow coloured, flat, round beveled edged uncoated tablet with break line on one side and plain on another side.
2.0	<b>Identification</b>  a) Chlorphenamine Maleate (By HPLC)  b) Phenylephrine Hydrochloride (By HPLC)  c) Caffeine (By HPLC)  d) Paracetamol (By HPLC)	<p>The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Chlorphenamine Maleate in the standard preparation as obtained in assay.</p> <p>The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Phenylephrine Hydrochloride in the standard preparation as obtained in assay.</p> <p>The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Caffeine in the standard preparation as obtained in assay.</p> <p>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.</p>
3.0	Average weight of tablet	635.0 mg $\pm$ 3 % (615.9 mg to 654.0 mg)




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Name	S.SANTHI	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	04/05/24	06/05/2024	07/05/2024

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	<b>Safetab Life Science</b> <b>Puducherry</b>			
	<b>PRODUCT SPECIFICATION</b>			<b>Market</b>
<b>Name of Product</b>	<b>LITACOLD FLU</b> (Chlorphenamine Maleate, Phenylephrine Hydrochloride, Caffeine and Paracetamol Tablets)			
<b>Specification No.</b>	SPEC-978-00	<b>Revision No.</b>	00	<b>Product Code:</b> 978
<b>Supersedes</b>	FGSTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 4 of 12

S.NO	TEST (s)	SPECIFICATION (s)
4.0	Uniformity of weight	Not more than 2 of the individual weights deviate from the average weight by more than $\pm 5\%$ and none deviate by more than $\pm 10.0\%$ .
5.0	Diameter	$12.70 \pm 0.20\text{mm}$ (12.50 – 12.90)
6.0	Thickness	$4.30 \pm 0.20\text{mm}$ (4.10 – 4.50mm)
7.0	Hardness	100 N – 250N
8.0	Disintegration time	Not more than 15 minutes
9.0	Friability	Not more than 1.0%
10.0	<b>Dissolution:</b>  Chlorphenamine Maleate BP  Phenylephrine Hydrochloride BP  Caffeine (Anhydrous) BP  Paracetamol BP	Not less than 80% of the stated amount of Chlorphenamine Maleate dissolved in 45 Minutes.  Not less than 80% of the stated amount of Phenylephrine Hydrochloride dissolved in 45 Minutes.  Not less than 80% of the stated amount of Caffeine dissolved in 45 Minutes.  Not less than 80% of the stated amount of Paracetamol dissolved in 45 Minutes.



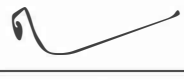
Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	S.SANTHI	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
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	<b>PRODUCT SPECIFICATION</b>			
		<b>Market</b>	<b>Export</b>	
<b>Name of Product</b>	<b>LITACOLD FLU</b> (Chlorphenamine Maleate, Phenylephrine Hydrochloride, Caffeine and Paracetamol Tablets)			
<b>Specification No.</b>	SPEC-978-00	<b>Revision No.</b>	00	<b>Product Code:</b> 978
<b>Supersedes</b>	FGSTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 5 of 12

S.NO	TEST (s)	SPECIFICATION (s)
11.0	<b>Uniformity of content</b>  Chlorphenamine Maleate BP  Phenylephrine Hydrochloride BP	Not less than 85.0% and not more than 115.0% of the average value.  Not less than 85.0% and not more than 115.0% of the average value.
12.0	<b>Related Substances (By HPLC)</b>  (i) Single maximum unknown impurity  (ii) Total impurities	Not more than 0.20%  Not more than 0.50%
13.0	<b>Assay: Each Uncoated tablet contains:</b>  Chlorphenamine Maleate BP      2mg  Phenylephrine Hydrochloride BP      5mg  Caffeine (Anhydrous) BP      30mg  Paracetamol BP      500mg	1.9mg to 2.2mg (95.0% to 110.0% of the labeled claim)  4.75mg to 5.50mg (95.0% to 110.0% of the labeled claim)  28.5mg to 33.0mg (95.0% to 110.0% of the labeled claim)  475.0mg to 550.0mg (95.0% to 110.0% of the labeled claim)

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
<b>Name</b>	<b>S.SANTHI</b>	<b>M.VIJAYAKUMAR</b>	<b>S.MARAN</b>
<b>Designation</b>	<b>Asst. Manager-QC</b>	<b>GM-QC</b>	<b>AGM-QA</b>
<b>Signature</b>			
<b>Date</b>	04/05/24	06/05/2024	07/05/2024




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	<b>PRODUCT SPECIFICATION</b>			
				<b>Market</b>
<b>Name of Product</b>	<b>LITACOLD FLU</b> (Chlorphenamine Maleate, Phenylephrine Hydrochloride, Caffeine and Paracetamol Tablets)			
<b>Specification No.</b>	SPEC-978-00	<b>Revision No.</b>	00	<b>Product Code:</b> 978
<b>Supersedes</b>	FGSTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 6 of 12


**RELEASE SPECIFICATION – FINISHED PRODUCT**  
**SPECIFICATION CODE: SPEC-978-FP**

S.NO	TEST (s)	SPECIFICATION (s)
1.0	Description	Light yellow coloured, flat, round beveled edged uncoated tablet with break line on one side and plain on another side.
2.0	<b>Identification*</b>  b) Chlorphenamine Maleate (By HPLC)  b) Phenylephrine Hydrochloride (By HPLC)  c) Caffeine (By HPLC)  d) Paracetamol (By HPLC)	<p>The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Chlorphenamine Maleate in the standard preparation as obtained in assay.</p> <p>The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Phenylephrine Hydrochloride in the standard preparation as obtained in assay.</p> <p>The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Caffeine in the standard preparation as obtained in assay.</p> <p>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.</p>
3.0	Average weight of tablet	635.0 mg $\pm$ 3 % (615.9 mg to 654.0 mg)

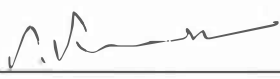


Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
<b>Name</b>	<b>S.SANTHI</b>	<b>M.VIJAYAKUMAR</b>	<b>S.MARAN</b>
<b>Designation</b>	<b>Asst. Manager-QC</b>	<b>GM-QC</b>	<b>AGM-QA</b>
<b>Signature</b>			
<b>Date</b>	04/05/24	06/05/2024	07/05/2024

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	<b>PRODUCT SPECIFICATION</b>		<b>Market</b>	<b>Export</b>
<b>Name of Product</b>	<b>LITACOLD FLU</b> (Chlorphenamine Maleate, Phenylephrine Hydrochloride, Caffeine and Paracetamol Tablets)			
<b>Specification No.</b>	SPEC-978-00	<b>Revision No.</b>	00	<b>Product Code:</b> 978
<b>Supersedes</b>	FGSTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 7 of 12

S.NO	TEST (s)	SPECIFICATION (s)
4.0	Uniformity of weight	Not more than 2 of the individual weights deviate from the average weight by more than $\pm 5\%$ and none deviate by more than $\pm 10.0\%$ .
5.0	Diameter*	$12.70 \pm 0.20\text{mm}$ (12.50 – 12.90)
6.0	Thickness*	$4.30 \pm 0.20\text{mm}$ (4.10 – 4.50mm)
7.0	Hardness*	100 N – 250N
8.0	Disintegration time	Not more than 15 minutes
9.0	Friability*	Not more than 1.0%
10.0	<b>Dissolution*:</b>  Chlorphenamine Maleate BP  Phenylephrine Hydrochloride BP  Caffeine (Anhydrous) BP  Paracetamol BP	Not less than 80% of the stated amount of Chlorphenamine Maleate dissolved in 45 Minutes.  Not less than 80% of the stated amount of Phenylephrine Hydrochloride dissolved in 45 Minutes.  Not less than 80% of the stated amount of Caffeine dissolved in 45 Minutes.  Not less than 80% of the stated amount of Paracetamol dissolved in 45 Minutes.




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	<b>PRODUCT SPECIFICATION</b>			
		Market	Export	
<b>Name of Product</b>	<b>LITACOLD FLU</b> (Chlorphenamine Maleate, Phenylephrine Hydrochloride, Caffeine and Paracetamol Tablets)			
<b>Specification No.</b>	SPEC-978-00	<b>Revision No.</b>	00	<b>Product Code:</b> 978
<b>Supersedes</b>	FGSTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 8 of 12

S.NO	TEST (s)	SPECIFICATION (s)
11.0	<b>Uniformity of content*</b>  Chlorphenamine Maleate BP  Phenylephrine Hydrochloride BP	Not less than 85.0% and not more than 115.0% of the average value.  Not less than 85.0% and not more than 115.0% of the average value.
12.0	<b>Related Substances(By HPLC)*</b>  (i) Single maximum unknown impurity  (ii) Total impurities	Not more than 0.20%  Not more than 0.50%
13.0	<b>Assay: Each Uncoated tablet contains*:</b>  Chlorphenamine Maleate BP      2mg  Phenylephrine Hydrochloride BP      5mg  Caffeine (Anhydrous) BP      30mg  Paracetamol BP      500mg	1.9mg to 2.2mg (95.0% to 110.0% of the labeled claim)  4.75mg to 5.50mg (95.0% to 110.0% of the labeled claim)  28.5mg to 33.0mg (95.0% to 110.0% of the labeled claim)  475.0mg to 550.0mg (95.0% to 110.0% of the labeled claim)



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Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
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	<b>PRODUCT SPECIFICATION</b>			
				<b>Market</b>
<b>Name of Product</b>	<b>LITACOLD FLU</b> (Chlorphenamine Maleate, Phenylephrine Hydrochloride, Caffeine and Paracetamol Tablets)			
<b>Specification No.</b>	SPEC-978-00	<b>Revision No.</b>	00	<b>Product Code:</b> 978
<b>Supersedes</b>	FGSTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 10 of 12


**STABILITY SPECIFICATION**  
**SPECIFICATION CODE: SPEC-978-ST**

S.NO	TEST (s)	SPECIFICATION (s)
1.0	Description	Light yellow coloured, flat, round beveled edged uncoated tablet with break line on one side and plain on another side.
2.0	Average weight of tablet	635.0 mg $\pm$ 3 % (615.9 mg to 654.0 mg)
3.0	<b>Dissolution:</b>  Chlorphenamine Maleate BP  Phenylephrine Hydrochloride BP  Caffeine (Anhydrous) BP  Paracetamol BP	Not less than 80% of the stated amount of Chlorphenamine Maleate dissolved in 45 Minutes.  Not less than 80% of the stated amount of Phenylephrine Hydrochloride dissolved in 45 Minutes.  Not less than 80% of the stated amount of Caffeine dissolved in 45 Minutes.  Not less than 80% of the stated amount of Paracetamol dissolved in 45 Minutes.
4.0	<b>Related Substances(By HPLC)</b>  (i) Single maximum unknown impurity  (ii) Total impurities	Not more than 0.20%  Not more than 0.50%

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
<b>Name</b>	<b>S.SANTHI</b>	<b>M.VIJAYAKUMAR</b>	<b>S.MARAN</b>
<b>Designation</b>	<b>Asst. Manager-QC</b>	<b>GM-QC</b>	<b>AGM-QA</b>
<b>Signature</b>			
<b>Date</b>	04/05/24	06/05/2024	07/05/2024




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	<b>PRODUCT SPECIFICATION</b>			<b>Market</b>
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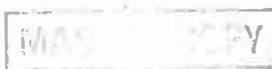
S.NO	TEST (s)	SPECIFICATION (s)
5.0	<b>Assay: Each Uncoated tablet contains:</b>  <div>Chlorphenamine Maleate BP                      2mg</div> <div>Phenylephrine Hydrochloride BP                      5mg</div> <div>Caffeine (Anhydrous) BP                      30mg</div> <div>Paracetamol BP                      500mg</div>	<div>1.8mg to 2.2mg (90.0% to 110.0% of the labeled claim)</div> <div>4.5mg to 5.50mg (90.0% to 110.0% of the labeled claim)</div> <div>27.0mg to 33.0mg (90.0% to 110.0% of the labeled claim)</div> <div>450.0mg to 550.0mg (90.0% to 110.0% of the labeled claim)</div>
6.0	<b>Microbial contamination#</b>  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	<div>Not more than 1000 cfu/g</div> <div>Not more than 100 cfu/g</div> <div>Should be absent/g</div> <div>Should be absent/10g</div> <div>Should be absent/g</div> <div>Should be absent/g</div>

# Mark test will performed on 6<sup>th</sup> month of Accelerated stability and every 12<sup>th</sup> month of Long term stability.

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	<b>PRODUCT SPECIFICATION</b>		<b>Market</b>	<b>Export</b>
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<b>Specification No.</b>	SPEC-978-00	<b>Revision No.</b>	00	<b>Product Code:</b> 978
<b>Supersedes</b>	FGSTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 12 of 12

**REVISION HISTORY:**



Specification No.	Reason for Review	Change control No.	Effective Date
FGSTSL022-00	New specification prepared.	NA	03-03-2020
FGSTSL022-01	Thickness and Hardness test limits has revised.	ST/CC/20/032	09-07-2020
FGSTSL022-02	Thickness and Hardness test limits has revised.	ST/CC/20/094	07-12-2020
FGSTSL022-03	(i) Market detail incorporated in Header space of Specification and STP.	ST/CC/21/052	23-11-2021
	(ii) Specification format revised as per SOP No. ST/QC/058 for better clarity.		
	(iii) There is no change in specification. The ROA procedure has been elaborated for better clarity.	ST/CC/21/157	
SPEC-978-00	Specification format and numbering system has revised as per Sop No: ST/QC/058.	ST/CC/23/063	08/05/2024

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




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Name	S.SANTHI	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	04/05/24	06/05/2024	07/05/2024

Format No: ST/QC/058:A1

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	<b>Safetab Life Science</b> <b>Puducherry</b>			
	<b>STANDARD TESTING PROCEDURE</b>		<b>Market</b>	<b>Export</b>
<b>Name of Product</b>	<b>LITACOLD FLU</b> (Chlorphenamine Maleate, Phenylephrine Hydrochloride, Caffeine and Paracetamol Tablets)			
<b>STP No.</b>	STP-978-00	<b>Revision No.</b>	00	<b>Product Code:</b> 978
<b>Supersedes</b>	FGTTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 1 of 24

<b>1.0</b>	<b><u>DESCRIPTION:</u></b> (By Visual Inspection)  <b>Blend:</b> Spread about 1 to 2 g of sample on a white surface and note the observation.  <b>Tablets:</b> Take 10 tablets on a white background and note the colour, shape, coated or uncoated, embossing and other observations, if any.
<b>2.0</b>	<b><u>IDENTIFICATION:</u></b> (By HPLC)  <b>a) Chlorphenamine Maleate:</b>  The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Chlorphenamine Maleate in the standard preparation as obtained in assay.  <b>b) Phenylephrine Hydrochloride:</b>  The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Phenylephrine Hydrochloride in the standard preparation as obtained in assay.  <b>c) Caffeine:</b>  The retention time of one of major peak in the chromatogram of the sample preparation corresponds to the peak due to Caffeine in the standard preparation as obtained in assay.  <b>d) Paracetamol:</b>  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
<b>3.0</b>	<b><u>AVERAGE WEIGHT OF TABLET:</u></b>  Weigh and note down the weight of 20 tablets.

Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
Name	S.SANTHI	M.VIJAYAKUMAR	S.MARAN
Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	09/05/24	06/05/2024	09/05/2024

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	<b>STANDARD TESTING PROCEDURE</b>		<b>Market</b>	<b>Export</b>
<b>Name of Product</b>	<b>LITACOLD FLU</b> (Chlorphenamine Maleate, Phenylephrine Hydrochloride, Caffeine and Paracetamol Tablets)			
<b>STP No.</b>	STP-978-00	<b>Revision No.</b>	00	<b>Product Code:</b> 978
<b>Supersedes</b>	FGTTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 2 of 24

Weight of 20 tablets (g)

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.

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:**

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


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

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




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<b>Name of Product</b>	<b>LITACOLD FLU</b> (Chlorphenamine Maleate, Phenylephrine Hydrochloride, Caffeine and Paracetamol Tablets)			
<b>STP No.</b>	STP-978-00	<b>Revision No.</b>	00	<b>Product Code:</b> 978
<b>Supersedes</b>	FGTTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 3 of 24

<b>5.0</b>	<b><u>DIAMETER AND THICKNESS:</u></b>  Select randomly 10 tablets and measure the Diameter and thickness using a suitable Vernier caliper. Record the values. Calculate the average thickness of the tablets as follows:  $\text{Average thickness (in mm)} = \text{Total thickness of 10 tablets (in mm)} / 10$ $\text{Average diameter (in mm)} = \text{Total diameter of 10 tablets (in mm)} / 10$  Report the average, minimum and maximum values.
<b>6.0</b>	<b><u>HARDNESS:</u></b>  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:  $\text{Average hardness (in N)} = \text{Total hardness of 10 tablets (in N)} / 10.       $
<b>7.0</b>	<b><u>DISINTEGRATION TIME:</u></b>  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 $37^{\circ}\text{C} \pm 2^{\circ}\text{C}$ 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.
<b>8.0</b>	<b><u>FRIABILITY:</u></b>  Weigh 11 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).




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<b>Supersedes</b>	FGTTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 4 of 24



<b>9.0</b>	$\% \text{ of Friability} = \frac{\text{Initial Weight(a)} - \text{Final weight (b)}}{\text{Initial Weight (a)}} \times 100$																				
	<b>DISSOLUTION:</b>																				
	<b>Reference:</b> In House <b>Procedure:</b> By HPLC																				
	<b>Chemicals/Reagents/Standards:</b>																				
	<table border="0"> <tr> <td>Chlorphenamine Maleate</td> <td>: Working standard</td> </tr> <tr> <td>Phenylephrine Hydrochloride</td> <td>: Working standard</td> </tr> <tr> <td>Caffeine anhydrous</td> <td>: Working standard</td> </tr> <tr> <td>Paracetamol</td> <td>: Working standard</td> </tr> <tr> <td>Potassium Dihydrogen orthophosphate</td> <td>: AR grade</td> </tr> <tr> <td>Orthophosphoric acid</td> <td>: AR grade</td> </tr> <tr> <td>Methanol</td> <td>: HPLC grade</td> </tr> <tr> <td>Acetonitrile</td> <td>: HPLC grade</td> </tr> <tr> <td>Sodium Hydroxide</td> <td>: AR grade</td> </tr> <tr> <td>Purified Water</td> <td>: Milli-Q water (or) equivalent</td> </tr> </table>		Chlorphenamine Maleate	: Working standard	Phenylephrine Hydrochloride	: Working standard	Caffeine anhydrous	: Working standard	Paracetamol	: Working standard	Potassium Dihydrogen orthophosphate	: AR grade	Orthophosphoric acid	: AR grade	Methanol	: HPLC grade	Acetonitrile	: HPLC grade	Sodium Hydroxide	: AR grade	Purified Water
Chlorphenamine Maleate	: Working standard																				
Phenylephrine Hydrochloride	: Working standard																				
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Sodium Hydroxide	: AR grade																				
Purified Water	: Milli-Q water (or) equivalent																				
<b>Dissolution parameters:</b>																					
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<b>STP No.</b>	STP-978-00	<b>Revision No.</b>	00	<b>Product Code:</b> 978
<b>Supersedes</b>	FGTTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 5 of 24

#### Preparation of Dissolution medium:




Dissolve 68 gm of Potassium dihydrogen phosphate and 9.8 gm of Sodium hydroxide pellets in 10 liters of purified water and mix well. Adjust pH  $6.8 \pm 0.05$  with dilute Sodium hydroxide or dilute Orthophosphoric acid and mix well.

#### Preparation of Buffer:

Weigh accurately about 6.8 g of potassium Di-hydrogen orthophosphate in 1000 mL of milli-Q water, sonicate to dissolve. Adjust pH to  $3.0 \pm 0.05$  with Orthophosphoric acid. Filter through  $0.45\mu$  membrane filter.



#### Chromatographic Conditions:

Column	:	Inertsil ODS-3V, 250 mm X 4.6 mm, $5\mu$ m (or) equivalent
Wave length	:	220 nm
Column Temperature	:	40°C
Cooler temperature	:	15°C
Flow Rate	:	1.2 mL/min
Injection Volume	:	20 $\mu$ L
Run time	:	30.01 Minutes
Retention time	:	About 4.6 minutes for Phenylephrine Hydrochloride, about 10.5 minutes for Paracetamol, about 12.7 minutes for Caffeine and about 14.8 minutes for Chlorphenamine maleate,

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<b>Supersedes</b>	FGTTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 6 of 24

**Gradient Program:**

Time	Mobile phase A %	Mobile phase B%
0.01	100	0
6.0	100	0
7.0	70	30
9.0	70	30
10.0	45	55
25.0	45	55
27.0	100	0
30.01	100	0

**Preparation of Mobile phase-A:**

Prepare a degassed mixture of buffer and acetonitrile in the ratio 95:5 v/v.

**Preparation of Mobile phase-B:**




100% Methanol

**Preparation of Blank solution:**

Use Dissolution medium as a blank.



**Preparation of Diluent:**

Prepare a degassed mixture of Buffer and methanol in the ratio 50:50 v/v.




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<b>Supersedes</b>	FGTTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 7 of 24

	<p><b>Preparation of Standard stock solution:</b></p> <p>Weigh accurately and transfer about 28 mg of Chlorphenamine maleate working standard and 68 mg of Phenylephrine Hydrochloride working standard and 83 mg of Caffeine working standard into a 250 mL volumetric flask, add 20 mL of diluent and sonicate to dissolve and make up to volume with dissolution medium and mix.</p> <p><b>Preparation of Standard solution:</b></p> <p>Weigh accurately and transfer about 22 mg of Paracetamol working standard into a 200 mL volumetric flask. Add 20 mL of diluent and sonicate to dissolve and add 4 mL of Standard stock solution and make up to volume with dissolution medium and mix.</p> <p><b>Test Preparation :</b></p> <p><b>Preparation of sample solution(A) (For Chlorphenamine maleate and Phenylephrine Hydrochloride)</b></p> <p>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 and filter through 0.45µ PVDF filter.</p> <p><b>Preparation of Sample Solution-B:(For Paracetamol and Caffeine)</b></p> <p>Further dilute 10 mL of above filtered solution to 50 mL with Dissolution medium and mix.</p> <p><b>Procedure:</b></p> <p>Inject the solutions as mentioned below and measure the responses of the peaks due to Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine maleate, Caffeine.</p>
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<b>Supersedes</b>	FGTTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 8 of 24

**Injection sequence:**

S. No	Sample Name	No. of injections
1	Dissolution medium (blank)	1
2	Standard preparation	5
3	Sample solution A (1 injection each)	6
4	Sample solution B (1 injection each)	6
5	Bracketing standard	1 (After every 6 injections)




**System suitability:**

Theoretical plate count : NLT 2000 for Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine maleate, Caffeine peak.  
 Tailing factor : NMT 2.0 for Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine maleate, Caffeine peak.  
 Relative standard deviation : NMT 2.0% for five replicate injections of Paracetamol, Phenylephrine hydrochloride, Chlorphenamine maleate, Caffeine peak.

**Calculations:**


**Calculate % drug release of Chlorphenamine maleate as follows:**

$$= \frac{AT}{AS} \times \frac{WS}{250} \times \frac{4}{200} \times \frac{900}{1} \times \frac{P}{100} \times \frac{100}{LC}$$

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<b>Supersedes</b>	FGTTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 9 of 24

Where,

- AT = Area of peak due to Chlorphenamine maleate in Sample solution A.
- AS = Average area of peak due to Chlorphenamine maleate in standard preparation.
- WS = Weight of Chlorphenamine maleate working standard in mg.
- P = Potency of Chlorphenamine maleate working standard in % on as such basis.
- LC = Label claim of Chlorphenamine maleate in mg.

**Calculate % drug release of Phenylephrine Hydrochloride as follows:**




$$= \frac{AT}{AS} \times \frac{WS}{250} \times \frac{4}{200} \times \frac{900}{1} \times \frac{P}{100} \times \frac{100}{LC}$$

Where,

- AT = Area of peak due to Phenylephrine hydrochloride in Sample solution A.
- AS = Average area of peak due to Phenylephrine hydrochloride in standard preparation.
- WS = Weight of Phenylephrine hydrochloride working standard in mg.
- P = Potency of Phenylephrine hydrochloride working standard in % on as such basis.
- LC = Label claim of Phenylephrine hydrochloride in mg.



**Calculate % drug release of Caffeine as follows:**

$$= \frac{AT}{AS} \times \frac{WS}{250} \times \frac{4}{200} \times \frac{900}{1} \times \frac{50}{10} \times \frac{P}{100} \times \frac{100}{LC}$$




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<b>Supersedes</b>	FGTTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 10 of 24

<p>Where,</p> <p>AT = Area of peak due to Caffeine in Sample solution B.</p> <p>AS = Average area of peak due to Caffeine in standard preparation.</p> <p>WS = Weight of Caffeine working standard in mg.</p> <p>P = Potency of Caffeine working standard in % on as such basis.</p> <p>LC = Label claim of Caffeine in mg.</p> <p><b>Calculate % drug release of Paracetamol as follows:</b></p> $= \frac{AT}{AS} \times \frac{WS}{200} \times \frac{900}{1} \times \frac{50}{10} \times \frac{P}{100} \times \frac{100}{LC}$ <p>Where,</p> <p>AT = Area of peak due to Paracetamol in Sample solution B.</p> <p>AS = Average area of peak due to Paracetamol in standard preparation.</p> <p>WS = Weight of Paracetamol working standard in mg.</p> <p>P = Potency of Paracetamol working standard in % on as such basis.</p> <p>LC = Label claim of Paracetamol in mg.</p> <p><b>10.0 UNIFORMITY OF CONTENT:</b></p> <p><b>(Chlorphenamine maleate and Phenylephrine hydrochloride)</b></p> <p><b>Reference:</b> In House</p> <p><b>Procedure:</b> By HPLC</p> <p><b>Note 1:</b> Buffer preparation, Diluent, Mobile phase A, Mobile phase B, Chromatographic condition and gradient program proceed as directed under dissolution test.</p>	
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<b>Supersedes</b>	FGTTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 11 of 24

**Note 2: Standard preparation use under assay test.**

**Test preparation:**

Take 1 tablet into 100 ml volumetric flask. Add about 10 ml of purified water and shake gently to disperse the tablet completely. Add about 60 ml of diluent, sonicate for 20 minutes with intermediate shaking, cool and dilute up to the volume with diluent and Centrifuge this solution at 3000rpm for 10 Minutes. Further dilute 10 ml of this solution to 25ml with diluent. Repeat the same procedure for another 9 tablets.

**Procedure:**

Equilibrate the chromatographic system with mobile phase till a stable baseline is obtained. Separately inject equal volumes (20 µl) of solutions as per Sequence of injections into the chromatograph and record the peak area responses for the major peaks and check for the System suitability requirements.




**Injection sequence:**

S. No	Sample Name	No. of injections
1	Diluent (blank)	1
2	Standard preparation	5
3	Test preparation	10
4	Bracketing standard	1 (After every 10 injections)

**System suitability:**


Theoretical plate count : NLT 2000 for Chlorphenamine maleate and Phenylephrine Hydrochloride peak.

Tailing factor : NMT 2.0 for Chlorphenamine maleate and Phenylephrine Hydrochloride peak.




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<b>Supersedes</b>	FGTTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 12 of 24


<p>Relative standard deviation : NMT 2.0% for five replicate injections of Chlorphenamine maleate and Phenylephrine Hydrochloride peak.</p> <p><b>Calculation:</b></p> <p><b>Calculate the % content of Chlorphenamine maleate by using following formula:</b></p> $= \frac{AT}{AS} \times \frac{WS}{200} \times \frac{10}{200} \times \frac{100}{1} \times \frac{25}{10} \times \frac{P}{100} \times \frac{100}{LC}$ <p>Where,</p> <p>AT = Area of peak response of Chlorphenamine maleate obtained with Test preparation</p> <p>AS = Average area peak response of Chlorphenamine maleate obtained with replicate injections of standard preparation</p> <p>WS = Weight of Chlorphenamine maleate working standard in mg.</p> <p>P = Potency of Chlorphenamine maleate working standard in % on as such basis.</p> <p>LC = Label claim of Chlorphenamine maleate in mg.</p> <p><b>Calculate the % content of Phenylephrine Hydrochloride by using following formula:</b></p> $= \frac{AT}{AS} \times \frac{WS}{200} \times \frac{10}{200} \times \frac{100}{1} \times \frac{25}{10} \times \frac{P}{100} \times \frac{100}{LC}$ <p>Where,</p> <p>AT = Area of peak response of Phenylephrine hydrochloride obtained with Test preparation.</p> <p>AS = Average area of peak response of Phenylephrine hydrochloride obtained with replicate injections of standard preparation.</p>
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<b>Supersedes</b>	FGTTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 13 of 24

<b>11.0</b>	WS = Weight of Phenylephrine Hydrochloride working standard in mg. P = Potency of Phenylephrine Hydrochloride working standard in % on as such basis. LC = Label claim of Phenylephrine Hydrochloride in mg.																	
	<b>RELATED SUBSTANCES:</b>																	
	<b>Reference:</b> In House <b>Procedure:</b> By HPLC																	
	<b>Chemicals/Reagents/Standards:</b>																	
	<table border="0"> <tr> <td>Chlorphenamine maleate</td> <td>: Working standard</td> </tr> <tr> <td>Phenylephrine Hydrochloride</td> <td>: Working standard</td> </tr> <tr> <td>Caffeine Anhydrous</td> <td>: Working standard</td> </tr> <tr> <td>Paracetamol</td> <td>: Working standard</td> </tr> <tr> <td>Potassium Di-hydrogen orthophosphate</td> <td>: AR grade</td> </tr> <tr> <td>Acetonitrile</td> <td>: HPLC grade</td> </tr> <tr> <td>Orthophosphoric acid</td> <td>: AR grade</td> </tr> <tr> <td>Methanol</td> <td>: HPLC grade</td> </tr> <tr> <td>Purified water</td> <td>: Milli-Q water or equivalent</td> </tr> </table>	Chlorphenamine maleate	: Working standard	Phenylephrine Hydrochloride	: Working standard	Caffeine Anhydrous	: Working standard	Paracetamol	: Working standard	Potassium Di-hydrogen orthophosphate	: AR grade	Acetonitrile	: HPLC grade	Orthophosphoric acid	: AR grade	Methanol	: HPLC grade	Purified water
Chlorphenamine maleate	: Working standard																	
Phenylephrine Hydrochloride	: Working standard																	
Caffeine Anhydrous	: Working standard																	
Paracetamol	: Working standard																	
Potassium Di-hydrogen orthophosphate	: AR grade																	
Acetonitrile	: HPLC grade																	
Orthophosphoric acid	: AR grade																	
Methanol	: HPLC grade																	
Purified water	: Milli-Q water or equivalent																	
	<b>Chromatographic Conditions:</b>																	
	<table border="0"> <tr> <td>Column</td> <td>: Kromasil C8, 250 mm X 4.6 mm, 5µm (or) equivalent</td> </tr> <tr> <td>Wave length</td> <td>: 220 nm</td> </tr> <tr> <td>Column Temperature</td> <td>: 30°C</td> </tr> </table>	Column	: Kromasil C8, 250 mm X 4.6 mm, 5µm (or) equivalent	Wave length	: 220 nm	Column Temperature	: 30°C											
Column	: Kromasil C8, 250 mm X 4.6 mm, 5µm (or) equivalent																	
Wave length	: 220 nm																	
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Particulars	PREPARED BY	REVIEWED BY	APPROVED BY
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Designation	Asst. Manager-QC	GM-QC	AGM-QA
Signature			
Date	04/05/24	06/05/2024	07/05/2024

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<b>Name of Product</b>	<b>LITACOLD FLU</b> (Chlorphenamine Maleate, Phenylephrine Hydrochloride, Caffeine and Paracetamol Tablets)			
<b>STP No.</b>	STP-978-00	<b>Revision No.</b>	00	<b>Product Code:</b> 978
<b>Supersedes</b>	FGTTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 14 of 24

	<p>Flow Rate : 1.0 mL/min</p> <p>Injection Volume : 20 µl</p> <p>Run time : 15 minutes for Standard solution 40 minutes for Blank, System suitability solution, placebo solution and Sample solution</p> <p>Retention time : About 3.5 minutes for Chlorphenamine maleate, about 4.1 minutes for Phenylephrine Hydrochloride, about 8.4 minutes for Paracetamol and about 27.0 minutes for Caffeine</p> <p><b>Preparation of Buffer:</b></p> <p>Weigh accurately about 6.8g of potassium Di-hydrogen orthophosphate in 1000 mL of Purified water, sonicate to dissolve. Adjust pH 3.0±0.05 with Orthophosphoric acid. Filter through 0.45µ membrane filter.</p> <p><b>Preparation of Mobile phase:</b></p> <p>Prepare a degassed mixture of buffer and methanol in the ratio 85:15 v/v.</p> <p><b>Preparation of Diluent:</b></p> <p>Prepare a degassed mixture of water and methanol in the ratio 80:20 v/v.</p> <p><b>Preparation of Placebo solution:</b></p> <p>Weigh accurately and transfer about 55 mg of Plain Placebo into 100mL volumetric flask. Add 50 mL of diluent and sonicate for 10 minutes with intermittent shaking, cool and make up to volume with diluent and mix. Further dilute 5 mL of above solution into 50 mL with diluent. Filter through 0.45µ PVDF filter.</p>
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<b>Supersedes</b>	FGTTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 15 of 24

	<p><b>Preparation of Standard solution:</b></p> <p>Weigh accurately and transfer about 60 mg of Paracetamol 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. Dilute 1 mL of this solution to 100 mL with diluent and mix. Further dilute to 5 mL of above solution into 50 mL with diluent and mix.</p> <p><b>Preparation of system suitability stock solution:</b></p> <p>Weigh accurately and transfer about 180 mg of Caffeine working standard, 12 mg of Chlorphenamine maleate working standard and 30 mg of Phenylephrine hydrochloride 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.</p> <p><b>Preparation of system suitability solution:</b></p> <p>Weigh accurately and transfer about 30 mg of Paracetamol working standard into a 100 mL volumetric flask.</p> <p>Add 1 mL of system suitability standard stock solution and 50 mL of diluent and sonicate to dissolve. Make up to volume with diluent and mix.</p> <p><b>Test preparation:</b></p> <p>Weigh accurately 20 tablets, calculate the average weight and make powder by using mortar and pestle. Weigh and transfer sample powder equivalent to 300 mg of Paracetamol, into a 100 mL volumetric flask. Add about 50 mL of diluent and sonicate for 10 minutes with intermittent shaking dilute up to the volume with diluent and mix. Further dilute 10 mL of above solution into 100 mL with diluent. Filter through 0.45µ PVDF filter.</p> <p>Inject 20 µL of the above solution (blank, system suitability solution, standard, placebo and sample) as per following sequence and measure the area due to any unknown impurity peak.</p>
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<b>Supersedes</b>	FGTTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 16 of 24

**Injection sequence:**

S. No	Sample Name	No. of injections
1	Diluent (blank)	1
2	System suitability solution	1
3	Standard solution	5
4	Placebo Preparation	1
5	Test preparation	1
6	Bracketing standard	1 (Each after every 6 sample injections)




**Calculation:**

**Single maximum unknown impurity:**

$$= \frac{ATI}{AST} \times \frac{WS}{100} \times \frac{1}{100} \times \frac{5}{50} \times \frac{100}{WT} \times \frac{100}{10} \times AW \times \frac{P}{100} \times \frac{100}{500}$$



Where,

- ATI = Area of peak due to Single maximum unknown impurity in test preparation.  
AST = 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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<b>Name of Product</b>	<b>LITACOLD FLU</b> (Chlorphenamine Maleate, Phenylephrine Hydrochloride, Caffeine and Paracetamol Tablets)			
<b>STP No.</b>	STP-978-00	<b>Revision No.</b>	00	<b>Product Code:</b> 978
<b>Supersedes</b>	FGTTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 17 of 24

12.0	<b>Total impurities:</b>
	$= \frac{AT_T}{AST} \times \frac{WS}{100} \times \frac{1}{100} \times \frac{5}{50} \times \frac{100}{WT} \times \frac{100}{10} \times AW \times \frac{P}{100} \times \frac{100}{500}$
	Where,
	AT <sub>T</sub> = Area of peak due to Total impurities in test preparation.
	AS <sub>T</sub> = 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.
	<b>12.0 ASSAY:</b>
<b>Reference:</b> In House <b>Procedure:</b> By HPLC	
<b>Note:</b> For reagents, buffer preparation, Diluent, Mobile phase-A, Mobile phase-B, Chromatographic conditions and Gradient program proceed as directed in dissolution Test.	
<b>Preparation of Standard stock solution:</b>	
Weigh accurately and transfer about 32 mg of Chlorphenamine maleate working standard, 80 mg of Phenylephrine Hydrochloride working standard and 24 mg of Caffeine working standard into a 200 mL volumetric flask. Add 120 mL of diluent and sonicate to dissolve and make up to volume with diluent and mix.	




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<b>Name of Product</b>	<b>LITACOLD FLU</b> (Chlorphenamine Maleate, Phenylephrine Hydrochloride, Caffeine and Paracetamol Tablets)			
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<b>Supersedes</b>	FGTTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 18 of 24

<p><b>Preparation of Standard solution:</b></p> <p>Weigh accurately and transfer about 20 mg of Paracetamol working standard into a 200 mL volumetric flask. Add 120 mL of diluent and sonicate to dissolve and add 10 mL of standard stock solution (Chlorphenamine, Phenylephrine and Caffeine) and make up to volume with diluent and mix.</p> <p><b>Test preparation: (For blend)</b></p> <p><b>Preparation of Sample Solution-A: (For Chlorphenamine maleate and Phenylephrine Hydrochloride)</b></p> <p>Weigh about 20g of sample and crush to fine powder by using mortar and pestle. Weigh accurately and transfer sample powder equivalent to 500 mg of Paracetamol, into a 250 mL volumetric flask. Add about 170 mL of diluent and sonicate for 30 minutes with intermittent shaking. Make up to the volume with diluent and mix and centrifuge this solution at 3000RPM for 10 minutes.</p> <p><b>Preparation of Sample Solution-B:(For Paracetamol and Caffeine)</b></p> <p>Further dilute 5 mL of above supernatant solution to 100 mL with diluent and mix.</p> <p><b>Test preparation: (For tablets)</b></p> <p><b>Preparation of Sample Solution-A: (For Chlorphenamine maleate and Phenylephrine Hydrochloride)</b></p> <p>Weigh accurately 20 tablets and make powder by using mortar and pestle. Weigh and transfer sample powder equivalent to 500 mg of Paracetamol, into a 250 mL volumetric flask. Add about 170 mL of diluent and sonicate for 30 minutes with intermittent shaking. Make up to the volume with diluent and mix and Centrifuge this solution at 3000rpm for 10minutes.</p> <p><b>Preparation of Sample Solution-B:(For Paracetamol and Caffeine)</b></p> <p>Further dilute 5 mL of above solution to 100 mL with diluent and mix.</p>
--




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<b>Name of Product</b>	<b>LITACOLD FLU</b> (Chlorphenamine Maleate, Phenylephrine Hydrochloride, Caffeine and Paracetamol Tablets)			
<b>STP No.</b>	STP-978-00	<b>Revision No.</b>	00	<b>Product Code:</b> 978
<b>Supersedes</b>	FGTTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 19 of 24

<p><b>Procedure:</b></p> <p>Inject the solutions as mentioned below and measure the responses of the peaks due to Paracetamol, Phenylephrine, Chlorphenamine maleate, Caffeine.</p> <p><b>Injection sequence:</b></p> <table border="1"> <thead> <tr> <th>S. No</th> <th>Sample Name</th> <th>No. of injections</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Diluent (blank)</td> <td>1</td> </tr> <tr> <td>2</td> <td>Standard preparation</td> <td>5</td> </tr> <tr> <td>3</td> <td>Sample solution-A</td> <td>2</td> </tr> <tr> <td>4</td> <td>Sample solution B</td> <td>2</td> </tr> <tr> <td>5</td> <td>Bracketing standard</td> <td>1</td> </tr> </tbody> </table> <p><b>System suitability:</b></p> <p>Theoretical plate count : NLT 2000 for Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine maleate, Caffeine peak.</p> <p>Tailing factor : NMT 2.0 for Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine maleate, Caffeine peak.</p> <p>Relative standard deviation : NMT 2.0% for five replicate injections of Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine maleate, Caffeine peak.</p>	S. No	Sample Name	No. of injections	1	Diluent (blank)	1	2	Standard preparation	5	3	Sample solution-A	2	4	Sample solution B	2	5	Bracketing standard	1	
	S. No	Sample Name	No. of injections																
	1	Diluent (blank)	1																
	2	Standard preparation	5																
3	Sample solution-A	2																	
4	Sample solution B	2																	
5	Bracketing standard	1																	

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<b>Name</b>	<b>S.SANTHI</b>	<b>M.VIJAYAKUMAR</b>	<b>S.MARAN</b>
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<b>Name of Product</b>	<b>LITACOLD FLU</b> (Chlorphenamine Maleate, Phenylephrine Hydrochloride, Caffeine and Paracetamol Tablets)			
<b>STP No.</b>	STP-978-00	<b>Revision No.</b>	00	<b>Product Code:</b> 978
<b>Supersedes</b>	FGTTSLO22-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 20 of 24

### Calculations:

Calculate the assay of Chlorphenamine maleate in mg/tablet as follows:

$$= \frac{AT}{AS} \times \frac{WS}{200} \times \frac{10}{200} \times \frac{250}{WT} \times \frac{P}{100} \times AW$$

Where,

- AT = Average area of peak due to Chlorphenamine maleate in Sample solution A.  
AS = Average area of peak due to Chlorphenamine maleate in standard preparation.  
WS = Weight of Chlorphenamine maleate working standard in mg.  
WT = Weight of sample taken in mg.  
AW = Average weight of tablet in mg.  
P = Potency of Chlorphenamine maleate working standard in % on as such basis.




Calculate the assay of Chlorphenamine maleate in % as follows:

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

LC = Label claim of Chlorphenamine maleate in mg/tablet.

Calculate the assay of Phenylephrine Hydrochloride in mg/tablet as follows:



$$= \frac{AT}{AS} \times \frac{WS}{200} \times \frac{10}{200} \times \frac{250}{WT} \times \frac{P}{100} \times AW$$

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<b>Supersedes</b>	FGTTSLO22-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 21 of 24

	<p>Where,</p> <p>AT = Average area of peak due to Phenylephrine Hydrochloride in Sample solution A.</p> <p>AS = Average area of peak due to Phenylephrine Hydrochloride in standard preparation.</p> <p>WS = Weight of Phenylephrine Hydrochloride working standard in mg.</p> <p>WT = Weight of sample taken in mg.</p> <p>AW = Average weight of tablet in mg.</p> <p>P = Potency of Phenylephrine Hydrochloride working standard in % on as such basis.</p> <p><b>Calculate the assay of Phenylephrine Hydrochloride in % as follows:</b></p> $= \frac{\text{mg/tablet}}{\text{LC}} \times 100$ <p>LC = Label claim of Phenylephrine Hydrochloride in mg/tablet.</p> <p><b>Calculate the assay of Caffeine in mg/tablet as follows:</b></p> $= \frac{\text{AT}}{\text{AS}} \times \frac{\text{WS}}{200} \times \frac{10}{200} \times \frac{250}{\text{WT}} \times \frac{100}{5} \times \frac{\text{P}}{100} \times \text{AW}$ <p>Where,</p> <p>AT = Average area of peak due to Caffeine in Sample solution B.</p> <p>AS = Average area of peak due to Caffeine in standard preparation.</p> <p>WS = Weight of Caffeine working standard in mg.</p> <p>WT = Weight of sample taken in mg.</p>
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<p>AW = Average weight of tablet in mg.</p> <p>P = Potency of Caffeine working standard in % on as such basis.</p> <p><b>Calculate the assay of Caffeine in % as follows:</b></p> $= \frac{\text{mg/tablet}}{\text{LC}} \times 100$ <p>LC = Label claim of Caffeine in mg/tablet.</p> <p><b>Calculate the assay of Paracetamol in mg/tablet as follows:</b></p> $= \frac{\text{AT}}{\text{AS}} \times \frac{\text{WS}}{200} \times \frac{250}{\text{WT}} \times \frac{100}{5} \times \frac{\text{P}}{100} \times \text{AW}$ <p>Where,</p> <p>AT = Average area of peak due to Paracetamol in Sample solution B.</p> <p>AS = Average area of peak due to Paracetamol in standard preparation.</p> <p>WS = Weight of Paracetamol working standard in mg.</p> <p>WT = Weight of sample taken in mg.</p> <p>AW = Average weight of tablet in mg.</p> <p>P = Potency of Paracetamol working standard in % on as such basis.</p> <p><b>Calculate the assay of Paracetamol in % as follows:</b></p> $= \frac{\text{mg/tablet}}{\text{LC}} \times 100$ <p>LC = Label claim of Paracetamol in mg/tablet.</p>
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<b>Supersedes</b>	FGTTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 23 of 24

### 13.0 MICROBIAL CONTAMINATION:

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



#### REVISION HISTORY:

STP No.	Reason for Review	Change control No.	Effective Date
FGTTSL022-00	New specification prepared.	NA	03-03-2020
FGTTSL022-01	Thickness and Hardness test limits has revised.	ST/CC/20/032	09-07-2020
FGTTSL022-02	Thickness and Hardness test limits has revised.	ST/CC/20/094	07-12-2020
FGTTSL022-03	(i) Market detail incorporated in Header space of Specification and STP. (ii) Specification format revised as per SOP No. ST/QC/058 for better clarity. (iii) There is no change in specification. The ROA procedure has been elaborated for better clarity.	ST/CC/21/052   ST/CC/21/157	23-11-2021

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<b>Supersedes</b>	FGTTSL022-03	<b>Effective Date:</b>	08/05/2024	<b>Page No.:</b> 24 of 24

STP No.	Reason for Review	Change control No.	Effective Date
STP-978-00	(i) Dissolution test and Related substances test chromatographic condition is changed as based on Analytical method validation.	ST/CC/23/246	08/05/2024
	(ii) STP format and numbering system has revised as per Sop No: ST/QC/058.	ST/CC/23/063	

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

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