Trypsin and Chymotrypsin Gastro-resistant Tablets

Published on: 07.08.2026 **Last date for comments: 21.09.2026**

This draft proposal contains general chapter text for inclusion in the Indian Pharmacopoeia (IP). The content of this draft document is not final, and the text may be subject to revisions before publication in the IP. This draft does not necessarily represent the decisions or the stated policy of the IP or Indian Pharmacopoeia Commission (IPC).

Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

Please send any comments you may have on this draft document to lab.ipc@gov.in, with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.

Document History and Schedule for the Adoption Process

Description	**Details**
Document version	1.0
Monograph proposed for inclusion	Addendum to IP 2026
Tentative effective date of monograph	April, 2028
First draft published on IPC website for public comments	
Draft revision published on IPC website for public comments	
Further follow-up action as required.	

Trypsin and Chymotrypsin Gastro-resistant Tablets

Trypsin and Chymotrypsin Gastro-resistant Tablets contain not less than 90.0 per cent of the stated amount of trypsin and chymotrypsin enzymatic activity (Supplied by a purified concentrate which has specific trypsin and chymotrypsin activity in a ratio of approximately six to one).

Usual strength. 1,00,000 Armour units of enzymatic activity.

Identification

[NOTE-Use water for injection or HPLC water, having conductivity less than 1.3 µS per cm at 25° and keep all the solution including water in close container.

When examined in the range 400 nm to 800 nm (2.4.7), the test solution and reference solution obtained in the Assay shows absorption maxima at about 660 nm and the absorbance obtained with the test solution corresponds to the absorbance obtained with the reference solution.

Tests

Disintegration (2.5.1). The tablets should not show sing of cracks in *0.1 M hydrochloric acid* for 2 hours. The tablets should disintegrate within 60 minutes in *mixed phosphate buffer pH 6.8*.

Microbial contamination (2.2.9). Total aerobic viable count is not more than 10^3 CFU per g and the total combined molds and yeasts count is not more than10^2 CFU per g. 1 g is free from *Escherichia coli*, *Staphylococcus aureus*, *Pseudomonas aeruginosa* and 10 g is free from *Salmonella*.

Uniformity of dosage units (2.5.4). Complies with the test stated under Uniformity of dosage units.

Other tests. Comply with the tests stated under Tablets.

Assay.

Dilute phenol reagent. Transfer 10 ml of *phenol reagent* into a 50-ml beaker, containing 30 ml of *water*. *[NOTE-phenol reagent should be yellow in colour]*

Hemoglobin substrate. Weigh and transfer 4.8 g of *hemoglobin powder* (nitrogen content 17.7 per cent) to a 250-ml conical flask, add 75 ml of freshly boiled and cooled *water*, stir to dissolve for 15 minutes by using magnetic stirrer, add 80 g of *urea*, 16 ml of *1 M sodium hydroxide* and 48 ml of *water*. Keep one hour for denaturation, add 40 ml of *1 M potassium dihydrogen phosphate* and 16 ml of *1 M sodium hydroxide* and mix.

NOTE- Prepare test solution and reference solution in duplicate.

Test solution. Weigh and powder 20 tablets. Weigh and transfer a quantity of the powder containing 500000 AU of proteolytic enzyme concentrate into a 1000-ml volumetric flask, add 700 ml of *0.001 M hydrochloric acid*, sonicate for 30 minutes with intermediate shaking and dilute to volume with *0.001 M hydrochloric acid*. Dilute 5.0 ml of the solution to 100.0 ml with *0.001 M hydrochloric acid*. *[NOTE- Before weighing, remove the coating by washing the tablets with water. Dry the tablets with the help of tissue paper]*

Reference solution. Dissolve 100000 AU of *proteolytic enzyme mixture IPRS* into a 200-ml volumetric flask, add 100 ml of *0.001 M hydrochloric acid* with the aid of ultrasound, below 25°, flask to attain the room temperature and dilute to volume with *0.001 M hydrochloric acid*. Dilute 5.0 ml of the solution to 100.0 ml with *0.001 M hydrochloric acid*.

NOTE- Maintain the temperature of sonicator bath below 25° during a test solution and reference solution preparation.

Procedure for Proteolytic activity.

	Reference solution (Blank)	Reference solution preparation 1	Reference solution preparation 2	Test solution (Blank)	Test solution preparation 1	Test solution preparation 2
NOTE- maintain the temperature of enzymatic reaction at 25° ± 1°						
Reference solution	2 ml	2 ml	2 ml	---	---	---
Test solution	---	---	---	2 ml	2 ml	2 ml
0.3 M trichloroacetic acid	10 ml	---	---	10 ml	---	---
NOTE- Addition of hemoglobin substrate at a fixed time intervals (i.e. if addition of hemoglobin substrate at 0 minutes, then stop the reaction by addition of 0.3 M trichloroacetic acid at 20 minutes.)						
hemoglobin substrate	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml
NOTE- Stand for 20 minutes						
0.3 M trichloroacetic acid	---	10 ml	10 ml	---	10 ml	10 ml
NOTE- Stand for 10 minutes, filter.						

Transfer 5.0 ml of filtrate from each solution into a 25-ml volumetric flask, add 10.0 ml of *0.5 M sodium hydroxide* and immediately add 3 ml of dilute phenol reagent to, each of, the tubes. Maintain the temperature of solutions at 22° ± 2° for 15 minutes. Exactly after 15 minutes, measure the absorbance of blank, reference solution and the solution using 1 cm cell/cuvette at about 660 nm (2.4.7).

Trypsin-Chymotrypsin (in per cent) $= \frac{TA-TB}{SA-SB} \times \frac{Sw \times SAV}{200} \times \frac{5}{100} \times \frac{1000}{Tw} \times \frac{100}{5} \times \frac{AW}{LC} \times 100$

where,

TA= mean absorbance of test solution,
TB = absorbance of blank (test solution),
SA = mean absorbance of reference solution,
SB = absorbance of blank (reference solution),
Sw = weight of reference substance (in mg),
SAV = activity of the reference substance in AU per mg,
Tw = weight of tablets (in mg),
AW = average weight of decoated/decolorized tablets (in mg),
LC = label claim of tablet in AU.

Storage. Store protected from moisture, at a temperature not exceeding 25°.

Labelling. The label states the strength in terms of the equivalent to armour units of enzymatic activity.

4.2. General Reagents

Page 1213
Insert before **Heparin**
Hemoglobin Powder: Red to brown powder, commercially available
SOLUBILITY – A 10 mg portion dissolves in 10 ml of *0.06 M hydrochloric acid*.
LOSS ON DRYING (2.4.19) – Not more than 10 per cent when dried at 105° for 2 hours.
RESIDUE ON IGNITION – Not more than 5 per cent.
Store at a temperature below 30°**.**