



Edition: BP 2025 (Ph. Eur. 11.6 update)

## Pancreatin

### [General Notices](#)

### Action and use

Enzyme; treatment of pancreatic exocrine deficiency.

### Preparations

[Pancreatin Gastro-resistant Capsules](#)

[Pancreatin Granules](#)

[Pancreatin Gastro-resistant Tablets](#)

## DEFINITION

Pancreatin is a preparation of mammalian pancreas containing enzymes having protease, lipase and amylase activity. It may contain Sodium Chloride.

### Potency

Pancreatin contains in 1 mg not less than 1.4 Units of free protease activity, not less than 20 Units of lipase activity and not less than 24 Units of amylase activity.

## PRODUCTION

Pancreatin is prepared in conditions designed to minimise the degree of microbial contamination.

## CHARACTERISTICS

A white or buff amorphous powder.

Soluble or partly soluble in [water](#) forming a slightly turbid solution; practically insoluble in [ethanol \(96%\)](#) and in [ether](#).

## IDENTIFICATION

- A. It demonstrates free protease activity in the Assay for Free protease activity.
- B. Triturate 0.25 g with 10 mL of [water](#) and adjust to pH 8.0 by the addition of 1M [sodium hydroxide](#) using [cresol red solution](#) as indicator. Divide the resulting solution into two equal portions. Boil one portion [solution (1)] and leave the other untreated [solution (2)]. Dissolve 0.1 g of [soluble starch](#) in 100 mL of boiling [water](#), boil for 2 minutes, cool and dilute to 150 mL with [water](#). Add solution (1) to half the starch mucilage and solution (2) to the remainder and maintain the mixtures at 38° to 40° for 5 minutes. To 1 mL of each mixture add 10 mL of [iodinated potassium iodide solution](#). The liquid containing solution (2) retains the colour of the solution of iodine and the liquid containing solution (1) acquires an intense blue colour.

## TESTS

### Fat

Extract 1 g with [\*petroleum spirit\*](#) (boiling range, 40° to 60°) for 3 hours in an apparatus for the [\*continuous extraction of drugs\*](#), [Appendix XI F](#), evaporate the extract and dry the residue at 105° for 2 hours. The residue weighs not more than 30 mg.

### [Loss on drying](#)

When dried at 60° at a pressure not exceeding 0.7 kPa for 4 hours, loses not more than 5.0% of its weight. Use 0.5 g.

### Microbial contamination

1 g is free from [\*Escherichia coli\*](#); 10 g is free from [\*Salmonella\*](#), Appendix XVI B1.

## ASSAY

Carry out the *Assay of pancreatin*, [Appendix XIV I](#).

## STORAGE

Pancreatin should be stored at a temperature not exceeding 15°.

## LABELLING

The label states (1) the minimum number of Units of activity of free protease, lipase and amylase per mg; (2) the name of any added substance; (3) the date after which the material is not intended to be used; (4) the conditions under which it should be stored.