



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

Pancreatin Granules

[General Notices](#)

Action and use

Enzyme; treatment of pancreatic exocrine deficiency.

DEFINITION

Pancreatin Granules contain Pancreatin and may also contain suitable gastro-resistant substances.

The granules comply with the requirements stated under Granules and with the following requirements.

Content of pancreatin

Not less than 90.0% of the stated minimum number of Units of free protease activity, of lipase activity and of amylase activity.

IDENTIFICATION

- A. The granules demonstrate free protease activity in the Assay for Free protease activity.
- B. Triturate a quantity of powdered granules containing 2.5 g of Pancreatin with 100 mL of [water](#) and filter. Adjust 10 mL of the liquid 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.

ASSAY

Carry out the *Assay of pancreatin*, [Appendix XIV.I](#), using in the determination of each activity a quantity of the powdered granules estimated to contain the number of Units specified in the method.

STORAGE

Pancreatin Granules should be stored at a temperature not exceeding 15°, unless otherwise justified and authorised.

LABELLING

The label states (1) the minimum number of Units of free protease activity, of lipase activity and of amylase activity per g; (2) where applicable, that the granules contain gastro-resistant substances.

