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Pancreatin Gastro-resistant Tablets

[General Notices](#)

Pancreatin Tablets

Gastro-resistant Pancreatin Tablets

Action and use

Enzyme; treatment of pancreatic exocrine deficiency.

DEFINITION

Pancreatin Gastro-resistant Tablets contain Pancreatin. They are made gastro-resistant by enteric-coating or by other means.

PRODUCTION

A validated dissolution test capable of characterising the *in vitro* release of pancreatin, relevant to the dosing schedule recommended by the manufacturer, should be applied to demonstrate batch to batch consistency in dissolution characteristics.

The tablets comply with the requirements stated under Tablets and with the following requirements.

Content of pancreatin

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

IDENTIFICATION

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

Weigh and powder 20 tablets. Carry out the Assay of pancreatin, [Appendix XIV I](#), for Free protease activity, Lipase activity and Amylase activity.

STORAGE

Pancreatin Gastro-resistant Tablets should be stored at a temperature not exceeding 15°, unless otherwise justified and authorised.

LABELLING

The label states the minimum number of Units of free protease activity, of lipase activity and of amylase activity in each tablet.