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Pancreatin Gastro-resistant Capsules

General Notices

Pancreatin Capsules

Action and use

Enzyme; treatment of pancreatic exocrine deficiency.

DEFINITION

Pancreatin Gastro-resistant Capsules contain Pancreatin. They may be prepared by filling capsules with granules or particles that are covered with a gastro-resistant coating.

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 capsules comply with the requirements stated under Capsules 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. It demonstrates the presence of free protease activity in the Assay for Free protease activity.
B. Triturate a quantity of the contents of the capsules containing 2.5 g of Pancreatin with 100 mL of *water* and adjust to pH 8.0 by the addition of 1M *sodium hydroxide* using *cresol red solution* as indicator. Divide 10 mL of 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 1mL 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, for Free protease activity, Lipase activity and Amylase activity.

STORAGE

Pancreatin Gastro-resistant Capsules 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 capsules contain gastro-resistant substances.