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 Do not distribute

Pancreatin Tablets

» Pancreatin Tablets contain not less than 90.0 percent of the labeled amount of pancreatin.

Packaging and storage—Preserve in tight containers, preferably at a temperature not exceeding 30°.

Labeling—Label the Tablets to indicate minimum pancreatin fat digestive power; i.e., single strength, double strength, triple strength.

USP REFERENCE STANDARDS (11)—

[USP Bile Salts RS](#)
[USP Pancreatin Amylase and Protease RS](#)
[USP Pancreatin Lipase RS](#)

MICROBIAL ENUMERATION TESTS (61) and TESTS FOR SPECIFIED MICROORGANISMS (62)—Tablets meet the requirements of the test for absence of *Salmonella* species and *Escherichia coli*.

DISINTEGRATION (701): 60 minutes.

Assay for amylase activity (Starch digestive power)—Weigh and finely powder not fewer than 20 Tablets, avoiding the production of heat during the process. Proceed as directed in the Assay for amylase activity under [Pancreatin](#), using as the assay preparation an accurately weighed portion of the powder, equivalent to 40 mg of pancreatin. (Use an inversely proportionate amount of the powder if the Tablets are labeled to contain a whole-number multiple of the minimum requirement for pancreatin digestive activity.)

Assay for lipase activity (Fat digestive power)—

Acacia solution, Olive oil substrate, Buffer solution, Bile salts solution, and Standard test dilution—Prepare as directed in the Assay for lipase activity under [Pancreatin](#).

Assay test dilution—Proceed as directed for Assay test dilution in the Assay for lipase activity under [Pancreatin](#), using as the assay preparation an accurately weighed portion of the powder, prepared as directed in the Assay for amylase activity, equivalent to about 200 mg of pancreatin. *Procedure and Calculation of potency*—Proceed as directed in the Assay for lipase activity under [Pancreatin](#).

Assay for protease activity (Casein digestive power)—

Casein substrate, Buffer solution, Trichloroacetic acid solution, Filter paper and Standard test dilution—Prepare as directed in the Assay for protease activity under [Pancreatin](#).

Assay test dilution—Add an accurately weighed portion of the powder, prepared as directed in the Assay for amylase activity, equivalent to about 100 mg of pancreatin, to 100.0 mL of *Buffer solution*, and mix by shaking intermittently at room temperature for 25 minutes. Dilute quantitatively with *Buffer solution* to obtain a dilution that corresponds in activity to the *Standard test dilution*.

Procedure and Calculation of potency—Proceed as directed in the Assay for protease activity under [Pancreatin](#).

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
PANCREATIN TABLETS	Julie Zhang Associate Science & Standards Liaison	BIO2 Biologics Monographs 2 - Proteins
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO2 Biologics Monographs 2 - Proteins

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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