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Pancrelipase Delayed-Release Capsules

» Pancrelipase Delayed-Release Capsules contain an amount of Pancrelipase equivalent to not less than 90.0 percent and not more than 165.0 percent of the labeled lipase. It contains not less than 90.0 percent of the labeled activities of amylase and protease expressed in the respective USP Units.

Packaging and storage—Preserve in tight containers at controlled room temperature.

Labeling—Label the Capsules to indicate lipase, amylase, and protease activities in USP Units. The label also indicates that the Capsule contents are enteric-coated.

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⟩—Capsules meet the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*.

Dissolution ⟨711⟩—

Part 1—

Medium: simulated gastric fluid TS, without enzyme; 800 mL.

Apparatus 1: 100 rpm.

Time: 60 minutes.

Part 2—

pH 6.0 phosphate buffer—Dissolve 8 g of sodium chloride and 36.8 g of monobasic potassium phosphate in 4000 mL of water. Adjust with 2 N sodium hydroxide to a pH of 6.0 ± 0.1.

Medium: pH 6.0 phosphate buffer; 800 mL.

Apparatus 2: 100 rpm.

Time: 30 minutes.

Standard solution—Proceed as directed under *Standard test dilution* in the *Assay for lipase activity* under *Pancrelipase*, except to use the *Dissolution Medium* in place of cold water.

Test solution—Empty the contents of 10 Capsules, and transfer an accurately weighed portion of the contents, equivalent to the concentration of USP Units of lipase activity per mL in the *Standard solution* (between 8 and 16 Units per mL), to *Apparatus 1*.

Procedure—Proceed according to the conditions for *Part 1*. After 1 hour, remove the baskets, and allow the excess *Dissolution Medium* to drain. Transfer the contents of each basket to the dissolution vessels in *Part 2* with the aid of a few mL of *Dissolution Medium*. Proceed according to the conditions for *Part 2*. After 30 minutes, remove a 10-mL portion of the solution under test, transfer to a test tube, and cool to 4°. Proceed as directed in the *Assay for lipase activity* under *Pancrelipase*.

Tolerances—Not less than 75% *(Q)* of the labeled USP Units of lipase activity per Capsule is dissolved.

Loss on drying ⟨731⟩—Dry the contents of 10 Capsules in vacuum at 60° for 4 hours: the test specimen loses not more than 5.0% of its weight.

Assay—Weigh the contents of not less than 10 Capsules, and determine the average weight per Capsule. Grind the contents, mix the combined contents, and proceed as directed in the *Assay for lipase activity*, the *Assay for amylase activity*, and the *Assay for protease activity* under *Pancrelipase*.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
PANCRELIPASE DELAYED-RELEASE CAPSULES	Jennifer Tong Sun Senior Scientist II	BIO2 Biologics Monographs 2 - Proteins

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO2 Biologics Monographs 2 - Proteins

Chromatographic Database Information: Chromatographic Database

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