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Pancrelipase Capsules

» Pancrelipase Capsules contain an amount of Pancrelipase equivalent to not less than 90.0 percent and not more than 150.0 percent of the labeled lipase activity expressed in USP Units, the labeled activity being not less than 8000 USP Units per Capsule. They contain, in each Capsule, the pancrelipase equivalent of not less than 30,000 USP Units of amylase activity, and not less than 30,000 USP Units of protease activity.

Packaging and storage—Preserve in tight containers, preferably with a desiccant, at a temperature not exceeding 25°.

Labeling—Label the Capsules to indicate lipase activity in USP Units.

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*.

LOSS ON DRYING (731).—Dry the contents of 10 Capsules in vacuum at 60° for 4 hours: it 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. Mix the combined contents, and proceed as directed for Assay for amylase activity, Assay for lipase activity, and [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 CAPSULES	Jennifer Tong Sun Senior Scientist II	BI02 Biologics Monographs 2 - Proteins
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BI02 Biologics Monographs 2 - Proteins

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:
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