



Scientific Protein Laboratories LLC
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Technical Data Sheet PANCRELIPASE USP

Pancrelipase USP contains enzymes (principally lipase, amylase, and protease) and is obtained from porcine raw materials gathered under the continuous inspection of the United States Department of Agriculture and/or Agriculture Canada under the Federal Meat Inspection Act. The facilities and controls used for its manufacture are in conformity with FDA current Good Manufacturing Practice regulations and SPL Pancrelipase USP meets all the declared standards, tests, assays, and other specifications of the current revision of the United States Pharmacopoeia (USP).

DESCRIPTION

Pancrelipase USP is a cream-colored, amorphous powder, having a faint, characteristic (meaty), but not offensive odor.

USES

Pancrelipase USP is used for treatment of pancreatic insufficiency. In addition, Pancrelipase USP is used in many industrial and food applications.

SPECIFICATIONS

| | |
|--------------------------|--------------------------------|
| Lipase | Not Less Than 24 USP Units/mg |
| Protease | Not Less Than 100 USP Units/mg |
| Amylase | Not Less Than 100 USP Units/mg |
| Fat | Not More Than 5.0% |
| Loss on Drying | Not More Than 5.0% |
| Salmonella | Negative |
| E. Coli | Negative |

CERTIFICATION

Each lot is carefully analyzed at the time of manufacture. A Certificate of Analysis and Material Safety Data Sheet accompany each order.

SOLUBILITY

Pancrelipase USP is partly soluble in water and insoluble in alcohol.

PACKAGING

Pancrelipase USP is routinely packaged in polyethylene liners inside heat-sealed foil pouches.

STORAGE

Preserve in tight containers, preferably at a temperature not exceeding 25° C.