



Scientific Protein Laboratories LLC
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Technical Data Sheet PANCREATIN 8X USP

Pancreatin 8X 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 Pancreatin 8X USP meets all the declared standards, tests, assays, and other specifications of the current revision of the United States Pharmacopoeia (USP).

DESCRIPTION

Pancreatin 8X USP is a cream-colored, amorphous powder, having a faint, characteristic, but not offensive odor. Pancreatin 8X USP converts not less than 200 times its weight of USP Potato Starch Reference Standard into soluble carbohydrates and not less than 200 times its weight of casein into proteoses. Pancreatin 8X USP hydrolyzes fats to glycerol and fatty acids, changes protein into proteoses and derived substances, and converts starch into dextrans and sugar. It is more active in neutral or faintly alkaline media.

USES

Pancreatin 8X USP is used for treatment of pancreatic insufficiency. In addition, Pancreatin 8X USP is used in many industrial and food applications.

SPECIFICATIONS

Lipase	Not Less Than 16 USP Units/mg
Protease	Not Less Than 200 USP Units/mg
Amylase	Not Less Than 200 USP Units/mg
Fat	Not More Than 6.0%
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

Pancreatin 8X USP is partly soluble in water and insoluble in alcohol.

PACKAGING

Pancreatin 8X USP is routinely packaged in polyethylene liners inside heat-sealed foil pouches.

STORAGE

Preserve in tight containers at a temperature not exceeding 30° C.

EXPIRATION DATE: 24 months