

HIGH LIPASE PANCREATIC ENZYME CONCENTRATE

Description

High Lipase Pancreatic Enzyme Concentrate is a brown to light brown colored powder that contains enzymes (principally lipase, amylase, and protease) derived from porcine pancreas glands that are gathered in accordance with United States Department of Agriculture and/or European Union regulations and accompanied by all required Veterinary or Health

Certificates. Pancreatic Enzyme Concentrate is manufactured in conformity with FDA Current Good Manufacturing Practice regulations and meets all declared standards, assays, and other specifications of the current version of the United States Pharmacopeia Monograph for Pancrelipase.

Uses

High Lipase Pancreatic Enzyme Concentrate is used for the treatment of pancreatic insufficiency in humans, especially when the digestion of lipids is of high

importance. It may also be used in the treatment of animals, if applicable.

Specifications

Lipase Activity	40 - 140 USP Units/mg ¹
Protease Activity	280 - 440 USP Units/mg ¹
Amylase Activity	210 - 570 USP Units/mg ¹
Fat	Not More than 5.0%
Loss on Drying	Not More than 5.0%
Total Aerobic Microbial Count	Not More than 2,000 CFU/g
Total Yeast and Molds Count	Not more than 100 CFU/g
Salmonella	Negative
Escherichia coli	Negative

¹ Customized enzyme activity ranges can be targeted to meet project-specific needs.

Certification

Each lot is analyzed at the time of manufacture in accordance with the USP monograph for Pancrelipase. Other test results, customized product specifications,

and compliance documentation may be available upon request. Minimally, a Certificate of Analysis and Material Safety Data Sheet accompany each order.

Packaging

Routinely packaged in poly-liners inside heat-sealed foil pouches inside a fiber or poly drum.

Storage

Preserved in airtight containers. Store up to 25°C (77°F); excursions permitted between 15°C and 30°C (59°F and 86°F).