Pancreatin

— · CAS 8049-47-6 · Pancreatin, powder

CATALOG TDS — CONFIRMED IN WRITING AT QUOTATION

CHEMICAL FORM	FORMULA	CAS	PRIMARY ASSAY
Pancreatin, powder	—	8049-47-6	≥25 USP U/mg
METHOD	**MINIMUM ORDER**	**LEAD TIME**	**STANDARD PACK**
USP activity assays (amylase, protease, lipase)	1 kg	1–7 days	1 kg foil pouch · 25 kg fiber drum

DESCRIPTION

Pancreatin specified to the USP triad: amylase, protease and lipase activities; the three units, the assay substrates and the ratio are the specification.

SPECIFICATION

PARAMETER	SPECIFICATION	METHOD / NOTE
Amylase activity	≥25 USP U/mg	As stated
Protease activity	≥25 USP U/mg	As stated
Lipase activity	≥2 USP U/mg	As stated
Appearance	Off-white to light tan powder	As stated
Identification	Activity assay and IR conform	As stated
Loss on drying	≤5.0%	As stated
Heavy metals	Pb ≤3 · As ≤2 · Cd ≤1 · Hg ≤0.1 mg/kg	As stated
Microbiology	APC ≤1,000 cfu/g · yeast and mould ≤100 cfu/g · E. coli and Salmonella absent	As stated
Particle size	≥95% through 40 mesh	As stated
Marker set	Pancreatin: amylase ≥25, protease ≥25, lipase ≥2 USP U/mg	Identity
Solubility	Soluble in water; the solution is slightly turbid.	Matrix dependent

APPLICATIONS

- Capsules and tablets
- Powder blends

AVAILABLE FORMS

- Powder, 40 mesh
- Granulated on request

PACKING

- 1 kg foil pouch

STORAGE

• 25 kg fiber drum	Store in a cool, dry, well-ventilated area, away from direct sunlight and moisture. Keep the pack closed after sampling. The lot-specific retest date is shown on the batch COA.

DOCUMENTATION RELEASED WITH EACH LOT

- Batch-specific certificate of analysis
- Technical data sheet and safety data sheet
- Allergen, GMO, origin and residual-solvent statements
- Third-party reports on request

> **Catalog document.** This TDS describes the grade we can quote. The final specification, pack and documentation are confirmed in writing before the order. It is not a batch COA and does not report a result for a specific lot.

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