Pancreatin

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

INDICATIVE SPECIFICATION — 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

SPECIFICATION

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

APPLICATIONS

- Capsules and tablets
- Powder blends

AVAILABLE FORMS

- Powder, 40 mesh
- Granulated on request

WHAT TO CONFIRM BEFORE ORDERING

- Name the standard: pancreatin is a triad, not a single activity; the three units and substrates must travel with the number.
- Ask for the ratio of amylase, protease and lipase; a high total with the wrong ratio is not the same product.
- The enzymes lose activity with heat and moisture; the pack and the storage condition belong in the specification.

- Do not use the page as a label or a claim: the finished product's status is a separate legal question.

> **Indicative document.** This sheet describes the grade we can quote; it is not a batch COA and does not confirm a result for a specific lot. Final specification, contaminant limits and documentation are agreed in writing before the order. The form, hydrate state, ligand ratio and method are release parameters, not marketing descriptions.

DOCUMENTATION RELEASED WITH EACH LOT

DOCUMENT	CONTENT	SCOPE
Certificate of analysis	Assay, identity, physical parameters, contaminant panel and the release decision for the lot.	Batch-specific
Technical data sheet	Form, hydrate state, CAS, specification ranges, solubility, bulk density, storage and packing.	Product-level
Safety data sheet	Sixteen sections covering hazards, handling, storage, transport and emergency response.	Grade-specific
Allergen and GMO statements	Major allergens, gluten, animal-derived inputs and GMO status.	Batch-specific
Origin and traceability record	Manufacturing site and the link between the lot and the retained sample.	Batch-specific
Residual-solvent statement	The crystallisation system and the solvent class, where applicable.	Batch-specific

HOW TO REQUEST THIS GRADE

01 · BRIEF

Send the target specification, quantity, dosage form and destination market.

02 · COUNTER-SPEC

We confirm what can be matched and the documents available for the grade.

03 · SAMPLE & QUOTE

A sample with its own COA, followed by packing, lead time and terms in writing.

No claim is made here. This sheet does not claim a therapeutic effect, a product certification or a regulatory approval. Health claims belong to the brand that makes them and to the market that authorises them.

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