Pancreatin

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

SPECIMEN — LIMITS ONLY · BATCH RESULTS ISSUED WITH THE LOT

PRODUCT	CHEMICAL FORM	CAS	SPECIFICATION VERSION
Pancreatin	Pancreatin, powder	8049-47-6	Catalog · confirmed at quotation
BATCH NUMBER	**MANUFACTURE DATE**	**RETEST DATE**	**RELEASE DECISION**
Issued with the lot	Issued with the lot	Issued with the lot	Issued with the lot

RELEASE SPECIFICATION

PARAMETER	SPECIFICATION	METHOD
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

LOT FIELDS

A batch-specific certificate replaces the fields above with the measured result, the method actually used, the batch number, the manufacture and retest dates, and the release signature. The catalog limits on this page are the release window, not a result.

STATEMENT

This specimen shows the format and the release specification. It is not a batch COA and must not be presented as one. The COA that ships with a lot is issued from the released batch and is available before dispatch.

Pack and storage. 1 kg foil pouch · 25 kg fiber drum. Store closed in a cool, dry place, away from direct sunlight and moisture. The lot-specific retest date is shown on the batch certificate.