

DATASHEET

Cat.No. 30303

Neutral Protease NB GMP Grade

Origin	<i>Clostridium histolyticum</i>	
Composition	Neutral Protease	
Molecular weight	34 kDa	
Special features	Manufactured according to international cGMP guidelines	
Characters	Beige to brown, 0.2 μm filtered, chromatographically purified, lyophilisate	
Protein content	Lowry assay	approx. 85%
Identification	SDS-PAGE	Main band must comply
Test	Water	$\leq 15\%$ (w/w)
Microbiological examination	Total viable aerobic bacteria and fungi (Pharm. Eur.)	$\leq 10/\text{Vial}$
	Absence of <i>Clostridia</i> (Pharm. Eur.)	Must comply
	Abnormal toxicity (General-Safety-Test; Pharm. Eur.)	Must comply
Activities	Neutral Protease (DMC assay ¹)	≥ 100 U/Vial
	Neutral Protease (DMC assay ¹)	≥ 0.50 U/mg lyophilisate
Bacterial endotoxins	LAL assay	≤ 100.0 EU/mg lyophilisate
Long term storage	+2 to +8°C	
Long term stability data	5°C \pm 3°C	3 years (after manufacture)

Unit definition

Neutral Protease (DMC assay¹)

1 DMC Unit catalyzes the cleavage of 1 μmol peptide bond from dimethylcasein per minute at 25°C, pH 7.0, expressed in terms of newly formed terminal amino groups, determined with trinitrobenzene sulfonic acid (TNBS).

¹ Lin, Y. et al.; J. Biol. Chem. **244**, 789-93 (1969).