



Trafa Pharmaceutical Inc.

140 Padgette Street, Unit D
Chicopee, MA 01022, USA

Tel: 1-866-99-Trafa (87232) FAX: 1-800-627-1880

Sales@TrafaPharma.com www.TrafaPharma.com


SPECIFICATION SHEET

Product Name	Pancreatin 4X USP
--------------	-------------------

TEST	SPECIFICATION	METHOD
Appearance	Fine white to cream powder with characteristic odour and taste	Visual
Protease Activity (USP units/mg)	≥105 USP units/mg	USP Monograph
Amylase Activity (USP units/mg)	≥105 USP units/mg	USP Monograph
Lipase Activities (USP units/mg)	10 min USP units/mg	USP Monograph
Fat content	≤6.0%	USP Monograph
Loss on drying	≤5.0%	USP <731>
Heavy metals	20 ppm max.	USP <231>
Lead	1 ppm max	USP <251>
Arsenic	1 ppm max	USP <211>
Particle Size	80-100 mesh	US Screen
Total Bacteria count	≤1000/g	USP <61>
Yeast and Moulds	≤100/g	USP <61>
E. Coli	Negative	USP <62>
Salmonellae	Negative	USP <62>

Storage: In a cool & dry place, do not freeze. Keep away from strong light and heat.

Note: The above information is based on the specification sheet received from the manufacturer of this product and not intended as a substitute for strict quality control analysis by the purchaser of this product.

Reviewed by : 
Abdullah Malik (QA)