



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 8x USP
Batch Quantity	500kgs

TEST	SPECIFICATION	METHOD
Appearance	Fine white to cream powder with characteristic odor and taste	Visual
Protease Activity (USP units/mg)	≥ 200 USP units/mg	USP Monograph
Amylase Activity (USP units/mg)	≥ 200 USP units/mg	USP Monograph
Lipase Activities (USP units/mg)	≥ 20 USP units/mg	USP Monograph
Fat content	$\leq 5.0\%$	USP Monograph
Loss on drying	$\leq 5.0\%$	USP <731>
Heavy metals	20 ppm max.	USP <231>
Lead	1 ppm max	USP <251>
Arsenic	2 ppm max	USP <211>
Particle Size	60 mesh	US Screen
Total Bacteria count	$\leq 1000/g$	USP <61>
Yeast and Moulds	$\leq 100/g$	USP <61>
E. Coli	Negative	USP <62>
Salmonella	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 certificate of analysis 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)