

Trafa Pharmaceutical Inc.

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Specification Sheet

Product Name		OX BILE POWDER	
Animal Origin		Bovine	
Country of Origin		Argentina	
1) Animal Species : Bovine			
2) All animal born, raised and was slaughtered in Argentine			
3) Argentine is a country free from BSE (Bovine Spongiform Encephalopathy)			
4) The product is free from: Additives, hormones, solvents residues and pesticides			
EXAMINATION	SPECIFICATION		METHOD
Description	Brownish powder with characteristic odor and		
			-
	taste		
PH 20°C (5% sol)	6 to 12		<791>USP valid method
Loss on drying	NMT 5%		<731>USP valid method
Cholic Acid dry base	40% to 45%		HPLC
Heavy Metals	Less than 20 ppm		<231>valid method (I)
Arsenic	2 ppm		ICP-MS
Cadmium	1 ppm		ICP-MS
Lead	1 ppm		ICP-MS
Mercury	0.5 ppm		ICP-MS
MICROBIOLOGICAL ANALYSIS			
Total aerobic microbial count	Less than 3,000cfu/g		<61>USP valid method
Mold and Yeast	Less than 100 cfu/g		<61>USP valid method
Salmonella species	Negative		<62>USP valid method
Escherichia coli	Negative		<62>USP valid method
Staphylococcus aureus	Negative		<62>USP valid method
Pseudomona aeruginosa	Negative		<62> USP valid method
Coliforms	Absence		<62> USP valid method

Note: The above information is based on the ur geldledqp'uj ggv received from the manufacturer of this product and not intended as a substitute for strict quality control analysis by the purchaser qh'yj ku'product.

Reviewed by:

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