



# Trafa Pharmaceutical Inc.

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## SPECIFICATION SHEET

Product Name	PORCINE SPLEEN SUBSTANCE POWDER	
Country of Origin	Argentina	
EXAMINATION	SPECIFICATION	METHOD
Description		-
PH 20 °C (5% sol)	4.5 to 5.5	USP valid method<791>
Loss on drying	No More Than 6%	USP valid method<731>
Residue on ignition	No More Than 7.3%	USP valid method<281>
Nitrogen	11.2% to 14%	USP valid method<461>
Proteins	70% to 87.50%	Nitrogen * 6.25
Fat	No More Than 4.5%	Pancreatin USP valid method page 4702
Particle size distribution	90% to 100% 80 mesh	USP valid method<786>
Heavy metals	Less than 20 ppm	USP valid method(I)<231>
MICROBIOLOGICAL ANALYSIS		
MICROBIOLOGICAL CONTROL		
Total aerobic microbial count	Less than 10.000 cfu/g	USP valid method<61>
Mold and Yeast	Less than 1000 cfu/g	USP valid method<61>
Salmonella	Negative	USP valid method<62>
Escherichia coli	Negative	USP valid method<62>
Staphylococcus aureus	Negative	USP valid method<62>
Pseudomona aeruginosa	Negative	USP valid method<62>
Coliforms	Absence	USP valid method<62>

Three years from COFA date.  
Periodic Stability Test.

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 : \_\_\_\_\_  
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