

TITAN BIOTECH LIMITED

A-902A, RIICO INDUSTRIAL AREA PHASE-III

BHIWADI- 301019, (Raj.)

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STANDARD TESTING SPECIFICATION

For

OX BILE DRIED (REFINED) (FOR ROUTINE USE) CODE -1520

PHYSICAL PARAMETERS

S.L. No.	PRODUCT PARAMETERS	SPECIFICATION
1.	Appearance	Greenish yellow colour free flowing powder having characteristic bile odour but not pungent smell.
2.	Solubility (2% soln. at 25 °C)	Soluble in distilled water and alcohol.
3.	Clarity (2% Soln. at 121 °C.)*	Slightly opalescent, near to clear.

* -After Autoclave

CHEMICAL PARAMETERS

S.L. No.	PRODUCT PARAMETERS	SPECIFICATION
1.	pH (2% soln. at 25 °C)	6.0-7.5
2.	Loss on drying (at 105 °C)	NMT-5.0%
3.	Bile Acid (As Cholic Acid)	NLT- 45.0%
4.	Total Ash	NMT-18.0%
5.	Chloride (as NaCl)	NMT- 6.0%

MICROBIAL PARAMETERS

S.L. No.	PRODUCT PARAMETERS	SPECIFICATION
1.	Total viable count	NMT-10,000cfu/gm
2.	<i>Escherichia coli</i>	Negative
3.	<i>Salmonella spp.</i>	Negative
4.	<i>Staphylococcus aureus</i>	Negative
5.	Yeast & molds	100/gm

GROWTH PROMOTION TEST

Cultural Characteristic observed in MacConkey agar 0.5% Ox Bile Dried (Refined) after incubation at 35-37°C for 18-24 hours.

S.L. No.	MICROORGANISMS	ATCC	GROWTH
1.	<i>Staphylococcus aureus</i>	25923	Inhibited
2.	<i>Escherichia coli</i>	25922	Good-Luxuriant
3.	<i>Enterococcus faecalis</i>	29212	Good-Luxuriant
4.	<i>Streptococcus pyogenes</i>	19615	Good-Luxuriant

Std Packing : 25.0 Kg. HDPE Drum/Paper Bag.

Best Before : 36 Months

Storage : Hygroscopic in nature, store below 25 °C and protect direct sunlight.

Checked by

Approved by