

Product Specification

PRODUCT	PROGESTIVE® 15 Billion	WEF : APR 2010
Specf No: FPS/PG/01	Revision No : 01	Page No : 01 of 03
Review Period : 2 Yr		
Prepared By : J Anand	Verified By: A Mishra	Approved By : Dr Ajay

Name of Species	<i>Bacillus coagulans</i>
Country of Origin	India
Description	Off white dry powder with characteristic odor
Best before	2 Yr From Manufacturing date.

SPECIFIED TEST	LIMITS	PROTOCOL OF ANALYSIS
1) Physiochemical Analysis		
Identification	By Microscopy	As per IHP
Solubility in Water	Partly Soluble	As per IHP
pH of w/v suspension	3 - 7	As per API
Loss On Drying (Moisture)	< 5% W/W	As per API
Ash content	< 10.0 % w/w	As per API
Acid insoluble ash	< 2.0% W/W	As per API
Bulk density	0.5 - 0.8 gm/ml	As per API
Heavy Metals content	< 20 ppm	As per API
Arsenic (As)	<1ppm	As per API
Plumbum (Pb)	<10ppm	As per API
Cadmium (Cd)	<0.3ppm	As per API
Mercury (Hg)	< 1.0ppm	As per API
Particle Size	90% through 60 Mesh	As per IHP

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2) Microbiological		
Total Fungal Count	<100 CfU/g	as per I.P / B.P
Total Enterobacteriaceae	<100 CfU/g	As per B.P
E. coli	Negative/ 1Gm	as per I.P / B.P
Salmonella typhii	Negative/ 10gm	as per I.P / B.P
S. aureus	Negative/ 1gm	as per I.P / B.P
P.aeruginosa	Negative/ 1gm	as per I.P / B.P
3) Active Analysis		
Viable Spore count	>15000 Million/Gram	As per IHP
Lactic Acid Producing Capacity	> 10ml of 0.05 N NaOH	As per IHP
Other organism	< 7.5 million cfu/gm	As per IHP

1. Storage Condition : Store in dry place at Room temperature