



Sabinsa Poland Sp. z o.o.

*Pharmaceuticals *Phytochemicals

*Fine Chemicals *Herbal Extracts

*Cosmeceuticals *Specialty Chemicals

CERTIFICATE OF ANALYSIS

Page 1 of 3

Product Name LactoSpore® (15 Billion Units/Gm)
Product Code 1200
Batch No. G220129
TR No. NL22F0074
Date of Manufacture February 2022
Date of Expiry January 2025

Strain	Bacillus coagulans MTCC 5856		
Preparation type	Fermentation		
Standardization	Bacillus coagulans viable spore count		
Excipient used	Maltodextrin		
	Excipient name	%Used	CAS No.
	Maltodextrin	85% to 90%	9050-36-6
Parameters	Result	Limit	Reference
PHYSICAL			
Description	Complies	White to off white powder with mild characteristic odour	Visual and Organoleptic
Microscopy	Complies	Complies	USP <776>
Solubility	Complies	Slightly soluble in water, insoluble in methanol	USP
Loss on drying	4.57 % w/w	Not more than 8.0% w/w (dried at 105°C)	EP 2.2.32
Lactic acid producing capacity	12.30 ml	Not less than 10ml of 0.05 N NaOH is consumed	SLL/STP-L-015
Sieve Test (Passes through)			USP <786>
- 20 mesh	100.00 % w/w	Not less than 100% w/w	
- 40 mesh	100.00 % w/w	Not less than 95% w/w	
- 80 mesh	93.21 % w/w	Not less than 90% w/w	
CHEMICAL			
Assay			
Bacillus coagulans viable spore count	20300.00 million spores/g	Not less than 15,000 million spores per gram	SLL/STP-B-014

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Parameters	Result	Limit	Reference
OTHERS			
Lead	<0.2 ppm (µg/g)	Not more than 3ppm (µg/g)	USP <2232>
Arsenic	<0.2 ppm (µg/g)	Not more than 1ppm (µg/g)	USP <2232>
Cadmium	<0.2 ppm (µg/g)	Not more than 1ppm (µg/g)	USP <2232>
Mercury	<0.02 ppm (µg/g)	Not more than 0.1ppm (µg/g)	USP <2232>
MICROBIOLOGICAL PROFILE			
Other aerobic microorganisms	0.0025 Million cfu/g	Not more than 0.1 Million cfu/g	SLL/STP-O-009
Total yeasts and molds count	<10 cfu/g	Not more than 100cfu/g	EP 2.6.12
Escherichia coli	Complies	Negative/10g	EP 2.6.13
Salmonella	Complies	Negative/10g	EP 2.6.13
Staphylococcus aureus	Complies	Negative/10g	EP 2.6.13
Pseudomonas aeruginosa	Complies	Negative/10g	EP 2.6.13
Bile tolerant Gram negative bacteria	<100 cfu/g	Not more than 100cfu/g	EP 2.6.13
Coliforms	<10 cfu/g	Less than 10cfu/g	BAM 2001, 8th Edition, Chapter 4
ADDITIONAL INFORMATION			
Sanitising treatment	Non-irradiated and not treated with ETO		
Certification Status (Kosher/Halal)	Kosher certified, Halal certified		

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Genetic Modification Status	Non-GMO Project Verified
BSE/TSE status	BSE / TSE free
Country of Origin	India
Storage condition	Store at room temperature
Manufactured By	Sami-Sabinsa Group Limited 19/1,19/2 I Main, II Phase,Peenya Industrial Area,Bangalore - 560058, Karnataka, India
Manufactured At	Sami-Sabinsa Group Limited- Nelamangala No. 19/3, 20/1 & 20/2/2, Bhavikere Village, Kasaba Hobli,Nelamangala - 562123

The above certificate of analysis is based **Specifications Issue No: 6 Dated: September 16, 2020** on

****In-House developed and validated methods**

NAP:Not Applicable

NAV:Not Available

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