

**FINISHED PRODUCT SPECIFICATION**

Product Boswellin® HBD	Issue No. 8	Supersedes Issue No.7, dtd 14/06/2021	Page Number Page 1 of 3
Prepared by Supriya Shetty Documentation Officer	Approved by Dr. Satish Sawant Vice President Analytical R&D		Effective date June 24, 2022

Product code	0246
Category	Intended for Nutraceutical application
Botanical/Scientific name	Boswellia serrata
CAS No	97952-72-2
Plant part	Gum resin exudate
Preparation type	Extraction
Final extract ratio	5:1 to 10:1
Standardization	Total boswellic acids
Excipient used	None



Parameters	Limit	Reference
PHYSICAL		
Description	Off white to pale brown powder with characteristic odour	Visual and Organoleptic
Identification	To comply by HPLC	SLL/STP-B-002
Solubility	Soluble in alcohol and insoluble in water	USP
Water content by KF method	Not more than 5.0% w/w	USP <921>
Ash content	Not more than 3.0% w/w	EP 2.4.16 Method - II
pH (1% w/v suspension in water)	Between 4.0 and 6.0	USP <791>
Specific optical rotation (0.75% w/v solution in chloroform at room temperature)	Not less than +40° on anhydrous basis	USP <781>
Melting range	Not less than 85°C	USP <741>
Tapped bulk density	Between 0.50g/ml and 0.80g/ml	EP 2.9.34 Method - I
Loose bulk density	Between 0.30g/ml and 0.60g/ml	EP 2.9.34 Method - I
Sieve Test (Passes through)		USP <786>
- 20 mesh	Not less than 95% w/w	
- 40 mesh	Not less than 70% w/w	
- 80 mesh	Not less than 40% w/w	
CHEMICAL		
Assay		
-Content of total boswellic acids by Titration	Not less than 70.0% w/w and not more than 85.0% w/w on anhydrous basis	SLL/STP-B-002
-Comprised of identified β -boswellic acids by HPLC	Not less than 20.0% w/w and not more than 30.0% w/w on anhydrous basis	SLL/STP-B-002
-Content of 3-O-Acetyl-11-keto- β -boswellic acid by HPLC	Not less than 2.0% w/w	SLL/STP-B-002
OTHERS		

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Parameters	Limit	Reference
Lead	Not more than 2ppm (µg/g)	USP <2232>
Arsenic	Not more than 1ppm (µg/g)	USP <2232>
Cadmium	Not more than 1ppm (µg/g)	USP <2232>
Mercury	Not more than 0.1ppm (µg/g)	USP <2232>
Residual solvents	To comply as per EU Directive 2009/32/EC	USP <467>
Residual pesticides	To comply as per the EU REGULATION (EC) No 396/2005	USP <561>
Total aflatoxins (B1, B2, G1 and G2)	Not more than 4ppb (µg/kg)	SLL/STP-A-044
-Aflatoxin B1	Not more than 2ppb (µg/kg)	SLL/STP-A-060
Poly Aromatic Hydrocarbons (PAH)		SLL/STP-P-054
-Benzo(a)pyrene	Not more than 10ppb (µg/kg)	
-PAH4 (Sum of Benzo(a)pyrene, Benz(a)anthracene, Benzo(b)fluoranthene and Chrysene)	Not more than 50ppb (µg/kg)	
Ethylene oxide (Sum of Ethylene oxide and 2-Chloroethanol)	Not more than 100ppb (µg/kg)	SLL/STP-E-015

MICROBIOLOGICAL PROFILE

Total aerobic microbial count	Not more than 5000cfu/g	EP 2.6.31
Total yeasts and molds count	Not more than 100cfu/g	EP 2.6.31
Escherichia coli	Negative/10g	EP 2.6.31
Salmonella	Negative/25g	EP 2.6.31
Staphylococcus aureus	Negative/10g	EP 2.6.13
Pseudomonas aeruginosa	Negative/10g	EP 2.6.13
Bile tolerant Gram negative bacteria	Not more than 100cfu/g	EP 2.6.31
Coliforms	Less than 10cfu/g	BAM Chapter 4

ADDITIONAL INFORMATION

Sanitising treatment	Non-irradiated and not treated with ETO
Certification Status (Kosher/Halal)	Kosher and Halal certified
BSE/TSE status	BSE / TSE free
Genetic Modification Status	Non-GMO Project Verified
Cultivated or wild crafted	Wild crafted
Country of Origin	India
Storage condition	Store at room temperature
Shelf Life	5 Year(s)
Manufactured by	Sami-Sabinsa Group Limited - Peenya 19/1, 19/2, I Main II Phase, Peenya Industrial Area, Bangalore. 560 058, Karnataka, India



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*Since it is a herbal product, there is likely to be minor colour variation from batch to batch of the product because of the geographical and seasonal variations of the raw material.

*Natural products can be hygroscopic and may agglomerate sometimes. It is suggested to sift the product before use.

**Material complies to USP <561> and European Regulation 396/2005/CE pesticides analysis, based on historical data review and routine testing.

Sabinsa sells product at B2B level globally; end client must take into consideration local finished product legislations and authorizations.