

SABINSA CORPORATION

FINISHED PRODUCT SPECIFICATION

Product PTEROWHITE® 90%		Issue No. 3.0	Supercedes Issue No.2 dtd 05/16/2011	Page Number Page 1 of 2
Prepared by	Approved by		Effective date	Review date
CHAYADEVI Junior Executive	Dr.S Natarajan Executive Vice President		June 14, 2014	June 13, 2017

Product code	1675					
Category	Intended for Cosmeceutical applicat	ion				
Botanical/Scientific name	Pterocarpus marsupium					
CAS No	Pterostilbene: 537-42-8 (trans)					
Plant part	Wood					
Preparation type	Extraction					
Solvent used for extraction	Methanol					
Solvent used in manufacture	Hexane, Ethyl acetate and Ethanol					
Final extract ratio	200:1 to 225:1					
Standardization	Pterostilbene					
Excipient used	None					
Parameters	Limit	Reference				
PHYSICAL						
Description	Off white powder*	Visual				
Identification	To comply by HPLC	SLL/STP-P-011**				
Solubility	Soluble in alcohol, insoluble in water	USP				
Loss on drying	Not more than 2.0% w/w (dried at 80°C, under vacuum)	USP <731>				
Tapped bulk density	Between 0.35g/ml and 0.55g/ml	USP <616>				
Loose bulk density	Between 0.25g/ml and 0.45g/ml	USP <616>				
Sieve Test(Passes Through)		USP <786>				
- 20 Mesh	Not less than 100% w/w					
- 40 Mesh	Not less than 85 % w/w					
- 80 Mesh	Not less than 70 % w/w					
CHEMICAL						
Assay						
-Content of Pterostilbene by HPLC	Not less than 90.0% w/w and not more than 95.0% w/w on dry basis	SLL/STP-P-011**				
OTHERS						
Total heavy metals	Not more than 20 ppm (µg/g)	USP <231> Method II				
Lead	Not more than 3 ppm (µg/g)	ICP-OES, SLL/STP-H-006**				
Arsenic	Not more than 1 ppm (µg/g)	ICP-OES, SLL/STP-H-006**				
Cadmium	Not more than 1ppm (µg/g)	ICP-OES, SLL/STP-H-006**				
Mercury	Not more than 0.1ppm (µg/g)	ICP-OES, SLL/STP-H-006**				
Residual solvents	To comply as per USP	USP <467>				
Residual pesticides	To comply as per USP	USP <561>				
MICROBIAL						



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Parameters	Limit		Reference		
Total aerobic microbial count	Not more than 5000cfu/g		USP <61>		
Fotal yeasts and molds count	Not more than 100cfu/g		USP <61>		
Escherichia coli	Negative/10g		USP <62>		
Salmonella	Negative/10g		USP <62>		
Staphylococcus aureus	Negative/10g		USP <62>		
Pseudomonas aeruginosa	Negative/10g		USP <62>		
ADDITIONAL INFORMATION					
Sanitizing treatment	Non-irradiated and not treated with ETO				
Certification status (Kosher/Halal)	Kosher certified, Halal certified				
Genetic Modification Status	GMO free				
BSE/TSE status	BSE / TSE free				
Country of origin	India				
Cultivated or wild crafted	Cultivated				
Storage condition	Store at room temperature				
Shelf Life	5 Year(s)				
Manufactured by	Sami Labs Limited 19/1,19/2 I Main, II Phase,Peenya Industrial Area,Bangalore - 560058, Karnataka, India				

*Since it is a herbal product, there is likely to be minor color variation because of the geographical and seasonal variations of the raw material. *Natural products can be hygroscopic and tend to agglomerate sometimes. It is suggested to sift before use.

**In-House developed and validated methods NAP:Not Applicable NAV:Not Available