



## FINISHED PRODUCT SPECIFICATION

<b>Product</b> FORSLEAN® (COLEUS FORSKOHLII EXTRACT 10%)	<b>Issue No.</b> 11.0	<b>Supersedes</b> Issue No.10 dtd 05/27/2010	<b>Page Number</b> Page 1 of 2
<b>Prepared by</b> CHAYADEVI Junior Executive	<b>Approved by</b> Dr.S Natarajan Executive Vice President	<b>Effective date</b> October 01, 2013	<b>Review date</b> September 30, 2016

Product code	0488		
Category	Intended for Nutraceutical application		
Botanical/Scientific name	Coleus forskohlii		
CAS No	66575-29-9		
Plant part	Roots		
Preparation type	Extraction		
Solvent used for extraction	95% Ethanol		
Final extract ratio	25:1 to 35:1		
Standardization	Forskolin		
Excipient used	Maltodextrin		
	<b>Excipient Name</b>	<b>%Used</b>	<b>CAS No.</b>
	Maltodextrin	50% to 75%	9050-36-6
<b>Parameters</b>	<b>Limit</b>	<b>Reference</b>	
<b>PHYSICAL</b>			
Description	Light brown to brown powder with characteristic odor*	Visual and Organoleptic	
Identification	a) To comply by TLC b) To comply by HPLC	SLL/STP-F-006**	
Solubility		SLL/STP-S-028**	
-Water solubles (1% w/v solution in water)	Not less than 30.0% w/w		
-Alcohol solubles (1% w/v solution in 95% v/v alcohol)	Not less than 30.0% w/w		
Loss on drying	Not more than 6.0% w/w (dried at 105°C)	USP <731>	
Tapped bulk density	Between 0.30g/ml and 0.70g/ml	USP <616>	
Loose bulk density	Between 0.15g/ml and 0.45g/ml	USP <616>	
Sieve Test (Passes Through)		USP <786>	
- 60 Mesh	Not less than 95% w/w		
<b>CHEMICAL</b>			
Assay			
-Content of Forskolin by HPLC	Not less than 10.0% w/w and not more than 12.0% w/w on dry basis	SLL/STP-F-006**	
<b>OTHERS</b>			
Total heavy metals	Not more than 20ppm (µg/g)	USP <231> Method II	
Lead	Not more than 3ppm (µg/g)	ICP-OES, SLL/STP-H-006**	
Arsenic	Not more than 1ppm (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**	



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Parameters	Limit	Reference
Residual solvents	To comply as per USP	USP <467>
Residual pesticides	To comply as per USP	USP <561>
<b>MICROBIAL</b>		
Total aerobic microbial count	Not more than 5000cfu/g	USP <2021>
Total yeasts and molds count	Not more than 100cfu/g	USP <2021>
Escherichia coli	Negative/10g	USP <2022>
Salmonella	Negative/10g	USP <2022>
Staphylococcus aureus	Negative/10g	USP <2022>
Pseudomonas aeruginosa	Negative/10g	USP <62>
Bile tolerant gram negative bacteria	Negative/10g	USP <2021>

### 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**