



FINISHED PRODUCT SPECIFICATION

Product Gymnema Sylvestre Extract 25%	Issue No. 3	Supersedes Issue No. 2 dtd 08/06/2016	Page Number Page 1 of 3
Prepared by Latha K.G Supervisor Documentation	Approved by Dr. Satish Sawant Vice President Analytical R&D		Effective date October 18, 2017

Product code	0760
Category	Intended for Nutraceutical application
Botanical/Scientific name	Gymnema sylvestre
CAS No	90045-47-9
Plant part	Leaves
Preparation type	Extraction
Solvent used for extraction	Ethanol
Solvent used in manufacture	DM Water
Final extract ratio	6:1 to 9:1
Standardization	Gymnemic acids
Excipient used	Maltodextrin

Excipient Name	%Used	CAS No.
Maltodextrin	15% to 20%	9050-36-6

Parameters

PHYSICAL

Description	Greenish brown powder with bitter taste*	Visual and Organoleptic
Identification	To comply by TLC	SLL/STP-G-007
Solubility		SLL/STP-S-028
-Water solubles (1% w/v solution in water)	Not less than 90.0% w/w	
-Alcohol solubles (1% w/v solution in 95% v/v alcohol)	Not less than 50.0% w/w	
Loss on drying	Not more than 6.0% w/w (dried at 105°C)	EP 2.2.32
Ash content	Not more than 25.0% w/w	EP 2.4.16 Method - II
Tapped bulk density	Between 0.30g/ml and 0.70g/ml	EP 2.9.34 Method - I
Loose bulk density	Between 0.20g/ml and 0.50g/ml	EP 2.9.34 Method - I
Sieve Test (Passes through)		USP <786>
- 20 mesh	Not less than 100% w/w	
- 80 mesh	Not less than 85% w/w	

CHEMICAL

Assay		
-Content of Gymnemic acids by Gravimetry	Not less than 25.0% w/w and not more than 30.0% w/w on dry basis	SLL/STP-G-007

OTHERS

Lead	Not more than 3ppm (µg/g)	USP <2232>
Arsenic	Not more than 1ppm (µg/g)	USP <2232>
Cadmium	Not more than 1ppm (µg/g)	USP <2232>



FINISHED PRODUCT SPECIFICATION

Product Gymnema Sylvestre Extract 25%	Issue No. 3	Supersedes Issue No. 2 dtd 08/06/2016	Page Number Page 2 of 3
Prepared by Latha K.G Supervisor Documentation	Approved by Dr. Satish Sawant Vice President Analytical R&D		Effective date October 18, 2017

Parameters	Limit	Reference
Mercury	Not more than 0.1ppm ($\mu\text{g/g}$)	USP <2232>
Residual solvents	To comply as per EU Directive 2009/32/EC	USP <467>
Residual pesticides	To comply as per EP	USP <561>
Poly Aromatic Hydrocarbons (PAH)		SLL/STP-P-108
-Benzo(a)pyrene	Not more than 10ppb ($\mu\text{g/kg}$)	
-PAH4 (Sum of Benzo(a)pyrene, Benz(a)anthracene, Benzo(b)fluoranthene and Chrysene)	Not more than 50ppb ($\mu\text{g/kg}$)	
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	Negative/10g	EP 2.6.13
Coliforms	Less than 10cfu/g	BAM 2001, 8th Edition, Chapter 4
ADDITIONAL INFORMATION		
Nature	Hygroscopic	
Storage condition	Store at room temperature in a air tight container. Avoid exposure to moisture.	
Sanitising treatment	Non-irradiated and not treated with ETO	
Certification Status (Kosher/Halal)	Kosher and Halal certified	
Genetic Modification Status	GMO free	
BSE/TSE status	BSE / TSE free	
Country of Origin	India	
Cultivated or wild crafted	Cultivated	
Shelf Life	5 Year(s)	
Manufactured by	Sami-Sabinsa Group 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 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.



FINISHED PRODUCT SPECIFICATION

Product Gymnema Sylvestre Extract 25%	Issue No. 3	Supercedes Issue No. 2 dtd 08/06/2016	Page Number Page 3 of 3
Prepared by Latha K.G Supervisor Documentation	Approved by Dr. Satish Sawant Vice President Analytical R&D		Effective date October 18, 2017

NAP:Not Applicable

NAV:Not Available