



FINISHED PRODUCT SPECIFICATION

Product : **AMLA EXTRACT (SABERRY)**

Issue No. 5.0	Effective date April 29 , 2016	Supersedes Issue No.4 dtd 25/11/2014	Page Number Page 1 of 3
Prepared by Sreenivasa Raju M Senior Scientist - Analytical R&D		Reviewed by Mubarak Pasha Senior Manager - Analytical R&D	Approved by Dr. Satish N. Sawant Vice President - Analytical R&D

Specification No. FPS/ARD/266
Product Code 1901
Category Intended for Nutraceutical and Cosmeceutical application
Botanical name Emblica officinalis
CAS No 90028-28-7
Plant part Fruits
Preparation type Cold pressed & Spray dried
Final extract ratio 50:1 to 60:1
Standardization β -glucogallin, Gallic acid
Excipients used None

Parameter

Physical

Description
Identification
Solubility
-Water solubles (1% w/v solution in water)
Water content by KF method
Ash content
Tapped bulk density
Loose bulk density

Limit

Beige colour powder, odourless*
To comply by TLC
Not less than 90.0% w/w
Not more than 5.0% w/w
Not more than 15.0% w/w
Between 0.45g/ml and 0.80g/ml
Between 0.35g/ml and 0.60g/ml

Reference

Visual and Organoleptic
SLL/STP-A-025
SLL/STP-S-028
USP <921>
EP 2.4.16 Method - II
EP 2.9.34 Method - I
EP 2.9.34 Method - I

Chemical

Assay
-Content of β -glucogallin by HPLC
-Content of Gallic acid by HPLC

Not less than 10.0% w/w on anhydrous basis
Not more than 5.0% w/w on anhydrous basis

SLL/STP-A-025
SLL/STP-A-025

Others

Total heavy metals
Lead
Arsenic
Cadmium
Mercury
Residual solvents
Residual pesticides
Total aflatoxins (B1, B2, G1 and G2)
Poly Aromatic Hydrocarbons (PAH)
-Benzo(a)pyrene
-PAH4 (Sum of Benzo(a)pyrene,
Benz(a)anthracene, Benzo(b)fluoranthene

Not more than 20ppm (μ g/g)
Not more than 3ppm (μ g/g)
Not more than 1ppm (μ g/g)
Not more than 1ppm (μ g/g)
Not more than 0.1ppm (μ g/g)
Not applicable
To comply as per EP
Not more than 20ppb
Not more than 10ppb (μ g/kg)
Not more than 50ppb (μ g/kg)

EP 2.4.8
ICP-OES, SLL/STP-H-006
ICP-OES, SLL/STP-H-006
ICP-OES, SLL/STP-H-006
ICP-OES, SLL/STP-H-006
USP <561>
SLL/STP-A-038
SLL/STP-P-071



- *Pharmaceuticals*
- *Fine Chemicals*
- *Cosmeceuticals*
- *Phytochemicals*
- *Herbal Extracts*
- *Speciality Chemicals*

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Parameter	Limit	Reference
and Chrysene)		
Microbiological Profile		
Total aerobic microbial count	Not more than 5000cfu/g	EP 2.6.12
Total yeasts and molds count	Not more than 100cfu/g	EP 2.6.12
Escherichia coli	Negative/10g	EP 2.6.13
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	BAM2001, 8th Edition, Chapter 4
Additional Information		
Nature	Hygroscopic	
Storage condition	Store at room temperature and protect from heat, light and moisture	
Sanitising 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	
Shelf Life	3 Years	
Manufactured By	Sami Labs Limited, 19/1 & 19/2, I Main, II Phase, Peenya Industrial Area, Bangalore - 560058 Karnataka,India	



- *Pharmaceuticals*
- *Fine Chemicals*
- *Cosmeceuticals*
- *Phytochemicals*
- *Herbal Extracts*
- *Speciality Chemicals*

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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.**

Disclaimer: Suitability of this product for its particular use is at the sole discretion of the purchaser.

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