



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

## FINISHED PRODUCT SPECIFICATION

Product : <b>AMLA EXTRACT (SABERRY)</b>			
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		
<b>Parameter</b>	<b>Limit</b>	<b>Reference</b>	
<b>Physical</b>			
Description	Beige colour powder, odourless*	Visual and Organoleptic	
Identification	To comply by TLC	SLL/STP-A-025	
Solubility		SLL/STP-S-028	
-Water solubles (1% w/v solution in water)	Not less than 90.0% w/w		
Water content by KF method	Not more than 5.0% w/w	USP <921>	
Ash content	Not more than 15.0% w/w	EP 2.4.16 Method - II	
Tapped bulk density	Between 0.45g/ml and 0.80g/ml	EP 2.9.34 Method - I	
Loose bulk density	Between 0.35g/ml and 0.60g/ml	EP 2.9.34 Method - I	
<b>Chemical</b>			
Assay			
-Content of β-glucogallin by HPLC	Not less than 10.0% w/w on anhydrous basis	SLL/STP-A-025	
-Content of Gallic acid by HPLC	Not more than 5.0% w/w on anhydrous basis	SLL/STP-A-025	
<b>Others</b>			
Total heavy metals	Not more than 20ppm (µg/g)	EP 2.4.8	
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	
Residual solvents	Not applicable		
Residual pesticides	To comply as per EP	USP <561>	
Total aflatoxins (B1, B2, G1 and G2)	Not more than 20ppb	SLL/STP-A-038	
Poly Aromatic Hydrocarbons (PAH)		SLL/STP-P-071	
-Benzo(a)pyrene	Not more than 10ppb (µg/kg)		
-PAH4 (Sum of Benzo(a)pyrene, Benz(a)anthracene, Benzo(b)fluoranthene	Not more than 50ppb (µg/kg)		



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<p><b>*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.</b></p> <p><b>*Natural products can be hygroscopic and may agglomerate sometimes. It is suggested to sift the product before use.</b></p> <p><b>Disclaimer:</b> Suitability of this product for its particular use is at the sole discretion of the purchaser.</p> <p><b>** In-House developed and validated methods</b></p>			