

## AMLA PLUS TABLETS

Monograph No. – 0703664 ver 3.0

Issue No: 03

Date of Issue: 03/10/2022

Text Reference : Ayurvedic Proprietary Medicine

Amendment No : 00

Amendment Date : --

Shelf Life: 3 years

### Description

Light brown to brown coloured caplet shape coated tablets

### Loss on Drying at 105°

Not more than 10 % w/w

### Friability

Not more than 1 % w/w

### Disintegration Time

Not more than 60 min.

### Hardness

Not less than 2 kg/cm<sup>2</sup>

### Thickness

5.0 ± 0.5 mm

### length

17.5 ± 0.5 mm

### Average Weight

705 mg ± 5 %

### Uniformity of weight on 20 tablets

Not more than 2 tablets deviate by more than 5 % of the average weight and none by more than 10 % of the average weight

### Ash

Not more than 20 % w/w

### Acid insoluble ash

Not more than 5 % w/w

### Water soluble extractive

Not less than 25 % w/w

### Alcohol soluble extractive

Not less than 10 % w/w

### pH (1% aq. solution)

4.0 – 6.0

### Thin Layer Chromatography Mobile Phase

Chloroform : Ethyl Acetate : Formic Acid  
( 5 : 4 : 1.6 )

### Details

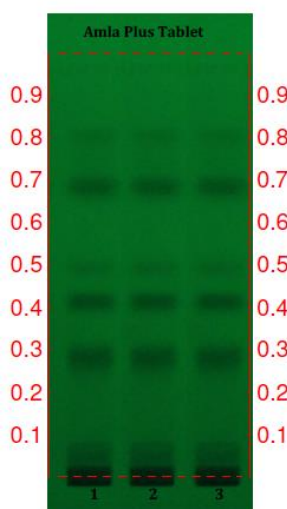
Solvent of Extraction – Methanol

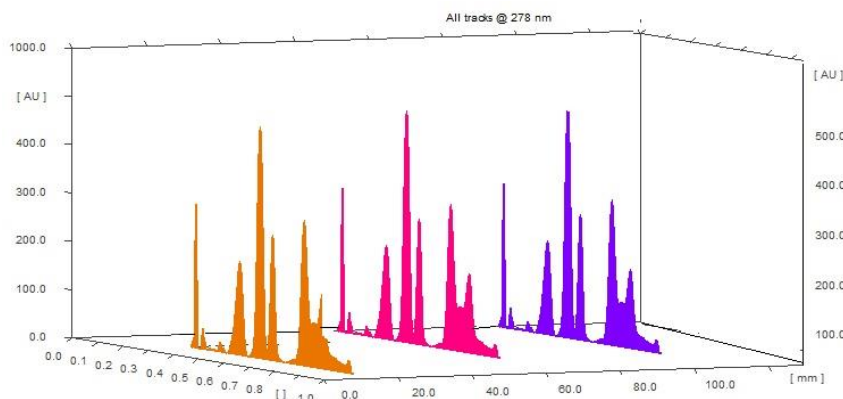
Distance traveled by solvent front – 90 mm

Total No. of Major spots – 5

Detection – Under UV at 254nm

Major Spots	Color	Approx. Rf.
1	Black	0.29
2	Black	0.41
3	Light Gray	0.49
4	Gray	0.68
5	Light Gray	0.80

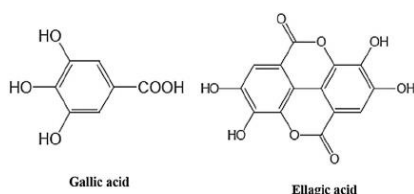




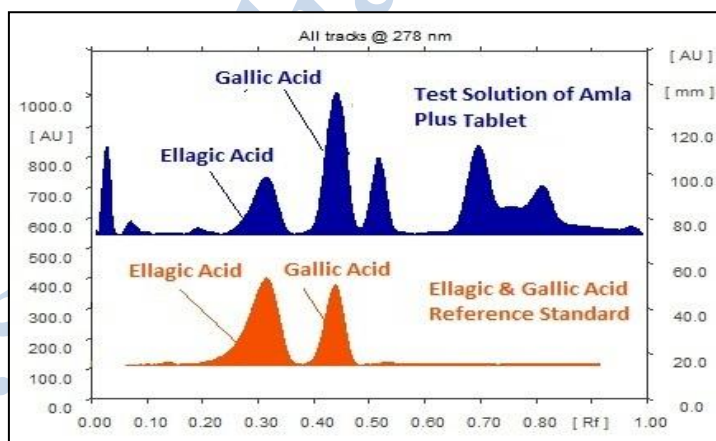
**3D Peak Display of Amla Plus Tablets at 278 nm**

## HPTLC Profile <sup>†</sup>

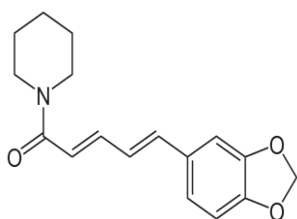
### i) Total Polyphenols (as Gallic acid & Ellagic acid)



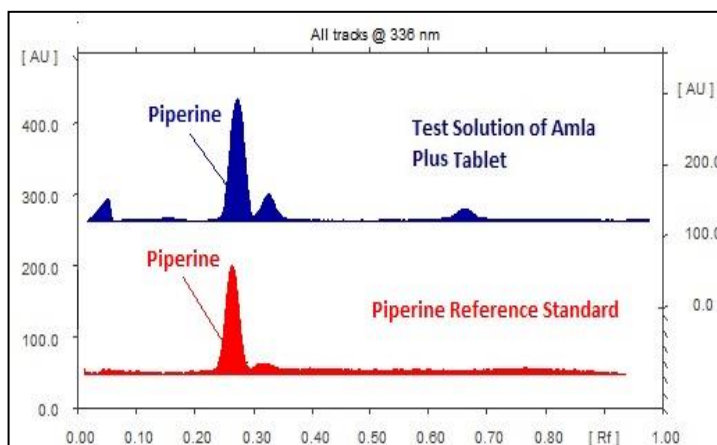
When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 290 nm for Gallic acid & 278 nm for Ellagic acid corresponding with Gallic acid & Ellagic acid standard.



### ii) Piperine



When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 336 nm corresponding with piperine standard.



### Heavy metal

<b>Lead (Pb)</b>	NMT 10 ppm
<b>Mercury (Hg)</b>	NMT 1 ppm
<b>Arsenic (As)</b>	NMT 3 ppm
<b>Cadmium (Cd)</b>	NMT 0.3 ppm
<b><i>E. coli</i></b>	Absent/g
<b><i>P. aeruginosa</i></b>	Absent/g
<b><i>Salmonella sp.</i></b>	Absent/g
<b><i>Staphylococcus sp.</i></b>	Absent/g
<b>Total Microbial plate count (TPC)</b>	NMT 10 <sup>5</sup> c.f.u./g
<b>Total Yeast &amp; Mould count (TYMC)</b>	NMT 10 <sup>3</sup> c.f.u./g
<b>Pesticide Residue <sup>†</sup> (OC+OP)</b>	Complies as per API
<b>Aflatoxins B1,B2,G1,G2 <sup>†</sup></b>	Complies as per API

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