

## AMALAKI TABLET

### Monograph No. – 2100324 ver 3.0

Issue No: 03

Date of Issue: 05/04/2021

Text Reference : API, Part I, Volume I, Monograph no. 4

Amendment No : 00

Amendment Date : --

Shelf Life: 3 years

#### Description

Yellowish brown to Light Brown colour caplet shape coated tablet having SDL mark on one side

#### Loss on Drying at 105°

Not more than 7 % 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

5.5 ± 0.5 mm

#### Length

18 ± 0.2 mm

#### Average Weight

670 mg ± 5 %

#### Uniformity of weight of 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 8 % w/w

#### Acid insoluble ash

Not more than 3 % w/w

#### Water soluble extractive

Not less than 30 % w/w

#### Alcohol soluble extractive

Not less than 20 % w/w

#### Elemental Assay

#### Thin Layer Chromatography Solvent system

Chloroform : Ethyl acetate : Glacial Acetic Acid  
( 5 : 4 : 1.6 )

#### Details

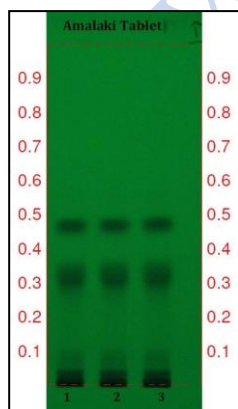
Solvent of Extraction – Methanol

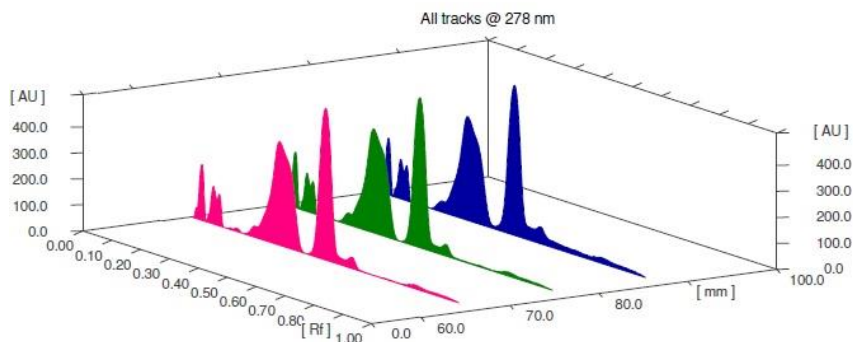
Solvent front – 90 mm

Total No. of Major spots – 3

Detection – Under UV at 254 nm

Major Spots	Colour	Approx. Rf.
1	Black	0.08
2	Gray	0.14
3	Black	0.20
4	Black	0.30



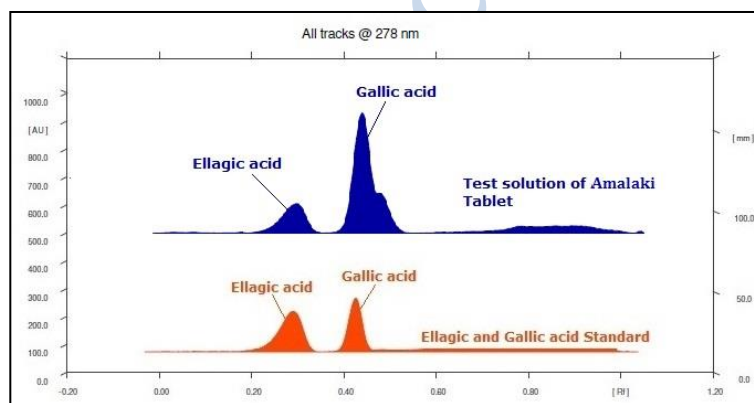
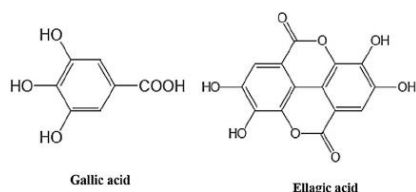


**3D Peak Display of Amalaki Tablet 278 at nm**

## 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.



## 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>E. coli <sup>+</sup></b>	Absent/g
<b>P. aeruginosa <sup>+</sup></b>	Absent/g
<b>Salmonella sp. <sup>+</sup></b>	Absent/g
<b>Staphylococcus sp. <sup>+</sup></b>	Absent/g
<b>Total Microbial plate count (TPC) <sup>+</sup></b>	NMT 10 <sup>5</sup> c.f.u./g
<b>Total Yeast &amp; Mould count<sup>+</sup></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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