

## ARJUNA TABLETS

### Monograph No. – 2100244 ver 3.0

Issue No: 03

Date of Issue: 15/04/2021

Text Reference : API, Part I, Volume II, Monograph no. 8

Amendment No : 00

Amendment Date : --

Shelf Life: 3 years

#### Description

Brownish red to Brown colour caplet shape coated tablets having SDL mark on one side.

#### Loss on Drying at 105°

Not more than 8 % 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 ± 0.2 mm

#### Average Weight

670 mg ± 5 %

#### pH

5.0 – 6.5

#### 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 36 % w/w

#### Acid insoluble ash

Not more than 1 % w/w

#### Water soluble extractive

Not less than 7 % w/w

#### Alcohol soluble extractive

Not less than 7 % w/w

#### Thin Layer Chromatography Solvent system

Toluene : Ethyl acetate : Acetic Acid  
( 5 : 5 : 0.5 )

#### Details

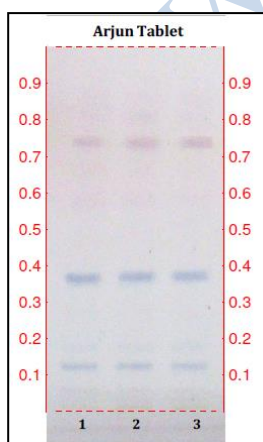
Solvent of Extraction – Ethyl acetate

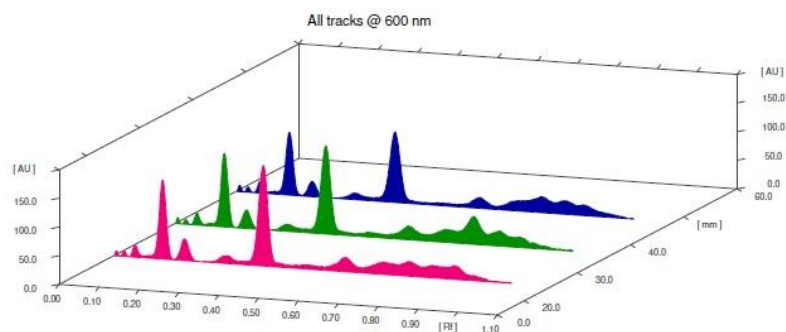
Solvent front – 90 mm

Total No. of Major spots – 4

Detection – After spray with Anisaldehyde Sulfuric acid

Major Spots	Colour	Approx. Rf.
1	Blue	0.12
2	Light Blue	0.18
3	Blue	0.37
4	Purple	0.74



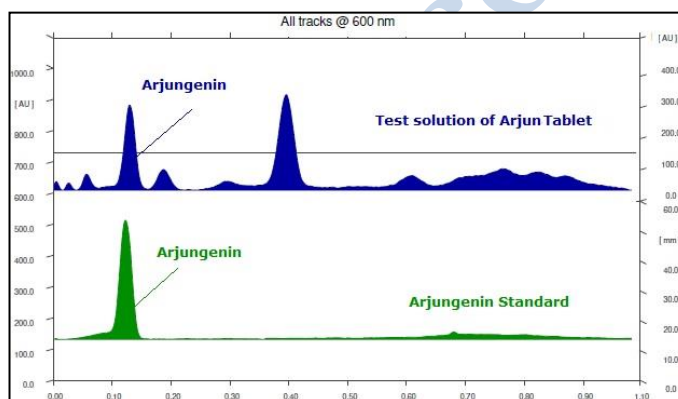
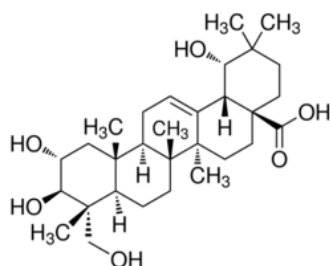


**3D Peak Display of Arjuna Tablet at 600 nm**

**HPTLC Profile<sup>†</sup>**

**i) Arjungenin**

When examined in the range of 400 nm to 700 nm, the test solution shows absorption maxima at about 600 nm corresponding with Arjungenin 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