

## SHIRAHSHOOLADRI VAJRA RASA

**Monograph No. – 0800304 ver 3.0**

Issue No: 03

Amendment No : 02

Date of Issue: 28/10/2016

Amendment Date : 29/07/2023

Text Reference : Bhaishajya Ratnavali (Shiroroga) 65/55-59

Shelf Life: 5 years

### Description

Dark gray to black colour, round convex coated tablet having SDL mark on one side.

### Loss on Drying at 105°

Not more than 6 % 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

### Diameter

8.0 ± 0.5 mm

### Average Weight

306 mg ± 5 %

### Uniformity of weight

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 30 % w/w

### Acid insoluble ash

Not more than 12 % w/w

### Water soluble extractive

Not less than 15 % w/w

### Alcohol soluble extractive

Not less than 4 % w/w

### pH (1 % Aq. Solution)

4.0 – 6.0

### Elemental Assay

#### Mercury (Hg)

14 – 20 mg/tab

#### Iron (Fe)

10 – 14 mg/tab

#### Sulphur (S)

18 – 25 mg/tab

#### Copper (Cu)

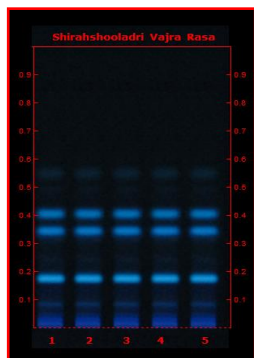
8 – 12 mg/tab

### Thin Layer Chromatography

#### Solvent system

Toluene : Acetone  
( 9 : 1 )

### Details



Solvent of Extraction – Methanol

Solvent front – 90 mm

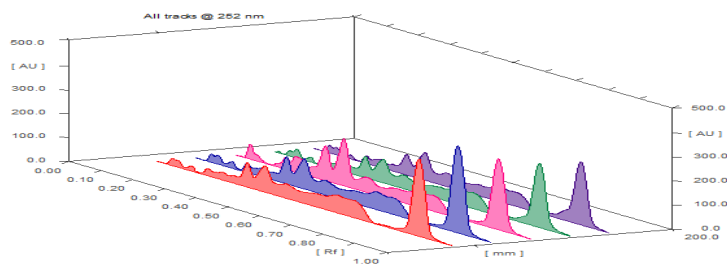
Total No. of Major spots – 5

Detection – Under UV at 366 nm

Major Spots	Colour	Approx. Rf.
1	Blue	0.08
2	Fluorescent Blue	0.18
3	Fluorescent Blue	0.34
4	Fluorescent Blue	0.40
5	Light Blue	0.55

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Note : <sup>†</sup> : These extra tests can be performed on every batch at extra cost. Tests can be ascertained on request.

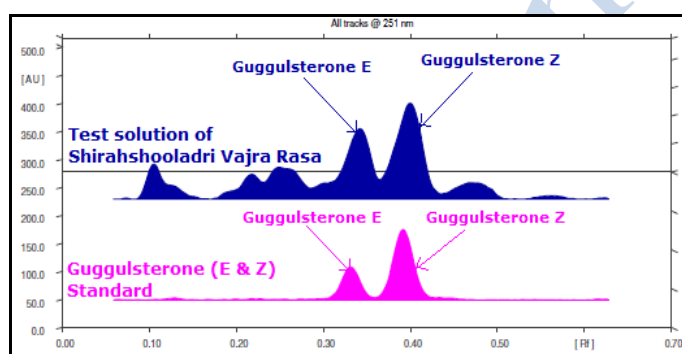
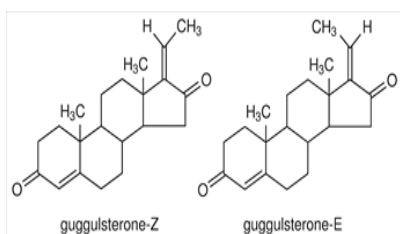


**3D Peak Display of Shirahshooladri Vajra Rasa at 252 nm**

## HPTLC Profile<sup>+</sup>

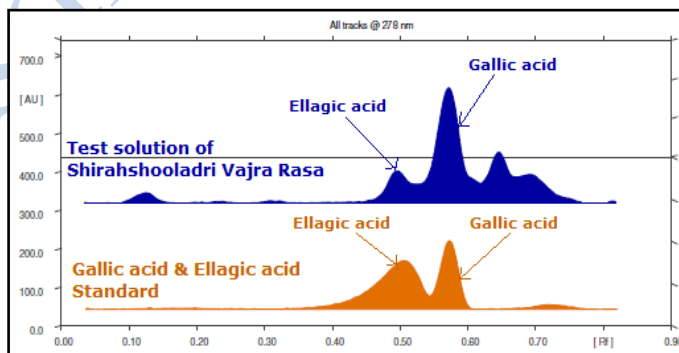
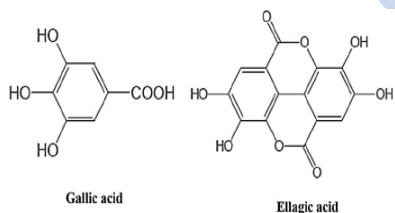
### i) Guggulsterone (E & Z)

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 251 nm corresponding with Guggulsterone (E & Z) standard.



### ii) 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.



**E. coli**

Absent/g

**P. aeruginosa**

Absent/g

**Salmonella sp.**

Absent/g

**Staphylococcus sp.**

Absent/g

**Total Microbial plate count (TPC)** NMT 10<sup>5</sup> c.f.u./g

**Total Yeast & Mould count (TYMC)** NMT 10<sup>3</sup> c.f.u./g

**Pesticide Residue<sup>+</sup> (OC+OP)** Complies as per API

**Aflatoxins B1,B2,G1,G2<sup>+</sup>** Complies as per API

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