

SHIRAHSHOOLADRI VAJRA RASA

Monograph No. – 0800304 ver 3.0

Issue No: 03

Date of Issue: 28/10/2016

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

Amendment No : 02

Amendment Date : 29/07/2023

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/cm²

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/tablet

Iron (Fe)

10 – 14 mg/tablet

Sulphur (S)

18 – 25 mg/tablet

Copper (Cu)

8 – 12 mg/tablet

Thin Layer Chromatography

Solvent system

Toluene : Acetone
(9 : 1)

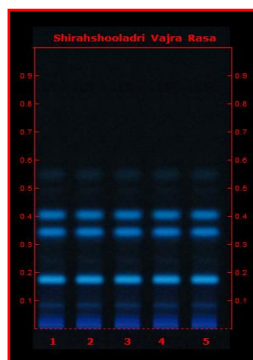
Details

Solvent of Extraction – Methanol

Solvent front – 90 mm

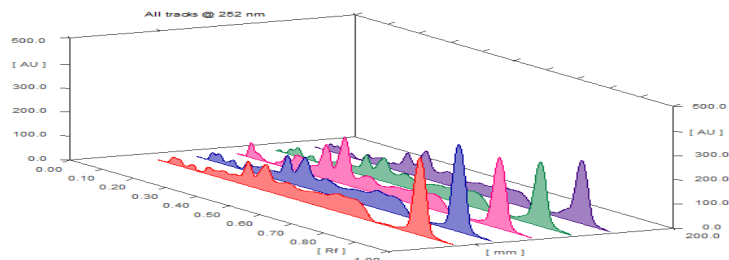
Total No. of Major spots – 5

Visualization – 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



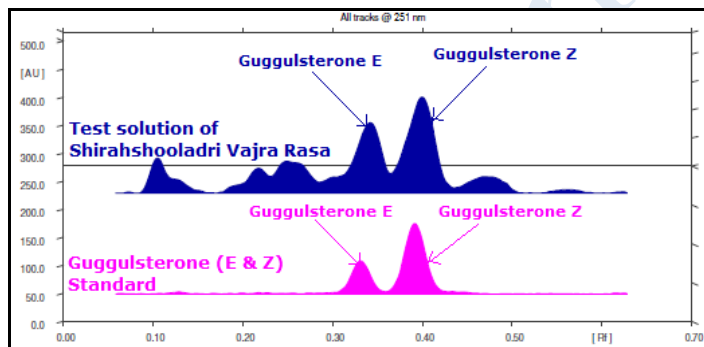
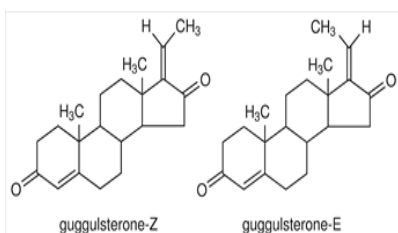


3D Peak Display of Shirahshooladri Vajra Rasa at 252 nm

HPTLC Profile[†]

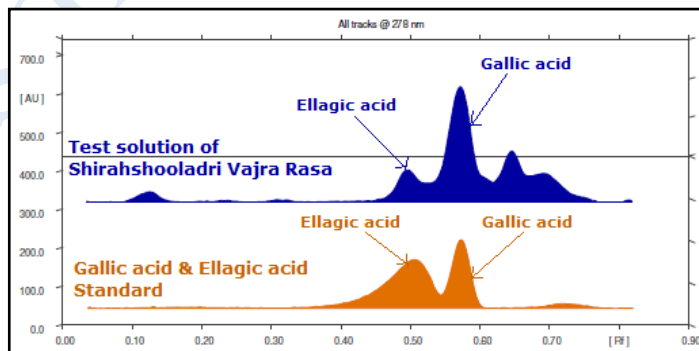
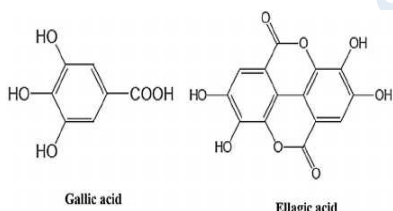
i) Guggulsterone (E & Z)

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)

Not more than 10⁵ c.f.u./g

Total Yeast & Mould count (TYMC)

Not more than 10³ c.f.u./g

Pesticide Residue[†] (OC+OP)

Complies as per API

Aflatoxins B1,B2,G1,G2[†]

Complies as per API