

AROGYAVARDHANI

Monograph No. – 0800044 ver 3.0

Issue No: 03

Date of Issue: 28/10/2016

Text Reference : Bharat Bhaishajya Ratnakar 1/448

Amendment No : 03

Amendment Date : 16/07/2024

Shelf Life: 5 years

Description

Gray to Blackish gray colour, round convex coated tablet having SDL mark on one side.

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/cm²

Thickness

5.0 ± 0.5 mm

Diameter

8.0 ± 0.5 mm

Average Weight

304.5 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 25 % w/w

Acid insoluble ash

Not more than 10 % w/w

Water soluble extractive

Not less than 25 % w/w

Alcohol soluble extractive

Not less than 15 % w/w

pH (1 % Aq. Solution)

4.2 - 6.6

Elemental assay

Mercury (Hg)

6 – 9 mg/tablet

Iron (Fe)

4 – 7 mg/tablet

Copper (Cu)

2.4 – 4.5 mg/tablet

Thin Layer Chromatography Solvent system

Ethyl acetate : Formic acid : Methanol
(6 : 0.6 : 0.4)

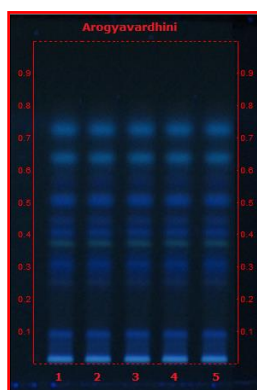
Details

Solvent of Extraction – Methanol

Solvent front – 90 mm

Total No. of Major spots – 9

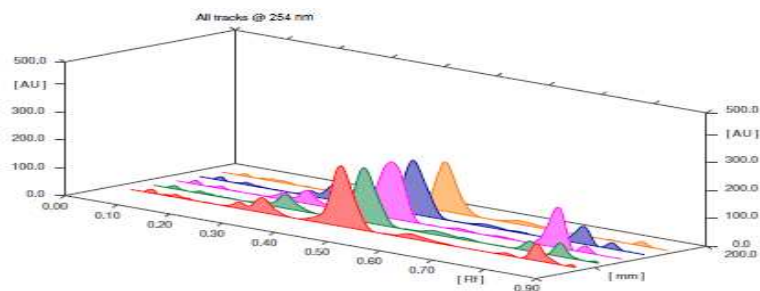
Visualization – Under UV at 366 nm



Major Spots	Colour	Approx. Rf.
1	Fluorescent Blue	0.09
2	Light Blue	0.25
3	Blue	0.31
4	Greenish Blue	0.38
5	Blue	0.42
6	Light Blue	0.45
7	Fluorescent Blue	0.51
8	Fluorescent Blue	0.65
9	Fluorescent Blue	0.74

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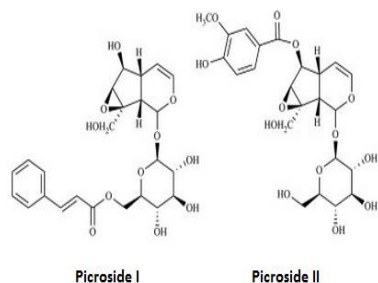
Note : † : These extra tests can be performed on every batch at extra cost. Tests can be ascertained on request.



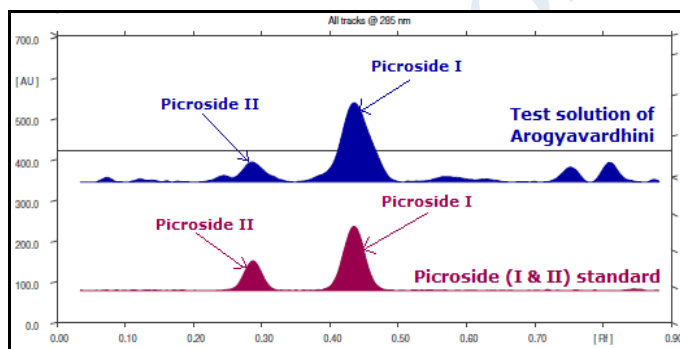
3D Peak Display of Arogyavardhani at 254 nm

HPTLC Profile⁺

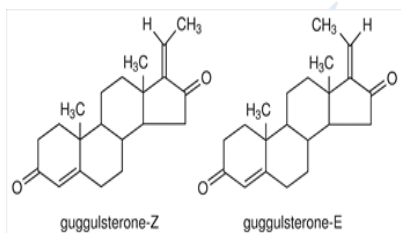
i) Kutkin (Picroside I & II)



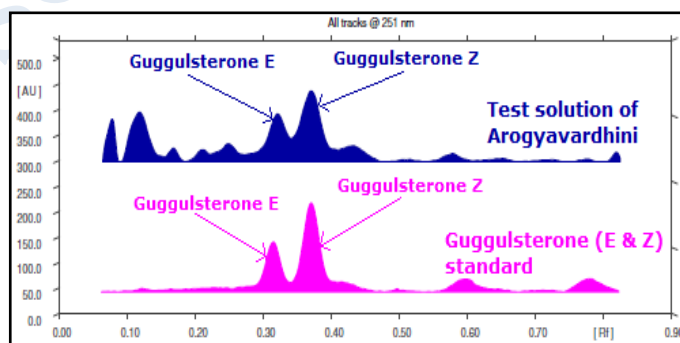
When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 285 nm for Picroside I & 297 nm for Picroside II corresponding with Picroside I & Picroside II standard.



ii) 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.



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

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Note : ⁺ : These extra tests can be performed on every batch at extra cost. Tests can be ascertained on request.