

SOOTASHEKHAR RASA (PLAIN)

Monograph No. – 0800214 ver 3.0

Issue No: 03

Date of Issue: 28/10/2016

Text Reference : Bharat Bhaishajya Ratnakar 5/8261

Amendment No : 04

Amendment Date : 16/07/2024

Shelf Life: 5 years

Description

Gray to Dark Gray colour, round biconvex 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

300 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 5 % w/w

Water soluble extractive

Not less than 20 % w/w

Alcohol soluble extractive

Not less than 5 % w/w

pH (1 % Aq. Solution)

6.0 - 9.0

Elemental Assay

Mercury (Hg)

13 – 17 mg/tablet

Sulphur (S)

16 – 24 mg/tablet

Copper (Cu)

7.5 – 11 mg/tablet

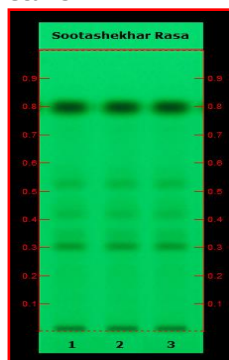
Calcium (Ca)

Not less than 5 mg/tablet

Thin Layer Chromatography Solvent system

Toluene : Ethyl acetate
(7 : 3)

Details



Solvent of Extraction – Methanol

Solvent front – 90 mm

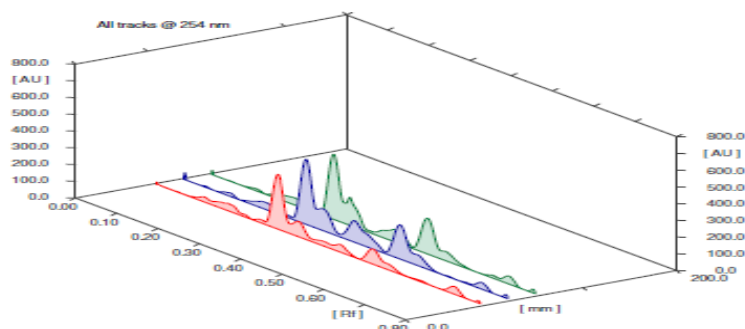
Total No. of Major spots – 5

Visualization – Under UV at 254 nm

Major Spots	Colour	Approx. Rf.
1	Gray	0.30
2	Light Gray	0.34
3	Light Gray	0.42
4	Light Gray	0.52
5	Black	0.80

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

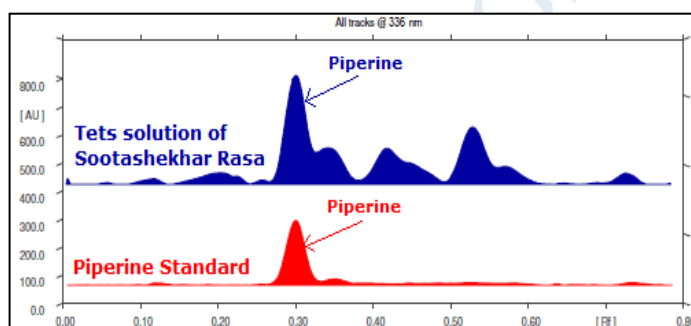
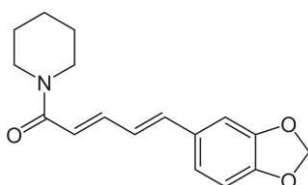


3D Peak Display of Sootashekhar Rasa (Plain) at 254 nm

HPTLC Profile[†]

i) Piperine

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 336 nm corresponding with Piperine 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 10^5 c.f.u./g

Total Yeast & Mould count (TYMC)

Not more than 10^3 c.f.u./g

Pesticide Residue[†] (OC+OP)

Complies as per API

Aflatoxins B1,B2,G1,G2[†]

Complies as per API