

SAPTAMRUT LOHA

Monograph No. – 1800014 ver 3.0

Issue No: 03

Amendment No : 02

Date of Issue: 26/04/2018

Amendment Date : 01/09/2021

Text Reference : Bhaishajya Ratnavali (Netraroga) 64/232-236

Shelf Life: 5 years

Description

Light brown to Blackish brown coloured, round biconvex coated tablets having SDL mark on one side.



Loss on Drying at 105°

Not more than 6 % w/w

Hardness

Not less than 2 kg/cm²

Thickness

5.0 +/- 0.5 mm

Diameter

8.0 +/- 0.5 mm

Disintegration Time

Not more than 60 min.

Average Weight

305 mg +/- 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 30 % w/w

Acid insoluble ash

Not more than 25 % w/w

Water soluble extractive

Not less than 20 % w/w

Alcohol soluble extractive

Not less than 20 % w/w

Elemental Assay

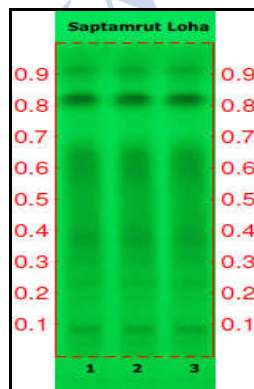
Iron (Fe)

25 - 40 mg/tab

Thin Layer Chromatography Solvent system

Ethyl acetate : Methanol : Water : formic acid
(15 : 2 : 1 : 1)

Details



Solvent of Extraction – Methanol

Solvent front – 90 mm

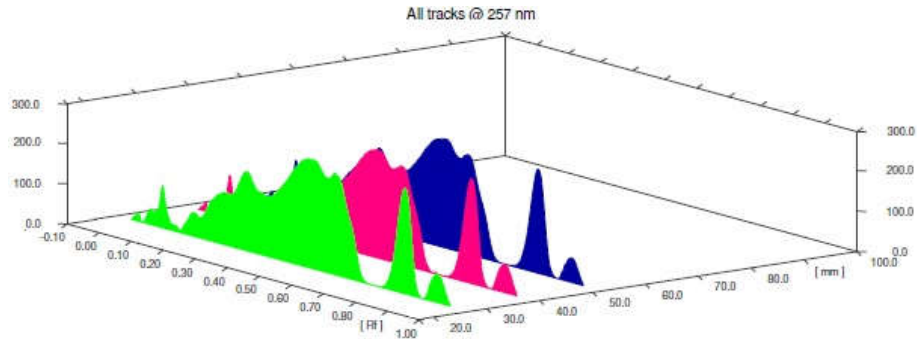
Total No. of Major spots – 9

Detection – Under UV at 254 nm

Major Spots	Colour	Approx. Rf.
1	Light Gray	0.04
2	Gray	0.09
3	Light Gray	0.18
4	Light Gray	0.23
5	Light Gray	0.31
6	Gray	0.38
7	Gray	0.64
8	Black	0.82
9	Gray	0.89

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

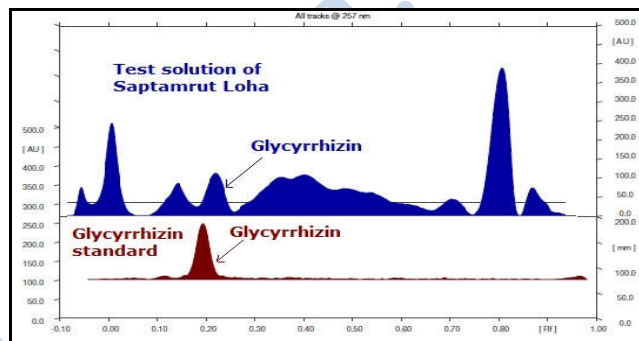
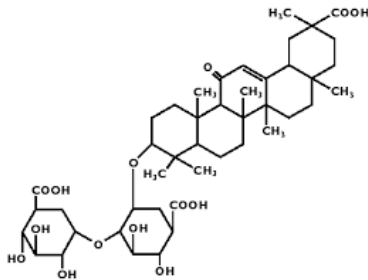


3D Peak Display of Saptamrut Loha at 257nm

HPTLC Profile

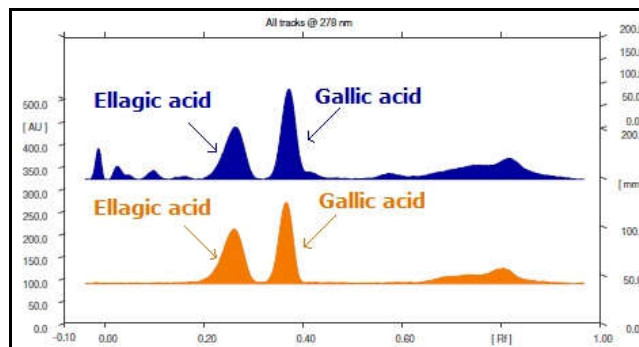
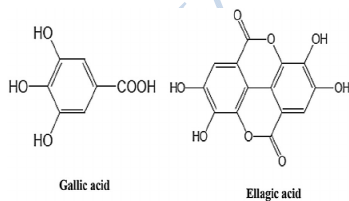
i) Glycyrrhizin

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 257 nm for Glycyrrhizin corresponding with Glycyrrhizin 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 ⁵ c.f.u./g
Total Yeast & Mould count †	NMT 10 ³ c.f.u./g
Pesticide Residue † (OC+OP)	Complies as per API
Aflatoxins B1,B2,G1,G2 †	Complies as per API