

## SAPTAMRUT LOHA

**Monograph No. – 1800014 ver 3.0**

Issue No: 03

Date of Issue: 26/04/2018

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

Amendment No : 03

Amendment Date : 25/11/2024

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

### 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

305 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 25 % w/w

### Water soluble extractive

Not less than 20 % w/w

### Alcohol soluble extractive

Not less than 20 % w/w

### pH (1% Aq. Solution)

3.5 – 5.5

### Elemental Assay

#### Iron (Fe)

25 - 40 mg/tablet

### Thin Layer Chromatography

#### Solvent system

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

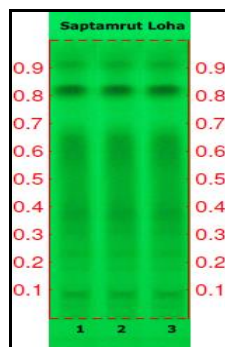
#### Details

Solvent of Extraction – Methanol

Solvent front – 90 mm

Total No. of Major spots – 9

Detection – Under UV at 254 nm



#### Major Spots

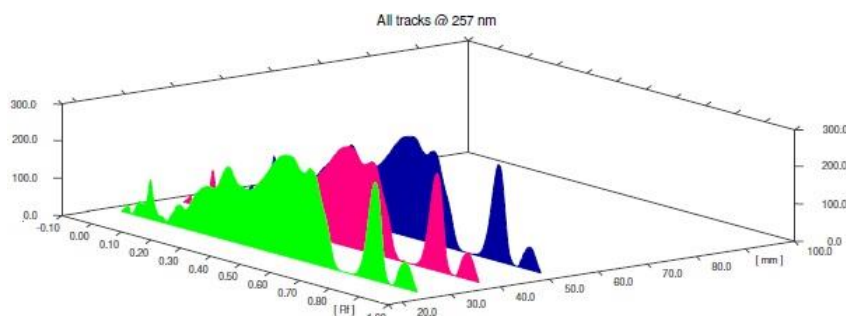
Major Spots	Colour
1	Light Gray
2	Gray
3	Light Gray
4	Light Gray
5	Light Gray
6	Gray
7	Gray
8	Black
9	Gray

#### Approx. Rf.

0.04
0.09
0.18
0.23
0.31
0.38
0.64
0.82
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.

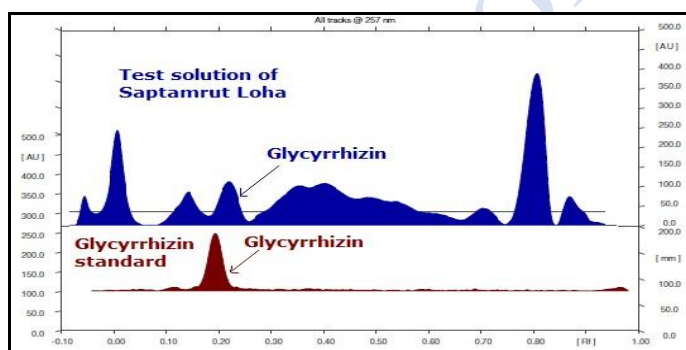
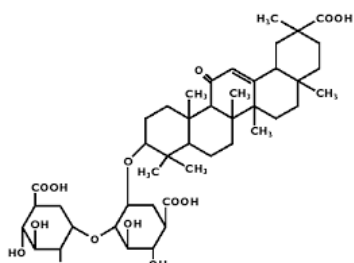


**3D Peak Display of Saptamrut Loha at 257nm**

## HPTLC Profile<sup>†</sup>

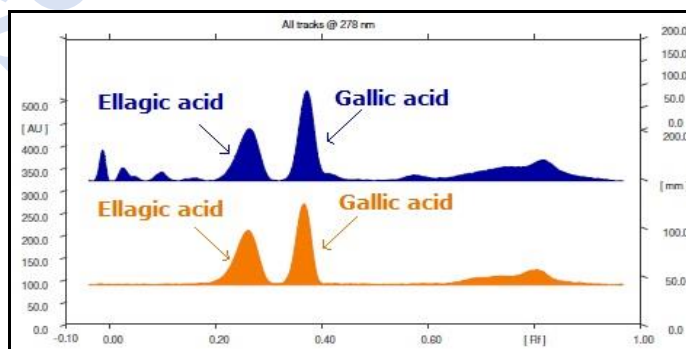
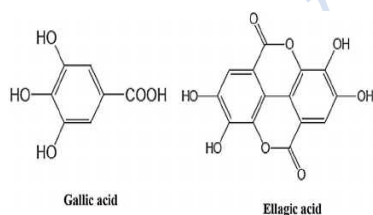
### i) Glycyrrhizin

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)**

Not more than 10<sup>5</sup> c.f.u./g

**Total Yeast & Mould count (TYMC)**

Not more than 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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Note : <sup>†</sup> : These extra tests can be performed on every batch at extra cost. Tests can be ascertained on request.