

SHILAJATVADI LOHA

Monograph No. – 1800044 ver 3.0

Issue No: 03

Amendment No : 02

Date of Issue: 22/06/2021

Amendment Date : 25/11/2024

Text Reference : Bhaishyajya Ratnavali (Rajaykshama) 14/86

Shelf Life: 5 years

Description

Brown to Dark brown colour round convex 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/cm²

Thickness

4.5 ± 0.5 mm

Diameter

8.0 ± 0.5 mm

Average Weight

340 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 65 % w/w

Acid Insoluble ash

Not more than 50 % w/w

Water Soluble Extractive

Not less than 12 % w/w

Alcohol Soluble Extractive

Not less than 7 % w/w

pH (1% Aq. Solution)

6.5 - 7.5

Elemental assay

Iron (Fe)

Not less than 75 mg/tablet

Copper (Cu)

Not less than 1.65 mg/tablet

Thin Layer Chromatography

Solvent system

Hexane : Ethyl Acetate
(6 : 4)

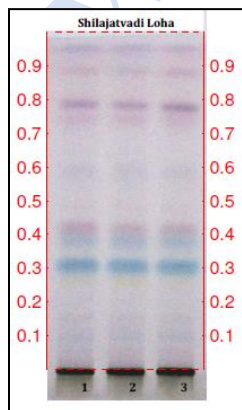
Details

Solvent of Extraction – Methanol

Solvent front – 90 mm

Total No. of Major spots – 10

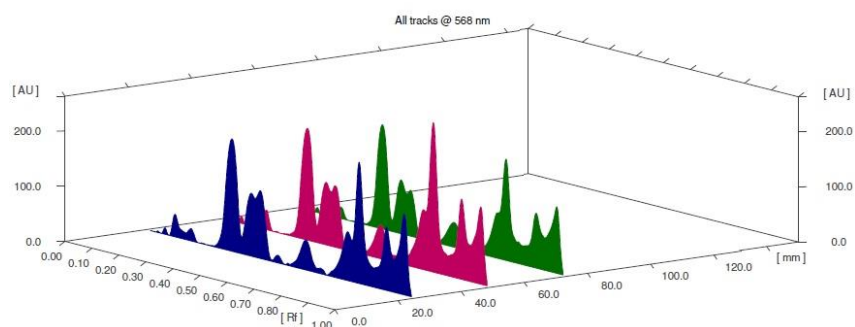
Detection – After spray with anisaldehyde sulfuric acid reagent



Major Spots	Colour	Approx. Rf.
1	Light Blue	0.11
2	Light Blue	0.16
3	Blue	0.31
4	Blue	0.38
5	Pink	0.42
6	Light Violet	0.58
7	Light Purple	0.74
8	Purple	0.78
9	Light Purple	0.89
10	Light Purple	0.95

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

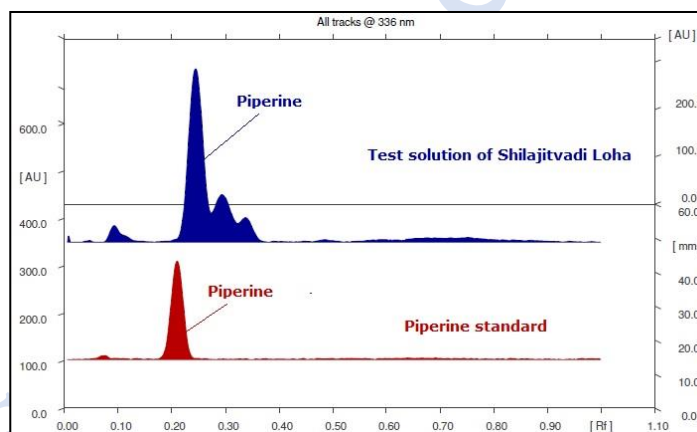
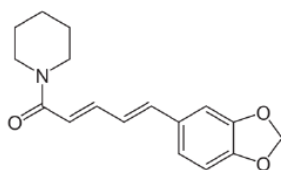


3D Peak Display of Shilajitvadi Loha Tablets at 568 nm

HPTLC Profile[†]

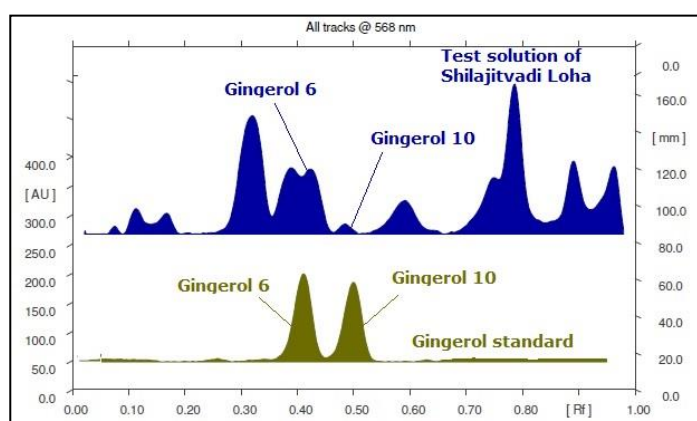
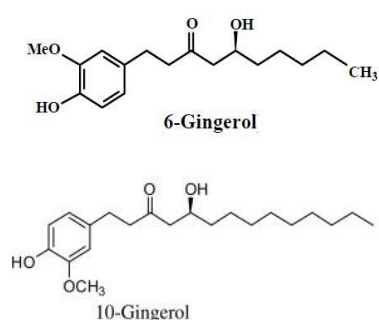
i) Piperine

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.



ii) Gingerol

When examined in the range of 500 nm to 700 nm, the test solution shows absorption maxima at about 568 nm corresponding with 6-Gingerol & 10-Gingerol standard.



<i>E. coli</i>	Absent/g
<i>P. aeruginosa</i>	Absent/g
<i>Salmonella sp.</i>	Absent/g
<i>Staphylococcus sp.</i>	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