

SHILAPRAVANG SPECIAL

Monograph No. – 0700074 ver 3.0

Issue No: 03

Amendment No : 01

Date of Issue: 28/10/2016

Amendment Date : 06/03/2020

Text Reference : Ayurvedic Proprietary Medicine

Shelf Life: 5 years

Description

Red colour round sugar coated tablets with polished smooth surface.



Loss on Drying at 105°

Not more than 6 % w/w

Hardness

Not less than 2 kg/cm²

Thickness

7.5 ± 0.5 mm

Diameter

13.5 ± 0.5 mm

Disintegration Time

Not more than 60 min.

Friability

Not more than 1 % w/w

Average Weight

950 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 12 % w/w

Water soluble extractive

Not less than 30 % w/w

Alcohol soluble extractive

Not less than 7 % w/w

Elemental Assay

Gold (Au)

Not less than 0.25 mg/tab

Iron (Fe)

7.0 – 12.0 mg/tab

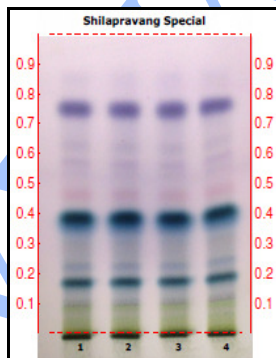
Copper (Cu)

Not less than 2.0 mg/tab

Thin Layer Chromatography Solvent system

Toluene : Ethyl acetate : Formic acid
(7 : 2 : 1)

Details



Solvent of Extraction – 5% Methanolic HCL + Chloroform

Solvent front – 90 mm

Total No. of Major spots – 10

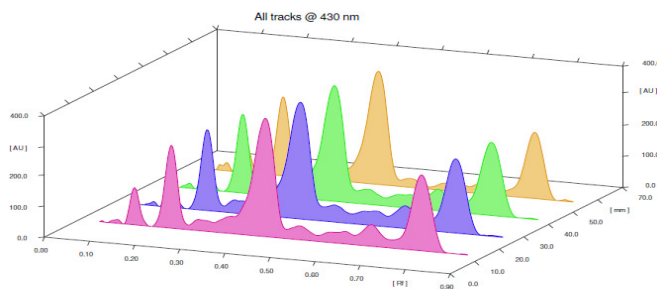
Detection – After spraying Anisaldehyde H₂SO₄

Major Spots	Colour	Approx. Rf.
1	Green	0.10
2	Blue	0.18
3	Light Blue	0.24
4	Blue	0.38
5	Pink	0.47
6	Gray	0.53
7	Light Purple	0.57
8	Light Purple	0.62
9	Violet	0.75
10	Light Violet	0.85

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

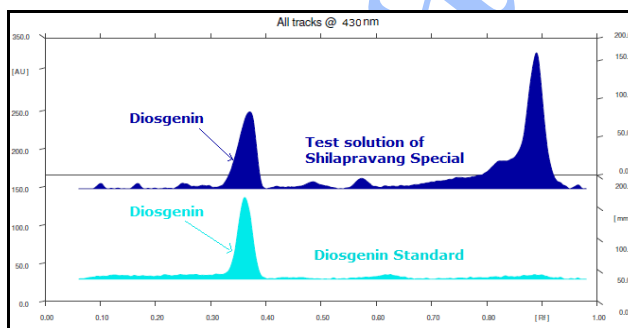
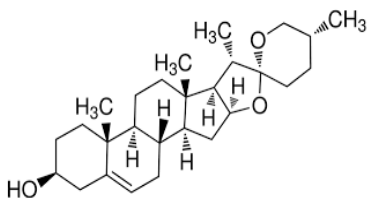


3D Peak Display of Shilapravang Special at 430 nm

HPTLC Profile +

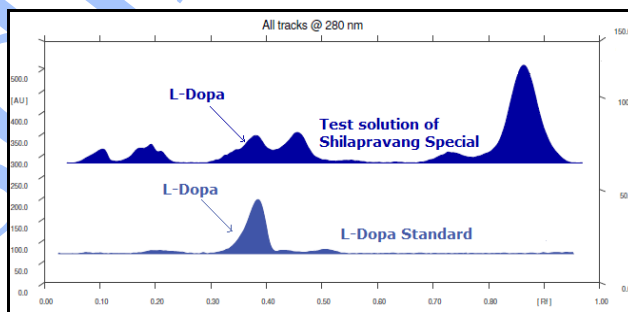
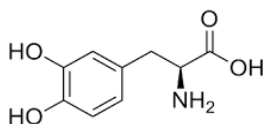
i) Diosgenin

When examined in the range of 400 nm to 700 nm, the test solution shows absorption maxima at about 430 nm corresponding with Diosgenin standard.



ii) L-Dopa

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 280 nm corresponding with L-Dopa 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