

## Shree Dhootapapeshwar Standards

### SHILAPRAVANG (WITH MOUKTIK)

### Monograph No. - 0700084 ver 3.0

Issue No: 03 Amendment No: 02

Date of Issue: 28/10/2016 Amendment Date: 05/03/2025

Text Reference: Ayurvedic Proprietary Medicine Shelf Life: 5 years

**Description** Light Brown to brown colour

round convex coated tablets 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/cm<sup>2</sup>

**Thickness** 5.0  $\pm$  0.5 mm

**Diameter**  $8.0 \pm 0.5 \text{ mm}$ 

Average Weight 275 mg  $\pm$  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

शिलाप्रवंग

weight.

Ash Not more than 45 % w/w

Acid insoluble ash Not more than 25 % w/w

Water soluble extractive Not less than 15 % w/w

Alcohol soluble extractive Not less than 10 % w/w

**pH (1% Aq. solution)** 6.5 – 8.5

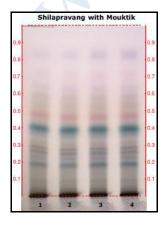
**Elemental Assay** 

Iron (Fe) 6 – 10 mg/tablet

Calcium (Ca) 10 – 20 mg/tablet

Thin Layer Chromatography Solvent system

**Details** 



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

Solvent of Extraction - 5% Methanolic HCL + Chloroform

Solvent front - 90 mm

Total No. of Major spots - 11

Visualization – After spraying Anisaldehyde H<sub>2</sub>SO<sub>4</sub>

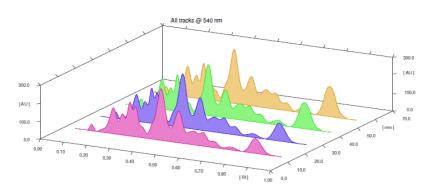
Major Spots	Colour	Approx. Rf.
1	Light Gray	0.10
2	Greenish Blue	0.18
3	Light Gray	0.22
4	Gray	0.24
5	Gray	0.28
6	Greenish Blue	0.39
7	Pink	0.47
8	Light Gray	0.59
9	Light Gray	0.64
10	Light Pink	0.71
11	Purple	0.83

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Note:  $^{\dagger}$ : These extra tests can be performed on every batch at extra cost. Tests can be ascertained on request.



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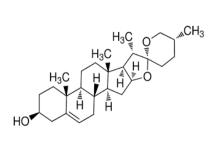


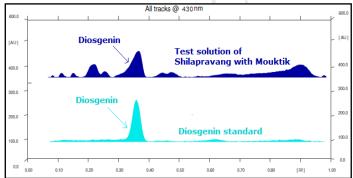
3D Peak Display of Shilapravang With Mouktik at 540 nm

### **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.





E. coli Absent/g

**P. aeruginosa** Absent/g

Salmonella sp. Absent/g

**Staphylococcus sp.** Absent/g

**Total Microbial plate count** Not more than 10<sup>5</sup> c.f.u./g

(TPC)
Total Yeast & Mould count

Not more than 10<sup>3</sup> c.f.u./g

(TVMC)

Pesticide Residue + (OC+OP) Complies as per API

Aflatoxins B1,B2,G1,G2 + Complies as per API