SHILAPRAVANG SPECIAL

Monograph No. – 0700074 *ver 3.0*

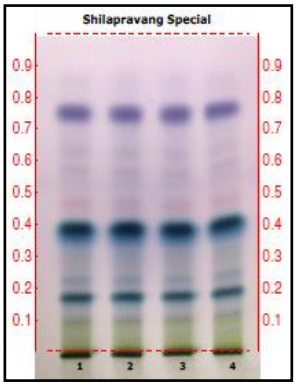
Issue No: 03 | Amendment No : 04

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

Text Reference : Ayurvedic Proprietary Medicine | Shelf Life: 5 years



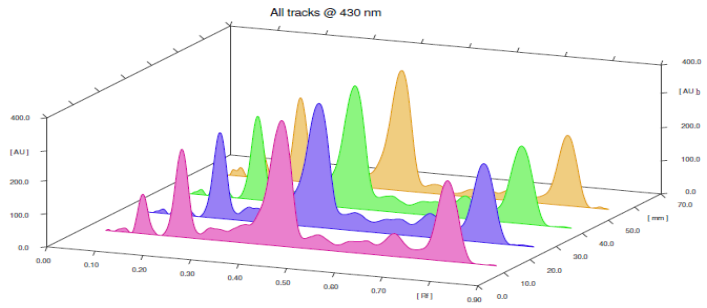
Description	Red colour round sugar coated tablets with polished smooth surface.
Loss on Drying at 105^0	Not more than 6 % w/w
Friability	Not more than 1 % w/w
Disintegration Time	Not more than 60 min.
Hardness	Not less than 2 kg/cm^2
Thickness	7.5 $\pm$ 0.5 mm
Diameter	13.0 $\pm$ 0.5 mm
Average Weight	950 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 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
pH (1% Aq. solution)	6.5 – 8.0
Elemental Assay	
Gold (Au)	Not less than 0.25 mg/tablet
Iron (Fe)	7.0 – 12.0 mg/tablet
Copper (Cu)	Not less than 2.0 mg/tablet
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 Visualization – After spraying Anisaldehyde H_2SO_4



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.

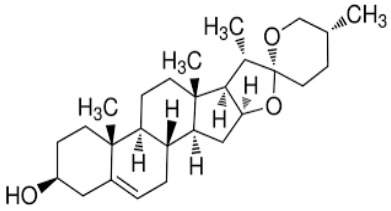


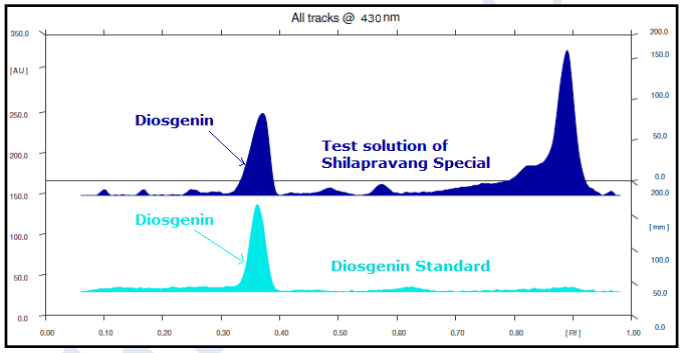
3D Peak Display of Shilapravang Special at 430 nm

HPTLC Profile †

i) Diosgenin

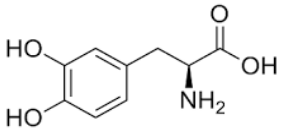
When examined in the range of 400 nm to 700 nm, the test solution shows absorption maxima at about 430 nm corresponding with Diosgenin standard.

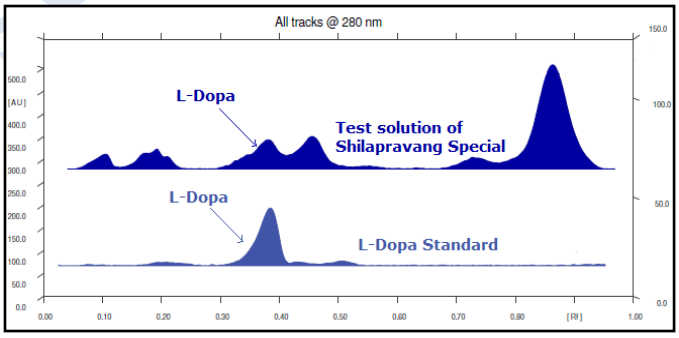




ii) L-Dopa

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)	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

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