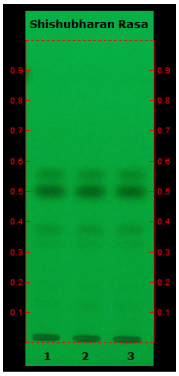
SHISHU BHARAN RASA

Monograph No. – 1902634 *ver 3.0*

Issue No: 03
Date of Issue: 16/11/2016
Text Reference : Ayurvedic Proprietary Medicine

Amendment No : 00
Amendment Date : --
Shelf Life: 5 years

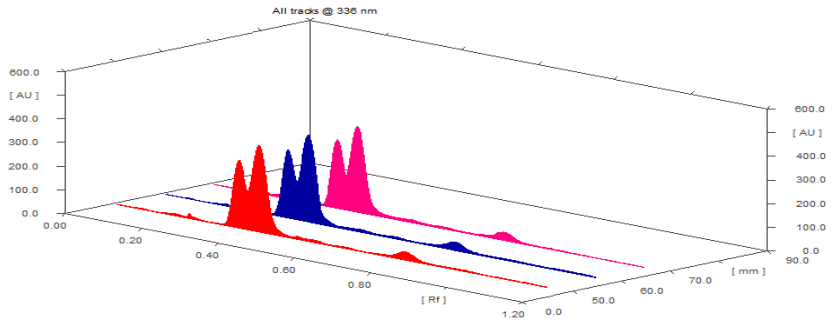
Description	Light blue colour, round biconvex film coated tablet having SDL mark on one side.
Loss on Drying at 105^0	Not more than 8 % w/w
Hardness	Not less than 2.5 kg/cm^2
Thickness	5.0 $\pm$ 0.5 mm
Diameter	8.0 $\pm$ 0.5 mm
Friability	Not more than 1 % w/w
Disintegration Time	Not more than 60 min.
Average Weight	325 mg ± 5 %
Elemental Assay	
Mercury (Hg)	3.2 – 6.3 mg/tab
Gold (Au)	1.2 – 1.9 mg/tab
Calcium (Ca)	Not less than 2 mg/tab
Iron (Fe)	Not less than 1 mg/tab
Zinc (Zn)	2.5 – 4.5 mg/tab
Copper (Cu)	Not less than 0.14 mg/tab
Thin Layer Chromatography Solvent system	Toluene : Ethyl acetate (7 : 3)
Details	Solvent of Extraction – Methanol Solvent front – 90 mm Total No. of Major spots – 4 Detection – Under UV at 254 nm



Major Spots	Colour	Approx. Rf.
1	Light Gray	0.33
2	Light Gray	0.38
3	Black	0.50
4	Gray	0.56

Confidential - photocopy prohibited

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

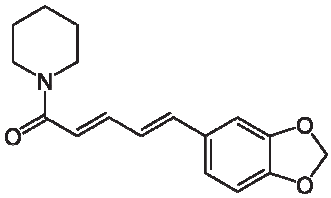


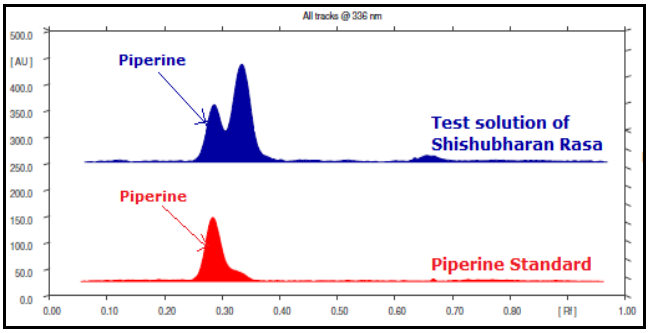
3D Peak display of Shishubharan Rasa at 366 nm

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.





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

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