SHISHU BHARAN RASA

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Amendment No : 01
Amendment Date : 05/03/2025
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
Friability	Not more than 1 % w/w
Disintegration Time	Not more than 60 min.
Hardness	Not less than 2.5 kg/cm^2
Thickness	5.0 $\pm$ 0.5 mm
Diameter	8.0 $\pm$ 0.5 mm
Average Weight	325 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 37 % w/w
Acid insoluble ash	Not more than 17 % w/w
Water soluble extractive	Not less than 31 % w/w
Alcohol soluble extractive	Not less than 3.5 % w/w
pH (1% Aq. solution)	5.5 – 7.5
Elemental Assay	
Mercury (Hg)	3.2 – 6.3 mg/tablet
Gold (Au)	1.2 – 1.9 mg/tablet
Calcium (Ca)	Not less than 2 mg/tablet
Iron (Fe)	Not less than 1 mg/tablet
Zinc (Zn)	2.5 – 4.5 mg/tablet
Copper (Cu)	Not less than 0.14 mg/tablet

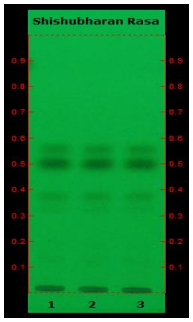


Thin Layer Chromatography

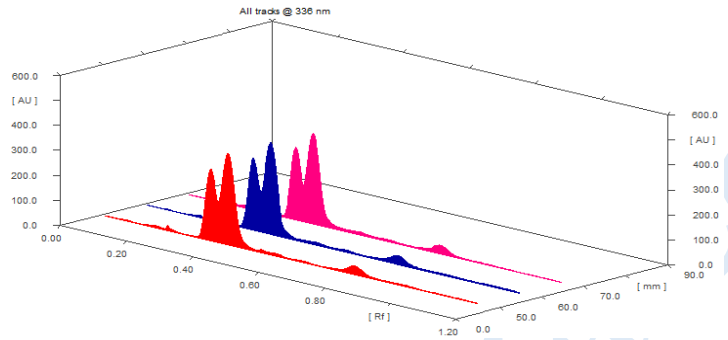
Solvent system	Toluene : Ethyl acetate (7 : 3)
Details	Solvent of Extraction – Methanol Solvent front – 90 mm Total No. of Major spots – 4 Visualization – Under UV at 254 nm

www.sdlindia.com

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



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

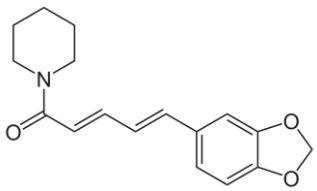


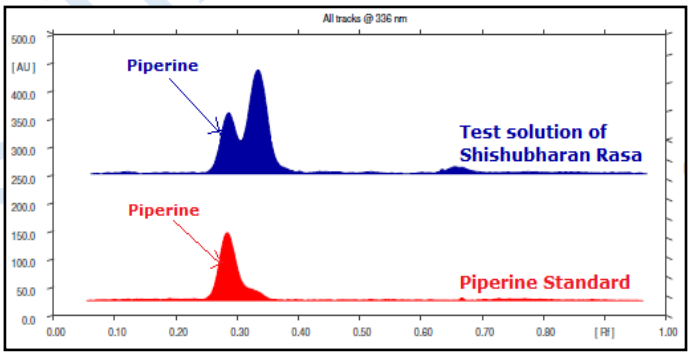
3D Peak display of Shishubharan Rasa at 336 nm

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)	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

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