BOLABADDHA RASA

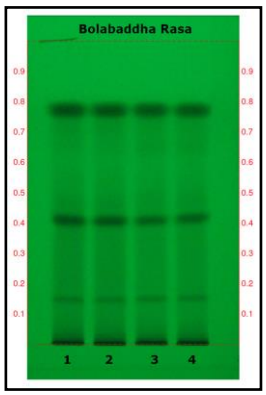
Monograph No. – 0800054 *ver 3.0*

Issue No: 03
Date of Issue: 28/10/2016
Text Reference : Bharat Bhaishajya Ratnakar 3/4753

Amendment No : 03
Amendment Date : 16/07/2024
Shelf Life: 5 years

Description	Gray to Dark gray colour, round biconvex tablet having SDL mark on one side.
Loss on Drying at 105⁰	Not more than 10 % w/w
Friability	Not more than 1 % w/w
Disintegration Time	Not more than 30 min.
Hardness	Not less than 2 kg/cm^2
Thickness	4.5 $\pm$ 0.5 mm
Diameter	8.0 $\pm$ 0.5 mm
Average Weight	285 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 15 % w/w
Acid insoluble ash	Not more than 10 % w/w
Water soluble extractive	Not less than 15 % w/w
Alcohol soluble extractive	Not less than 7 % w/w
pH (1% Aq. Solution)	6.0 – 8.0
Elemental Assay	
Mercury (Hg)	33 – 50 mg/tablet
Sulphur (S)	33 – 50 mg/tablet
Thin Layer Chromatography Solvent system	Chloroform : Hexane : Methanol (5.0 : 4.0 : 1.0)
Details	Solvent of Extraction – Methanol Solvent front – 90 mm Total No. of Major spots – 3 Visualization – Under UV at 254 nm

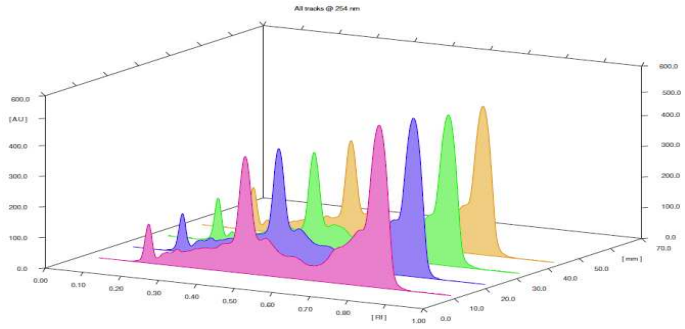




Major Spots	Colour	Approx. Rf.
1	Gray	0.15
2	Black	0.41
3	Black	0.78

www.sdindia.in

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



3D Peak Display of Bolbaddha Rasa at 254 nm

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

www.sdlindia.com

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