GANDHAK RASAYAN

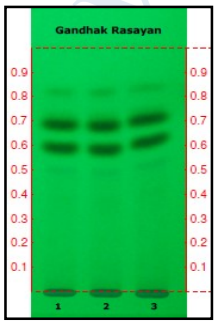
Monograph No. – 0500024 *ver 3.0*

Issue No: 03
Date of Issue: 27/07/2017
Text Reference : Bharat Bhaishajya Ratnakar 2/1533

Amendment No : 04
Amendment Date : 15/07/2024
Shelf Life: 5 years

Description	Cream to gray coloured, round biconvex coated tablets having SDL mark on one side.
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	4.5 mm ± 0.5 mm
Diameter	8.0 mm ± 0.5 mm
Average Weight	295 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 10 % w/w
Acid Insoluble Ash	Not more than 3 % w/w
Water soluble extractive	Not less than 15 % w/w
Alcohol soluble extractive	Not less than 10 % w/w
pH (1 % Aq. Solution)	5.0 - 7.0
Elemental assay	
Sulphur (S)	135 – 165 mg/tablet
Thin Layer Chromatography Solvent system	Chloroform : Ethyl acetate : Formic acid (5 : 4 : 1.6)
Details	Solvent of Extraction – Methanol Distance traveled by solvent front – 90 mm Total No. of Major spots – 4 Visualization – Under UV at 254nm

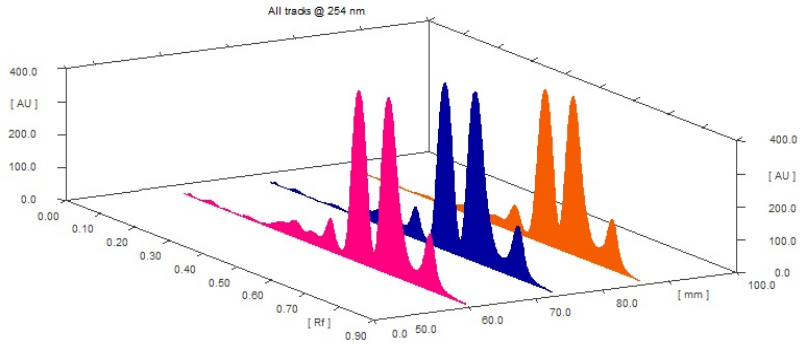




Major Spots	Colour	Approx. Rf.
1	Light Gray	0.50
2	Gray	0.59
3	Gray	0.68
4	Light Gray	0.83

www.sdindia.com

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



3D Peak Display of Gandhak Rasayan at 254nm

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.