ELADI GUTIKA

Monograph No. – 0500244 *ver 3.0*

Issue No: 03
Date of Issue: 16/11/2016
Text Reference : Ayurvedic Formulary of India, Part 1–12/3

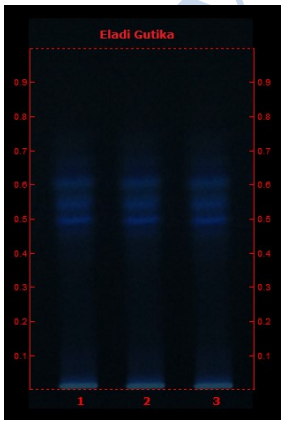
Amendment No : 01
Amendment Date : 27/07/2023
Shelf Life: 3 years

Description	Brown colour, round shape tablet 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 30 min.
Hardness	Not less than 2 kg/cm^2
Thickness	4.5 mm $\pm$ 0.5 mm
Diameter	8.0 mm $\pm$ 0.5 mm
Average Weight	277 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 39 % w/w
Acid Insoluble Ash	Not more than 10.8 % w/w
Water soluble extractive	Not less than 29 % w/w
Alcohol soluble extractive	Not less than 7.5 % w/w
pH (1 % Aq. Solution)	6.0 – 8.0
Thin Layer Chromatography Solvent system	Toluene : Ethyl acetate : Formic acid : Methanol (3 : 3 : 0.8 : 0.2)



Details

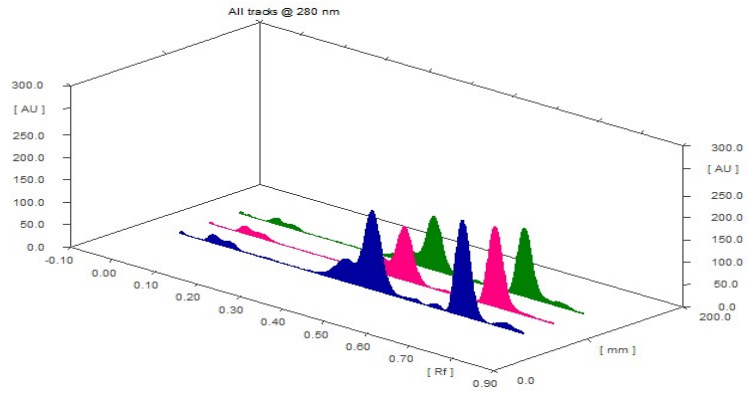
Solvent of Extraction – Methanol
Solvent front – 90 mm
Total No. of Major spots – 6
Visualization – Under UV at 366 nm



Major Spots	Colour	Approx. Rf.
1	Light Blue	0.46
2	Blue	0.50
3	Blue	0.55
4	Blue	0.61
5	Light Blue	0.67
6	Light Blue	0.72

www.sdindia.in

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

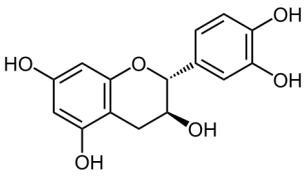


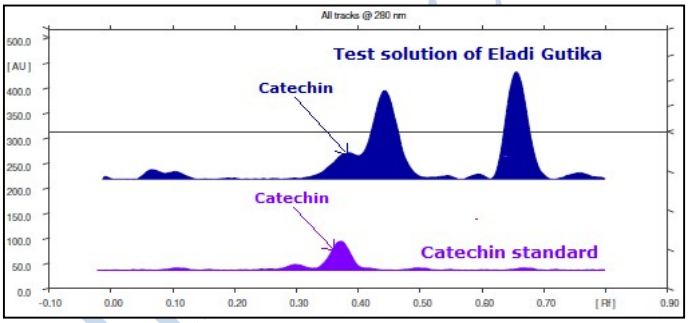
3D Peak Display of Eladi Gutika at 280 nm

HPTLC Profile†

i) Catechin

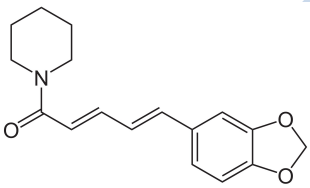
When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 280 nm corresponding with Catechin standard.

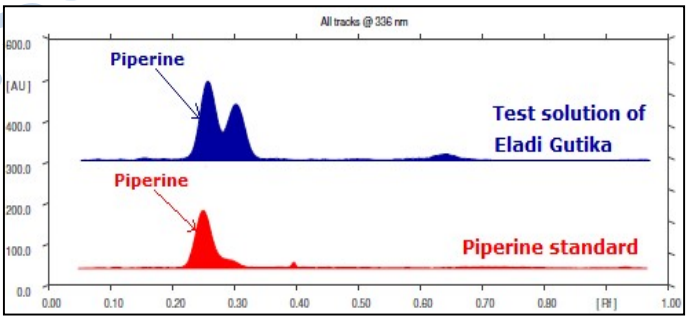




ii) Piperine

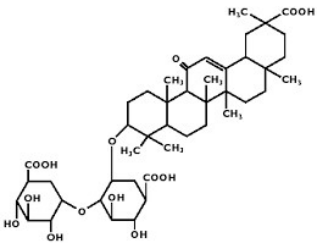
When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 336 nm corresponding with Piperine standard.

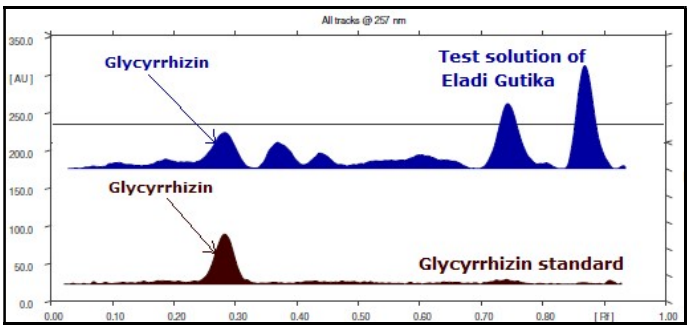




iii) Glycyrrhizin

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 257 nm for Glycyrrhizin corresponding with Glycyrrhizin standard.





Confidential - photocopy prohibited

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

Heavy metal	
Lead (Pb)	Not more than 10 ppm
Mercury (Hg)	Not more than 1 ppm
Arsenic (As)	Not more than 3 ppm
Cadmium (Cd)	Not more than 0.3 ppm
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.