AMRUTADI GUGGUL

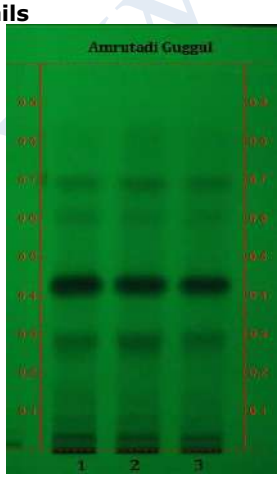
Monograph No. – 0400114 *ver 3.0*

Issue No: 03 | Amendment No : 04

Date of Issue: 28/10/2016 | Amendment Date : 08/04/2024

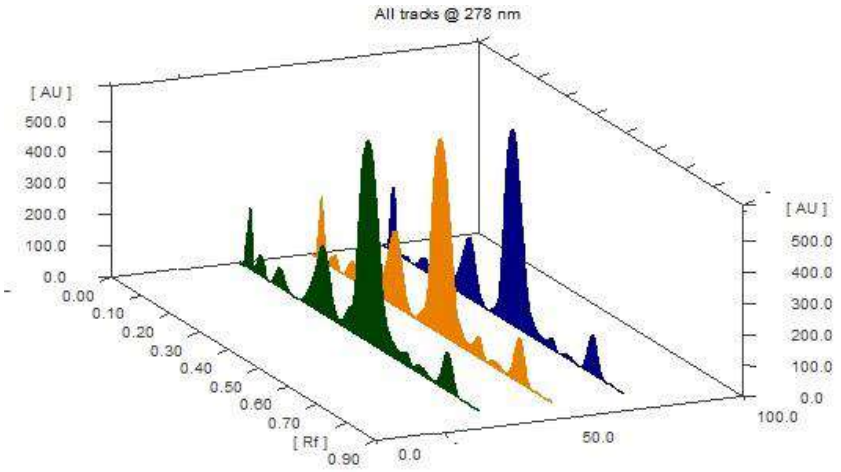
Text Ref : Bhavaprakash Madhyam Khanda (Vatarakta) 177-181 | Shelf Life: 5 years

Description	Brown to blackish brown colour, round biconvex 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 1.5 kg/cm^2
Thickness	5.0 $\pm$ 0.5 mm
Diameter	8.0 $\pm$ 0.5 mm
Average Weight	303 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 30 % w/w
Acid insoluble ash	Not more than 11 % w/w
Water soluble extractive	Not less than 14 % w/w
Alcohol soluble extractive	Not less than 12 % w/w
pH (1% Aq. Solution)	5.0 – 6.5
Thin Layer Chromatography Solvent system	Chloroform : Ethyl Acetate : Formic acid (5 : 4 : 1.6)
Details	Solvent of Extraction – Methanol Solvent front – 90 mm Total No. of Major spots – 5 Detection – Under UV at 254 nm



Major Spots	Colour	Approx. Rf.
1	Black	0.04
2	Gray	0.28
3	Black	0.42
4	Light Gray	0.60
5	Gray	0.69

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

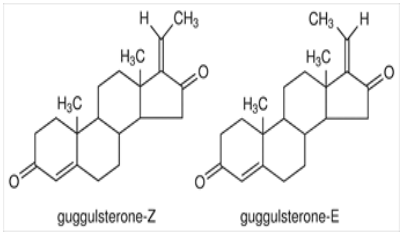


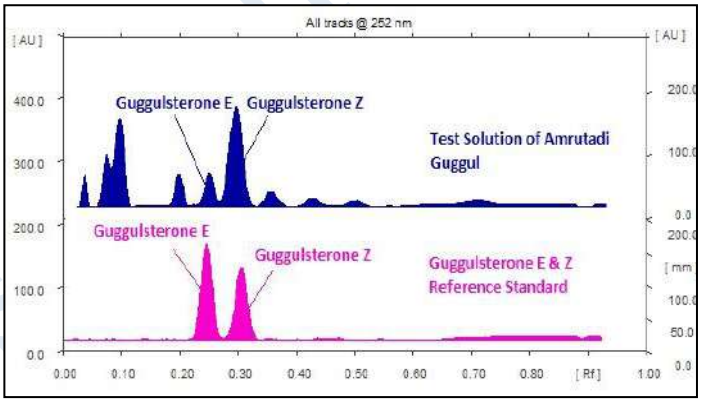
3D Peak Display of Amrutadi Guggul at 278 nm

HPTLC Profile†

i) Guggulsterone (E & Z)

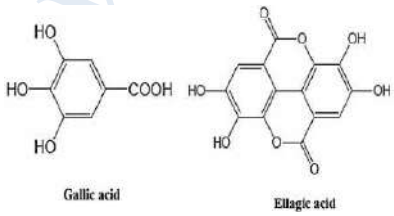
When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 252 nm corresponding with Guggulsterone (E & Z) standard.

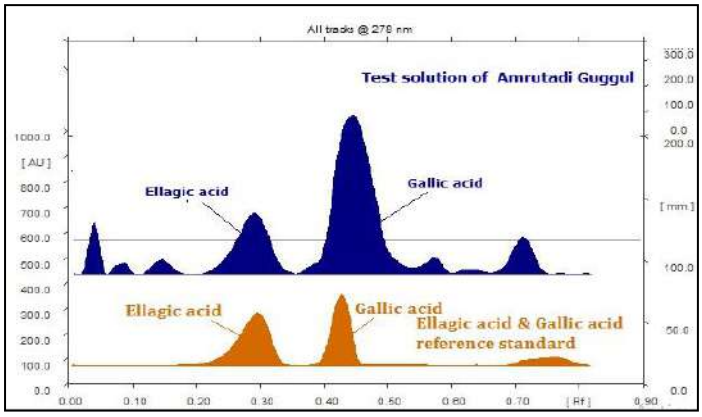




ii) Total Polyphenols (as Gallic acid & Ellagic acid)

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 290 nm for Gallic acid & 278 nm for Ellagic acid corresponding with Gallic acid & Ellagic acid standard.





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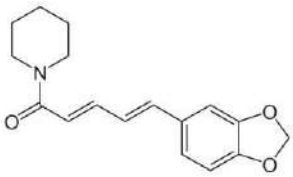
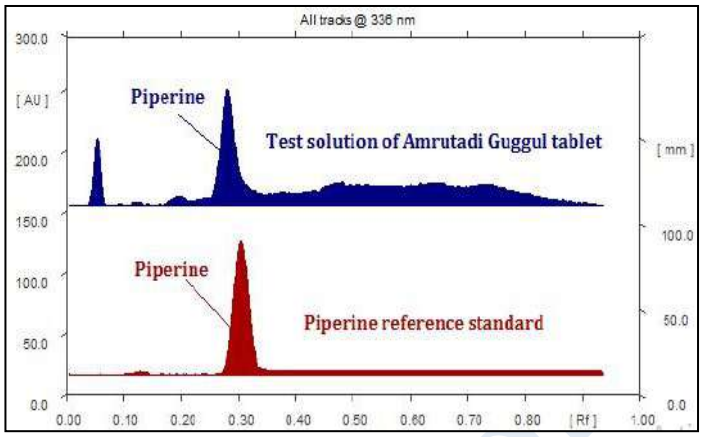
iii) Piperine

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.





Acute Toxicity	Nontoxic when single dose (10 x therapeutic dose) administered orally
Heavy metal	
Lead (Pb)	NMT 10 ppm
Mercury (Hg)	NMT 1 ppm
Arsenic (As)	NMT 3 ppm
Cadmium (Cd)	NMT 0.3 ppm
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 (TYMC)	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.