

KANCHANAR GUGGUL

Monograph No. – 0400074 ver 3.0

Issue No: 03

Amendment No : 04

Date of Issue: 28/10/2016

Amendment Date : 05/02/2024

Text Ref : Bhaishajya Ratnavali (Galagandadiroga) 44/64-69

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°

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/cm²

Thickness

5.5 ± 0.5 mm

Diameter

8.0 ± 0.5 mm

Average Weight

315 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 27 % w/w

Acid insoluble ash

Not more than 7 % w/w

Water soluble extractive

Not less than 20 % w/w

Alcohol soluble extractive

Not less than 9 % w/w

pH (1% Aq. Solution)

5.5 – 7.0

Thin Layer Chromatography Solvent system

Toluene : Acetone
(9.0 : 1.0)

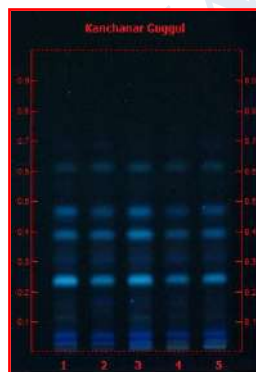
Details

Solvent of Extraction – Methanol

Solvent front – 90 mm

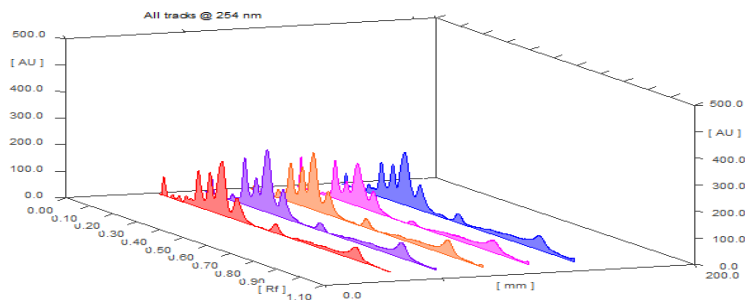
Total No. of Major spots – 10

Detection – Under UV at 366 nm



Major Spots	Colour	Approx. Rf.
1	Blue	0.03
2	Blue	0.06
3	Light Blue	0.11
4	Light Blue	0.16
5	Fluorescent Blue	0.23
6	Light Blue	0.31
7	Fluorescent Blue	0.39
8	Fluorescent Blue	0.46
9	Fluorescent Blue	0.61
10	Light Blue	0.68



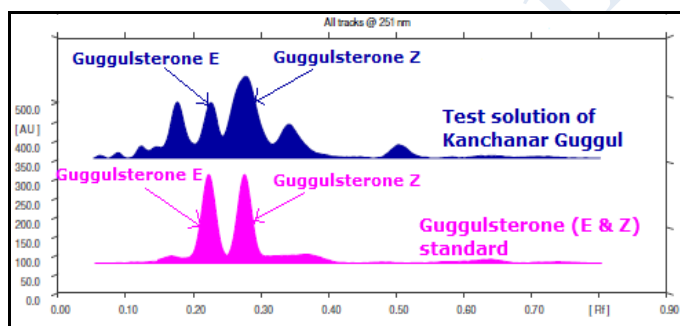
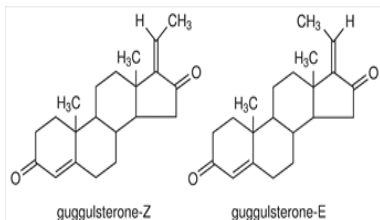


3D Peak Display of Kanchar Guggul at 254 nm

HPTLC Profile[†]

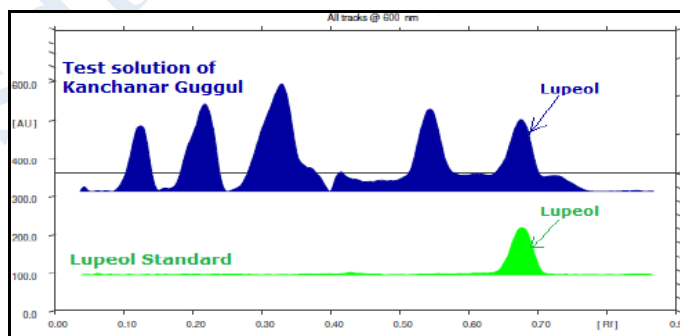
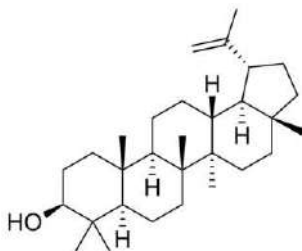
i) Guggulsterone (E & Z)

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 251 nm corresponding with Guggulsterone (E & Z) standard.



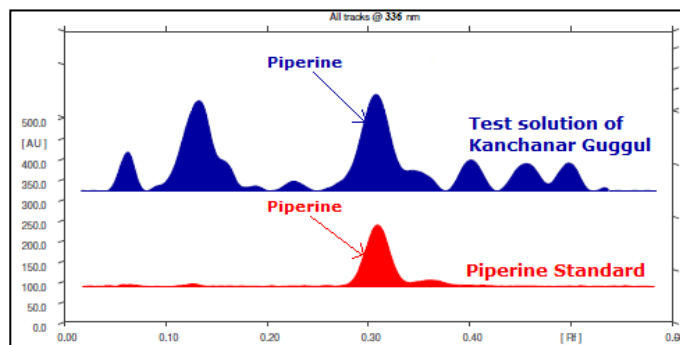
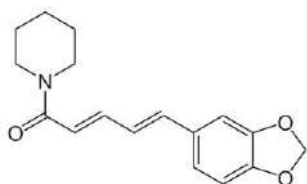
ii) Lupeol

When examined in the range of 400 nm to 700 nm, the test solution shows absorption maxima at about 600 nm corresponding with Lupeol standard.



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