

SANJEEVANI GUTIKA

Monograph No. – 0500104 ver 3.0

Issue No: 03

Amendment No : 02

Date of Issue: 27/07/2017

Amendment Date : 23/04/2022

Text Reference : Bharat Bhaishajya Ratnakar 5/8125

Shelf Life: 3 years

Description

Yellowish brown to brown colour, round convex coated tablet having SDL mark on one side.



Loss on Drying at 105°

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/cm²

Thickness

5.5 ± 0.5 mm

Diameter

8.0 ± 0.5 mm

Average Weight

290 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 15 % w/w

Acid insoluble ash

Not more than 5 % w/w

Water soluble extractive

Not less than 20 % w/w

Alcohol soluble extractive

Not less than 10 % w/w

pH (1 % Aq. Solution)

4.0 - 5.5

Thin Layer Chromatography Solvent system

Chloroform : Ethyl Acetate : Formic acid
(5 : 4 : 1.6)

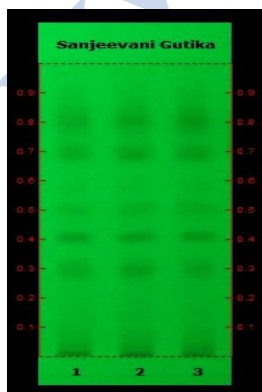
Details

Solvent of Extraction – Methanol

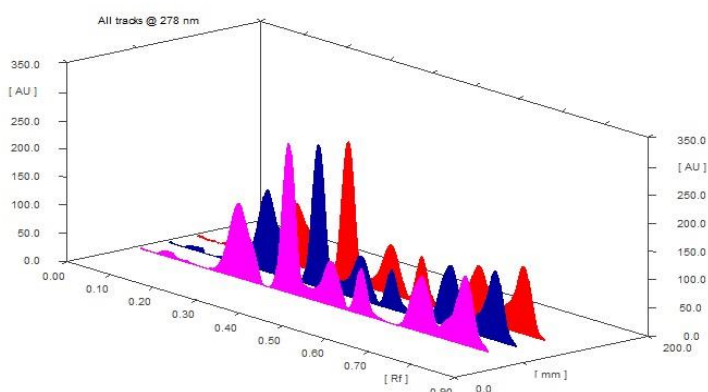
Distance traveled by solvent front – 90 mm

Total No. of Major spots – 6

Detection – Under UV at 254 nm



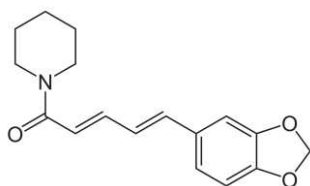
Major Spots	Colour	Approx. Rf.
1	Light Gray	0.03
2	Light Gray	0.29
3	Gray	0.41
4	Light Gray	0.50
5	Gray	0.69
6	Gray	0.80



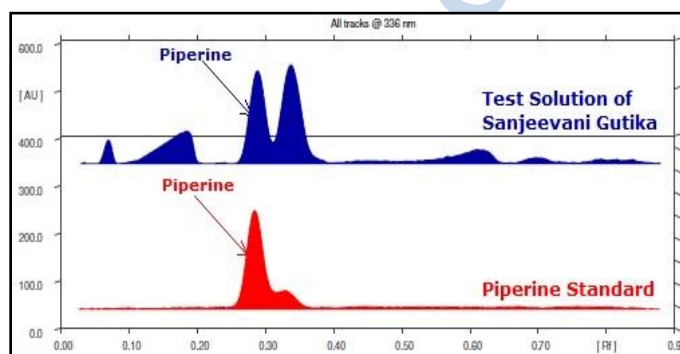
3D Peak Display of Sanjeevani Gutika at 278 nm

HPTLC Profile[†]

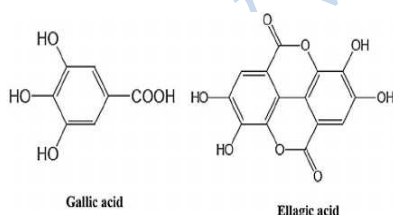
i) Piperine



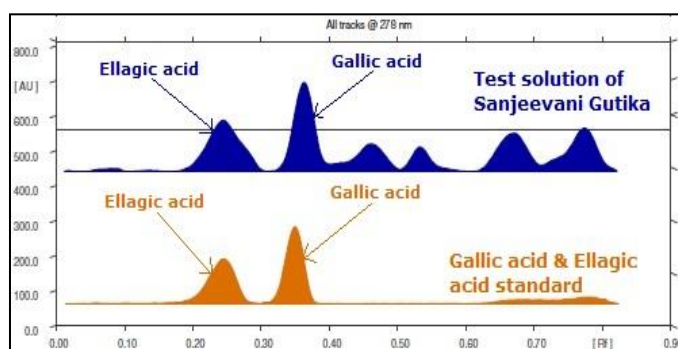
When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 336 nm corresponding with piperine standard.



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.



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

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

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

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