

BILVADI GUTIKA

Monograph No. – 0501474 ver 3.0

Issue No: 03

Date of Issue: 08/07/2021

Text Reference : Ayurvedic Formulary of India, Part I, 12:18

Amendment No : 02

Amendment Date : 28/01/2025

Shelf Life: 3 years

Description

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

Loss on Drying at 105°

Not more than 10 % 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

302 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 12 % w/w

Acid Insoluble Ash

Not more than 1.5 % w/w

Water Soluble Extractive

Not less than 24 % w/w

Alcohol Soluble Extractive

Not less than 15 % w/w

pH (1 % Aq. Solution)

5.0 – 7.0

Thin Layer Chromatography Solvent system

Chloroform : Ethanol : Glacial acetic acid
(9.4 : 0.5 : 0.1)

Details

Solvent of Extraction – Methanol

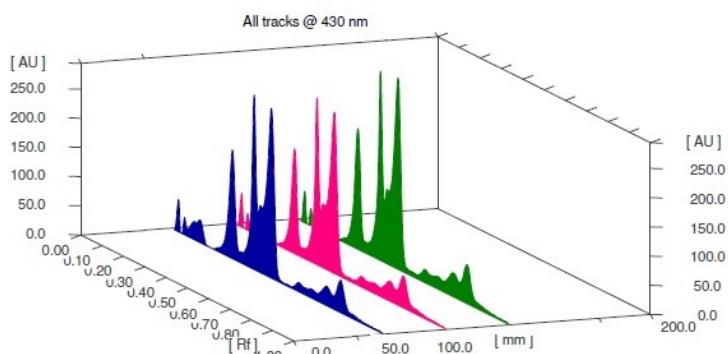
Solvent front – 60 mm

Total No. of Major spots – 5

Visualization – Under UV at 366 nm



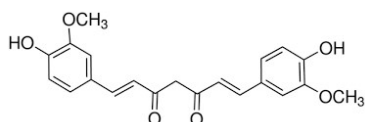
Major Spots	Colour	Approx. Rf.
1	Yellow	0.30
2	Yellow	0.40
3	Light Blue	0.44
4	Yellow	0.48
5	Fluorescent Blue	0.60



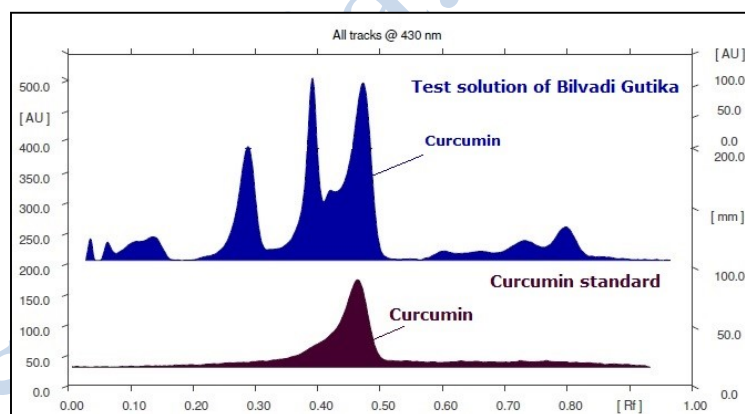
3D Peak Display of Bilvadi Gutika Tablets at 430 nm

HPTLC Profile[†]

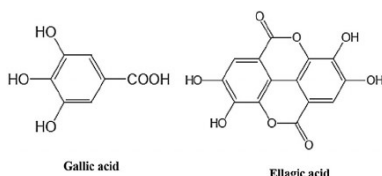
i) Curcumin



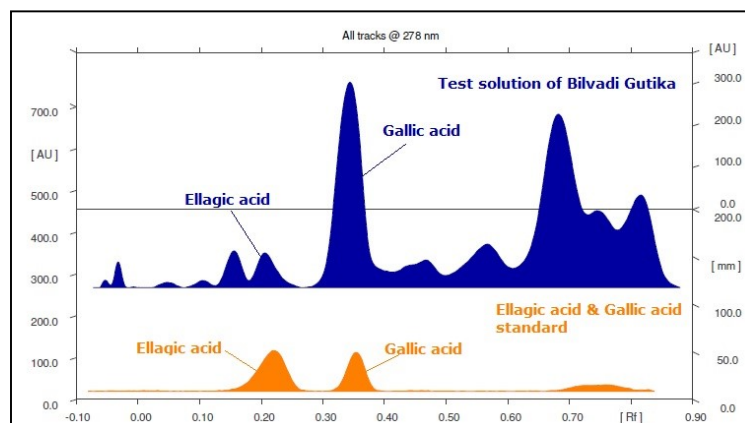
When examined in the range of 400 nm to 700 nm, the test solution shows absorption maxima at about 430 nm corresponding with Curcumin standard.



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

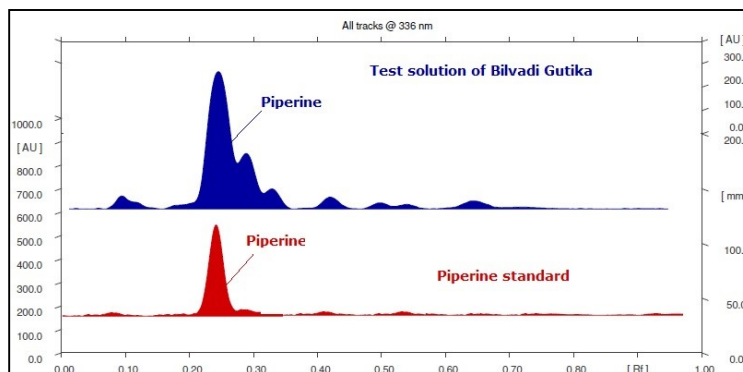
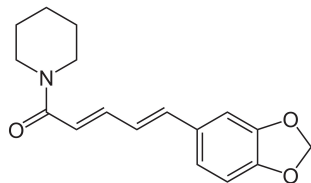


When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 290 nm for Gallic acid & 278 nm for Ellagic acid corresponding with Gallic acid & Ellagic acid standard.



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.



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