

## GUDUCHI TABLETS

### Monograph No. 2700144 ver 3.0

Issue No: 03

Date of Issue: 05/11/2020

Text Reference : API Part I, Volume I, Monograph No. 27

Amendment No : 02

Amendment Date : 11/04/2022

Shelf Life: 3 years

#### Description

Yellowish brown to light brown color caplet shape coated tablets having SDL mark on one side

#### Loss on Drying at 105°

Not more than 7 % w/w

#### Friability

Not more than 1 % w/w

#### Disintegration Time

Not more than 60 min.

#### Hardness

Not less than 2 kg/cm<sup>2</sup>

#### Thickness

5.5 ± 0.5 mm

#### Length

17.5 ± 0.5 mm

#### Average Weight

670 mg ± 5 %

#### Uniformity of weight of 20 tablets

Not more than 2 tablets deviate by more than 5% of the Average Weight and none by more than 10% of the Average Weight.

#### pH

5.5 – 8.0

#### Ash

Not more than 10 % w/w

#### Acid insoluble ash

Not more than 2 % w/w

#### Water soluble extractive

Not less than 30 % w/w

#### Alcohol soluble extractive

Not less than 15 % w/w

#### Thin Layer Chromatography Solvent system

Toluene : Acetone : Water  
( 5 : 15 : 1 )

#### Details

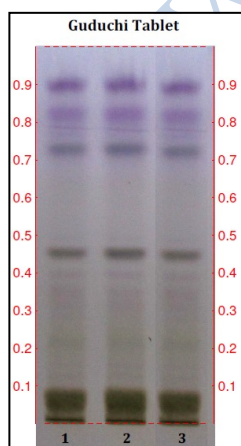
Solvent of Extraction – Methanol

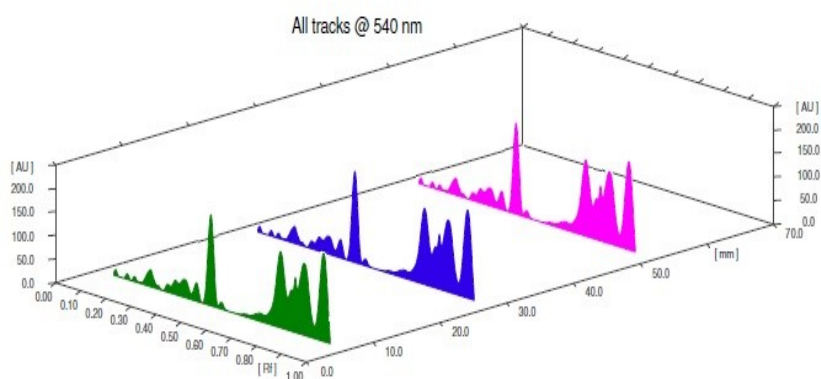
Solvent front – 90 mm

Total No. of Major spots – 7

Detection – After Spraying with Anisaldehyde Sulphuric acid Reagent

Major Spots	Colour	Approx. Rf.
1	Brown	0.07
2	Yellowish Brown	0.20
3	Purple	0.38
4	Brown	0.43
5	Violet	0.72
6	Purple	0.81
7	Purple	0.89



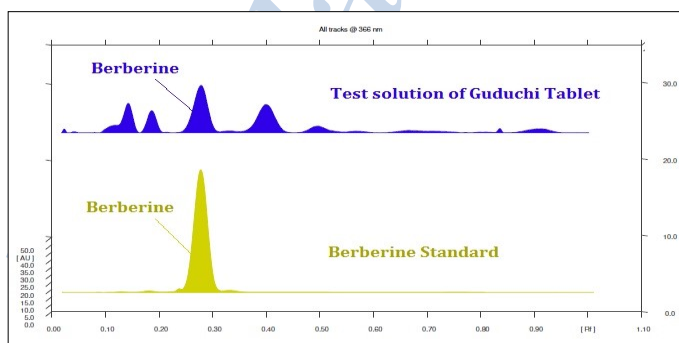
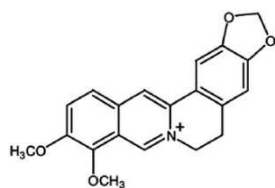


**3D Peak Display of Guduchi Tablet at 540 nm**

## HPTLC Profile<sup>†</sup>

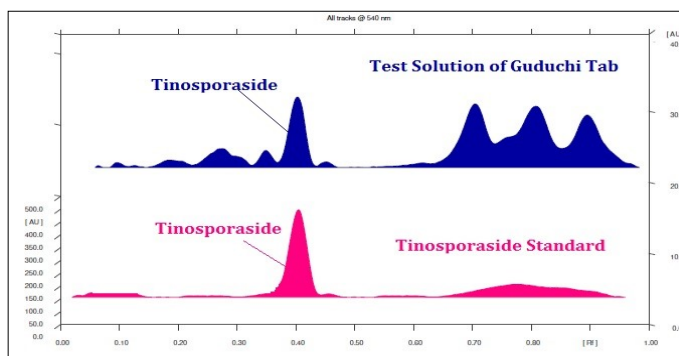
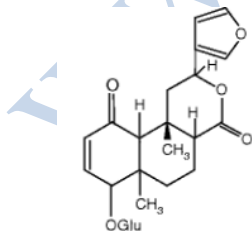
### i) Berberine

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 366 nm corresponding with Berberine standard



### ii) Tinosporaside

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 540 nm corresponding with Tinosporaside standard



## Heavy metal

<b>Lead (Pb)</b>	NMT 10 ppm
<b>Mercury (Hg)</b>	NMT 1 ppm
<b>Arsenic (As)</b>	NMT 3 ppm
<b>Cadmium (Cd)</b>	NMT 0.3 ppm
<b>E. coli</b>	Absent/g
<b>P. aeruginosa</b>	Absent/g
<b>Salmonella sp.</b>	Absent/g
<b>Staphylococcus sp.</b>	Absent/g
<b>Total Microbial plate Count (TPC)</b>	NMT 10 <sup>5</sup> c.f.u./g
<b>Total Yeast &amp; Mould Count (TYMC)</b>	NMT 10 <sup>3</sup> c.f.u./g
<b>Pesticide Residue + (OC+OP)</b>	Complies as per API
<b>Aflatoxins B1,B2,G1,G2 +</b>	Complies as per API

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