

## TULASI TABLETS

### Monograph No. – 2700054 ver 3.0

Issue No: 03

Date of Issue: 05/11/2020

Text Reference : API Part I, Volume II, Monograph No. 72

Amendment No : 01

Amendment Date : 11/04/2022

Shelf Life: 3 years

#### Description

Greenish brown to 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

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 15 % w/w

#### Water soluble extractive

Not less than 20 % w/w

#### Alcohol soluble extractive

Not less than 20 % w/w

#### pH (1% Aq. Solution)

5.0 – 7.0

#### Thin Layer Chromatography Solvent system

Toluene : Ethyl acetate  
( 9 : 1 )

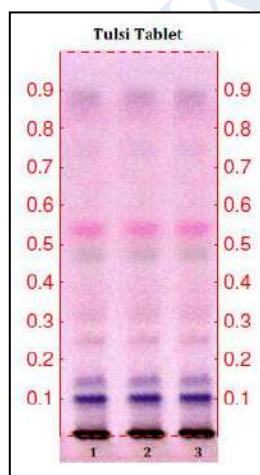
#### Details

Solvent of Extraction – Methanol

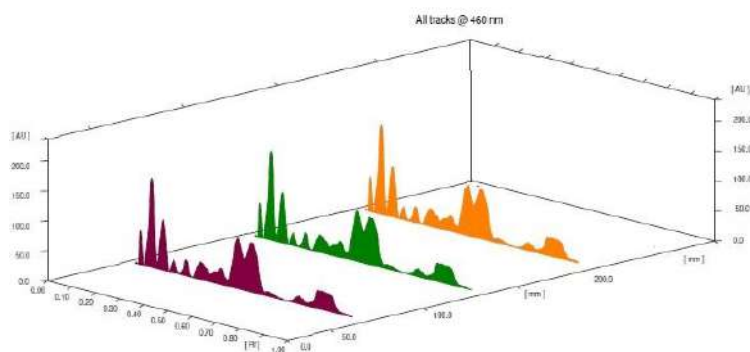
Solvent front – 90 mm

Total No. of Major spots – 10

Detection – After spraying with Anisaldehyde H<sub>2</sub>SO<sub>4</sub>



Major Spots	Colour	Approx. Rf.
1	Purple	0.05
2	Violet	0.1
3	Violet	0.15
4	Purple	0.19
5	Purple	0.24
6	Light Purple	0.31
7	Purple	0.38
8	Greenish Gray	0.47
9	Pink	0.53
10	Violet	0.87

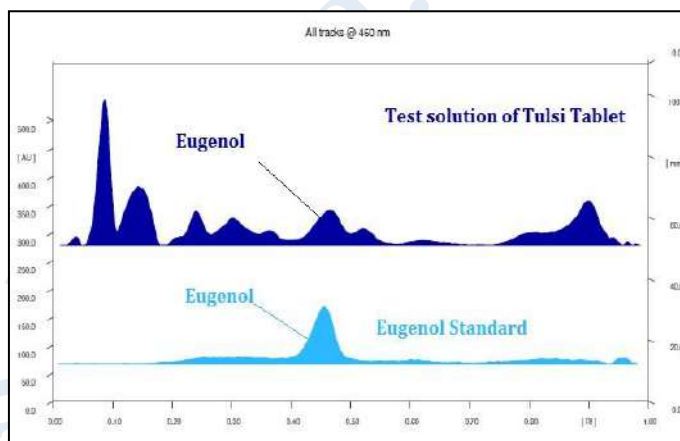
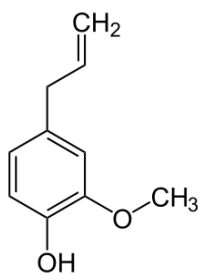


**3D Peak Display of Tulasi Tablet at 460 nm**

### HPTLC Profile<sup>†</sup>

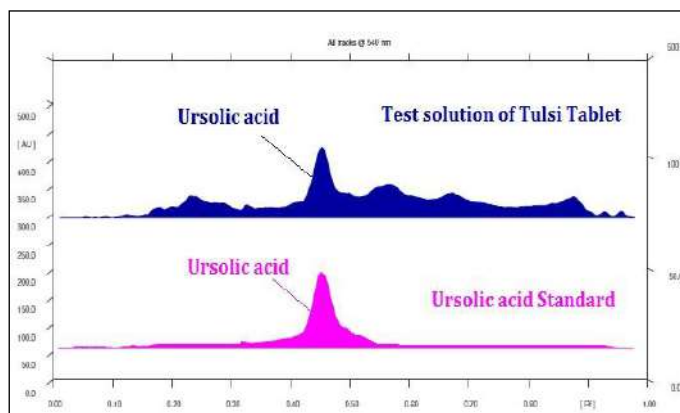
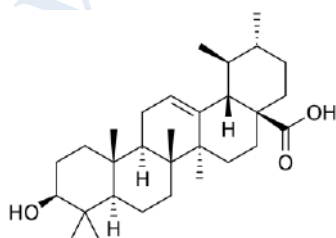
#### i) Eugenol

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 460 nm corresponding with Eugenol standard.



#### ii) Ursolic acid

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 540nm corresponding with Ursolic acid 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<sup>†</sup> (OC+OP)</b>	Complies as per API
<b>Aflatoxins B1,B2,G1,G2<sup>†</sup></b>	Complies as per API