

TULASI TABLETS

Monograph No. – 2700054 ver 3.0

Issue No: 03

Date of Issue: 05/11/2020

Text Reference : API Part I, Volume I, 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/cm²

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

5.0 – 7.0

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

Thin Layer Chromatography Solvent system

Toluene : Ethyl acetate
(9 : 1)

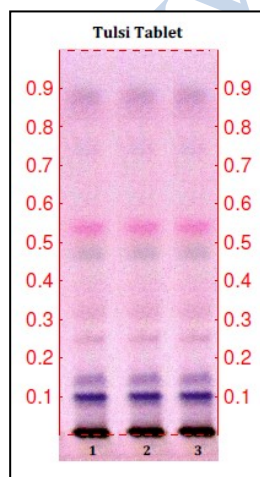
Details

Solvent of Extraction – Methanol

Solvent front – 90 mm

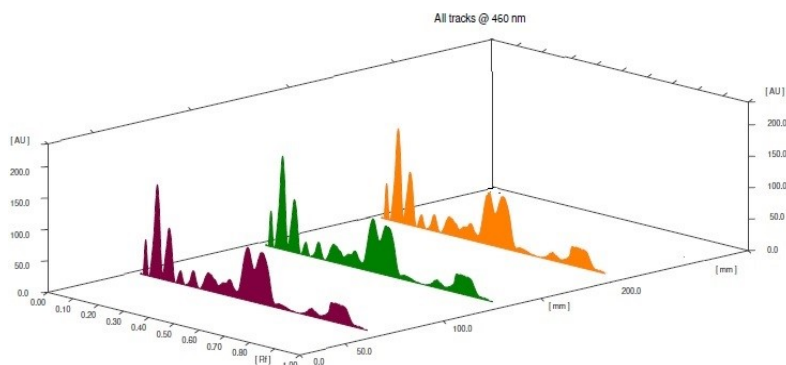
Total No. of Major spots – 10

Detection – After spraying with Anisaldehyde H₂SO₄



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

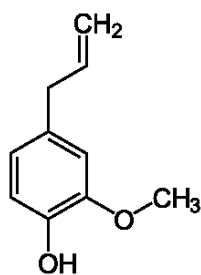




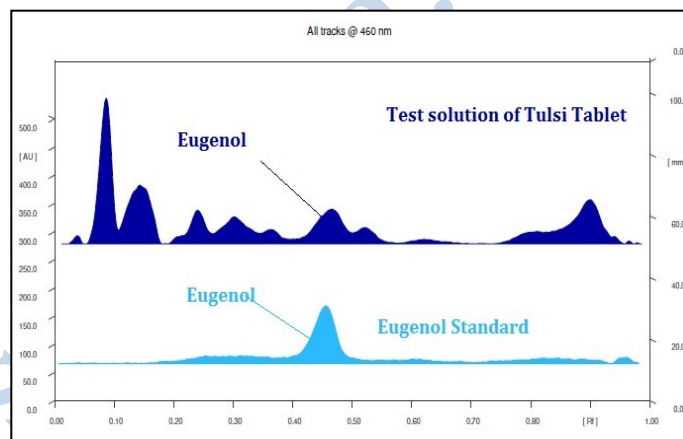
3D Peak Display of Tulasi Tablet at 460 nm

HPTLC Profile[†]

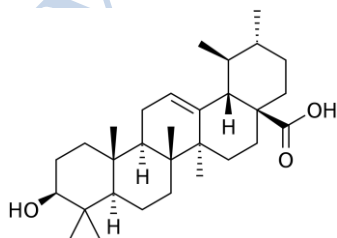
i) Eugenol



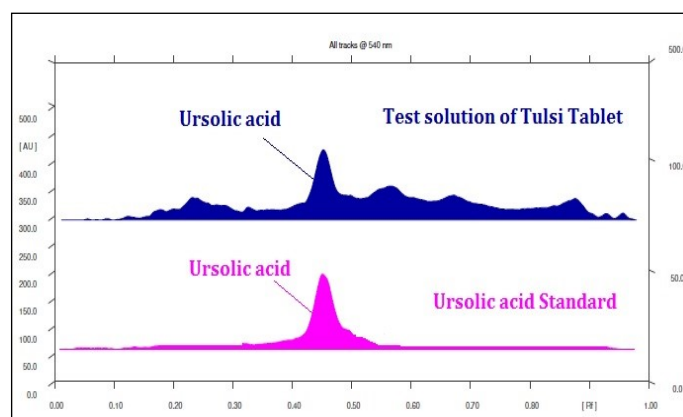
When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 460 nm corresponding with Eugenol standard.



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

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 10⁵ c.f.u./g

Total Yeast & Mould Count (TYMC) NMT 10³ 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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