

TAGARA TABLETS

Monograph No. – 2700034 ver 3.0

Issue No: 03

Amendment No : 00

Date of Issue: 19/09/2024

Amendment Date : --

Text Reference: API Part I, Volume I, Monograph No. 69

Shelf Life: 3 years

Description

Greenish brown to dark brown color caplet shape coated tablets having SDL mark on one side and strong odour.



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

5.3 ± 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 17.5 % w/w

Acid insoluble ash

Not more than 9.5 % w/w

Water soluble extractive

Not less than 20 % w/w

Alcohol soluble extractive

Not less than 19 % w/w

pH (1 % Aq. Solution)

5.0 – 7.0

Thin Layer Chromatography Solvent system

Pet Ether (60 to 80°C) : Ethyl methyl ketone
(8 : 2)

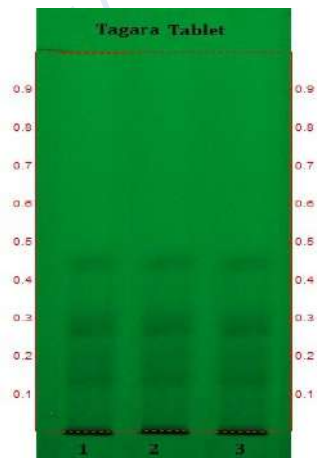
Details

Solvent of Extraction – Dichloromethane

Solvent front – 90 mm

Total No. of Major spots – 4

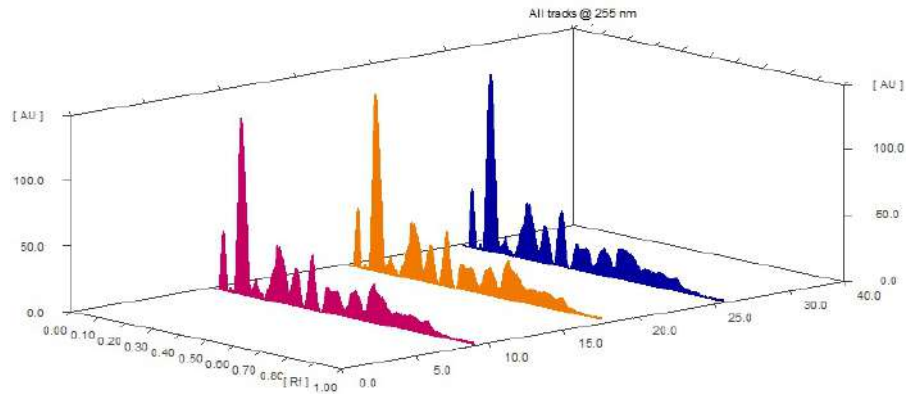
Visualization – Under UV at 254 nm



Major Spots	Colour	Approx. Rf.
1	Gray	0.14
2	Light Gray	0.18
3	Gray	0.29
4	Gray	0.44

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



3D Peak Display of Tagara Tablets at 255 nm

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