

TVAGROGJIT TABLETS

Monograph No. – 0703744 ver 3.0

Issue No: 03

Date of Issue: 15/11/2024

Text Reference : Ayurvedic Proprietary Medicine

Amendment No : 01

Amendment Date : 10/01/2026

Shelf life : 5 years

Description

Dark brown to blackish brown colour round biconvex coated tablets 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

12.0 ± 0.5 mm

Average Weight

660 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 29 % w/w

Acid insoluble ash

Not more than 9 % w/w

Water soluble extractive

Not less than 40 % w/w

Alcohol soluble extractive

Not less than 12 % w/w

pH (1% Aq. solution)

4.5 – 6.5

Elemental assay

Mercury (Hg)

3.5 – 10.0 mg/tablet

Iron (Fe)

3.5 – 8.0 mg/tablet

Copper (Cu)

2.0 – 5.5 mg/tablet

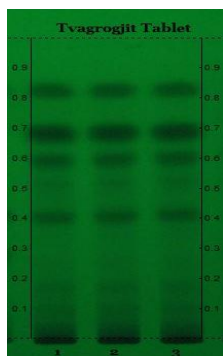
Sulphur (S)

Not less than 6.0 mg/tablet

Thin Layer Chromatography Solvent system

Chloroform : Ethyl acetate : Formic acid
(5 : 4 : 1.6)

Details



Solvent of Extraction – Methanol

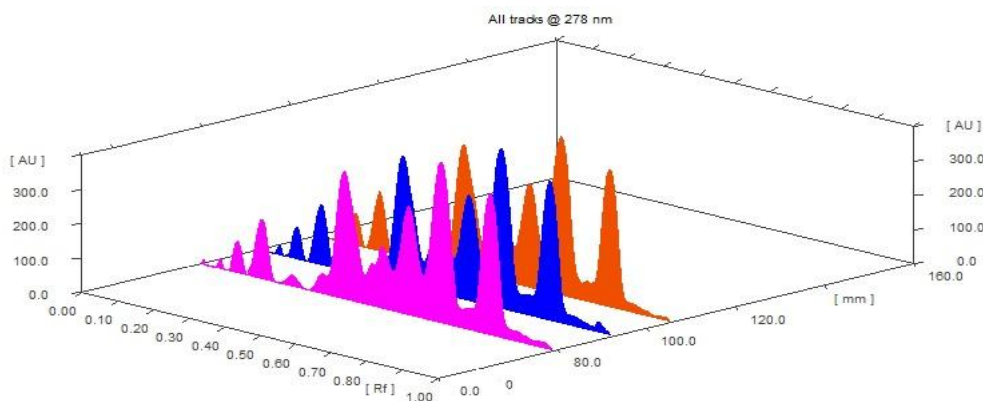
Solvent front – 90 mm

Total No. of Major spots – 7

Visualization – Under UV at 254 nm

Major Spots	Colour	Approx. Rf.
1	Light Gray	0.10
2	Light Gray	0.16
3	Black	0.40
4	Light Gray	0.50
5	Black	0.58
6	Black	0.68
7	Black	0.83



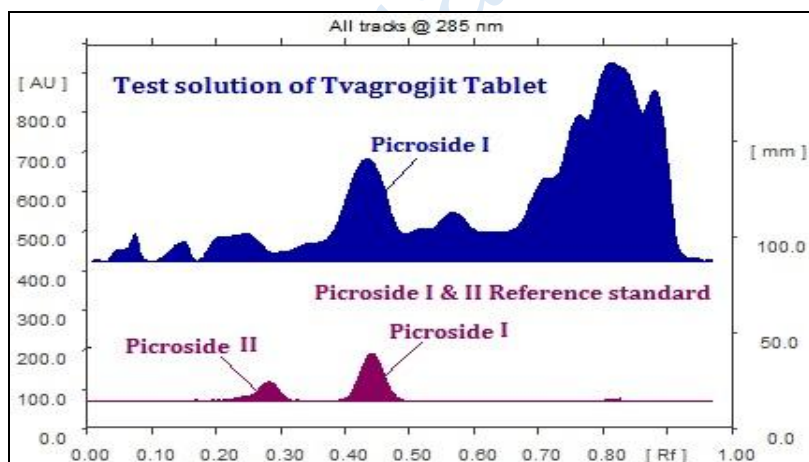
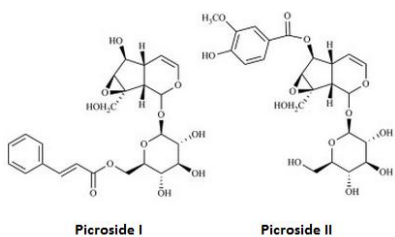


3D Peak Display of Tvagrogjit Tablets at 278 nm

HPTLC Profile [†]

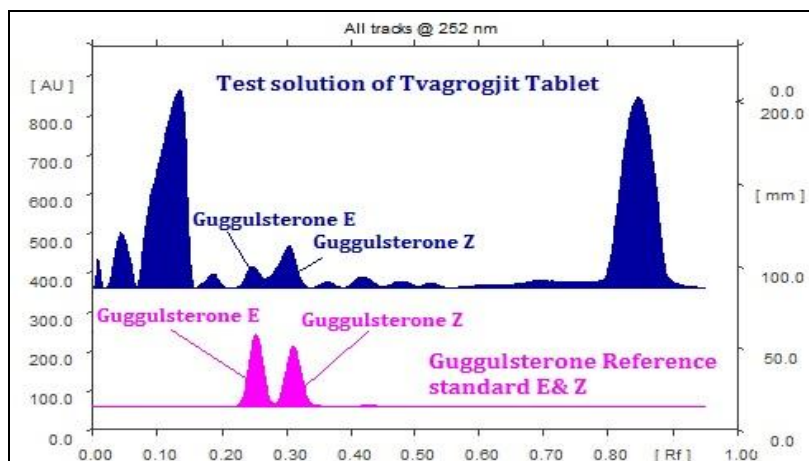
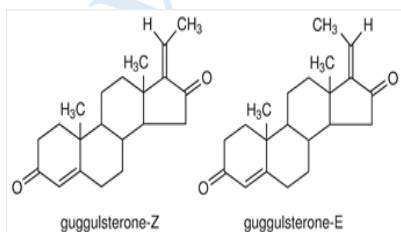
i) Picroside I

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 285 nm corresponding with Picroside I reference standard.



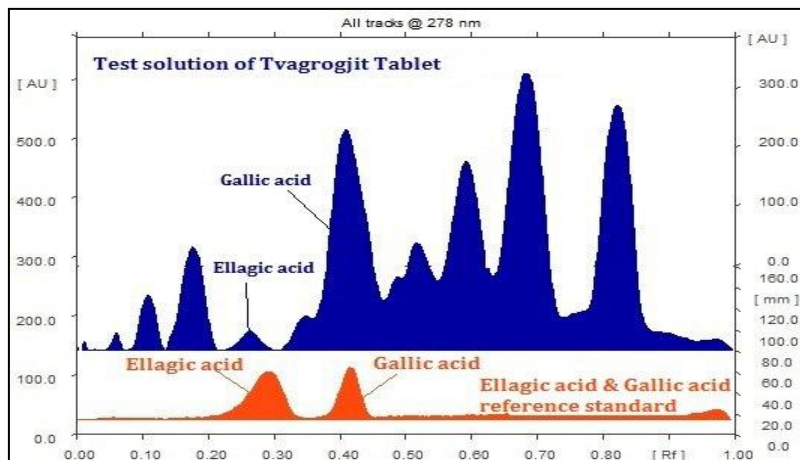
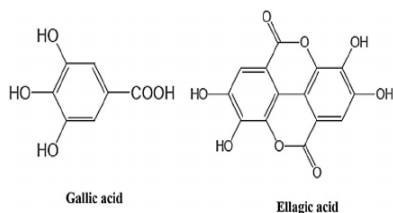
ii) Guggulsterone E & Z

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 252 nm corresponding with Guggulsterone E & Z reference standard.



iii) Total Polyphenols (as Ellagic acid & Gallic 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 reference standard.



<i>E. coli</i>	Absent/g
<i>P. aeruginosa</i>	Absent/g
<i>Salmonella sp.</i>	Absent/g
<i>Staphylococcus sp.</i>	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