

TRAYODASHANG GUGGUL

Monograph No. – 0400044 ver 3.0

Issue No: 03

Amendment No : 04

Date of Issue: 28/10/2016

Amendment Date : 06/07/2023

Text Reference : Bhaishajya Ratnavali (Vatavyadhi) 26/99-101

Shelf Life: 5 years

Description

Brown to Blackish brown colour, round biconvex coated tablet having SDL mark on one side.

Loss on Drying at 105°

Not more than 6 % w/w

Friability

Not more than 1 % w/w

Disintegration Time

Not more than 60 min.

Hardness

Not less than 1.5 kg/cm²

Thickness

5.5 ± 0.5 mm

Diameter

12.0 - 12.50 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 28 % w/w

Acid insoluble ash

Not more than 10 % w/w

Water soluble extractive

Not less than 30 % w/w

Alcohol soluble extractive

Not less than 6 % w/w

pH (1% Aq. Solution)

5.0 – 7.0

Thin Layer Chromatography Solvent system

Toluene : Acetone
(9.0 : 1.0)

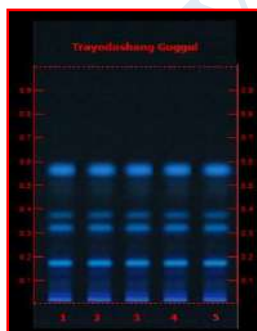
Details

Solvent of Extraction – Methanol

Solvent front – 90 mm

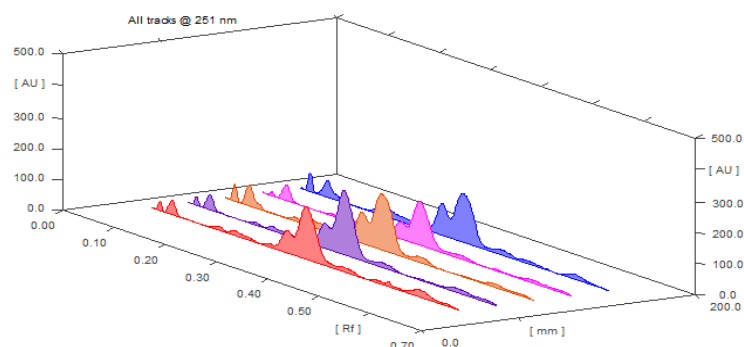
Total No. of Major spots – 4

Detection – Under UV at 366 nm



| Major Spots | Colour | Approx. Rf. |
|-------------|------------------|-------------|
| 1 | Fluorescent Blue | 0.17 |
| 2 | Fluorescent Blue | 0.32 |
| 3 | Fluorescent Blue | 0.38 |
| 4 | Fluorescent Blue | 0.56 |



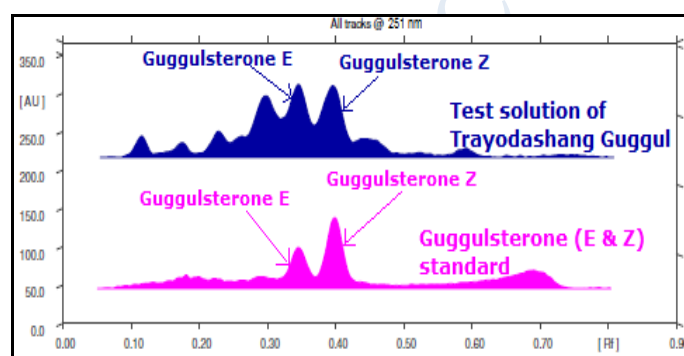
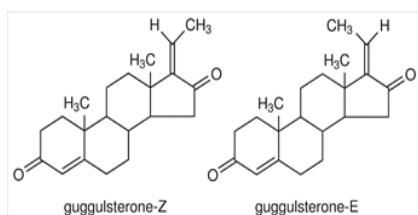


3D Peak Display of Trayodashang Guggul at 251 nm

HPTLC Profile[†]

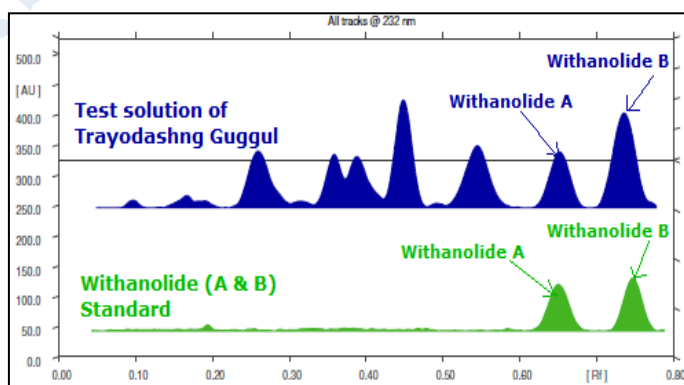
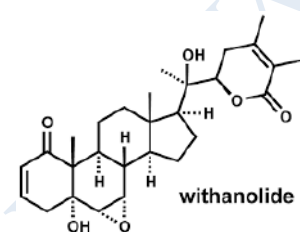
i) Guggulsterone (E & Z)

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 251 nm corresponding with Guggulsterone (E & Z) standard.



ii) Withanolide (A & B)

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 232 nm corresponding with Withanolide (A & B) 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 10^5 c.f.u./g |
| Total Yeast & Mould Count (TYMC) | NMT 10^3 c.f.u./g |
| Pesticide Residue [†] (OC+OP) | Complies as per API |
| Aflatoxins B1,B2,G1,G2 [†] | Complies as per API |