

### Shree Dhootapapeshwar Standards

#### **GOKSHURADI GUGGUL**

#### Monograph No. - 0400024 ver 3.0

Issue No: 03 Amendment No: 02

Date of Issue: 28/10/2016 Amendment Date: 02/05/2022

Text Reference : Bharat Bhaishajya Ratnakar 2/1337 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/cm<sup>2</sup>

**Thickness**  $5.0 \pm 0.5 \text{ mm}$ 

**Diameter**  $8.0 \pm 0.5 \text{ mm}$ 

Average Weight 300 mg  $\pm$  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 25 % w/w

Acid insoluble ash Not more than 8 % w/w

Water soluble extractive Not less than 25 % w/w

Alcohol soluble extractive Not less than 15 % w/w

**pH (1% Aq. Solution)** 4.8 – 6.0

Thin Layer Chromatography

Solvent system

Toluene : Acetone ( 9.0 : 1.0 )

Solvent of Extraction - Methanol

Solvent front - 90 mm

Total No. of Major spots - 5

Detection – Under UV at 366 nm

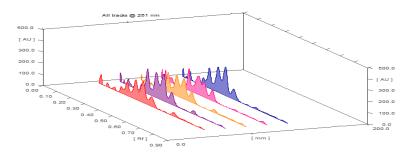


Major Spots	Colour	Approx. Rf.
1	Light Blue	0.07
2	Fluorescent Blue	0.15
3	Light Blue	0.21
4	Fluorescent Blue	0.30
5	Fluorescent Blue	0.35



Note:  $^{\dagger}$ : These extra tests can be performed on every batch at extra cost. Tests can be ascertained on request.

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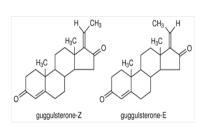


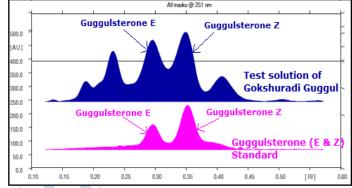
3D Peak Display of Gokshuradi Guggul at 251 nm

#### **HPTLC Profile**<sup>+</sup>

### i) Guggulsterone (E & Z)

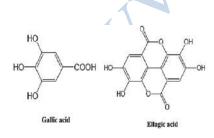
When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 251 nm corresponding with Guggulsterone (E & Z) standard.

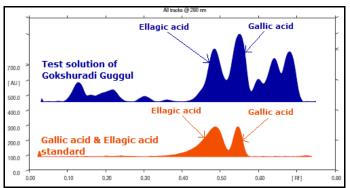




#### ii) Total Polyphenols (as Gallic acid & Ellagic acid)

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 standard.



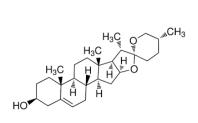


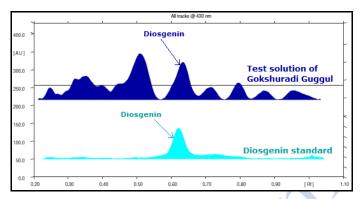


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#### iii) Diosgenin

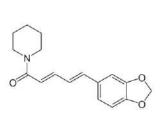
When examined in the range of 400 nm to 700 nm, the test solution shows absorption maxima at about 430 nm corresponding with Diosgenin standard.

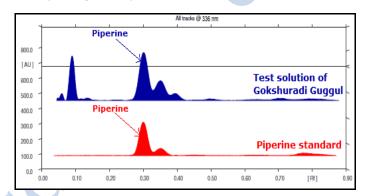




#### iv) Piperine

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 336 nm corresponding with Piperine 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** NMT 10<sup>5</sup> c.f.u./g

(TPC)

**Total Yeast & Mould Count** NMT 10<sup>3</sup> c.f.u./g

(TYMC)

Pesticide Residue + (OC+OP) Complies as per API

Aflatoxins B1,B2,G1,G2 + Complies as per API