

Shree Dhootapapeshwar Standards

SWAYAMBHUVA GUGGUL

Monograph No. - 0400284 ver 3.0

Issue No: 03 Amendment No: 03

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

Text Ref: Bhavaprakash Madhyam Khanda (Kushtharoga) 69-72 Shelf Life: 5 years

DescriptionBrown 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 5.0 \pm 0.5 mm

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

Average Weight 305 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

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weight.

Ash Not more than 30 % w/w

Acid insoluble ash Not more than 15 % w/w

Water soluble extractive Not less than 30 % w/w

Alcohol soluble extractive Not less than 15 % w/w

pH (1% Aq. Solution) 5.0 - 7.0

Elemental Assay

Copper (Cu) Not less than 1.7 mg/tab

Iron (Fe) 13 – 18 mg/tab

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 - 7

Detection - Under UV at 366 nm

100				
29-				
0.0				
41				
98				
20				
-				
0.0				
92-				
44 <u>-</u>				
-	annin		5	

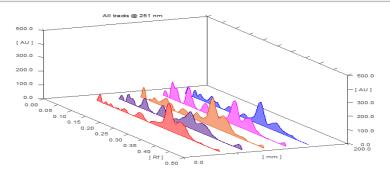
Major Spots	Colour	Approx. Rf.	
1	Blue	0.14	
2	Fluorescent Blue	0.19	
3	Light Blue	0.28	
4	Fluorescent Blue	0.37	
5	Fluorescent Blue	0.43	
6	Fluorescent Blue	0.51	
7	Light Blue	0.60	

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



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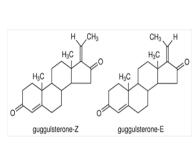


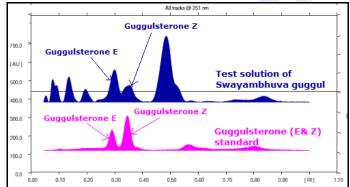
3D Peak Display of Swayambhuva Guggul at 251 nm

HPTLC Profile⁺

i) Guggulsterone (E & Z)

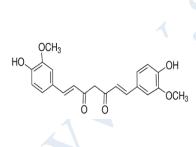
When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 251 nm corresponding with Guggulsterone (E & Z) standard.

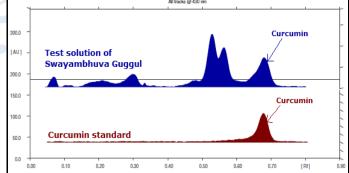




ii) Curcumin

When examined in the range of 200 nm to 700 nm, the test solution shows absorption maxima at about 430 nm corresponding with Curcumin standard.





E. coli

Absent/g

P. aeruginosa

Absent/g

Salmonella sp.

Absent/g

Staphylococcus sp.

Absent/g

Total Microbial Plate Count

NMT 10⁵ c.f.u./g

(TPC)

NIMT 103 - 6 .. /

Total Yeast & Mould Count (TYMC)

NMT 10³ c.f.u./g

(TYMC)
Pesticide Residue + (OC+OP)

Complies as per API

Aflatoxins B1,B2,G1,G2 +

Complies as per API