

KUNDURU (SHALLAKI) TABLET

Monograph No. – 2700074 ver 3.0

Issue No: 03

Date of Issue: 13/10/2022

Text Reference : API, Part I, Volume IV, Monograph No. 24

Amendment No : 00

Amendment Date : --

Shelf Life: 3 years

Description

Off white to Cream colour, caplet shape tablet having SDL mark on one side.

Loss on Drying at 105°

Not more than 8 % w/w

Friability

Not more than 1 % w/w

Disintegration Time

Not more than 30 min.

Hardness

Not less than 2 kg/cm²

Thickness

5.5 ± 0.5 mm

Length

21.0 ± 0.5 mm

Average Weight

1040 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 12 % w/w

Acid insoluble ash

Not more than 3 % w/w

Water soluble extractive

Not less than 15 % w/w

Alcohol soluble extractive

Not less than 25 % w/w

pH (1% aq. solution)

4.5 - 7.5

Thin Layer Chromatography Mobile Phase

Toluene : Ethyl acetate : Methanol
(8 : 2 : 1)

Details

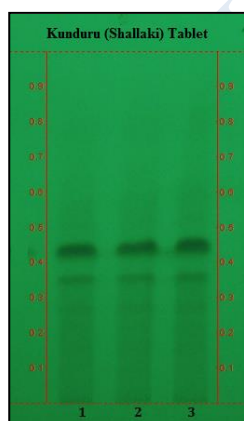
Solvent of Extraction – Methanol

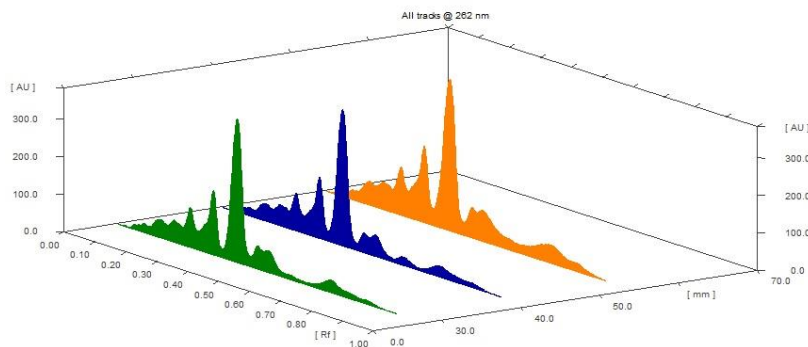
Distance traveled by solvent front – 90 mm

Total No. of Major spots – 3

Detection – Under UV at 254 nm

Major Spots	Color	Approx. Rf.
1	Light Gray	0.27
2	Gray	0.35
3	Black	0.43



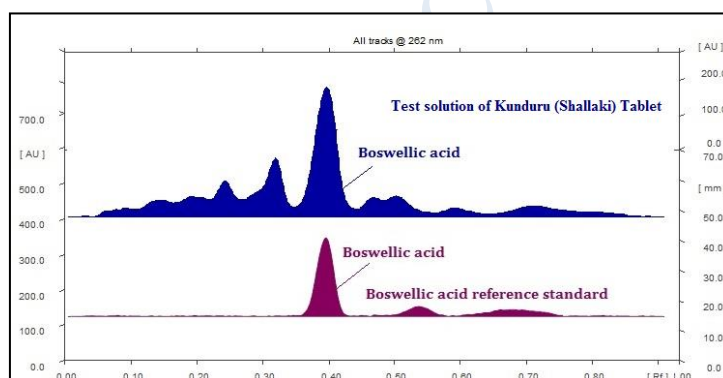
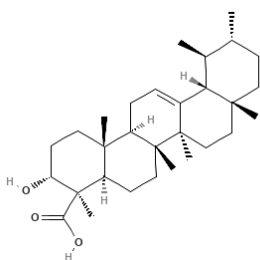


3D Peak Display of Kunduru (Shallaki) Tablet at 262 nm

HPTLC Profile[†]

i) Boswellic Acid

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 262 nm for Boswellic acid corresponding with Boswellic acid 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