

KARAVALLAKA (KARELA) TABLETS

Monograph No. – 2700094 ver 3.0

Issue No: 03

Amendment No : 00

Date of Issue: 22/10/2024

Amendment Date : --

Text Reference: API Part I, Volume II, Monograph No. 39

Shelf Life: 3 years

Description

Yellowish brown to brown color caplet shape coated tablets having SDL mark on one side.



Loss on Drying at 105°

Not more than 7 % w/w

Friability

Not more than 1 % w/w

Disintegration Time

Not more than 60 min.

Hardness

Not less than 2 kg/cm²

Thickness

5.0 ± 0.5 mm

Length

17.5 ± 0.5 mm

Average Weight

670 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 15 % w/w

Acid insoluble ash

Not more than 3 % w/w

Water soluble extractive

Not less than 25 % w/w

Alcohol soluble extractive

Not less than 5 % w/w

pH (1 % Aq. Solution)

6.0 – 7.0

Thin Layer Chromatography Solvent system

Toluene : Methanol
(9 : 1)

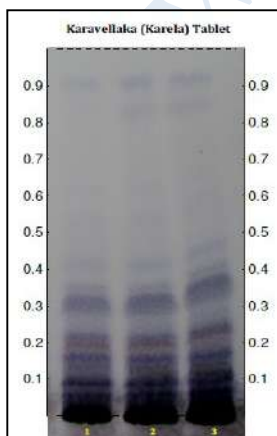
Details

Solvent of Extraction – Hexane → Methanol

Solvent front – 90 mm

Total No. of Major spots – 8

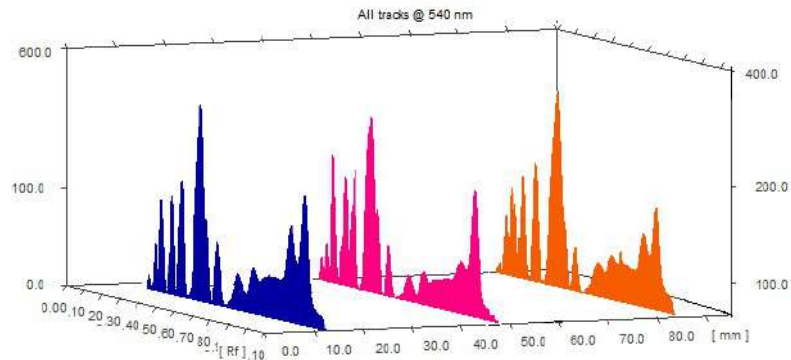
Visualization – After spray with Anisaldehyde Sulfuric acid



Major Spots	Colour	Approx. Rf.
1	Blue	0.09
2	Blue	0.18
3	Violet	0.21
4	Violet	0.30
5	Light Violet	0.33
6	Light Violet	0.40
7	Light Violet	0.85
8	Light Violet	0.91

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

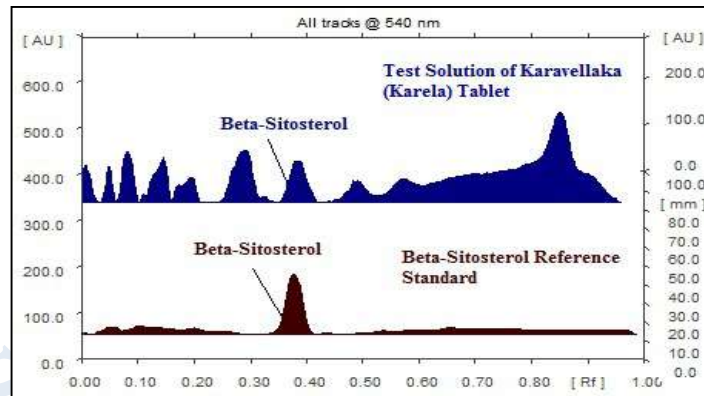
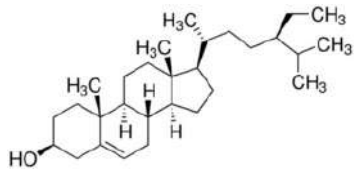


3D Peak Display of Karavallaka (Karela) Tablets at 540 nm

HPTLC Profile[†]

i) Beta-Sitosterol

When examined in the range of 400 nm to 700 nm, the test solution shows absorption maxima at about 540 nm corresponding with Beta-Sitosterol reference standard.



Heavy metal

Lead (Pb)	Not more than 10 ppm
Mercury (Hg)	Not more than 1 ppm
Arsenic (As)	Not more than 3 ppm
Cadmium (Cd)	Not more than 0.3 ppm
<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