NISHAMALAKI TABLET

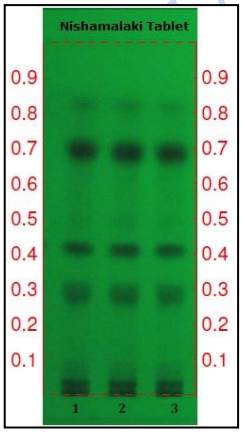
Monograph No. 3100044 *ver 3.0*

Issue No: 03
Date of Issue: 13/10/2021
Text Reference : Ashtang Hriday Chikitsa (Prameha) 12/5

Amendment No : 01
Amendment Date : 07/02/2023
Shelf Life: 3 years

Description	Yellowish brown to Light brown colour caplet shape coated tablet having SDL mark on one side.
Loss on Drying at 105^0	Not more than 8 % w/w
Friability	Not more than 1 % w/w
Disintegration Time	Not more than 60 min.
Hardness	Not less than 2 kg/cm^2
Thickness	5.0 $\pm$ 0.5 mm
Length	17.5 $\pm$ 0.5 mm
Average Weight	685 mg ± 5 %
pH (1 % Aq. Solution)	4.0 – 5.0
Uniformity of weight of 20 tablets	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 18 % w/w
Acid insoluble ash	Not more than 2 % w/w
Water soluble extractive	Not less than 23 % w/w
Alcohol soluble extractive	Not less than 8.5 % w/w
Thin Layer Chromatography Solvent system	Chloroform : Ethyl Acetate : Formic acid (5 : 4 : 1.6)
Details	Solvent of Extraction – Methanol Solvent front – 90 mm Total No. of Major spots – 7 Detection – Under UV at 254 nm



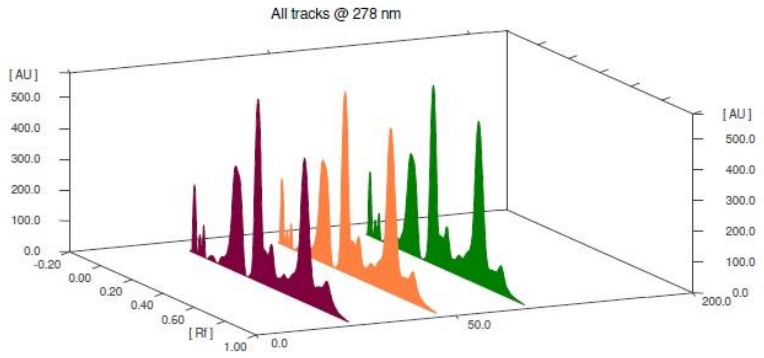


Major Spots	Colour	Approx. Rf.
1	Black	0.03
2	Light gray	0.08
3	Gray	0.28
4	Black	0.41
5	Light gray	0.50
6	Black	0.69
7	Gray	0.82

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

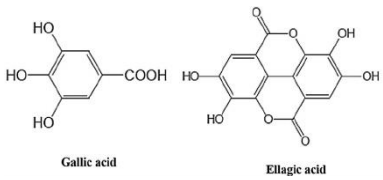


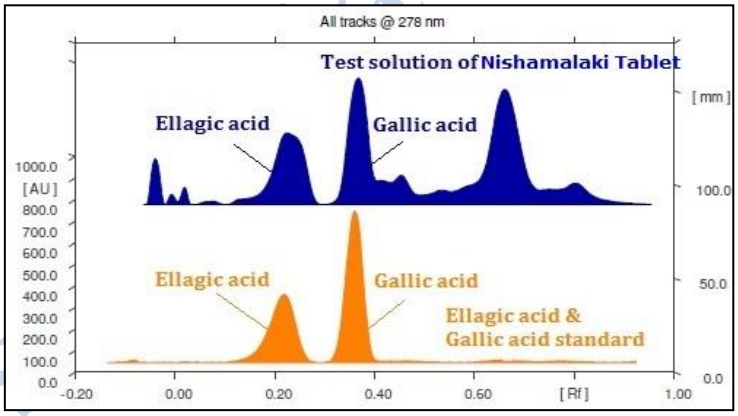
3D Peak Display of Nishamalaki Tablet at 278 nm

HPTLC Profile†

i) Total Polyphenols (as Gallic acid & Ellagic acid)

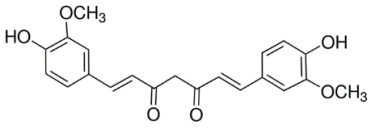
When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 290 nm for Gallic acid & 278 nm for Ellagic acid corresponding with Gallic acid & Ellagic acid standard.

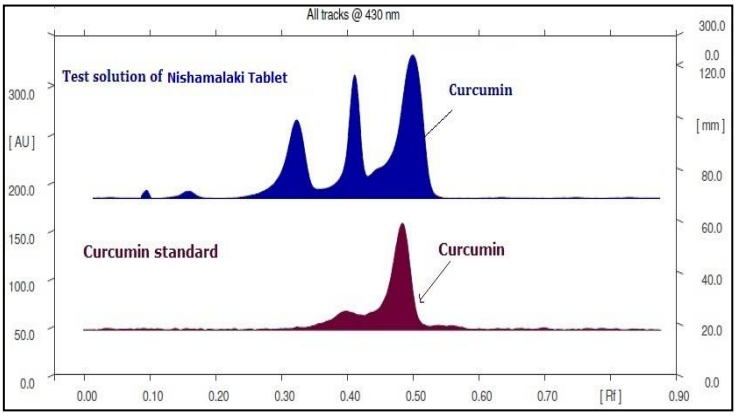




ii) Curcumin

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.





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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	NMT 10^3 c.f.u./g
Pesticide Residue † (OC+OP)	Complies as per API
Aflatoxins B1,B2,G1,G2 †	Complies as per API

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