

NIROCIL TABLET

Monograph No. – 070229 ver 3.0

Issue No: 03

Date of Issue: 28/10/2016

Text Reference : Ayurvedic Proprietary Medicine

Amendment No : 02

Amendment Date : 03/09/2024

Shelf Life: 3 years

Description

Pink coloured round biconvex film coated tablets.

Loss on Drying at 105°

Not more than 10 % w/w

Friability

Not more than 1 % w/w

Disintegration Time

Not more than 60 mins.

Hardness

Not less than 2.5 kg/cm²

Thickness

5.5 ± 0.5 mm

Diameter

12 - 12.5 mm

Average Weight

676 mg ± 5 %

Uniformity of weight on 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 32 % w/w

Acid insoluble ash

Not more than 9 % w/w

Water soluble extractive

Not less than 15 % w/w

Alcohol soluble extractive

Not less than 2.5 % w/w

pH (1% Aq. solution)

5.0 – 7.0

Thin Layer Chromatography Mobile Phase

Hexane : Ethyl acetate : Acetone
(6 : 3 : 1)

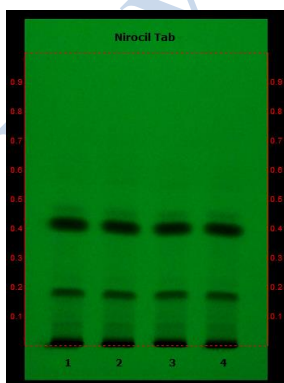
Details

Solvent of Extraction – Methanol

Solvent front – 90 mm

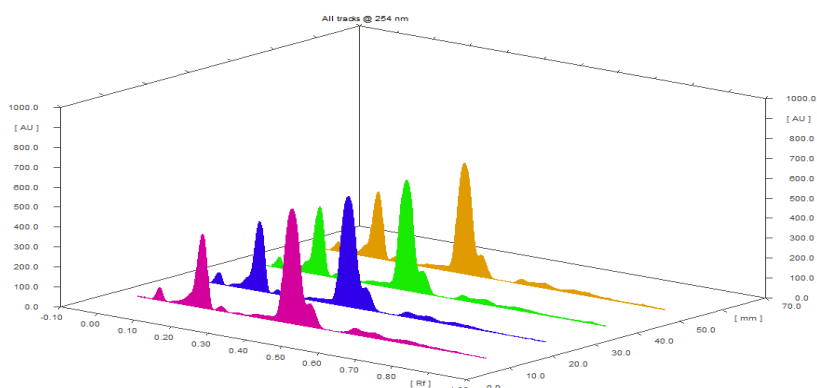
Total No. of Major spots – 4

Detection – Under UV at 254 nm



Major Spots	Colour	Approx. Rf.
1	Light Gray	0.06
2	Black	0.17
3	Black	0.40
4	Light Gray	0.45





3D Peak Display of Nirocil Tab at 254 nm

Acute Toxicity	Nontoxic when single dose (10 x therapeutic dose) administered orally
Heavy metal	
Lead (Pb)	NMT 10 ppm
Mercury (Hg)	NMT 1 ppm
Arsenic (As)	NMT 3 ppm
Cadmium (Cd)	NMT 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)	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