

## NIMBA (NEEM) TABLET

Monograph No. – 2700114 ver 3.0

Issue No: 03

Date of Issue: 22/10/2022

Text Reference : API, Part II, Volume II, Monograph No. 56

Amendment No : 00

Amendment Date : --

Shelf Life: 3 years

### Description

Yellowish brown to greenish brown colour, caplet shape coated tablet 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/cm<sup>2</sup>

### Thickness

5.5 ± 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 20 % w/w

### Acid insoluble ash

Not more than 6 % w/w

### Water soluble extractive

Not less than 19 % w/w

### Alcohol soluble extractive

Not less than 13 % w/w

### pH (1% aq. solution)

4.5 - 7.5

### Thin Layer Chromatography Mobile Phase

Ethyl acetate : Formic acid : Glacial acetic acid : Water  
( 10 : 1.1 : 1.1 : 0.6 )

### Details

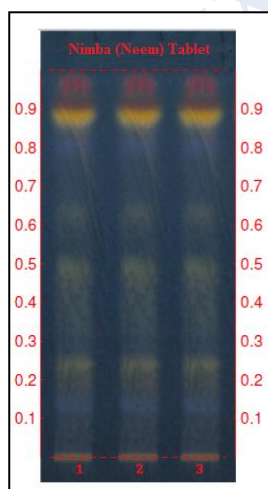
Solvent of Extraction – Methanol

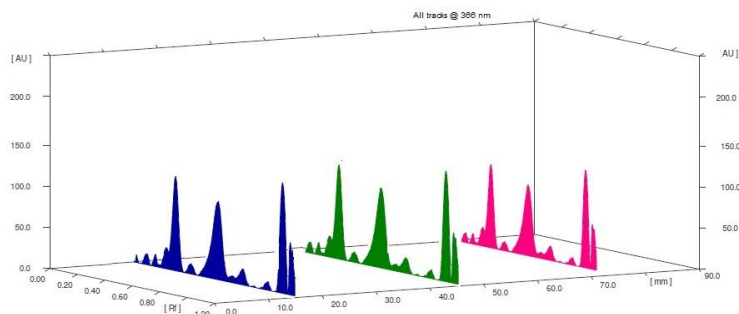
Distance traveled by solvent front – 90 mm

Total No. of Major spots – 7

Detection – Under 366 nm After spray with Natural Product reagent

Major Spots	Color	Approx. Rf.
1	Light Blue	0.12
2	Light Yellow	0.24
3	Light Yellow	0.48
4	Light Yellow	0.62
5	Yellow	0.87
6	Brown	0.90
7	Brown	0.96



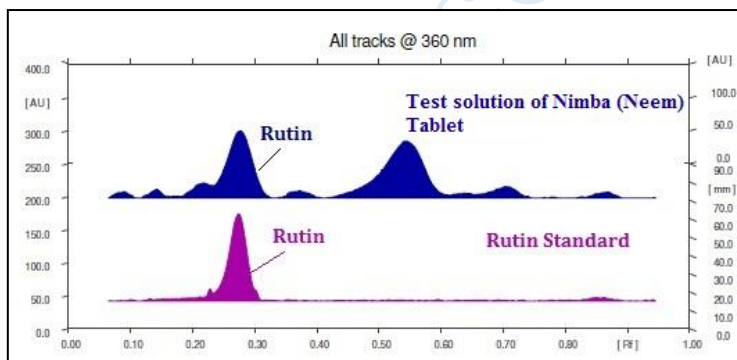
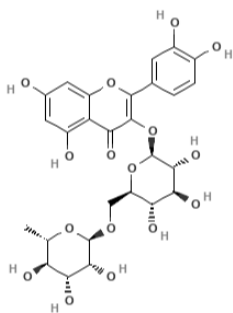


**3D Peak Display of Nimba (Neem) Tablet at 366 nm**

**HPTLC Profile<sup>†</sup>**

**i) Rutin**

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 360 nm for Rutin corresponding with Rutin standard.



**Heavy metal**

<b>Lead (Pb)</b>	NMT 10 ppm
<b>Mercury (Hg)</b>	NMT 1 ppm
<b>Arsenic (As)</b>	NMT 3 ppm
<b>Cadmium (Cd)</b>	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<sup>5</sup> c.f.u./g

**Total Yeast & Mould count (TYMC)** NMT 10<sup>3</sup> c.f.u./g

**Pesticide Residue<sup>†</sup> (OC+OP)** Complies as per API

**Aflatoxins B1,B2,G1,G2<sup>†</sup>** Complies as per API