

UNMATTA RASA

Monograph No. – 0802504 ver 3.0

Issue No: 03

Date of Issue: 17/06/2023

Text Reference : Rasa Yogasagar Part-1/402

Amendment No : 00

Amendment Date : --

Shelf Life: 5 years

Description

Dark gray to black colour, round convex tablets having SDL mark on one side.

Loss on Drying at 105°

Not more than 10 % w/w

Friability

Not more than 1 % w/w

Disintegration Time

Not more than 60 min.

Hardness

Not less than 2 kg/cm²

Thickness

4.7 ± 0.5 mm

Diameter

8.0 ± 0.5 mm

Average Weight

325 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 5 % w/w

Water soluble extractive

Not less than 8 % w/w

Alcohol soluble extractive

Not less than 2 % w/w

pH (1 % Aq. Solution)

5.0 – 6.5

Elemental Assay

Mercury (Hg)

50.0 – 75.0 mg/tab

Sulphur (S)

50.0 – 75.0 mg/tab

Thin Layer Chromatography

Mobile Phase

Toluene : Ethyl acetate
(7 : 3)

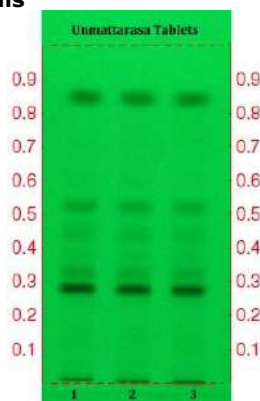
Details

Solvent of Extraction – Methanol

Solvent front – 90 mm

Total No. of Major spots – 5

Detection – Under UV at 254 nm

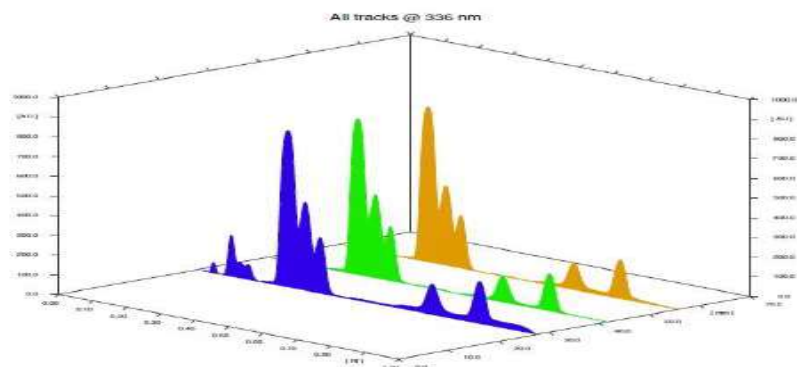


| Major Spots | Colour | Approx. Rf |
|-------------|-----------|------------|
| 1 | Black | 0.28 |
| 2 | Gray | 0.33 |
| 3 | Gray | 0.45 |
| 4 | Dark Gray | 0.53 |
| 5 | Black | 0.85 |

Confidential – photocopy prohibited

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



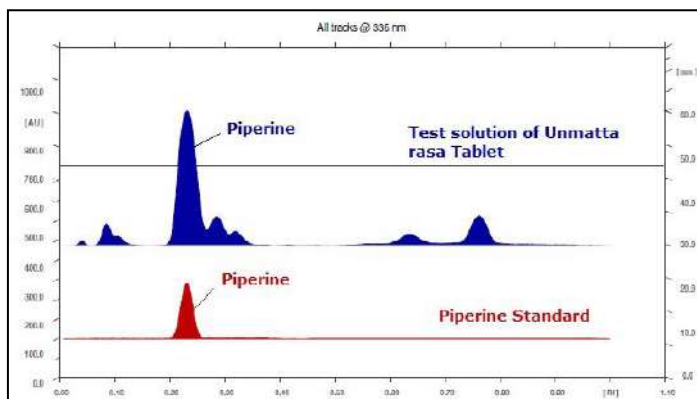
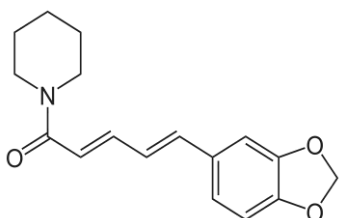


3D Peak Display of Unmatta Rasa at 336 nm

HPTLC Profile [†]

i) Piperine

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 336 nm corresponding with Piperine standard.



| | |
|---|------------------------------|
| 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 |

Confidential – photocopy prohibited

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