

AOIM-Z TABLET

Monograph No. – 070203 ver 3.0

Issue No: 03

Date of Issue: 28/10/2016

Text Reference : Ayurvedic Proprietary Medicine

Amendment No : 00

Amendment Date : --

Shelf Life: 5 years

Description

Light pink coloured, round biconvex film coated tablets.

Loss on Drying at 105°

Not more than 6 % w/w

Hardness

Not less than 2.5 kg/cm²

Thickness

5.5 ± 0.5 mm

Diameter

12.0 – 12.5 mm

Disintegration Time

Not more than 60 min.

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 25 % w/w

Acid insoluble ash

Not more than 10 % w/w

Water soluble extractive

Not less than 27 % w/w

Alcohol soluble extractive

Not less than 8 % w/w

Elemental Assay

Iron (Fe)

2.0 – 6.0 mg/tab

Zinc (Zn)

Not less than 9.0 mg/tab

Thin Layer Chromatography Mobile Phase

Chloroform : Ethanol : Glacial acetic acid
(9.4 : 0.5 : 0.1)

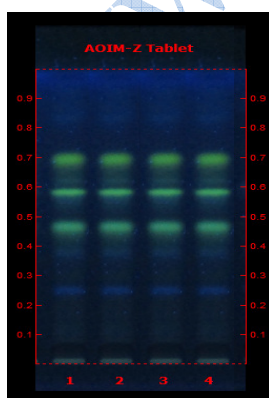
Details

Solvent of Extraction – Methanol

Solvent front – 90 mm

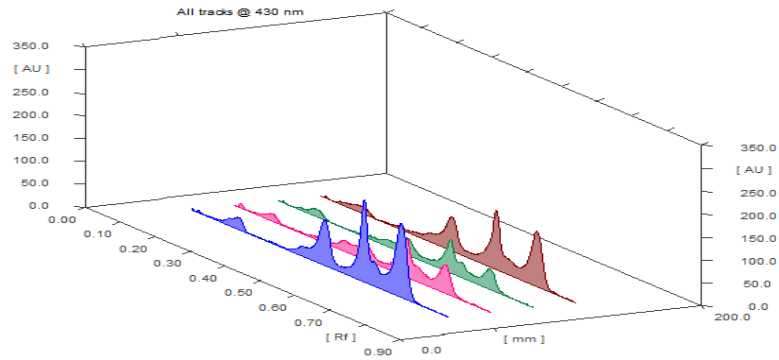
Total No. of Major spots – 8

Detection – Under UV at 366 nm



| Major Spots | Colour | Approx. Rf. |
|-------------|--------------|-------------|
| 1 | Black | 0.06 |
| 2 | Blue | 0.26 |
| 3 | Light Blue | 0.37 |
| 4 | Yellow | 0.46 |
| 5 | Yellow | 0.58 |
| 6 | Light Yellow | 0.62 |
| 7 | Yellow | 0.69 |
| 8 | Light Blue | 0.83 |



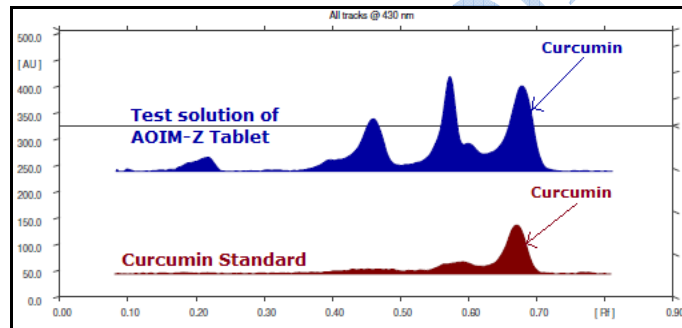
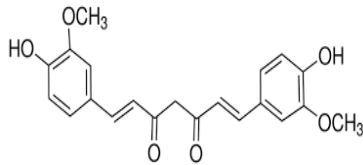


3D Peak Display of AOIM-Z Tablet at 430 nm

HPTLC Profile

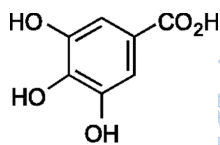
i) Curcumin

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.

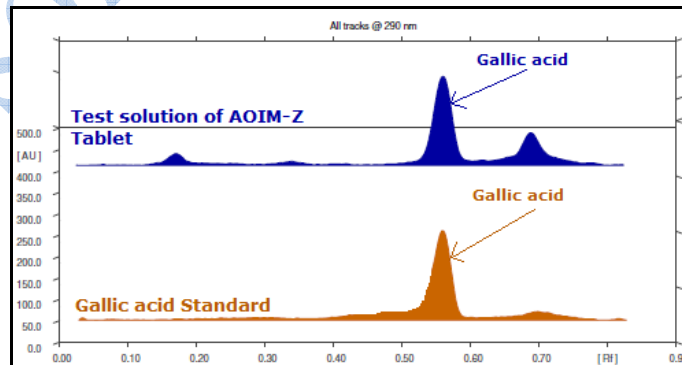


ii) Total Polyphenols (as Gallic acid)

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

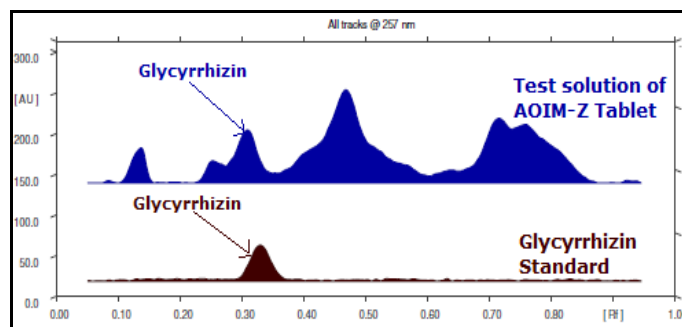
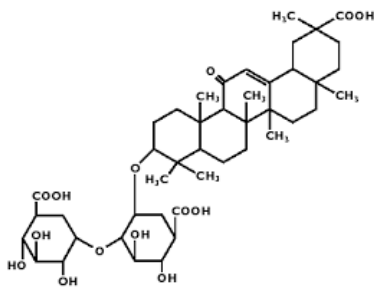


gallic acid (GA)



iii) Glycyrrhizin

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 257 nm for Glycyrrhizin corresponding with Glycyrrhizin standard.





Shree Dhootapapeshwar Standards

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