

ATMAGUPTA (KAUNCH BEEJ) TABLETS

Monograph No. – 2700214 ver 3.0

Issue No: 03

Amendment No : 00

Date of Issue: 26/10/2024

Amendment Date : --

Text Reference: API Part I, Volume III, Monograph No. 12

Shelf Life: 3 years

Description

Light brown to gray color caplet shape coated tablets 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/cm²

Thickness

5.0 ± 0.5 mm

Length

21.0 ± 0.5 mm

Average Weight

900 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 32 % w/w

Acid insoluble ash

Not more than 1.5 % w/w

Water soluble extractive

Not less than 10 % w/w

Alcohol soluble extractive

Not less than 2 % w/w

pH (1 % Aq. Solution)

5.5 – 7.5

Thin Layer Chromatography Solvent system

n-butanol : Acetic acid : Water
(4 : 1 : 1)

Details

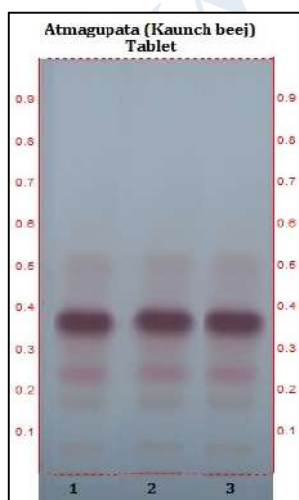
Solvent of Extraction – 0.01 M Methanolic HCl

Solvent front – 90 mm

Total No. of Major spots – 5

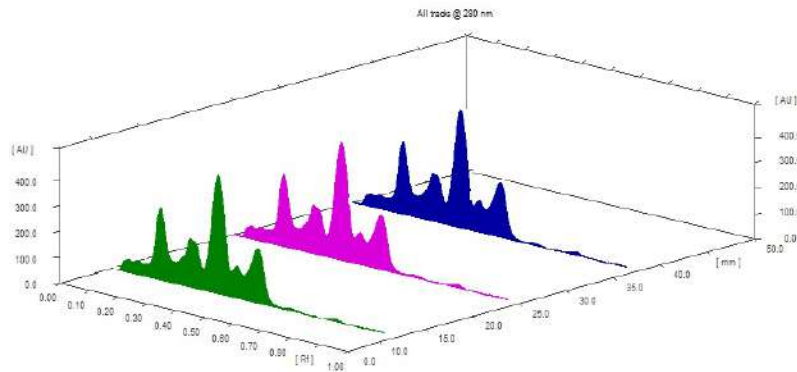
Visualization – After derivatization with Ninhydrin reagent

Major Spots	Colour	Approx. Rf.
1	Light Brown	0.06
2	Light Brown	0.18
3	Pink	0.25
4	Brown	0.38
5	Light Brown	0.52



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

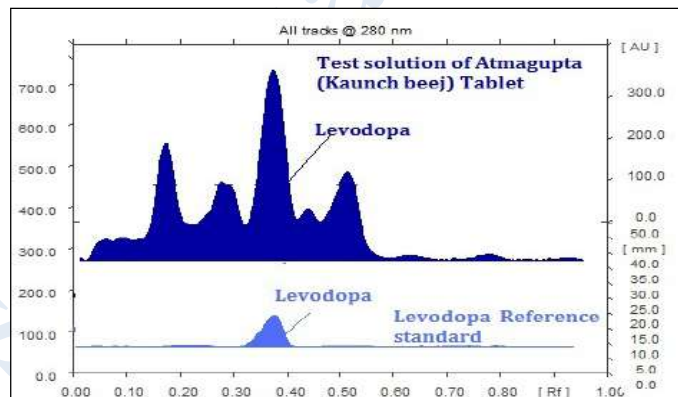
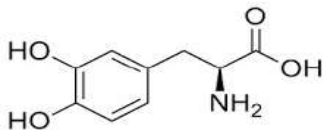


3D Peak Display of Atmagupta (Kaunch) Tablets at 280 nm

HPTLC Profile[†]

i) Levodopa (L-Dopa)

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 280 nm corresponding with Levodopa reference standard.



Heavy metal

Lead (Pb)	Not more than 10 ppm
Mercury (Hg)	Not more than 1 ppm
Arsenic (As)	Not more than 3 ppm
Cadmium (Cd)	Not more than 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)	Not more than 10 ⁵ c.f.u./g
Total Yeast & Mould count (TYMC)	Not more than 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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