

ARSHKEYT TABLETS (ARSHKEYT)

Monograph No. – 070258 ver 3.0

Issue No: 03

Date of Issue: 28/10/2016

Text Reference : Ayurvedic Proprietary Medicine

Amendment No : 00

Amendment Date : --

Shelf Life: 2 years

Description

Beige 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 mins.

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

Thin Layer Chromatography Mobile Phase

Toluene : Ethyl acetate : Formic acid
(4 : 6 : 2.5)

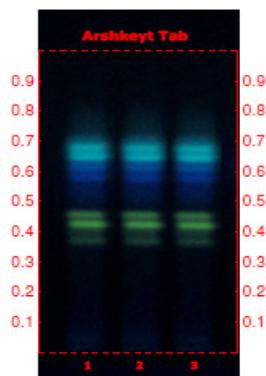
Details

Solvent of Extraction – Methanol

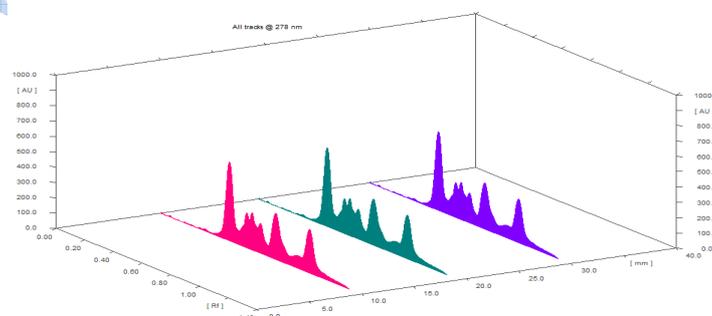
Solvent front – 90 mm

Total No. of Major spots – 7

Detection – Under UV at 366 nm



Major Spots	Colour	Approx. Rf.
1	Light Green	0.37
2	Light Green	0.42
3	Light Green	0.46
4	Blue	0.58
5	Blue	0.61
6	Light Blue	0.64
7	Light Blue	0.68



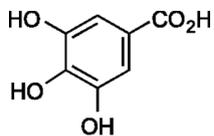
3D Peak Display of Arshkeyt Tab at 278 nm

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

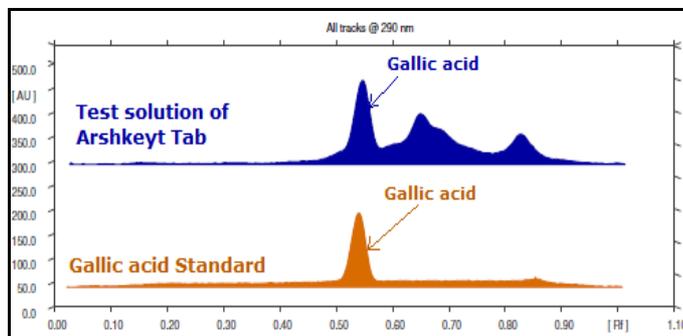
HPTLC Profile

i) Total Polyphenols (as Gallic acid)



gallic acid (GA)

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 290 nm corresponding with Gallic acid 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 [†]	NMT 10 ³ c.f.u./g
Pesticide Residue [†] (OC+OP)	Complies as per API
Aflatoxins B1,B2,G1,G2 [†]	Complies as per API

ARSHKEYT POWDER (ARSHKEYT)

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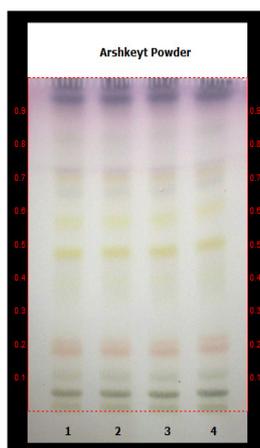
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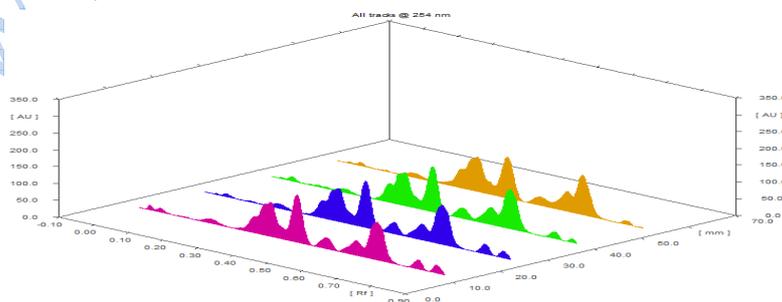
Amendment Date : --

Shelf Life: 2 years

Description	Beige coloured, moderately fine to fine powder, odour anise flavour, taste slightly bitter.
Bulk Density	0.65 – 0.75
Loss on Drying at 105°	Not more than 7 % w/w
Ash	Not more than 6.0 % w/w
Acid Insoluble Ash	Not more than 2.0 % w/w
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 Solvent front – 90 mm Total No. of Major spots – 10 Detection – After spraying Anisaldehyde H ₂ SO ₄



Major Spots	Colour	Approx. Rf.
1	Dark Green	0.05
2	Light Gray	0.09
3	Light Brown	0.17
4	Light Brown	0.20
5	Yellow	0.48
6	Yellow	0.58
7	Light Gray	0.67
8	Light Yellow	0.71
9	Violet	0.94
10	Violet	0.98

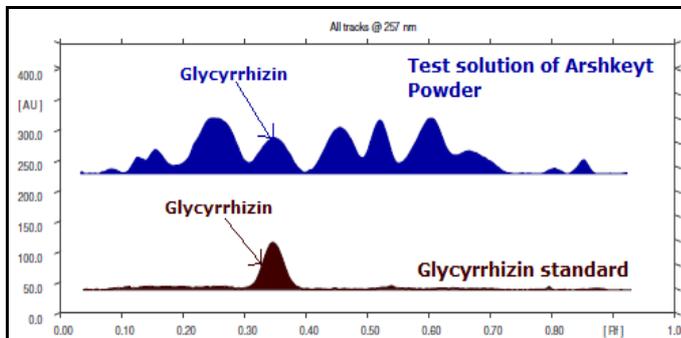
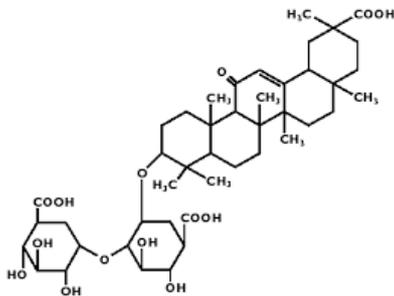


3D Peak Display of Arshkey Powder at 254 nm

HPTLC Profile

i) 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.



Heavy metal

Lead (Pb) NMT 10 ppm

Mercury (Hg) NMT 1 ppm

Arsenic (As) NMT 3 ppm

Cadmium (Cd) 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 10⁵ c.f.u./g

Total Yeast & Mould count [†] NMT 10³ c.f.u./g

Pesticide Residue [†] (OC+OP) Complies as per API

Aflatoxins B1,B2,G1,G2 [†] Complies as per API

ARSHKEYT CREAM (ARSHKEYT)

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Shelf Life: 2 years

Description Light cream to brown coloured, viscous creamy preparation.

Bulk Density 0.95 – 1.05

Loss on Drying at 105° Not less than 50 % w/w

pH (5% aqueous solution) 7.0 – 8.0

**Thin Layer Chromatography
Mobile Phase**

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

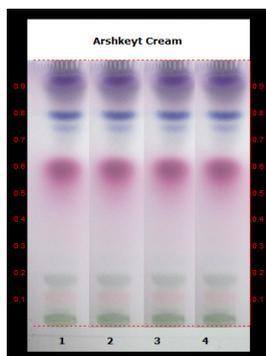
Details

Solvent of Extraction – Methanol

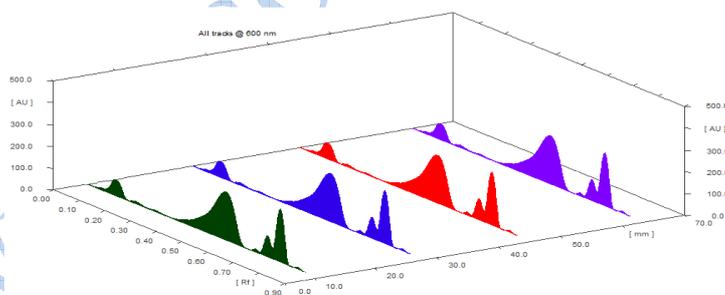
Solvent front – 90 mm

Total No. of Major spots – 5

Detection – After spraying Anisaldehyde H₂SO₄



Major Spots	Colour	Approx. Rf.
1	Light Green	0.17
2	Pink	0.57
3	Light Blue	0.73
4	Blue	0.78
5	Purple	0.92



3D Peak Display of Arshkeyt Cream at 600 nm

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