ASHA Cellulose

Indian Queries
Asha Cellulose (I) Pvt. Ltd.
Asha House, Plot 808/C,
Dr. B A Road, Dadar T.T.,
Mumbai 400 014, INDIA.
Phone: +91 22 2414 0020
+91 22 4541 1300
Fax: +91 22 2413 7190
Email: ashacel@ashacel.com

Website:www.ashacel.com

Global Queries
Good Hope International, Inc.
9729 Lackman Road
Lenexa KS 66219, USA
Phone: +1 913 888 8088
Email: rshah@goodhopeinc.com

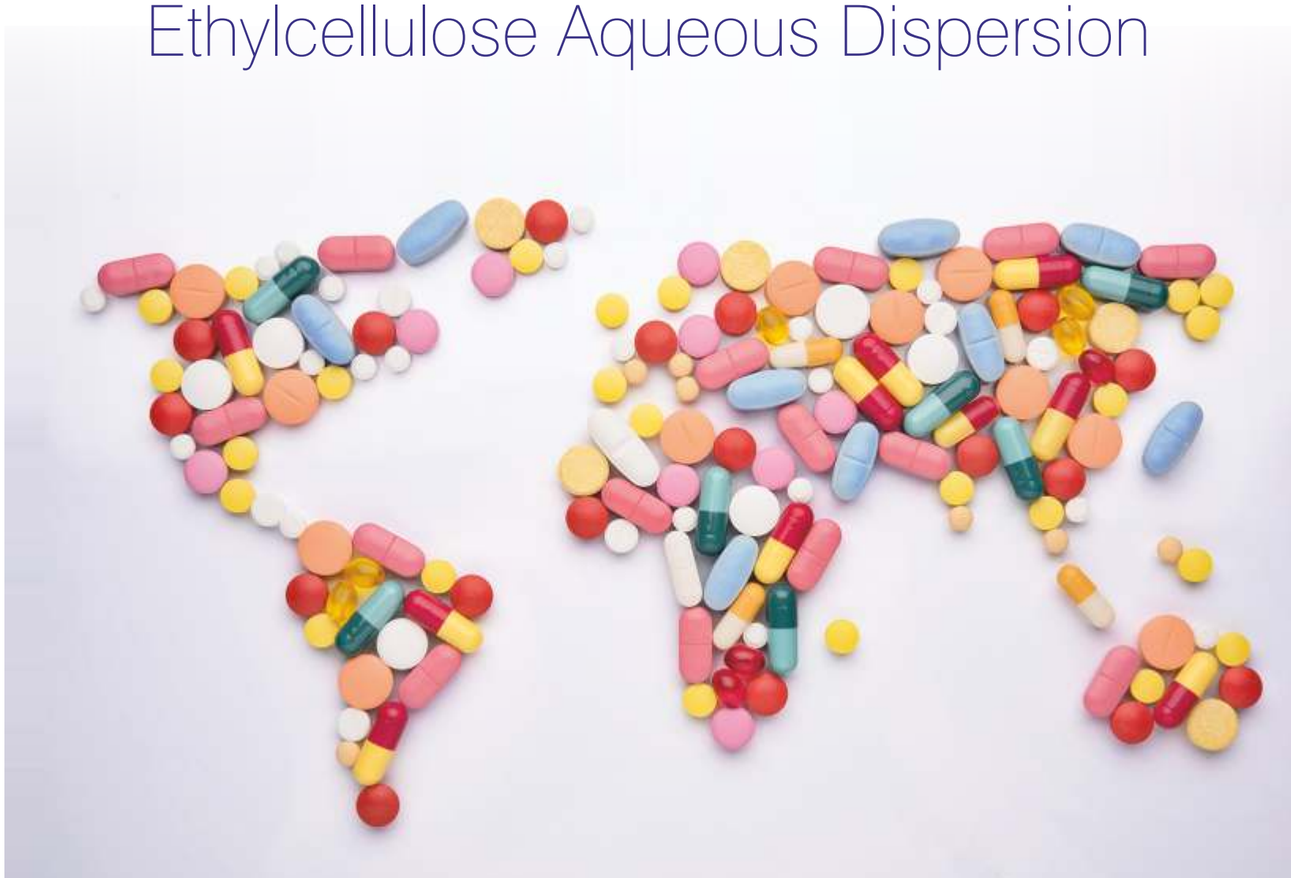
ASHA Cellulose

Ashacel®
Ethylcellulose Polymer

AshaKote®
Ethylcellulose Aqueous Dispersion

Asha Cellulose (I) Pvt Ltd
is the only company in the world to produce both the

Ethylcellulose Polymer
and
Ethylcellulose Aqueous Dispersion



ASHA Cellulose

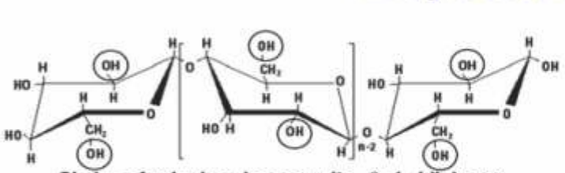
NOTES

ASHA Cellulose

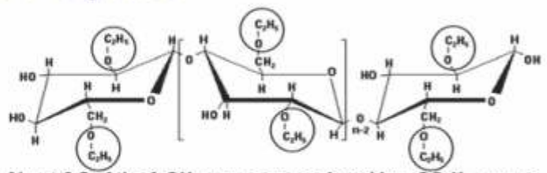
Asha Cellulose (I) Pvt. Ltd. is the first and only Indian company to manufacture and market Ethylcellulose and Ethylcellulose Aqueous Dispersion. With more than 25 years of experience in manufacturing Cellulose derivatives, Asha Cellulose consolidates its position in the market based on quality, business integrity, excellent customer service and reliability. The GMP certified facility is located in Valsad, in the state of Gujarat, in India. The company manufactures Industrial, Pharmaceutical and Electronic grade Ethylcellulose along with Ethylcellulose Aqueous Dispersion, making it the supplier of choice in the market.

Ashacel®

Ethylcellulose Polymer



Chains of anhydro-glucose units, β - 1, 4 linkages



About 2.5 of the 3-OH groups are replaced by $-OC_2H_5$ groups

Product type based on assay or extent of substitution Standard: 48.0 - 49.5%

Viscosity in a 5% solution of 80/20 Toluene/Ethanol at 25° C

ASHACEL® MP 100 Ethylcellulose

Trademark of Asha Cellulose

Approved for use in pharmaceutical applications. Compliant with USP/NF, BP, EP, JP, IP and FCC monographs

Pharmaceutical Application Overview

Product viscosity designation	Viscosity range cps[1]	% Ethoxy 48 - 49.5 M Type	CR	Micro-encapsulation	Tablet Coating	Granulation	Binder
4	3 - 5.5	Ashacel MP - 4	✓				✓
7	6 - 8	Ashacel MP - 7 *	✓		✓		✓
10	9 - 11	Ashacel MP - 10*	✓		✓	✓	✓
14	12.5 –15.5	Ashacel MP - 14	✓		✓	✓	✓
20	18 - 22	Ashacel MP - 20	✓		✓	✓	✓
45	41 - 49	Ashacel MP - 45		✓		✓	
50	45 - 55	Ashacel MP - 50		✓		✓	
100	90 - 110	Ashacel MP - 100*		✓			

[1] Majewicz, T.G., *et al*., eds., "Cellulose Ethers" Encylopedia of Polymer Science and Technology, John Wiley & sons, Inc., New York, **2002**

*** Fine Particle "FP" grade Ethycellulose is available**

Regulatory Information

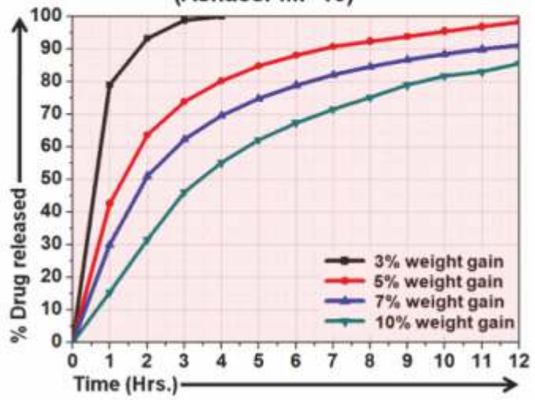
- Pharmacopoeial status.
- Limits and methods are listed on certificates of analysis.
- GMP certified facility by FDCA - Gujarat, India.
- USDMF registered.
- EXCiPACT certified.
- Kosher certified.
- Halal certified.
- ISO 9001:2015, ISO 14001:2015, & BS OHSAS 18001:2007 certified.
- 3 years shelf life from date of manufacturing.

Physicochemical Properties

- Insoluble in water.
- Soluble in common solvents: methonol, ethanol, isopropanol, methylene chloride, acetone.
- Film former (strong, flexible films).
- Binder (conventional coating techniques or granulation).
- Compatible with many plasticizers.
- Colorless, odorless, tasteless.
- Stable at pH 3 to 11.

Release Modulation: Coating Weight Gain

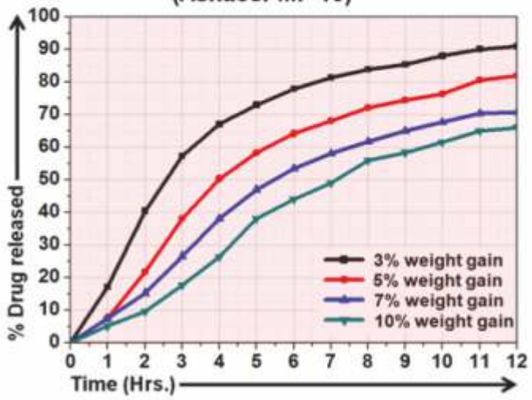
VFH release (Ashacel® MP 10)



Dissolution Conditions:

- Medium: 900 ml of 0.1N HCl.
- Apparatus: Paddle.
- Speed: 50 rpm.

Metoprolol succinate release (Ashacel® MP 10)

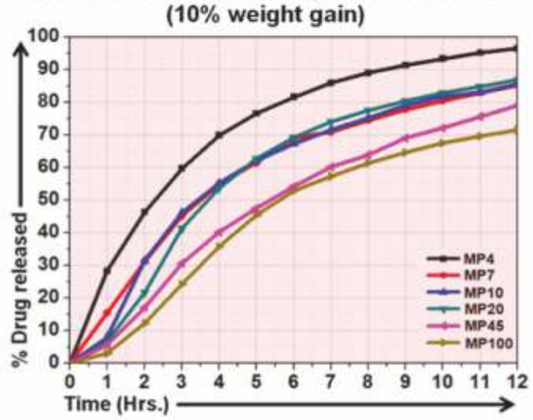


Dissolution Conditions:

- Medium: 900 ml of pH 1.2 buffer.
- Apparatus: Paddle.
- Speed: 50 rpm.

Release Modulation: Viscosity Effect

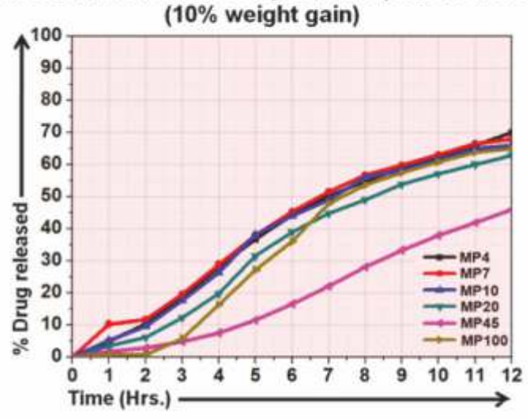
Effect of Ashacel® viscosity on VFH release (10% weight gain)



Dissolution Conditions:

- Medium: 900 ml of 0.1N HCl.
- Apparatus: Paddle.
- Speed: 50 rpm.

Effect of Ashacel® viscosity on metoprolol release (10% weight gain)



Dissolution Conditions:

- Medium: 900 ml of pH 1.2 buffer.
- Apparatus: Paddle.
- Speed: 50 rpm.

AshaKote®

Ethylcellulose Aqueous Dispersion

AshaKote® is 30% aqueous dispersion of Ethylcellulose, complying with Ethylcellulose Aqueous Dispersion USP NF monograph.

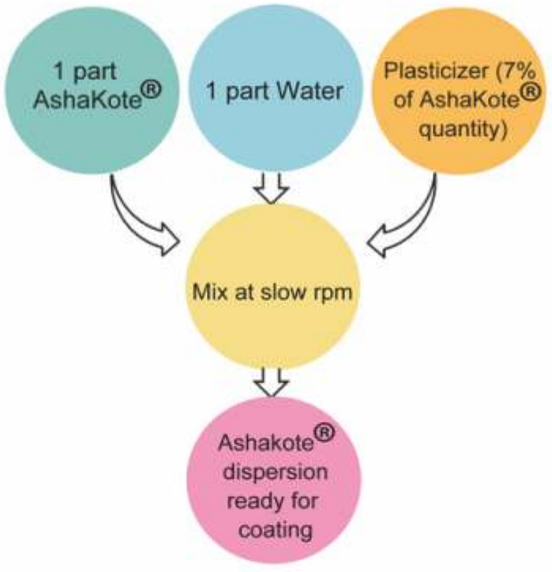
Benefits of AshaKote®

- Reduced coating process time.
- Environment friendly product.
- No residual solvent toxicity.
- Suitable for sustained release, taste-masking, and moisture barrier.
- pH independent release.
- No 'Fed state vs. Fasted state' issues.
- Lot of data in the form of research articles,and poster presentations already available.
- No ammonia system.
- Low viscosity.
- Non-tacky.
- Ease of cleaning.

Product Specifications

Test	Specification
Identification	Pass
pH	4.0 - 7.0
Specific gravity	1.025 – 1.040
Viscosity, cps	NMT 150
Loss on drying %	68.0 - 71.0
Ethyl cellulose %	24.5 - 29.5
Sodium lauryl sulphate %	0.9 - 1.7
Cetyl alcohol %	1.7 - 3.3
Hydrogen peroxide, ppm	NMT 50
Heavy metals %	NMT 0.001
Total aerobic microbial count/gm	NMT 100
Total yeast and mold count/gm	NMT 20

Method of Use



Packaging

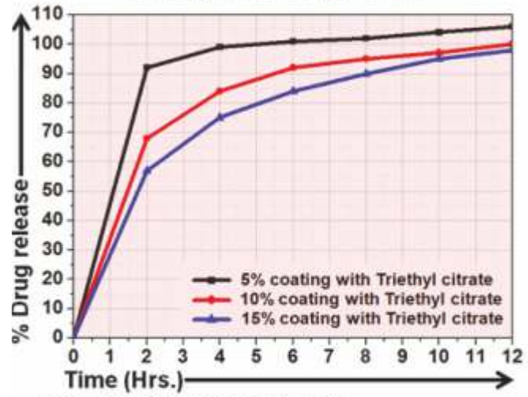
Storage:

- Should be stored at room temperature (20 - 25°C).
- Should not be exposed to freezing or near freezing temperatures and temperatures above 35°C.

Shelf Life:

- 24 months from the date of manufacturing.

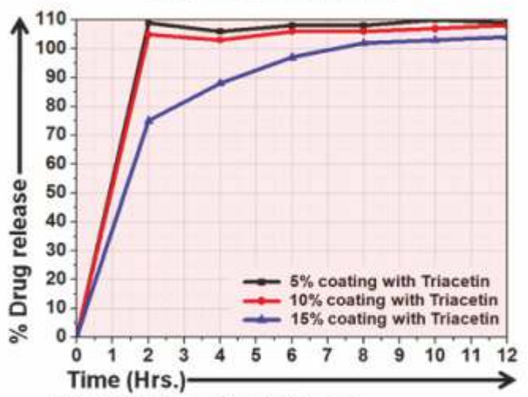
Comparative % drug release profile of Venlafaxine hydrochloride coated pellets with different % build up using Triethyl citrate as plasticizer



Dissolution Conditions:

- Medium: 900 ml of 0.1N HCl.
- Apparatus: Type II.
- Speed: 50 rpm

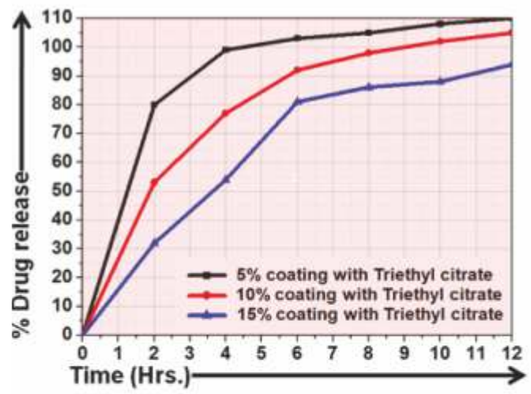
Comparative % drug release profile of Venlafaxine hydrochloride coated pellets with different % build up using Triacetin as plasticizer



Dissolution Conditions:

- Medium: 900 ml of 0.1N HCl.
- Apparatus: Type II.
- Speed: 50 rpm

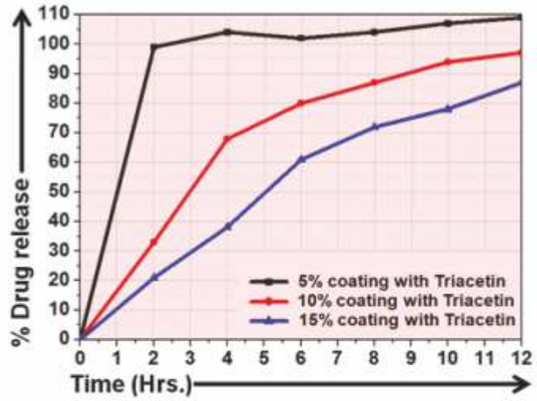
Comparative % drug release profile of Metoprolol succinate coated pellets with different % build up using Triethyl citrate as plasticizer



Dissolution Conditions:

- Medium: 900 ml of 0.1N HCl.
- Apparatus: Type II.
- Speed: 50 rpm

Comparative % drug release profile of Metoprolol succinate coated pellets with different % build up using Triacetin as plasticizer



Dissolution Conditions:

- Medium: 900 ml of 0.1N HCl.
- Apparatus: Type II.
- Speed: 50 rpm