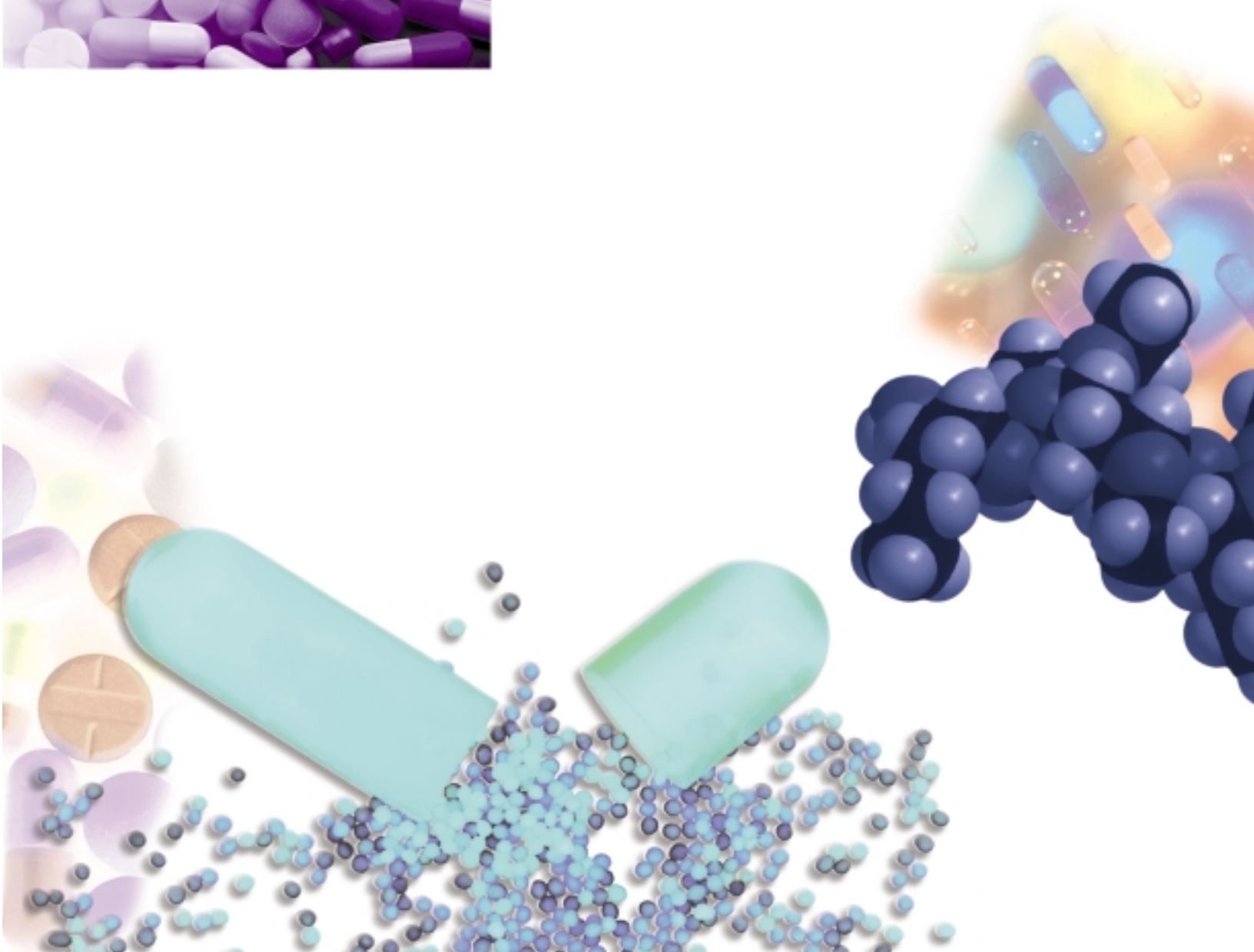




PRODUCT SPECIFICATION SHEET FOR



ETHOCEL FP POLYMERS



ETHOCEL FP Ethylcellulose Polymers

Introduction

The Dow Chemical Company manufactures and markets several grades of ETHOCEL* polymers. ETHOCEL FP polymer was developed to promote the physical properties of ethylcellulose which are enhanced by drastically reducing particle size. These properties open new doors to formulators in several markets, including pharmaceutical, food, and personal care.

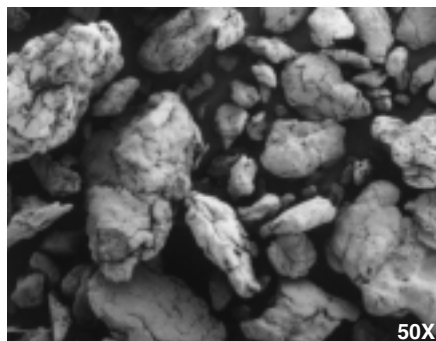
ETHOCEL FP Polymers in Controlled Release Matrix Systems

Ethylcellulose has been used as a controlled release excipient for several decades. In most applications, ethylcellulose has been solubilized in an organic solvent(s) and used as a film coating for tablets, beads, and particles to impart a controlled release or taste-masking effect.

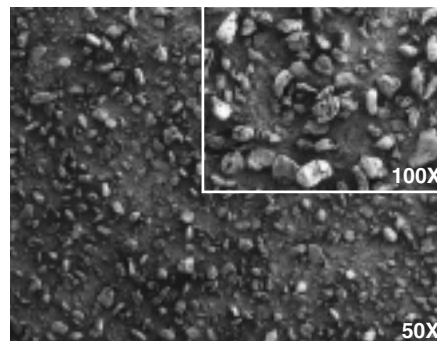
ETHOCEL FP polymers were developed specifically for use as controlled release excipients for use in controlled release matrix formulations.

When you need one or more of the advantageous characteristics of multiparticulate systems, ETHOCEL FP polymers offer an excellent route to controlling drug release.

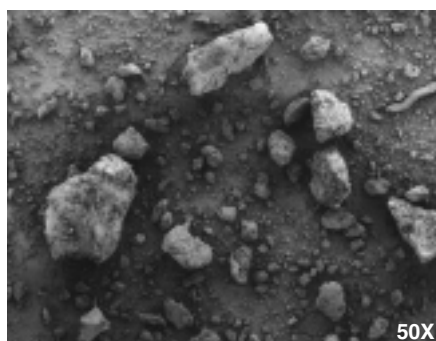
As water insoluble excipients, ETHOCEL polymers can effectively control the release of an active by modifying the size and length of the diffusion path. In this role, ETHOCEL polymer is typically used in combination with water-soluble actives and/or water-soluble excipients such as METHOCEL* cellulose ethers and/or DOW polyethylene glycols. By varying the type and amount of the insoluble excipient, and the particle size, a wide variety of release rate profiles can be achieved.



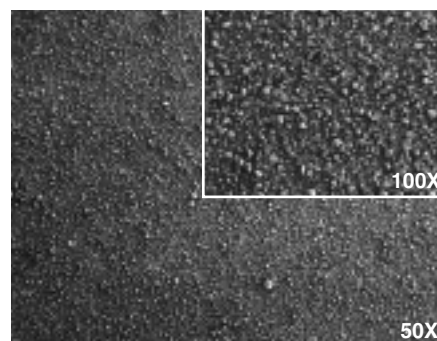
ETHOCEL Standard 100 Premium



ETHOCEL Standard 100 FP Premium



ETHOCEL Standard 7 Premium



ETHOCEL Standard 7 FP Premium

ETHOCEL FP polymers were developed to improve the performance characteristics of ETHOCEL when used with dry particles without using an organic solvent. The relationship of particle size of hydrophobic material in a matrix delivery system has been documented over the years. Additional studies conducted by Dow concur that particle size and concentration of a hydrophobic excipient such as ETHOCEL FP are determinant factors in the formulation of direct compression controlled release matrix formulations.

Another benefit that can be exploited when formulating with ETHOCEL FP polymers is the improved lipophilic properties which are realized by the dramatically increased surface area.

This property can be used to enhance controlled release of oily actives, improve stability of an active, and in viscosity modification.

ETHOCEL FP Polymers in Personal Care Formulations

ETHOCEL FP polymers may also broaden formulation options available in the area of personal care. ETHOCEL polymers have been used for decades in the hydrated state as water resistant film formers in sun-screens, lipsticks, and ointments. The enhanced lipophilic and hydrophobic properties of ETHOCEL FP polymers in the unhydrated state should open new formulation opportunities in cosmetic powders and lotions.

Specifications of ETHOCEL FP

- Description:** ETHOCEL Standard 7 FP Premium is a white particle, with a typical average particle size of 10 microns.
ETHOCEL Standard 10 FP Premium is a white particle, with a typical average particle size of 5 microns.
ETHOCEL Standard 100 FP Premium is a white particle, with a typical average particle size of 40 microns.
- Solubility:** Similar to ETHOCEL Standard Premium granular polymers, soluble in a wide variety of organic solvents, including aliphatic alcohols, ethers, ketones, aromatic hydrocarbons.
- Application:** ETHOCEL Premium polymers are well suited for controlled release matrix tablet formulations. These products were designed specifically for pharmaceutical formulations when the ETHOCEL is used in an unsolubilized form such as in direct compression SR tablets, granulation and/or agglomeration. In these applications, particle size has an effect on both release rate and tablet compressibility.

Description:	7 FP	10 FP	100 FP		
Viscosity	6.0–8.0	9.0–11.0	90.0–110.0	cP	NF
Ethoxyl Content	48.0–49.5	48.0–49.5	48.0–49.5	%	NF
Loss on Drying (moisture)	2.0	2.0	2.0	%	NF
Chloride (as NaCl), maximum	500	500	500	PPM	ASTM D914
Particle Size, maximum	140	100	150	Microns	Dow Method
Particle Size, mean	7–12	3–8	30–60	Microns	Dow Method
Residue on Ignition	.40	.40	.40	%	NF
Arsenic, maximum	2	2	2	PPM	NF
Lead, maximum	3	3	3	PPM	NF
Heavy Metal, maximum	10	10	10	PPM	NF
Product Number:	48353	51374	48359		

- Storage:** Below 32°C, (90°F). Store in dry area away from all sources of heat. Good housekeeping is required to prevent fine powders of ETHOCEL resin from reaching explosive levels in the air.
- Packaging:** 25 kg polyethylene-lined fiber drums
- Samples:** One pound
- Shelf Life:** Three years
- Regulatory Statutes:** ETHOCEL Premium complies with the compendial specifications of the National Formulary 19 (Ethylcellulose) and the Food Chemicals Codex III (Ethylcellulose).
- ETHOCEL Premium is covered by prior sanctions and is G.R.A.S. under the Food Additives Amendment for food packaging applications.

Food Additive Regulation Number	Application
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21 CFR 73.1 (b) 1 (i), (ii) and (b) (2)	Diluents in color additive mixtures for food use exempt from certifications. Diluent used in inks for marking certain foods. Ethylcellulose as defined in 172.868
21 CFR 73.1001 (b)	Diluent in color additive mixtures for drug use exempt from certification. Externally applied drugs. Ethylcellulose as defined in 172.868
21CFR 172.868 (b) (1) (b) (2) (b) (3)	Ethylcellulose—for use as: A binder and filler in dry vitamin preparations. A component of protective coatings for vitamin and mineral tablets. A fixative flavoring compound.
21 CFR 573.420	Ethylcellulose—for use as: A binder or filler in dry vitamin preparation or incorporated in animal feed.

Customer Notice

Dow encourages its customers and potential users of Dow products to review their applications of such products from the standpoint of human health and environmental quality. To help ensure that Dow products are not used in ways for which they are not intended or tested, Dow personnel will assist customers in dealing with ecological and product safety considerations. Your Dow sales representative can arrange the proper contacts. Dow product literature, including Material Safety Data Sheets, should be consulted prior to use of Dow products. These may be obtained by contacting Dow at the numbers below.

Bibliography

To help you get started, here is a brief listing of released papers on the effects of particle size on direct compression controlled release solid dosage forms:

1. ETHOCEL Premium Polymers for Pharmaceutical Applications, Dow Chemical Brochure (Form No. 198-02002).
2. S.M. Upadrasta, P.R. Katikaneni, G.A. Hileman, and P.R. Keshary, "Direct compression controlled release tablets using ethylcellulose matrices." *Drug Dev. Ind. Pharm.*, 19 (4), 449-460 (1993).
3. Drug Dissolution Testing—Method 711, United States Pharmacopeia/National Formulary XXIII, p. 1791 (1995).

For more information, complete literature, and product samples, you can reach a Dow representative at the following numbers:

From the United States and Canada	call 1-800-447-4369 fax 1-517-832-1465
From Mexico	call 95-800-447-4369 fax 95-517-832-1465
In Europe	toll-free +800.3694.6367 call + 31/20.691.6268 fax + 31/20.691.6418

Or you can contact us on the Internet at www.ethocel.com

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