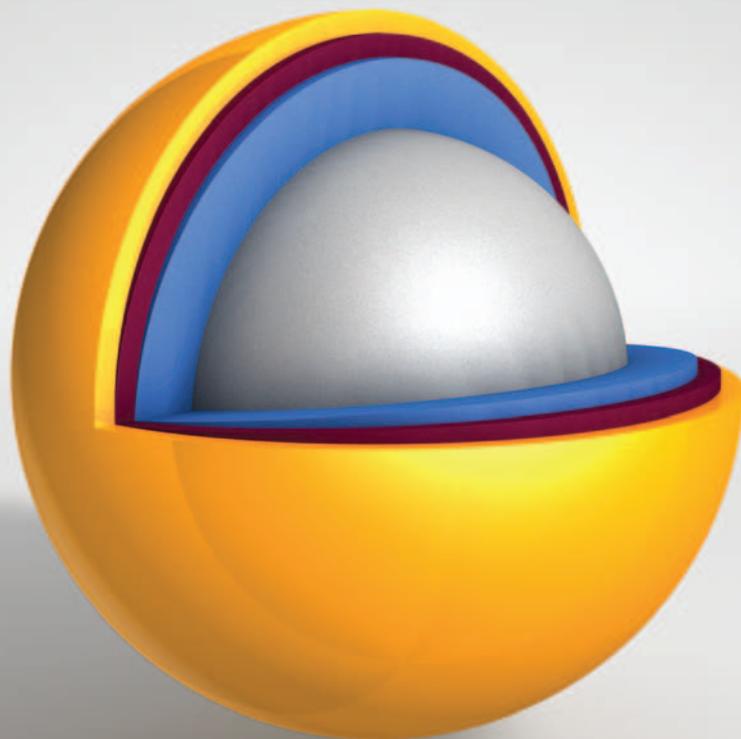




Pharma & Food Solutions

ETHOCEL™

One of the Few Water-Insoluble Polymers
Approved for Global Pharmaceutical Applications



ETHOCEL™ Premium Polymers are essentially tasteless, colorless, odorless, non-caloric and very inert physiologically. We offer nine different ETHOCEL™ Polymers for pharmaceutical applications. These include a variety of molecular weights, which translate into a range of viscosities. By selecting among these variables, it is possible to address an extensive range of product or process requirements.

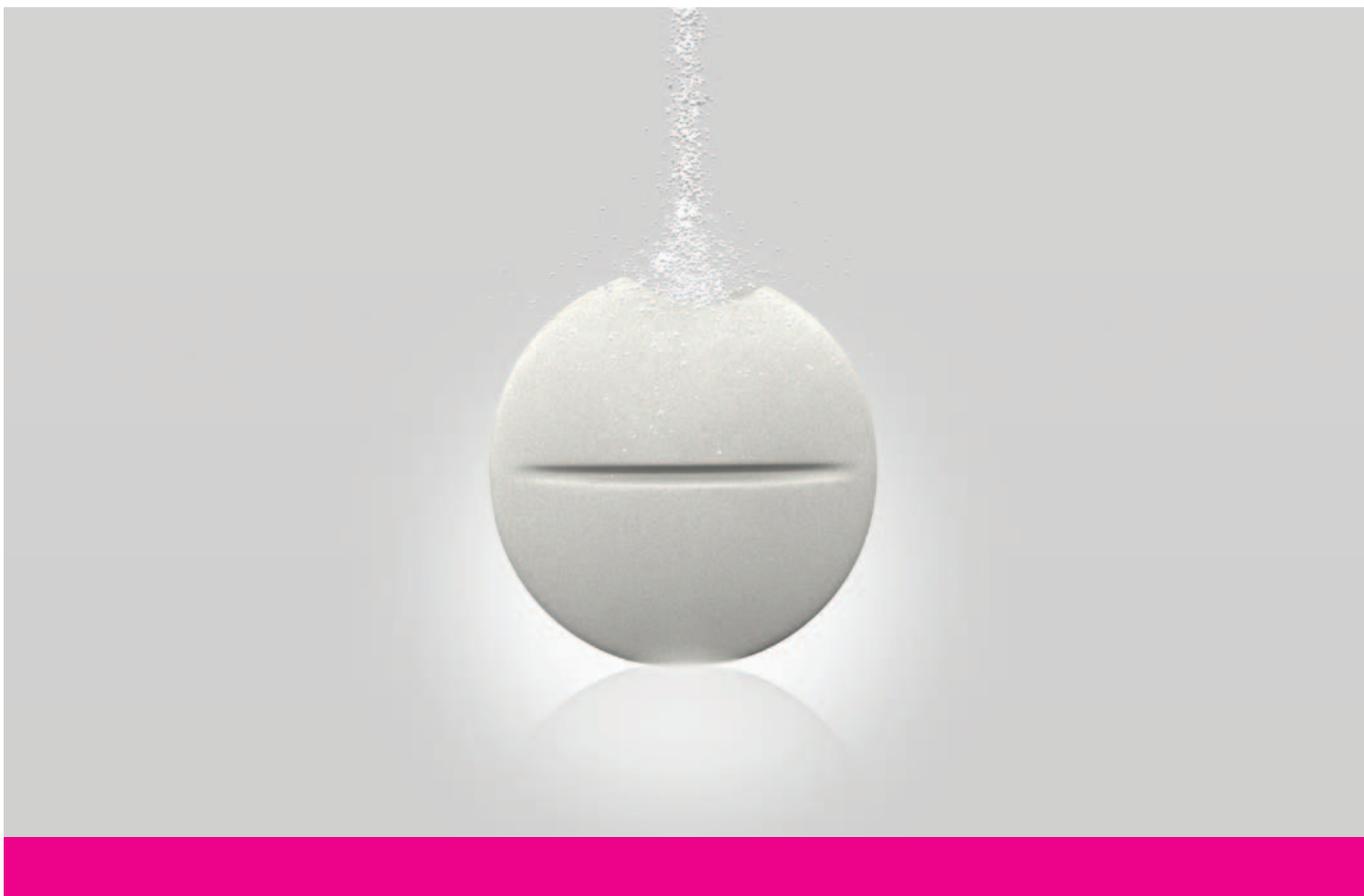
Their excellent compatibility allows use of ETHOCEL™ Polymers with many basic ingredients across a broad array of pharmaceutical applications. These polymers are soluble in a wide range of organic solvents, beginning with aliphatic alcohols such as ethanol and isopropanol, and are compatible with most other familiar organic solvent chemistries, including ether alcohols, ketones, aromatic hydrocarbons, and many more.

ETHOCEL™ Premium Polymers meet the requirements of the Food Chemicals Codex, the International Codex Alimentarius and the National Formulary (NF), as well as the Japanese Standards of Pharmaceutical Ingredients (JSPI), and are expected to meet the requirements of the European Pharmacopeia (EP) when finalized.

An Excellent Choice for a Variety of Formulation Needs Including:

- Extended release multi-particulate coatings
- Micro-encapsulation of actives
- Control release hydrophobic matrix systems
- Solvent and extrusion granulation
- Tablet binding for direct compression
- Taste-masking of bitter actives pharmaceutical ingredients and hot melt extrusion





For us at Dow Pharma & Food Solutions, it's not just about the products we sell; it's about providing customers with solutions to address their pharmaceutical needs.

ETHOCEL™ is one of Dow's oldest products. It has been providing leading pharmaceutical companies with consistent, high-quality materials for a variety of applications including: barrier coatings for controlled release formulations, granulation/direct compression modifiers, and taste-masking of bitter active pharmaceutical ingredients.

The extensive use of ETHOCEL™ in the pharmaceutical market is due to many distinctive characteristics of water-insoluble ethylcellulose polymers as well as processing versatility:

- Available in many viscosity grades
- Essentially colorless, odorless, non-caloric, inert physiologically
- Organo-soluble in a wide variety of solvents
- One of few water-insoluble polymers approved and accepted for pharmaceutical applications
- Combinable with water-soluble polymers (METHOCEL™ Premium products) to optimize the performance of controlled release systems
- Manufactured by precisely controlled product processes and verifiable with world-class analytical techniques.
- Capable of managing water-sensitive ingredients or those requiring greater taste masking
- Allows for reduced processing time and cost, better content uniformity and improved bioavailability of poorly soluble drugs
- Excellent compatibility in a wide variety of pharmaceutical systems and with both acidic and alkaline ingredients
- Thermoplastic properties can be optimized for hot melt extrusion

A Portfolio of Versatile Solutions

to Help Address a Variety of Formulation and Processing Needs

We offer nine different ETHOCEL™ products (TABLE 1) that give formulation flexibility to deliver the medicines (or to solve) customers need. These include a variety of molecular weights, which translate into a range of viscosities in solutions to meet product or process requirements (TABLE 2).

Table 1 – ETHOCEL™ Premium Polymers for Pharmaceutical Applications

Product Viscosity Designation	Solution Viscosity ⁽¹⁾ Range, cP	Ethocyl Content, %
ETHOCEL™ Standard 4 Premium	3 - 5.5	48 - 49.5
ETHOCEL™ Standard 7 Premium ²	6 - 8	48 - 49.5
ETHOCEL™ Standard 10 Premium ²	9 - 11	48 - 49.5
ETHOCEL™ Standard 20 Premium	18 - 22	48 - 49.5
ETHOCEL™ Standard 45 Premium	41 - 49	48 - 49.5
ETHOCEL™ Standard 100 Premium ²	90 - 110	48 - 49.5

⁽¹⁾ Viscosities are for 5% solutions measured at 25°C in an Ubbelohde viscometer. The solvent is 80% toluene and 20% alcohol.

⁽²⁾ ETHOCEL™ Standard 7, 10, and 100 Premium are also offered as a fine particle; designation ETHOCEL™ Standard 7 FP Premium, ETHOCEL™ Standard 10 FP Premium, and ETHOCEL™ Standard 100 FP Premium.



Table 2 – Selection of ETHOCEL™ Polymers for Pharmaceutical Applications

Application	Ethocel™ Polymer
Controlled release coatings	ETHOCEL™ Standard 7, 10, or 20 Premium
	ETHOCEL™ blended with METHOCEL™ E5 or E15LV Premium cellulose ether
Micro-Encapsulation	ETHOCEL™ Standard 45 or 100 Premium
Tablet Coating	ETHOCEL™ Standard 7, 10, or 20 Premium
	ETHOCEL™ Standard 10, 20, or 45 Premium
Binder / Direct Compression	ETHOCEL™ Standard 7 FP Premium, 10 FP Premium, or 100 FP Premium
Hot Melt Extrusion	ETHOCEL™ Standard 10 Premium



An Excellent Choice

For a Variety of Formulation Needs



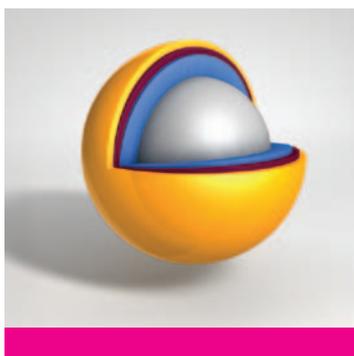
Controlled Release Tablet and Barrier Coating

ETHOCEL™ has long been used as a solvent-based matrix former and barrier coater for multiparticulates. It forms strong films with good adhesion. These polymers offer a versatile diffusion barrier with properties that can be modified by film thickness, the level of water soluble pore-forming additives (such as METHOCEL™), or by modifying the solvent(s) used and the molecular weight of ETHOCEL™. They also can be applied with conventional coating techniques such as pan and fluidized bed coating.



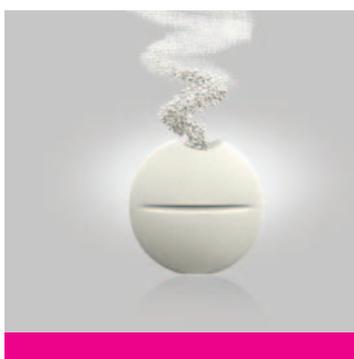
Microencapsulation of Pharmaceuticals

ETHOCEL™ Polymers are commonly used to encapsulate active pharmaceutical ingredients for sustained-release or taste masking applications. Microencapsulation is typically accomplished via coacervation techniques. ETHOCEL™ Coatings offer durable rate-modifying barriers which can be compressed without fracturing.



Controlled Release Hydrophobic Matrix Systems

ETHOCEL™ can be used in an inert matrix which does not swell or dissolve with time, but can be modulated to obtain specific modified release profiles. Using our different fine particle grades of ETHOCEL™ is one way to modify the release profile, as well as combining with excipients to achieve the necessary drug release rates.



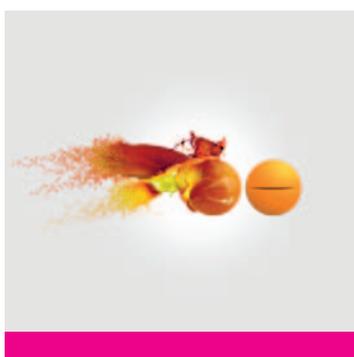
Solvent and Extrusion Granulation

ETHOCEL™ Polymers can be used for solvent granulation of water-sensitive materials. Tablets made with granulated materials formulated with ETHOCEL™ are strong, have low friability, and can offer a wide range of dissolution rates. Dissolution times may be extended or modified by varying the amount of ETHOCEL™ in the granulation or by adding a water-soluble excipient to the granulating fluid containing ETHOCEL™.



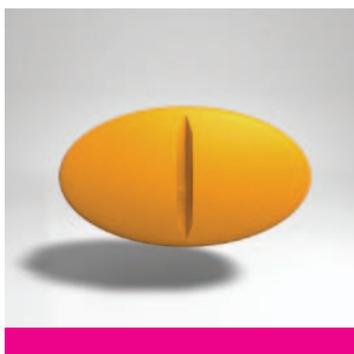
Tablet Binding/Compression:

ETHOCEL™ fine powdered forms offer versatility in drug release rates as well as improvements in the processing conditions (easier to compress). ETHOCEL™ can be used as tablet binders in roller compaction granulation or direct compression tableting. In these applications they produce hard tablets with very low friability. When used in small but effective amounts, ETHOCEL™ should not adversely affect tablet disintegration or dissolution rates.



Hot Melt Extrusion

ETHOCEL™ possesses excellent thermoplasticity and softens between 135 °C to 160 °C (Figure 1). This softening point can be reduced by the incorporation of additives such as plasticizers providing a wide temperature window in which to operate. ETHOCEL™ is a versatile and powerful tool in hot melt extrusion of pharmaceutical formulations allowing researchers to obtain specific release profiles while producing a wide variety of final dosage forms including tablets, multiparticulates and core-sheath systems.



Quality by Design (QbD)

Starting in 2013, the FDA highly encourages drug product manufacturers to implement QbD. Consequently, drug product formulators will need to intensely study raw material variability and Dow Pharma & Food Solutions can provide the in-depth fundamental support needed for these studies as well as the product line and diversity of viscosity grades to satisfy QbD.



Storage Stability

The shelf life for ETHOCEL™ Polymers is two years. ETHOCEL™ Polymers should be stored at temperatures not exceeding 32°C (90°F) in a dry area away from all sources of heat. In storage or use, good housekeeping is required to prevent dusts or fine powders of ETHOCEL™ from reaching explosive levels in air.

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