Handbook of Pharmaceutical Excipients

SECOND EDITION

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AMERICAN PHARMACEUTICAL ASSOCIATION

Handbook of PHARMACEUTICAL EXCIPIENTS

Second Edition

Edited by
Ainley Wade and Paul J Weller

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Ethylcellulose

1. Nonproprietary Names

BP: Ethylcellulose
PhEur: Ethylcellulosum
USPNF: Ethylcellulose

2. Synonyms

Aquacoat; E462; *Ethocel*; *Surelease*.

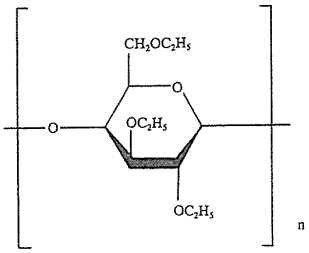
3. Chemical Names and CAS Registry Number

Cellulose ethyl ether [9004-57-3]

4. Empirical Formula Molecular Weight

Ethylcellulose is an ethyl ether of cellulose, a long-chain polymer consisting of anhydroglucose units joined together by acetal linkages. Each anhydroglucose unit has three replaceable hydroxyl groups which are substituted to the extent of 2.25-2.60 ethoxyl groups (OC_2H_5) per unit, equivalent to an ethoxyl content of 44-51%.

5. Structural Formula



Structure shown with complete ethoxyl substitution. *See also* Section 4.

6. Functional Category

Coating agent; tablet binder; viscosity-increasing agent.

7. Applications in Pharmaceutical Formulation or Technology

Ethylcellulose is widely used in oral and topical pharmaceutical formulations.

The main use of ethylcellulose in oral formulations is as a hydrophobic coating agent for tablets and granules.[1-5] Ethylcellulose coatings are used to modify the release of a drug,[5] to mask an unpleasant taste, or to improve the stability of a formulation, e.g. ethylcellulose dissolved in propan-2-ol is used to coat ascorbic acid granules to prevent oxidation. Modified release tablet formulations may also be produced using ethylcellulose as a matrix former.[6]

Ethylcellulose, dissolved in an organic solvent, or solvent mixture, can be used on its own to produce water-insoluble films. Higher viscosity ethylcellulose grades tend to produce stronger, tougher films. Ethylcellulose films may be modified, to alter their solubility, by the addition of hydroxypropylmethylcellulose[7] or a plasticizer, *see* Section 19. An aqueous polymer dispersion (or latex) of ethylcellulose such as *Aquacoat* (FMC Corporation) may also be used to produce ethylcellulose films without the need for organic solvents. With coats of hydrated ethylcellulose, drug release is via diffusion. This can be a slow process unless a large surface area is utilized and aqueous ethylcellulose dispersions tend therefore to be used to coat granules.[8,9]

Ethylcellulose is also widely used in drug microencapsulation,[10-14] high viscosity grades usually being used. Release of a drug from an ethylcellulose microcapsule is a function of the microcapsule wall thickness.[12]

In tablet formulations, ethylcellulose may additionally be employed as a binder, the ethylcellulose being blended dry or wet-granulated with a solvent such as ethanol (95%). Ethylcellulose produces hard tablets, with low friability; they may however demonstrate poor dissolution.

In topical formulations, ethylcellulose is used as a thickening agent in creams, lotions or gels, provided an appropriate solvent is used.

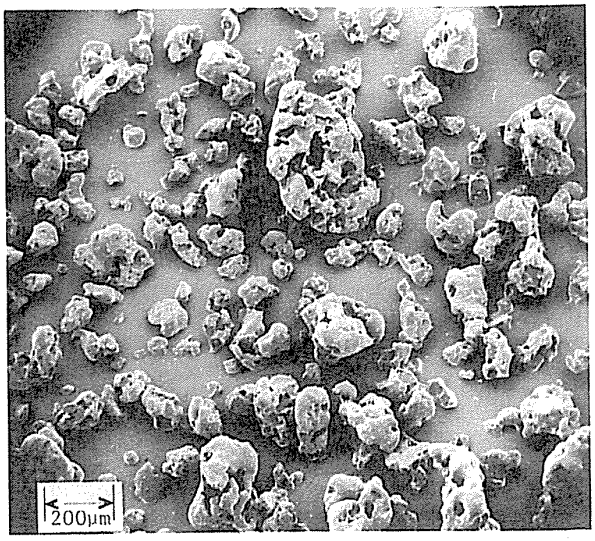
Ethylcellulose is additionally used in cosmetics and food products.

Use	Concentration (%)
Microencapsulation	10.0-20.0
Sustained release tablet coating	3.0-10.0
Tablet coating	1.0-3.0
Tablet granulation	1.0-3.0

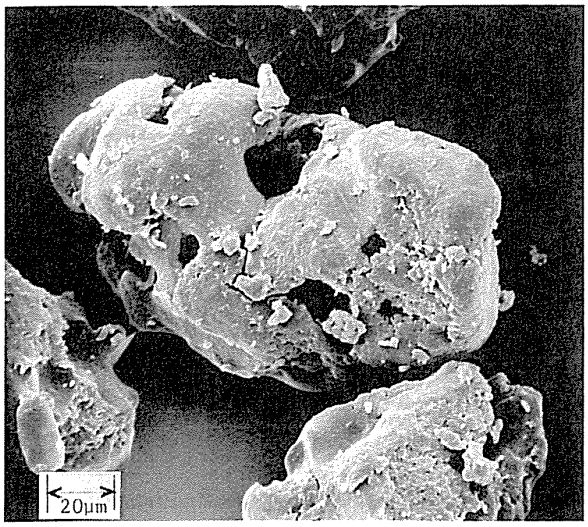
8. Description

Ethylcellulose is a tasteless, free-flowing, white to light tan colored powder.

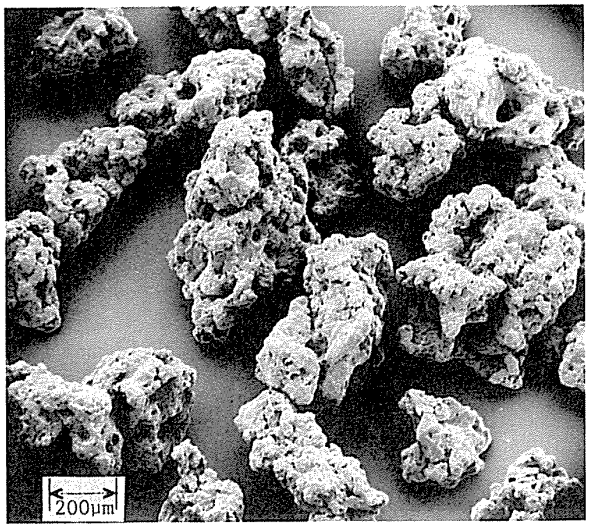
SEM: 1
Excipient: Ethylcellulose
Manufacturer: Hercules Ltd
Lot No.: 57911
Magnification: 60x
Voltage: 10 kV



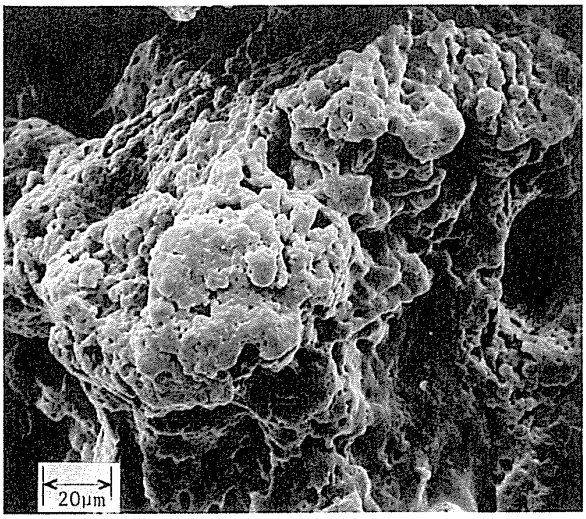
SEM: 2
Excipient: Ethylcellulose
Manufacturer: Hercules Ltd
Lot No.: 57911
Magnification: 600x
Voltage: 10 kV



SEM: 3
Excipient: Ethylcellulose (*Ethocel*)
Manufacturer: Dow Chemical Company
Lot No.: 103051
Magnification: 60x
Voltage: 10 kV



SEM: 4
Excipient: Ethylcellulose (*Ethocel*)
Manufacturer: Dow Chemical Company
Lot No.: 103051
Magnification: 600x
Voltage: 10 kV



9. Pharmacopeial Specifications

Test	PhEur 1993	USPNF XVII
Identification	+	+
pH (2% w/w suspension)	5.0-7.5	—
Viscosity	+	+
Loss on drying	⩽ 3.0%	⩽ 3.0%
Residue on ignition	—	⩽ 0.4%
Sulfated ash	⩽ 0.5%	—
Arsenic	—	⩽ 3 ppm
Lead	—	⩽ 10 ppm
Heavy metals	⩽ 20 ppm	⩽ 40 ppm
Acetaldehyde	⩽ 100 ppm	—
Chlorides	⩽ 0.05%	—
Assay (of ethoxyl groups)	—	44.0-51.0%

10. Typical Properties

Density (bulk): 0.4 g/cm^3
Glass transition temperature: 130-133°C[3]
Hygroscopicity: ethylcellulose absorbs very little water at high relative humidities or during immersion; any absorbed water evaporates readily.[15] *See also* HPE Data.
Solubility: practically insoluble in glycerin, propylene glycol and water. Ethylcellulose that contains less than 46.5% of ethoxyl groups is freely soluble in chloroform, methyl acetate, tetrahydrofuran, and in mixtures of aromatic hydrocarbons with ethanol (95%). Ethylcellulose that contains not less than 46.5% of ethoxyl groups is freely soluble in chloroform, ethanol (95%), ethyl acetate, methanol and toluene.
Specific gravity: 1.12-1.15
Viscosity: various grades of ethylcellulose are commercially available which differ in their ethoxyl content and degree of polymerization. They may be used to produce 5% w/v

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