

# EASTMAN™ CAP

Cellulose Acetate Phthalate, Enteric Coating Material

**Eastman™ CAP** (also known as Cellacefate) enteric coating material is a pH-sensitive cellulose derivative designed for coating pharmaceutical tablets or granules. It may also be used as a matrix material in solid dose forms. **Eastman™ CAP** enteric coating material withstands prolonged contact with acidic gastric fluids, but dissolves readily in the mildly acidic to neutral environment of the small intestine. It can be applied to tablets or granules from solutions of organic solvents. It is the subject of U.S. Drug Master File 8.

**Eastman™ CAP** meets USP and NF specifications and is available in powder and pellet form.

**Eastman™ CAP** contains around 33% of acetyl- and around 24% of phthalyl-groups, calculated on the anhydrous acid-free basis, and exhibits a  $pK_a$  of approx. 4.5. Both the  $pK_a$  value and the acetyl and phthalyl content influence the pH-dependent dissolution behaviour of the polymer. **Eastman™ CAP** coated tablets and capsules withstand 2 hours in the strongly acidic gastric environment, but dissolve completely within minutes at pH 6.5. The required coating thickness varies with the shape of the coated tablets or capsules, but around 3 mg/cm<sup>2</sup> tablet surface are in most cases a suitable range to assure sufficient acid-resistance and a fast dissolution in the intestine.

Beside the more common application as coating polymer, **Eastman™ CAP** can also be used in combination with other polymers as matrix former for sustained release tablets or to form gastric resistant solid dispersions.

**Eastman™ CAP** is best soluble in organic solvents like acetone or ethyl acetate. Suitable solvent systems are e.g. acetone:water (97:3), ethyl acetate:ethanol (50:50) or ethyl acetate:isopropanol (50:50). Due to the water-free coating solution, **Eastman™ CAP** is especially suitable as coating polymer for moisture-sensitive API's.

The properties of coatings made with **Eastman™ CAP** enteric polymer may be modified by adding a plasticizer to the polymer solution before coating. Plasticizers add film toughness (increased resistance to chipping or cracking) while lowering the  $T_g$  (glass transition temperature or softening point) of the polymeric film. In general, the optimum concentration of plasticizer is the minimum amount which provides the necessary flexibility to form a continuous coating. Suitable plasticizers are diethyl phthalate, dibutyl phthalate or triacetin in a polymer to plasticizer ratio of around 1 to 0.25 (w/w).

**Eastman™ CAP** is widely used for decades as enteric coating material and is generally regarded as well tolerated non-toxic material.

CAS-No.:	9004-38-0
Mol. Weight:	approx. 28,700 g/mol ( $M_w$ )
Packing:	50 kg fiber drum with inner PE-lining
Shelf life:	36 months (Pellets), 24 months (Powder)
Storage:	At ambient temperature, protected from moisture.



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