



SURELEASE®
AQUEOUS ETHYLCELLULOSE DISPERSION

Product Information

Formula No: E-7-19030

Surelease® is a complete, optimally plasticized aqueous dispersion designed specifically for modified release and taste masking applications. Using ethylcellulose as the rate controlling polymer, Surelease brings technological advances with dependable, reproducible extended release profiles that are consistent from laboratory to pilot and production scale processes.

Key Characteristics

- Aqueous dispersion
- Complete, optimally plasticized and formulated system
- Easy to use and environmentally friendly
- Consistent and reproducible drug release profile
- Regulatory acceptance in the United States, Europe and certain other regions.

Applications

- **Bead & Particle Coating:**
Surelease is used primarily as a barrier membrane for developing extended release dosage forms. Drug release can be effectively controlled by applying Surelease coating onto bead and particulate substrates. Fluid-bed coating is the most commonly used technique for coating of small particles.
- **Matrix Granulation:**
Surelease can be used as a binder in wet granulation applications for production of free flowing granules, which can subsequently be compressed into tablets to achieve an extended drug release profile.
- **Taste Mask Coating:**
Ethylcellulose, the rate controlling polymer in Surelease is water insoluble and provides highly effective taste masking properties for unpalatable actives.

General Manufacturing Process Description

Ethylcellulose is blended with Oleic Acid and Dibutyl Sebacate, then extruded and melted. The molten plasticized ethylcellulose is then directly emulsified in ammoniated water in a high shear mixing device under pressure. Ammonium Oleate is formed in situ to stabilize and form the dispersion of plasticized ethylcellulose particles. Additional Purified Water is added to achieve the final solids content. Colloidal Anhydrous Silica is then dispersed into material to form the final product. (Reference: U.S Patents 4,123,403 and 4,502,888).

Stability

Surelease provides dependable drug release characteristics and dissolution performance throughout its shelf life period. Some degradation of the Dibutyl Sebacate and Oleic Acid occurs during the manufacturing process. The extent of this degradation and identification/qualification of the specific degradants is currently under investigation.

Packaging

Surelease is supplied as 25% w/w dispersion in tightly sealed polyethylene containers. Surelease is available in multiples of 10.0kg weights.

Shelf Life

Surelease has a shelf life of 18 months from date of manufacture when properly stored.

Recommended Storage Conditions

Store in tightly sealed containers. Avoid exposure to high humidity and temperatures above 30°C (86°F).

Keep from Freezing

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