



SURELEASE[®]
AQUEOUS ETHYLCELLULOSE DISPERSION

Product Information

Formula No: E-7-19050

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Surelease[®] NG is a complete, optimally plasticized aqueous ethylcellulose dispersion designed specifically for extended release and taste masking applications. 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 formulated system
- Easy preparation and use
- Consistent and reproducible drug release profiles
- Enhanced stability

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, melted and extruded. 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 then added to achieve the final solids content. (Reference: U.S Patents 4,123,403 and 4,502,888).

Stability

Surelease NG has been tested at standard and accelerated conditions, and has been shown to provide consistent extended release dissolution performance in all cases.

Packaging

Surelease is supplied as 25% w/w dispersion in tightly sealed polyethylene containers. Surelease is available in multiples of 18.0 kg weights.

Shelf Life

Surelease **NG** has a shelf life of 24 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

Note: Surelease **NG** aqueous ethylcellulose dispersion (E-7-19050) has no precedence of use, having been only recently introduced as a commercial product. It has not yet been used in a drug product which has been approved for marketing by a drug regulatory agency. A product regulatory data sheet can be requested for additional details

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