

Delayed Release Coatings for Nutritional Supplements using Nutrateric®

Nutrateric®, nutritional enteric coating system, is an easy-to-use and reliable delayed release coating for nutritional supplements. This information sheet details the preparation, use and clean-up guidelines for this coating system.

NUTRATERIC USE GUIDELINES

- The Nutrateric coating dispersion is comprised of Surelease®, aqueous ethylcellulose dispersion, (E-7-19010 or E-7-19040) supplied as a liquid at 25% solids concentration, and NS Enteric®, nutritional enteric component (29Z series) supplied as a dry powder.
- EU market (E462 compliant)
- A final dispersion concentration of 10% solids is recommended for film uniformity.
- Typically 3 - 6% weight gain will give desired delayed release profiles; this depends on core characteristics.
- An optional sub-coat of Opadry® ns-g, gloss film coating for nutritional supplement, can be applied for water soluble compounds and friable, less robust cores;
- 1 - 2% weight gain is sufficient.
- If required, a seal-coat can be applied to further enhance finished product appearance; 1 - 3% weight gain is standard.

NUTRATERIC PREPARATION

GUIDELINES

Equipment

- Variable speed low shear mixer, capable of producing and maintaining a vortex.
- Mixing vessel large enough to contain a liquid volume 20% greater than the total suspension being prepared. This will accommodate high speed mixing.
- High efficiency propeller stirrer with blade diameter equivalent to 25-30% of the diameter of the mixing vessel.
- A peristaltic pump should be used for fluid transfer, because a gear pump may cause coagulation of the dispersion.

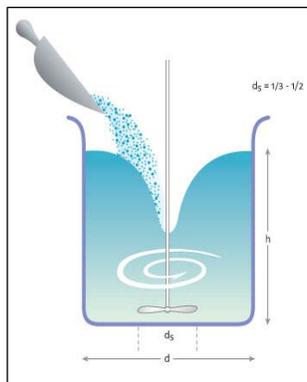
MATERIALS CALCULATION:

- Determine total solids required based on target coating weight and quantity of tablets to be coated.
 $\text{Quantity Tablets to be coated kg} \times \text{Target Coating Weight (\%)} = \text{Total Required Solids kg (A)}$
- Determine quantity of coating solution needed as a 10% solids dispersion.
 $\text{Total Required Solids kg (A)} / 0.10 = \text{Coating Solution kg (B)}$

- iii) Based on 85: 15 ratio of Surelease: NS Enteric solids, determine the quantity of each product required.
 Total Required Solids kg **(A)** x 85% = Surelease Solids kg **(C)**.
 Total Required Solids kg **(A)** x 15% = NS Enteric Solids kg **(D)**
- iv) Since Surelease is supplied as a 25% solids dispersion, determine the quantity needed based on required solids.
 Surelease solids kg **(C)** / 0.25 = Quantity Surelease Dispersion Required kg **(E)**
- v) Determine quantity water required.
 Quantity Surelease Dispersion kg **(E)** + NS Enteric solids kg **(D)** = **(F)**
 Coating Solution kg **(B)** - **(F)** = Quantity Water Required **(G)**

MIXING PROCEDURE

- i) Weigh the necessary quantity of water (G) into the mixing vessel.
- ii) Using the mixer and propeller stirrer, stir the water to form a vigorous vortex.
- iii) Weigh the necessary quantity of NS Enteric (D) and add the powder to the water in a slow steady stream while maintaining a vigorous vortex. An increase in volume of the suspension and some foaming will occur initially, but will subside rapidly.
- iv) Reduce mixer speed to low and continue to mix for 60 - 90 minutes to insure complete hydration.
- v) Gently agitate the Surelease container to ensure complete dispersion of solids prior to dispensing the required quantity (E). Add this to the vessel and continue mixing for 10 to 15 minutes. The suspension should be continuously mixed during the coating process.



NUTRATERIC CLEAN UP GUIDELINES

- For best results, the coating over-spray should be cleaned off of the equipment shortly after the end of the coating run. If the product is allowed to dry, the residual film can be difficult to remove.
- Coating pans can be cleaned with an aqueous solution of alkaline detergent (such as sodium bicarbonate) or mild soap and water. Fill the reservoir with cleaning solution and allow the pan to rotate through the solution for 30 minutes. The cleaning solution will not dissolve the film coating, but allows it to release from the metal so it can be washed away with a deionized water rinse.
- Spray equipment (guns and hoses) should be disassembled and cleaned with the cleaning solution. When cleaning spray guns, it is important to make sure the passages are free of residual coating material that can block the orifice and restrict flow. A thin brush or swab can be passed through the tip of the gun to insure all the coating material is removed. Avoid using hard substances because these can damage the gun parts.

FORMULATION (CLEAR SYSTEM):

NS Enteric Clear 29Z series (**D**)

Surelease Dispersion E-7-19010 or E-7-19040* (**E**)

Deionized Water (**G**)

* EU Market (E462 compliant)

Please contact your Colorcon Technical Representative if further technical advice is required.

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