

Preparation Guidelines

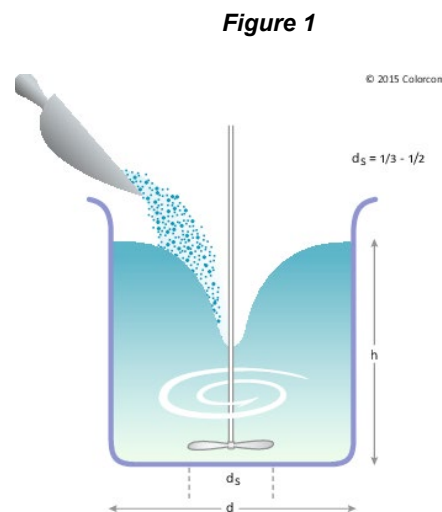
CoreleaseCA™ is a fully formulated semipermeable membrane coating system for osmotic pump tablets. CoreleaseCA provides one-step, quick and easy organic solution preparation.

MATERIALS

- CoreleaseCA powder
- Acetone and water (deionized or distilled preferred) or other solvent mixture at temperature range of 23-30°C. (Note: at temperatures below 23°C, the preparation time may take longer. If necessary, warm up the solvent to the target temperature before adding the CoreleaseCA powder.)

EQUIPMENT

- Variable-speed mixer capable of producing and maintaining a vortex.
- Propeller stirrer with a diameter equivalent to 1/3 - 1/2 the diameter of the mixing vessel (Figure 1).
- Mixing vessel suitable to contain a liquid volume 15-25% greater than the total solution being prepared. The liquid height should be equal to, or greater than, the vessel diameter. Vessel should have a suitable cover.



SOLUTION HANDLING

- CoreleaseCA solution should be prepared in a well ventilated area and covered at all times.
- Once prepared, the CoreleaseCA solution can be pumped directly from the preparation vessel, if desired.

MIXING PROCEDURE

Determine the amount of CoreleaseCA and solvents required, based on the quantity of tablets and the target coating weight gain. CoreleaseCA coating solution is recommended to be prepared at 5 - 8% solids w/w.

1. Weigh out required quantity of acetone (or alternative solvent) and water into the mixing vessel.
2. Position the propeller in the center and as close to the bottom of the vessel as possible. Stir the liquid to form a vortex and ensure sufficient mixing of acetone and water.
3. Weigh out required quantity of CoreleaseCA film coating system.
4. Steadily add the CoreleaseCA powder to the vortex, avoiding powder flotation on the liquid surface. If required, increase the stirrer speed to maintain the vortex.

5. Once all the CoreleaseCA powder has been added; slightly reduce the mixer speed, while still maintaining the vortex.
6. Continue stirring for 45 minutes until all particles dissolve, the coating solution will then be ready for use.

USE GUIDELINES

- Recommended coating weight gains of CoreleaseCA may be in a range of 8-12% w/w (9.92 - 14.88 mg/cm²) for push-pull osmotic pump applications, depending on the target release profile. To determine actual weight gain, laboratory coating trials should be conducted.
- A seal-coat may be used to improve the tablet cores, but is not required.
- A white or pigmented Opadry or Opadry II top-coat (approx. 6% w/w), is recommended to improve overall appearance of the final tablets and aid adhesion of printing ink (for branding and/or product identification).
- Your Colorcon Area Technical Manager (ATM) can assist you in optimizing the solvent type, solution solids levels, coating weight gain and process parameters to meet your required drug release profile.

CLEANING GUIDELINES

- For best results, clean equipment shortly after the end of the coating run.
- Clean the fluid delivery tubes and spray guns by pumping pure acetone for 2-3 minutes, then wash with cleaning solutions or deionized water.
- CoreleaseCA residues remaining on the coating equipment can easily be removed using a cleaning agent or deionized water. If equipped, fill the coating pan with cleaning solution and allow the pan to rotate through the solution for 30 minutes.
- Spray equipment (gun and hoses) should be disassembled, and soaked in the cleaning solution for 30 minutes.
- When cleaning spray guns, it is important to make sure the passages are free of residual coating materials that can block the orifice and restrict flow. A thin soft brush or swab may be passed through the tip of the gun to ensure all the coating material is removed. Avoid using hard objects that can damage the gun parts.
- All equipment should be rinsed with deionized water after cleaning.

Please contact your Colorcon Technical Representative if you require any further information.

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For more information, contact your Colorcon representative or call:

North America
+1-215-699-7733

Europe/Middle East/Africa
+44-(0)-1322-293000

Asia Pacific
+65-6438-0318

Latin America
+54-11-5556-7700

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