INSTACOATTM EN HPMC-P is an HPMC-P based ready-to-use enteric coating system for organic solvent use, which provides excellent enteric protection to solid oral dosage forms. Use of a seal coat to prevent interaction between active and polymer and to provide a uniform substrate is recommended.

Recommended Solvent System and Reconstitution Level

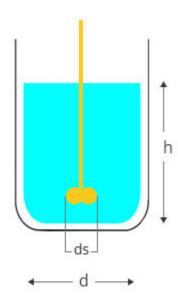
Hydroalcoholic: IPA 75% + Water 25% at up to 10% w/w solids.

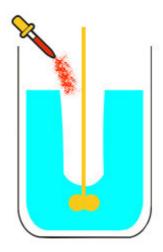
Organic: Methylene Chloride 65% + IPA 35% w/w at up to 5% w/w solids.

Equipment / Accessories

Variable-speed mechanical stirrer

Mixing Vessel





Determine the quantities of Instacoat EN HPMC-P (10% w/w solids) and IPA + water required, based on the quantity of tablets to be coated and the target coating weight gain. e.g.: For coating 1.0 kg of tablets to 8% wt. gain, weigh 88 gm Instacoat EN HPMC-P and 594 gm IPA + 198 gm purified water at room temperature (including 10% overage for losses)

Determine the quantities of Instacoat EN HPMC-P (5% w/w solids) and Methylene Chloride + IPA required, based on the quantity of tablets to be coated and the target coating weight gain. e.g.: For coating 1.0 kg of tablets to 8% wt. gain, weigh 88 gm Instacoat EN HPMC-P and 1087 gm Methylene Chloride + 585 gm IPA at room temperature (including 10% overage for losses)

Reconstitution Process

Add the weighed quantity of Isopropyl Alcohol to a mixing vessel.

Using the mechanical stirrer, stir the Isopropyl Alcohol to form a vortex.

Add required quantity of Instacoat EN-HPMCP to the centre of the solvent vortex in a slow steady stream, avoiding clumping and maintaining a vortex. Stir for 5 minutes, then add the weighed quantity of methylene chloride.

Once the entire quantity of Instacoat EN HPMCP has been added, reduce the stirrer speed to eliminate the vortex. Continue mixing for 45 minutes

It is recommended to continuously stir the coating suspension throughout the coating process.

Recommended Process Conditions

| | Side-vented (fully perforated) pans | Conventional (non perforated) pans |
|---------------------|--|---------------------------------------|
| Pan diameter (inch) | 24-60 | 12-36 |
| Tablet load (kg) | 10-300 | 0.5-50 |
| Weight gain (%) | 8.0–12.0 | - - |
| Number of guns | 1-6 | 1 |

| Liquid nozzle diameter (mm) | 1.0-1.5 | |
|---|---|--|
| Atomising air pressure (bar) | 1.0–3.5 | |
| Pattern air pressure | To achieve maximum uniform bed coverage | |
| Tablet bed temperature, hydro-alcoholic (ºC) | 36-40 | |
| Tablet bed temperature, organic (ºC) | 33-37 | |
| Inlet air temperature (°C) | Set to achieve required product bed temperature | |
| Suspension spray rate | Set to achieve required product bed temperature | |
| Exhaust air volume | To maintain slight negative pressure in pan | |
| Pan speed | Minimum for steady tablet flow through spray zone | |

*Tablet bed temperature offers the most effective way of controlling the coating process. Where this measurement is unavailable, exhaust temperature may be substituted. However, the relationship between the two measurements is complex and depends on several factors such as pan load, pan depression, pan design and airflow rate. Indicated exhaust temperature may be above or below the true bed temperature. It is recommended that the relationship between the two measurements is calibrated.

Typical Constituents

HPMC Phthalate; Plasticiser; Titanium Dioxide; Edible Pigments.