

Recommended Solvent System and Reconstitution Level

Purified water at up to 11% w/w solids

Organic:

I. IPA 35% + MDC 65% w/w at up to 5% solids

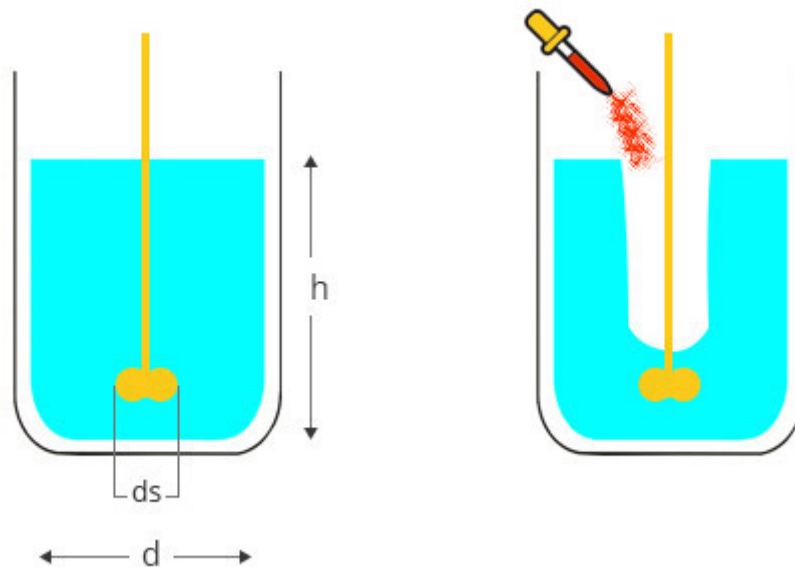
II. Ethanol 35% + Chloroform 65% w/w at up to 5% solids

Hydro-alcoholic: Water 50% + IPA 50% w/w at up to 9%

Equipment / Accessories

Variable-speed mechanical stirrer

Mixing Vessel



Calculation of Instacoat™ Universal and solvent quantities

Determine the quantities of Instacoat universal (11% w/w solids) and 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 3% wt. gain, weigh 33 g Instacoat and 267 gm purified water at room temperature (includes 10% overage for losses)

Determine the quantities of Instacoat universal (5% w/w solids) and IPA 35% + MDC 65% or Ethanol 35% + Chloroform 65% 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 3% wt. gain, weigh 33 g Instacoat and 627 gm IPA 35%+ MDC 65% or Ethanol 35% + Chloroform 65% at room temperature (includes 10% overage for losses)

Determine the quantities of Instacoat universal (9% w/w solids) and Water 50% + IPA 50% 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 3% wt. gain, weigh 33 g Instacoat and 333.67 gm Water 50% + IPA 50% at room temperature (includes 10% overage for losses)

Reconstitution Process

Instacoat universal (Aqueous):

Add the weighed quantity of water to a mixing vessel.

Using a mechanical stirrer, stir the purified water to form a vortex

Add required quantity of Instacoat Aqua II to the centre of the liquid vortex in a slow steady stream, avoiding clumping while maintaining a vortex. Once the entire quantity of Instacoat has been added, reduce the stirrer speed to eliminate the vortex. (Fig. 2) Continue mixing for 45 minutes.

Instacoat universal (Organic):

Add the weighed quantity of organic solvent to a mixing vessel.

Using a mechanical stirrer, stir the organic solvent to form a vortex

Add required quantity of Instacoat Universal to the centre of the liquid vortex in a slow steady stream, avoiding clumping while maintaining a vortex. Once the entire quantity of Instacoat has been added, reduce the stirrer speed to eliminate the vortex. (Fig. 3) Continue mixing for 45 minutes.

Instacoat Universal (hydro alcoholic):

Add the weighed quantity of hydro alcoholic solvent to a mixing vessel.

Using a mechanical stirrer, stir the hydro alcoholic solvent to form a vortex

Add required quantity of Instacoat Universal to the centre of the liquid vortex in a slow steady stream, avoiding clumping while maintaining a vortex. Once the entire quantity of Instacoat has been added, reduce the stirrer speed to eliminate the vortex. (Fig. 4) Continue mixing for 45 minutes.

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 (%) | 2.0-3.0% | |
| Number of guns | 1-6 | 1 |
| Liquid nozzle diameter (mm) | 1.0-1.2 | |
| Atomising air pressure (bar) | 2.5-3.5 | |
| Pattern air pressure | To achieve maximum uniform bed coverage | |
| Tablet bed temperature, Aqueous (°C) | 40-42 | |
| Tablet bed temperature, Organic (°C) | 36-38 | |
| Tablet bed temperature, Hydro-alcoholic (°C) | 38-40 | |
| 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

Water-soluble cellulosic polymer(s); Plasticiser; Titanium Dioxide; Edible Pigments, Glidant.