Instacoat EN Super II

INSTACOAT™ EN SUPER-II is a fully formulated enteric coating system based on Methacrylic Acid Copolymer Type C. It is a patented product for aqueous use. It is recommended in the cases where phthalate esters such as CAP or HPMCP are not compatible or pose other problems. Typically, a weight gain of around 9% provides reproducible delayed release profiles.

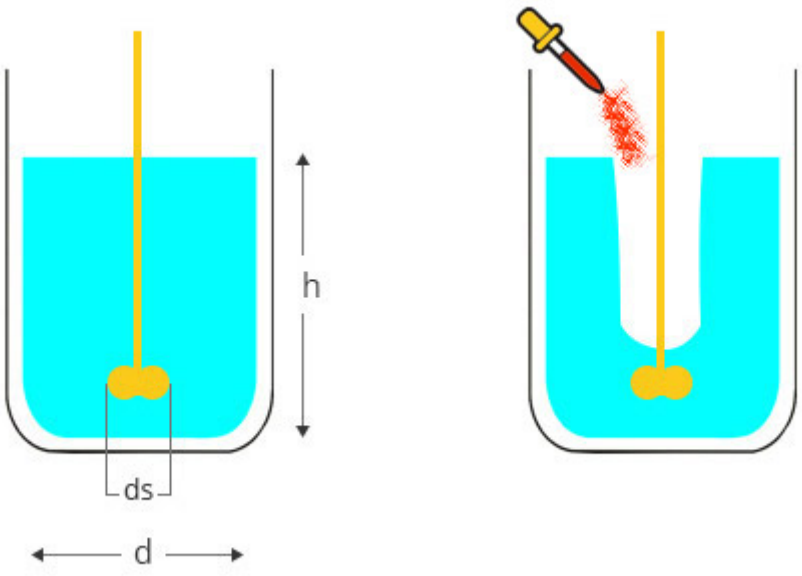
Recommended Solvent System and Reconstitution Level

Purified water at up to 20% w/w solids

Equipment / Accessories

Variable-speed mechanical stirrer (do not use high-shear equipment)

Mixing Vessel



Calculation of Instacoat EN SUPER-II and solvent quantities

Determine the quantities of Instacoat EN SUPER-II (20% 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 8% wt. gain, weigh 88 g Instacoat and 352 gm purified water at room temperature (includes 10% overage for losses).

Reconstitution Process

Add the weighed quantity of water to a mixing vessel.

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

Add the required quantity of Instacoat EN SUPER-II to the centre of the liquid vortex in a slow steady stream, avoiding clumping while maintaining a vortex and completing powder dispersion within 5 minutes. Once this has been achieved, reduce the stirrer speed to eliminate the vortex and 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 (%)	8-9 %	
Number of guns	1-6	1-2
Liquid nozzle diameter (mm)	1.0-1.5	
Atomising air pressure (bar)	1.5-2.5	
Pattern air pressure	To achieve maximum uniform bed coverage	
Tablet bed temperature (ºC)	30-35	
Inlet air temperature (ºC)	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

Methacrylic Acid Copolymer Type C; Plasticiser; Titanium Dioxide; Edible Pigments; Alkaliser; Glidant.