

Film coating application for Soft Gelatine Capsules

Soft capsules are oral solids forms where the active principal ingredient (Inner fill) is usually placed inside a solid capsule (outer shell). Soft gelatine capsules (SGC) are often coated with a film layer for different reasons, i.e., protection against degradation, functionality, mask bad tasting, patient compliance.

Coating of soft gelatine capsules is not an evident process. The special roughness of SGC surface and the low solubility of capsule shell in organic solvents means that the coating agents where the carrier is an organic solvent does not adhere properly to the shell, which leads to defects on the film coating, i.e., peeling of the fil layer or film cracking. On the other hand, the use of aqueous or hydroalcoholic suspensions may result in swelling or sticking capsules together because of the plasticizer effect that water has during the film coating process.



Application case

The aim of this application note is to propose initial process parameters for the film coating of soft gelatine capsules with a 100% aqueous suspension. The key point of the coating process is to stabilize the equilibrium between the amount of energy provided, by the means of inlet air and inlet temperature inlet temperature, and the amount of coating suspension provided.

The coating of 50 Kg the SGC with a Vivacoat® (from JRS Pharma) suspension was carried out in **TP R100 Optima** coating machine. Coating formulation is shown table 1. The SGC were mainly composed by sunflower oil and gelatine.

Coating suspension components

Purified water 83.0 %

Vivacoat® A 17.0 %

Red iron oxide 0.05 %

Process parameters

Phase	Heating	Spraying	Drying
Drum speed (rpm)	3	8	3
Inlet air Flow (m3/h)	1600	1600	1000
Underpressure (Pa)	250	250	250
Inlet air T (°C)	48	48	32
Product temperature (°C)	37	37	33
Outlet air T (°C)	42	40	33
Spray rate (g/min)	-----	100	-----
Atomization pressure (bar)	-----	2.0	-----
Spray pattern pressure (bar)	-----	2.0	-----
Nozzle (mm)	1.2 (2 guns)	1.2 (2 guns)	1.2 (2 guns)
Gun distance from tablets (mm)	160	160	160
Batch size (kg)	50	50	50
Coater drum filling (%) Bulk density 0.6 Kg/L	55%	55%	55%
Sprayed solution (kg)	-----	8.8	-----
Process time (min)	20	90	15
Appearance quality	Acceptable	Acceptable	Acceptable

Conclusions

The film coating of a 50 kg batch (around 55% capacity of a **TP R100 Optima**) of soft gelatin capsules has been carried out. The challenge of performing an aqueous coating process while maintaining the process temperature below the melting point of the gelatin capsules has been successfully achieved. The **Optima TP R100** managed to keep all process parameters stable throughout the whole process, which was the main factor for the success of the trial.

