



Reconstitution Protocol

TABSAFE En C

TABSAFE En C is an aqueous based enteric coating system based on Methacrylic Acid Copolymer Type C. For preparation of coating dispersion, it is required to add the TABSAFE En C powder to water and stirred for 45 minutes using overhead propeller stirrer.

SOLVENT SYSTEM : AQUEOUS

Recommended Solvent System

Deionized water at ambient temperature: 4 parts
Solids content ~ 20%

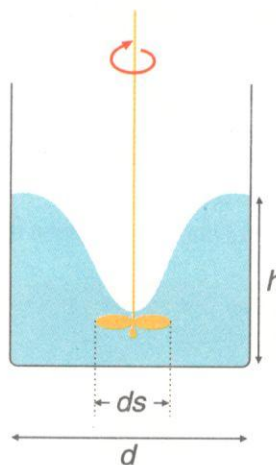
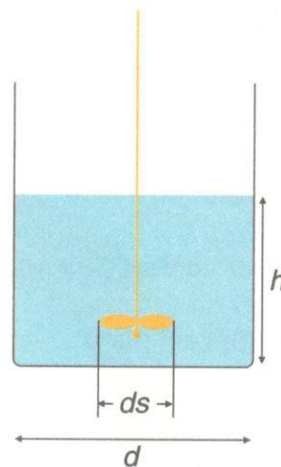
Equipment

- Stainless steel vessel with a capacity that is 25% higher than the total dispersion volume.
- The height of the vessel should be nearly 25% more than its diameter.
- The speed of the propeller of stirrer needs to be variable and diameter of its blade should be approximately 33% of the vessel's diameter.

Reconstitution procedure

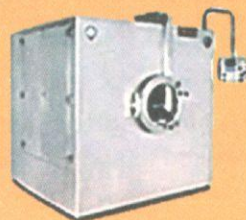
- Weigh the required quantity of IPA.
- Stir to form a vortex
- Add the required quantity of TABSAFE Uni to the vortex
- Stir for further 5 minutes
- Add required quantity of Water
- Reduce the speed to remove the vortex
- Continue stirring for 40 minutes

Position the stirrer centrally to prevent air entrapment.
Filter the solution through # 100
Continue stirring throughout the coating process.





Coating Parameters for TABSAFE En C: Organic Solvent System



Coating parameters for TABSAFE En C: Aqueous system

TABSAFE En C

	24"	48"	60"	12"	36"
Pan diameter	24"	48"	60"	12"	36"
Solvent	Water	Water	Water	Water	Water
Solids content (% w/w)	20	20	20	20	20
Pan Speed* (rpm)	10 - 14	3 - 5	1.5 - 3	18 - 20	8 - 12
Baffles	4 - 6	6 - 8	6 - 10	3	4
Tablet charge** (kg)	10 - 15	100 - 130	250 - 300	0.5 - 1	40 - 50
Tablet bed temperature (°C)	30 - 35	30 - 35	30 - 35	30 - 35	30 - 35
Spray nozzle (mm)	1	1.2-1.5	1.2-1.5	1	1.2
Number of spray guns	1	2-3	4-6	1	1
Atomizing air pressure (bars)	1.5 - 2.5	1.5 - 2.5	1.5 - 2.5	1.5 - 2	1.5 - 2.5
Spray procedure	Continuous	Continuous	Continuous	Continuous	Continuous
Spray rate (g/min)	15 - 20	125 - 175	275 - 325	4 - 6	50 - 60
Inlet air temperature (°C)	50 - 55	50 - 55	50 - 55	50 - 55	50 - 55
Drying air volume (cfm)	250 - 300	1500 - 2000	4500 - 5000	50	400 - 500
Weight gain (%)	8 - 10	8 - 10	8 - 10	8 - 10	8 - 10

* Pan speed would depend upon the tablet shape, size, friability and the number of baffles, so as to effect proper mixing during the coating process.