

Reconstitution Protocol

TABSAFE En A

Tab Safe En A is a unique, optimized enteric coating material suitable for use with organic solvents. Tab Safe En A is a Methacrylic Acid Copolymer Type A based enteric coating material which serves as a barrier to prevent chemical degradation of drug under acidic environment.

SOLVENT SYSTEM : ORGANIC

Recommended Solvent System

1. 100% IPA or Ethanol (9 - 10% reconstitution)
2. 60% IPA + 40% Acetone (9 - 10% reconstitution)

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 should be variable and its blade diameter should be approximately 33% of vessel diameter.

Reconstitution procedure

IPA or Ethanol

Weigh the required quantity of IPA or ethanol.

Stir to form a vortex

Add the required quantity of TABSAFE En A to the vortex

Reduce the speed to remove the vortex

Continue stirring for 150 minutes

Using IPA + Acetone

Weigh the required quantity of IPA.

Stir to form a vortex

Add the required quantity of TABSAFE En A to the vortex

Stir for further 5 minutes

Add required quantity of Acetone

Reduce the speed to remove the vortex
Continue stirring for 40

Position the stirrer centrally to prevent air entrapment.

Filter the solution through # 100

Continue stirring throughout the coating process.

Use Colloid Mill if required.

Coating Parameters for TABSAFE En A: Organic Solvent System

Coating parameters for TABSAFE En A: Organic Solvent system				TABSAFE En A	
Pan diameter	24"	48"	60"	12"	36"
Solvent	Organic	Organic	Organic	Organic	Organic
Solids content (% w/w)	9 - 10	9 - 10	9 - 10	9 - 10	9 - 10
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)	35 - 40	35 - 40	35 - 40	35 - 40	35 - 40
Spray nozzle (mm)	1	1.2-1.5	1.2-1.5	1	1.2
Number of spray guns	1	23	46	1	1
Atomizing air pressure (bars)	2.5 - 3.5	2.5 - 3.5	2.5 - 3.5	2.5 - 3.5	2.5 - 3.5
Spray procedure	Continuous	Continuous	Continuous	Continuous	Continuous
Spray rate (g/min)	25 - 35	200 - 250	350 - 400	8 - 12	60 - 75
Inlet air temperature (°C)	40 - 45	40 - 45	40 - 45	40 - 45	40 - 45
Drying air volume (cfm)	250 - 300	1500 - 2000	4500 - 5000	50	400 - 500
Weight gain (%)	Min 10	Min 10	Min 10	Min 10	Min 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.

** Tablet charge would vary depending upon the tablet shape and size.