

Reconstitution Protocol

TABSAFE SC

TabSafe SC is a unique, optimized seal coating material suitable for use with organic solvent. It is a blend of polymers, plasticizers other excipients which could be used with organic solvent system to give a transparent seal coating.

SOLVENT SYSTEM : ORGANIC

Recommended Solvent System

Organic: Reconstitution level 5% - 6% solids content

- a. 35% IPA + 65% MDC
- b. 35% Chloroform + 65% Ethanol

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/Choloroform.
- Stir to form a vortex
- Add the required quantity of TABSAFE SC to the vortex
- Stir for further 5 minutes
- Add required quantity of MDC/Ethanol.
- Reduce the speed to remove the vortex
- Continue stirring for 40 minutes. Use Colloid Mill if required.

Position the stirrer centrally to prevent air entrapment.

Filter the solution through # 100

Continue stirring throughout the coating process.

Coating Parameters for TABSAFE SC: Organic Solvent System

Coating parameters for TABSAFE SC: Organic Solvent system				TABSAFE SC	
Pan diameter	24"	48"	60"	12"	36"
Solvent	Organic	Organic	Organic	Organic	Organic
Solids content (% w/w)	5 - 6	5 - 6	5 - 6	5 - 6	5 - 6
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)	40 - 60	300 - 600	600 - 800	10 - 15	100 - 150
Inlet air temperature (°C)	55 - 65	55 - 65	55 - 65	55 - 65	55 - 65
Drying air volume (cfm)	250 - 300	1500 - 2000	4500 - 5000	50	400 - 500
Weight gain (%)	2 - 3	2 - 3	2 - 3	2 - 3	2 - 3

* 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.