

Reconstitution Protocol

TABSAFE MB

TabSafe MB is a unique, optimized moisture barrier coating material suitable for use with organic solvent. It is a blend of polymers, plasticizers, pigments, opacifiers and other excipients which could be used with organic solvent system to give protection against atmospheric moisture.

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 Sol 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

Position the stirrer centrally to prevent air entrapment.

Filter the solution through # 100

Continue stirring throughout the coating process.

Coating Parameters for TABSAFE MB: Organic Solvent System

| Coating parameters for TABSAFE MB: Organic Solvent system | TABSAFE MB | | | | |
|---|------------|-------------|-------------|------------|------------|
| | 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 | 2-3 | 4-6 | 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 - 350 | 600 - 700 | 20 - 25 | 80 - 100 |
| 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 (%) | 3 - 4 | 3 - 4 | 3 - 4 | 3 - 4 | 3 - 4 |

* 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.