



## Reconstitution Protocol

### TABSAFE SLV

TabSafe SLV 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

- 35% IPA + 65% MDC
- 35% Chloroform + 65% Ethanol

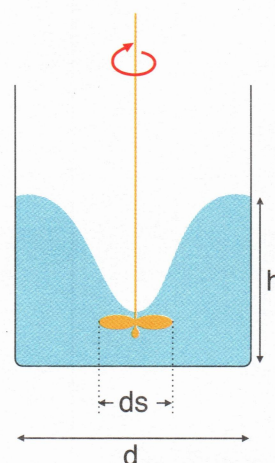
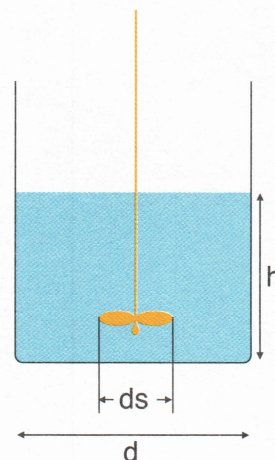
##### Equipment

- 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 SLV 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.

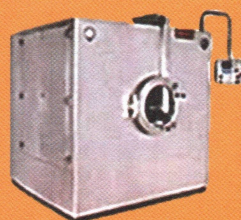
Position the stirrer centrally to prevent air entrapment.  
Filter the solution through # 100  
Continue stirring throughout the coating process.







# Coating Parameters for TABSAFE SLV: Organic Solvent System



## Coating parameters for TABSAFE SLV: Organic Solvent system

## TABSAFE SLV

|                                      | 24"            | 48"            | 60"            | 12"            | 36"            |
|--------------------------------------|----------------|----------------|----------------|----------------|----------------|
| <b>Pan diameter</b>                  | 24"            | 48"            | 60"            | 12"            | 36"            |
| <b>Solvent</b>                       | <b>Organic</b> | <b>Organic</b> | <b>Organic</b> | <b>Organic</b> | <b>Organic</b> |
| <b>Solids content (% w/w)</b>        | 5 - 6          | 5 - 6          | 5 - 6          | 5 - 6          | 5 - 6          |
| <b>Pan Speed* (rpm)</b>              | 10 - 14        | 3 - 5          | 1.5 - 3        | 18 - 20        | 8 - 12         |
| <b>Baffles</b>                       | 4 - 6          | 6 - 8          | 6 - 10         | 3              | 4              |
| <b>Tablet charge** (kg)</b>          | 10 - 15        | 100 - 130      | 250 - 300      | 0.5 - 1        | 40 - 50        |
| <b>Tablet bed temperature (°C)</b>   | 35 - 40        | 35 - 40        | 35 - 40        | 35 - 40        | 35 - 40        |
| <b>Spray nozzle (mm)</b>             | 1              | 1.2-1.5        | 1.2-1.5        | 1              | 1.2            |
| <b>Number of spray guns</b>          | 1              | 23             | 46             | 1              | 1              |
| <b>Atomizing air pressure (bars)</b> | 2.5 - 3.5      | 2.5 - 3.5      | 2.5 - 3.5      | 2.5 - 3.5      | 2.5 - 3.5      |
| <b>Spray procedure</b>               | Continuous     | Continuous     | Continuous     | Continuous     | Continuous     |
| <b>Spray rate (g/min)</b>            | 40 - 60        | 300 - 600      | 600 - 800      | 10 - 15        | 100 - 150      |
| <b>Inlet air temperature (°C)</b>    | 55 - 65        | 55 - 65        | 55 - 65        | 55 - 65        | 55 - 65        |
| <b>Drying air volume (cfm)</b>       | 250 - 300      | 1500 - 2000    | 4500 - 5000    | 50             | 400 - 500      |
| <b>Weight gain (%)</b>               | 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.





We deal with  
innovative  
Film Coating

## Reconstitution Protocol

### TABSAFE SLV

SLV is a unique, optimized film coating material suitable for use with organic solvents, hydroalcoholic solvents as well as aqueous media. This flexibility makes the system user friendly. The high speed stirrer is not recommended for reconstitution.

#### SOLVENT SYSTEM : AQUEOUS

##### Recommended Solvent System

DM Water: Reconstitution level 18% - 20% solids content

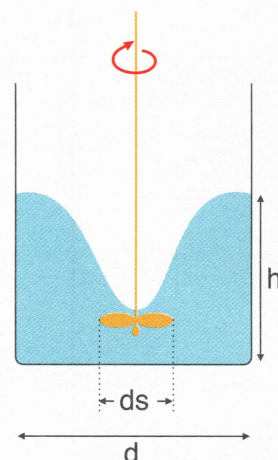
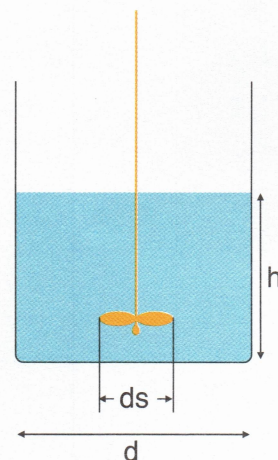
##### Equipment

- 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 DM Water.
- Stir to form a vortex
- Add the required quantity of TABSAFE SLV to the vortex
- Maintain the vortex by increasing speed.
- Add required color and flavour to this vortex by passing through #100 mesh sieve
- Continue stirring for 40 minutes. Use Colloid Mill (10-15 Mins) if required.

Position the stirrer centrally to prevent air entrapment.  
Filter the solution through # 80-100  
Continue stirring throughout the coating process.



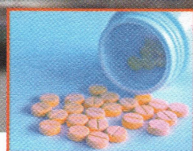
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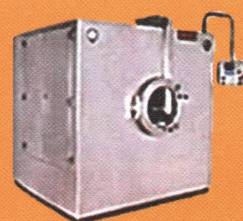
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# Coating Parameters for TABSAFE SLV: Aqueous Solvent System



## Coating parameters for TABSAFE SLV: Aqueous system

## TABSAFE SLV

|                                      | 24"          | 48"          | 60"          | 12"          | 36"          |
|--------------------------------------|--------------|--------------|--------------|--------------|--------------|
| <b>Pan diameter</b>                  | 24"          | 48"          | 60"          | 12"          | 36"          |
| <b>Solvent</b>                       | <b>Water</b> | <b>Water</b> | <b>Water</b> | <b>Water</b> | <b>Water</b> |
| <b>Solids content (%w/w)</b>         | 18 - 20      | 18 - 20      | 18 - 20      | 18 - 20      | 18 - 20      |
| <b>Pan speed* (rpm)</b>              | 10 - 14      | 3 - 5        | 1.5 - 3      | 18 - 20      | 8 - 12       |
| <b>Baffles</b>                       | 4 - 6        | 6 - 8        | 6 - 10       | 3            | 4            |
| <b>Tablet charge** (kg)</b>          | 10 - 15      | 100 - 130    | 250 - 300    | 0.5 - 1      | 40 - 50      |
| <b>Tablet bed temperature (°C)</b>   | 48 - 50      | 48 - 50      | 48 - 50      | 48 - 50      | 48 - 50      |
| <b>Spray nozzle (mm)</b>             | 1            | 1.2 - 1.5    | 1.2 - 1.5    | 1            | 1.2          |
| <b>Number of spray guns</b>          | 1            | 2 - 3        | 4 - 6        | 1            | 1            |
| <b>Atomizing air pressure (bars)</b> | 3 - 3.5      | 3 - 3.5      | 3 - 3.5      | 2.5 - 3      | 3 - 3.5      |
| <b>Spray procedure</b>               | Continuous   | Continuous   | Continuous   | Continuous   | Continuous   |
| <b>Spray rate (g/min)</b>            | 20 - 25      | 120 - 140    | 200 - 250    | 4 - 8        | 50 - 60      |
| <b>Inlet air temperature (°C)</b>    | 80 - 85      | 80 - 85      | 80 - 85      | 80 - 85      | 80 - 85      |
| <b>Drying air volume (cfm)</b>       | 250 - 300    | 1500 - 2000  | 4500 - 5000  | 50           | 400 - 500    |
| <b>Weight gain (%)</b>               | 2 - 2.5      | 2 - 2.5      | 2 - 2.5      | 2 - 2.5      | 2 - 2.5      |

\* 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.