Reconstitution Protocol

TABSAFE Uni 3009

Universal 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. 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

Recomended Solvent System
Water: Reconstitution level 10% - 12% 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 Water.
- Stir to form a vortex
- Add the required quantity of TABSAFE Uni 3009 to the vortex
- Maintain the vortex by increasing speed.
- Continue stirring for 40 minutes

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

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SOLVENT SYSTEM : ORGANIC

Recomended 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 Uni 3009 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.

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SOLVENT SYSTEM : HYDRO ALCOHOLIC

Recomended Solvent System

Hydro alcoholic: Reconstitution level 9% - 10% solids content
50% IPA + 50% Water

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 3009 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 UNI 3009: Organic Solvent Sytstem

Coating parameters for TABSAFE Uni 3009: Organic Solvent system				**TABSAFE Uni 3009**	
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 - 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.

Coating Parameters for TABSAFE UNI 3009: Organic Solvent Sytstem

Coating parameters for TABSAFE Uni 3009: Aqueous system				TABSAFE Uni 3009	
Pan diameter	24”	48”	60”	12”	36”
Solvent	**Water**	**Water**	**Water**	**Water**	**Water**
Solids content (%w/w)	10 - 12	10 - 12	10 - 12	10 - 12	10 - 12
Pan speed* (rpm)	10 - 14	35	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)	38 - 42	38 - 42	38 - 42	38 - 42	38 - 42
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)	3 - 3.5	3 - 3.5	3 - 3.5	2.5 - 3	3 - 3.5
Spray procedure	Continuous	Continuous	Continuous	Continuous	Continuous
Spray rate (g/min)	20 - 25	120 - 140	200 - 250	4 - 8	50 - 60
Inlet air temperature (°C)	65 - 75	65 - 75	65 - 75	65 - 75	65 - 75
Drying air volume (cfm)	250 - 300	1500 - 2000	4500 - 5000	50	400 - 500
Weight gain (%)	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.

Coating Parameters for TABSAFE UNI 3009: Organic Solvent Sytstem

Coating parameters for TABSAFE Uni 3009: Hydroalcoholic system				TABSAFE Uni 3009	
Pan diameter	24”	48”	60”	12”	36”
Solvent	**Hydro-alcoholic**	**Hydro-alcoholic**	**Hydro-alcoholic**	**Hydro-alcoholic**	**Hydro-alcoholic**
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)	37	37	37	37	37
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)	3 - 3.5	3 - 3.5	3 - 3.5	2.5 - 3	3 - 3.5
Spray procedure	Continuous	Continuous	Continuous	Continuous	Continuous
Spray rate (g/min)	20 - 25	120 -140	200 - 250	4 - 8	50 - 60
Inlet air temperature (°C)	60 - 70	60 - 70	60 - 70	60 - 70	60 - 70
Drying air volume (cfm)	250 - 300	1500 - 2000	4500 - 5000	50	400 - 500
Weight gain (%)	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.