

Reconstitution Protocol

TABSAFE Uni

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

Recommended 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 TABSAFEUni 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

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 TABSAFEUni 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

Recommended 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 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: Organic Solvent System

Coating parameters for TABSAFE Uni: Organic Solvent system	TABSAFE Uni				
	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: Organic Solvent System

Coating parameters for TABSAFE Uni: Aqueous system	TABSAFE Uni				
	24"	48"	60"	12"	36"
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: Organic Solvent System

Coating parameters for TABSAFE Uni: Universal: Hydroalcoholic system					TABSAFE Uni	
	24"	48"	60"	12"	36"	
Solvent	Hydro-alcoholic	Hydro-alcoholic	Hydro-alcoholic	Hydro-alcoholic	Hydro-alcoholic	Hydro-alcoholic
Solids content (%w/w)	9 - 10	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	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.

Reconstitution Protocol

TABSAFE Sol

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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 Sol: Organic Solvent System

Coating parameters for TABSAFE Sol: Organic Solvent system	TABSAFE Sol				
	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.

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.

SOLVENT SYSTEM : ORGANIC

Recommended Solvent System

1. 100% IPA or Ethanol (10% reconstitution)
2. 60% IPA + 40% Acetone (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 nearly 1/3rd of the 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.

Coating Parameters for TABSAFE En A: Organic Solvent System

Coating parameters for TABSAFE En A: Organic Solvent system	TABSAFE En A				
	24"	48"	60"	12"	36"
Solvent	Organic	Organic	Organic	Organic	Organic
Solids content (% w/w)	10	10	10	10	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 (%)	9 - 10	9 - 10	9 - 10	9 - 10	9 - 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.