



Reconstitution Protocol TABSAFE SC 1003

TabSafe SC 1003 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

❖ Requirements :

1. Uncoated tablets
2. Tablet coating powder (TabSafe SC 1003 - Transparent)
3. Solvent (IPA= Isopropyl alcohol & MDC= Methylene dichloride)

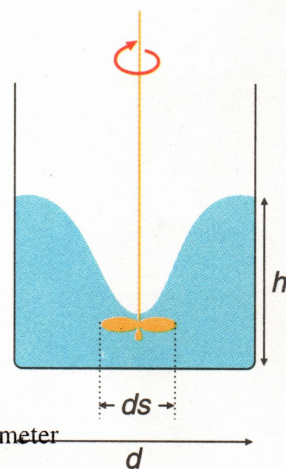
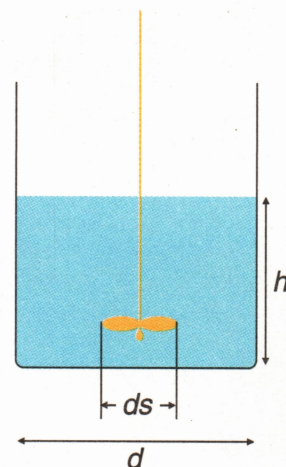
❖ Apparatus & Instruments :

1. Stainless steel vessel
2. Coating pan (pan diameter = ± 24 inch)
3. Spray gun (spray nozzle = ± 1 mm)

❖ Reconstitution Procedure (For 10 kg Tablet coating) :

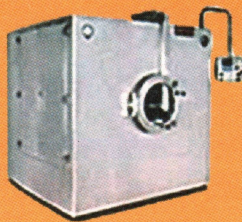
1. Weigh 2 kg of IPA in stainless steel vessel and stir it to form a vortex.
2. Weigh 300 g (for 3% weight gain) of TabSafe SC 1003 for 10 kg of core uncoated tablet coating.
3. Gradually add 300 g of TabSafe SC 1003 coating powder to the vortex.
4. Continue stirring for 5 minutes and add 3.7 kg of MDC to the vortex.
5. Continue stirring for 60 minutes. Use colloid mill if required.
6. Filter the solution through #100 sieve and continue the stirring throughout the coating process.
7. Perform coating on tablet bed using spray gun at a spray rate of ± 10 g/ min and a pan speed of ± 12 rpm.
8. Perform drying as required to get proper coated tablet.

For any variation in pan diameter, pan speed, spray nozzle and spray rate follow the coating parameter listed in page 2.





Coating Parameters for TABSAFE SC 1003: Organic Solvent System



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TABSAFE SC 1003

	24"	48"	60"	12"	36"
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.