



Reconstitution Protocol

TABSAFE En H

Tab safe en h is a ready mix enteric coating system reconstituted using organic solvents. Different reconstitution levels can be achieved using a blend of organic solvents. It is recommended to use a seal coat to provide uniform coat and act as a physical barrier between the active and the polymer.

SOLVENT SYSTEM : ORGANIC

Recommended Solvent System

35% IPA + 65% MDC (5% reconstitution)

Equipment

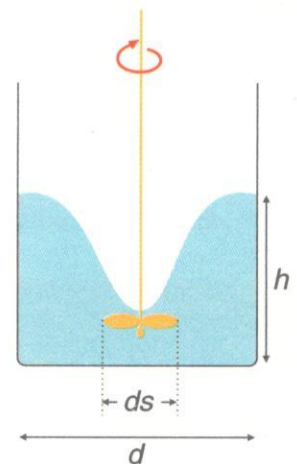
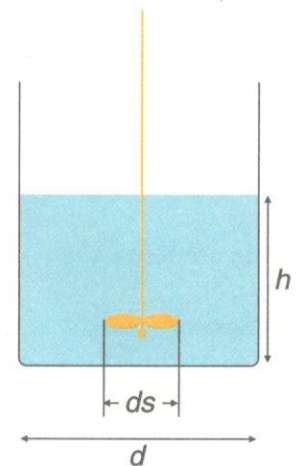
- Stainless steel vessel with a capacity that is 25% higher than the total dispersion volume.
- The height of the vessel should be nearly 25% more than its diameter.
- The speed of the propeller of stirrer should be variable and its blade diameter should be nearly 1/3rd of the vessel diameter

Reconstitution procedure

- Weigh the required quantity of Tabsafe en h
- Take required quantity of water in the vessel.
- Stir with propeller stirrer to form a vortex as show in figure. add the Tab safe en h in vortex, increasing the stirrer speed if required for complete dispersion of the powder for about 5 minutes
- Reduce the speed of the stirrer and continue mixing for a further period of 40 minutes
- Pass the solution through #80 and use for coating

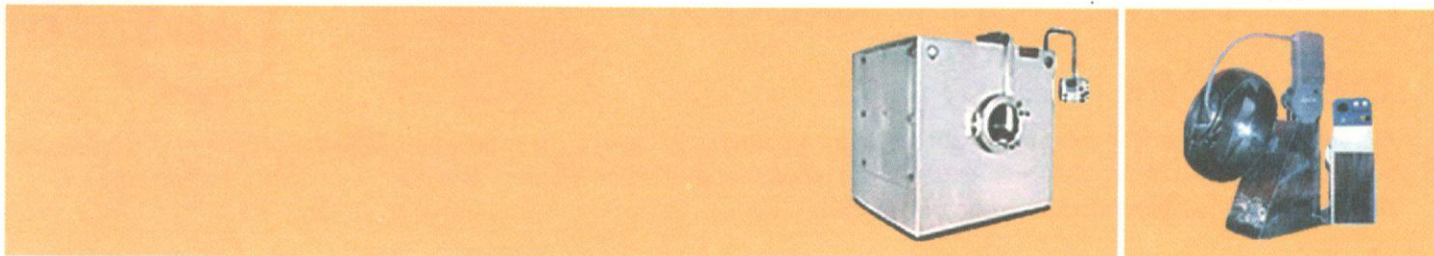
Precautions:

- The use of high speed stirrer or homogenizer is not recommended.
- The dispersion should not be passed through colloid mill.
- The dispersion may need gentle stirring during the operation to prevent settling.





Coating Parameters for TABSAFE En H: Organic Solvent System



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TABSAFE En H

	24"	48"	60"	12"	36"
Pan diameter	24"	48"	60"	12"	36"
Solvent	Organic	Organic	Organic	Organic	Organic
Solids content (% w/w)	5	5	5	5	5
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 - 38	35 - 38	35 - 38	35 - 38	35 - 38
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	2.5 - 3	2.5 - 3	2.5 - 3	2.5 - 3
Spray procedure	Continuous	Continuous	Continuous	Continuous	Continuous
Spray rate (g/min)	50 - 70	300 - 350	550 - 700	20-25	100 - 140
Inlet air temperature (°C)	60 - 65	60 - 65	60 - 65	60 - 65	60 - 65
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.