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EFFECT OF SOLVENTS ON TABLET COATING

By Suresh Pareek, Chetan Rajsharad, Ashok Mohanty & Aditi Golatkar



Chetan Raj Sharad Suresh Pareek Ashok Mohanty

What began as an act has evolved in Exacting Science. The coating of Pharmaceutical solid oral dosage forms like tablets, capsules and other solid dosage forms has become a highly developed scientific technology.

The film coating of Pharmaceutical dosage forms is done by dispersing the polymers, plasticizers, opacifier lubricant & pigments or Ready to use film coating material like INSTACOAT in the solvent system. The solvent system could be Organic, Aqueous or a combination of Organic and Aqueous. The most commonly used organic solvents are IPA and Methylene chloride.

Film coating of the tablets is a multivariable process, with many different factors, such as coating equipments. Process conditions, composition of the core tablet and solvent system, affect the quality of the final product.

In this article, we have examined the implication of change in solvent system on tablet coating. We have carried out six experiments using placebo tablets by conducting film coating trials in conventional coating pan (Semi automated).

The coating lot size was taken 500 gms. core tablets, the coating materials was used in two different colours- White and Blue (Indigo carmine) and the solvent system used are Aqueous, Hydro-alcoholic and Organic solvent.

The aim of the experiments is to determine the effect of organic solvents on coated tablets in respect of :

1. Change in appearance
2. Coating cost
3. DT of the finish product.

The details of the experiments are in table 1 and 2 (Table 1 gives the trial details for White colour coating and whereas Table 2 gives the details for Blue colour coating)

Table 1

Aim of the study : To determine the effect of organic solvents on coated tablets in respect of :

- 1) Appearance
- 2) Coating cost

Solvent system	Core	Aqueous	Hydroalcoholic	Organic
Total weight of core tablets to be coated	500 gms			
Core weight	342.3 mg			
Friability	0.147 %			
Diameter	9.62 mm			
Thickness	4.64 mm			
D.T	12 secs.			

	4 %	4 %	4 %
Wt. gain theoretical			
Coating material used	ISP - 001	ISP - 001	ISP - 001
Total qty. of Instacoat used	20 gms	20 gms	20 gms
Cost of Instacoat	Rs. 25.00	Rs. 25.00	Rs. 25.00
Reconstitution level (solid contents)	12 %	10 %	5 %
Solvent required			
Isopropyl alcohol kgs	----	90 gms	133 gms
D.M. water kgs	146 gms	90 gms	-----
MDC kgs	-----	-----	247 gms
Cost of solvents	-----	Rs. 4.32	Rs. 16.26
Spray rate / min	4 gms / min	6-7 gms / min	12-13 gms / min
Bed Temperature	38°C - 42°C	38°C - 40°C	35°C - 38°C
(Instrument used)	Multi Thermometer	Multi Thermometer	Multi Thermometer
Inlet air temperature	75°C	70°C	65°C
Dozing pump	Electrolab	Electrolab	Electrolab
Pan RPM	25 - 26	25 - 26	25 - 26
Pan used conventional - spray gun used.	Conventional Bullows	Conventional Bullows	Conventional Bullows
After coating results			
Total weight of tablets	515 gms	515 gms	515 gms
Friability	NIL	NIL	NIL
Diameter	9.66 mm	9.64 mm	9.66 mm
Thickness	4.72 mm	4.72 mm	4.70 mm
D.T	1 min 17 secs	1 min 04 secs	48 secs
a) Total time taken	40 min	30 min	30 min
b) appearance color matching	white	Off - white	White to off - white
Total cost of coating material & solvents	Rs. 25.00	Rs. 29.32	Rs. 41.26
Solvent used	D.M.Water	IPA / D.M.Water	IPA / MDC

Table 2

Aim of the study : To determine the effect of organic solvents on coated tablets in respect of :

- 1) Appearance
- 2) Coating cost

Solvent system	Core	Aqueous	Hydroalcoholic	Organic
Total weight of core tablets to be coated	500 gms			
Core weight	342.3 mg			
Friability	0.147 %			
Diameter	9.62 mm			
Thickness	4.64 mm			
D.T	12 secs.			
Wt. gain theoretical		4 %	4 %	4 %
Coating material used		ISP - 005	ISP - 005	ISP - 005
Total qty. of Instacoat used		20 gms	20 gms	20 gms
Cost of Instacoat		Rs. 25.00	Rs. 25.00	Rs. 25.00
Reconstitution level (solid contents)		12 %	10 %	5 %

Solvent required		----	90 gms	133 gms
Isopropyl alcohol kgs		146 gms	90 gms	-----
D.M. water kgs		-----	-----	247 gms
MDC kgs				
Cost of solvents		-----	Rs. 4.32	Rs. 16.26
Spray rate / min		4 gms / min	6-7 gms / min	12-13 gms / min
Bed Temperature		38°C - 42°C	38°C - 40°C	35°C - 38°C
(Instrument used)		Multi Thermometer	Multi Thermometer	Multi Thermometer
Inlet air temperature		75°C	70°C	65°C
Dozing pump		Electrolab	Electrolab	Electrolab
Pan RPM		25 - 26	25 - 26	25 - 26
Pan used conventional - spray gun used.		Conventional Bullows	Conventional Bullows	Conventional Bullows
After coating results				
Total weight of tablets		515 gms	515 gms	515 gms
Friability		NIL	NIL	NIL
Diameter		9.68 mm	9.66 mm	9.68 mm
Thickness		4.72 mm	4.70 mm	4.74 mm
D.T		1 min 17 secs	1 min 04 secs	48 secs
a) Total time taken		40 min	30 min	30 min
b) appearance color matching		Light	Medium	Dark
Total cost of coating material & solvents		Rs. 25.00	Rs. 29.32	Rs. 41.26
Solvent used		D.M.Water	IPA / D.M.Water	IPA / MDC

Cost of instacoat has been taken as Rs.1250/- per kg. & the cost of IPA @ Rs.49 per kg. & Methylene chloride @ Rs.40 Rs.per kg

Results and discussion:

1. In all the experiments nearly 3% coating weight gain was achieved, giving uniform coating and colour shade.
2. It was observed in White colour coating that the whiteness of the coated tablets was better in aqueous medium. The organic solvent based coating produced slightly off-white tablets though the tablet bed temperature was maintained at slightly lower level as compared to aqueous coating.
3. In case of blue colour coating, it was observed that aqueous coating produced slightly lighter shade than organic solvent based coating. This is probably due to the basic property of Indigo carmine colour.
4. The overall coating material cost was 40% less in case of aqueous coating as compared to organic solvent based coating.
5. It was observed that the DT of the finish product was slightly lower in case of organic solvent based coating than aqueous coating, however, the effect was not significant.

Conclusion :

The Instacoat coating material used for conducting various coating trials proved to the effect in different type of solvent system. It proved to be very coat effective in case of aqueous coating. The final product finish was also much better in case of aqueous coating in White colour. In case of Indigo carmine, the colour shade of the finish product should be decided based on the solvent system to be used, which should not be changed as it, the change in solvent system can change the colour shade of the finish product.