EFFECT OF PLASTICIZERS ON POLYSTYRENE AND POLY METHYL METHACRYLATE FILM COATED TABLETS

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Summary

In the present study, effect of plasticizers on the film properties when added in small concentrations to polymeric films and applying the different coating conditions as a function of disintegration time was studied. For this purpose, polystyrene and poly methyl methacrylate were used as polymers in different concentrations. Ethyl acetate and butyl acetate in both single solvent systems and mixed solvent systems were used and a comparative study of these solvent systems affecting polymer film at various coating conditions was made. Castoroil and liquid paraffin light were used as plasticizers. The objective of the study is to observe the effect of polymeric films in different solvents and the effect of these plasticizers on the polymeric films by applying different coating conditions i.e. coating at different concentration and coating temperature. Paracetamol tablets coated by dip coat method were weighed quantity of polymer was added to solvent system followed by addition of plasticizers in small concentrations. From the observations it could be analyzed that plasticizers in low concentrations were found to be optimum which shows increased disintegration time and the effect of plasticizers will vary according to the nature of polymer, solvent and coating conditions. Thus properties of materials involved in coating and coating conditions play main role while selecting the plasticizers.

Key words: Polystyrene, Poly methyl methacrylate, Castoroil, Liquid paraffin light, Ethyl acetate, Butyl acetate

Introduction

Film coating involves deposition of a thin but uniform layer of polymer on the surface of the substrate. Dip coating of tablets can be effected by placing the tablets in a perforated baskets and dipping in a coating solution[1]. Coated tablets were then subjected to drying in vaccum oven for an even polymeric film coating. In pharmaceutical film coating operation, mainly two types of forces operate, cohesion and adhesion[2]. The significance of the degree of cohesion in film structures is fundamental to film properties, which effects the film density, permeability and flexibility. The degree of adhesion ensures the ability of the film to afford mechanical protection to the tablet[3]. Therefore for the effective film coating of the tablets, a perfect balance between these two forces has to be achieved for which knowledge on polymer and plasticizer chemistry, polymer structural properties and solvent effect is needed[4].

Polymers with high molecular weights[5] and structures can combine significant cohesive strength and capacity for coalescence to produce fiber and film structures. Polystyrene which has high molecular weight and Poly methyl methacrylate[6] which has high degree of crystallinity were selected for their good mechanical and thermal properties apart from good processability, tensile strength and stiffness[7].

Plasticizers as the name implies, prevent the polymer film from becoming brittle with consequent risk of chipping. They function by modifying polymer to polymer molecular binding[8]. Plasticizers like Castor oil and liquid paraffin when added to the polymeric solution changes the permeability and diffusivity of the solvents through the polymeric films[9]. The film morphology is greatly effected by the solvent system employed in film coating[10]. By considering various factors like volatility, polymer solubility, degree of dissociation of functional groups on a linear polymer and cohesive energy density of the polymer, ethyl acetate and butyl acetate as single and mixed solvent systems were used. The objective of the study is to observe the effect of polymeric films in different solvents and the effect of these plasticizers on the polymeric films by applying different coating conditions i.e. coating at different concentration and coating temperature.

Materials and method

Paracetamol (500mg, Calpol Tablet), Castor oil (Prem Laboratories, Hyderabad, India). Liquid Paraffin light (S.D.Fine chemicals PVT Ltd, Boisar, India), Ethyl acetate (S.D.Fine chemicals PVT Ltd, Boisar. India), n-Butyl Acetate (S.D.Fine chemicals PVT Ltd, Boisar, India), Polystyrene (Hijls Gmbh company, USA), Poly methyl methacrylate (BDH chemicals Ltd, Poole, England), Electronic Balance (DHONA 200), Magnetic stirrer and Thermostat (Thoshniwal), Disintegration test apparatus (Magumps), Hardness Tester (Monsanto), Viscometer (Brook Field Digital Viscometer)

The required quantities of polymer (Polystyrene and Poly methyl methacrylate) were weighed to make 4%, 6%, 8% and 10% w/v solutions in different solvent systems namely, ethyl acetate, butyl acetate and 1:1 (by volume ratio) of ethyl acetate-butyl acetate and kept overnight for solvation. After the process of solvation, plasticizers measured exactly to the amount equivalent to 0.5% and 1% was added to the polymer solution and stirred on a magnetic stirrer. Paracetamol tablets were coated in this polymeric solution by dip coating method and then air dried followed

by drying in oven at 40^{o}C for the complete removal of the solvent. Different sets of tablets were coated at room temperature with a coating time of one minute (Tab.1). Coating was performed at different temperatures 30 ^{o}C, 35 ^{o}C, 45 ^{o}C, 60 ^{o}C and the above sets of tablets were subjected to analysis by performing disintegration tests.

Table 1: Formulation of different sets of tablets with varying concentrations of polymer, plasticizers and different solvent systems

Ingredients		F1	F2	F3	F4	F5	F6	F7	F8	F9
Drug(gm)		✓	✓	✓	✓	✓	✓	✓	✓	✓
Polymer	Polystyrene	✓	4%	6%	8%	10%	-	-	-	-
	PMMA	✓	-	-	-	-	4%	6%	8%	10%
Plastizers	Castor oil	-	0.5/1%	0.5/1%	0.5/1%	0.5/1%	0.5/1%	0.5/1%	0.5/1%	0.5/1%
	Liqparaffin	-	0.5/1%	0.5/1%	0.5/1%	0.5/1%	0.5/1%	0.5/1%	0.5/1%	0.5/1%
Solvents	Eth acetate	-	✓	✓	✓	✓	✓	✓	✓	✓
	But acetate	-	✓	✓	✓	✓	✓	✓	✓	✓
	Eth:But (50:50)	-	✓	✓	✓	✓	✓	✓	✓	✓

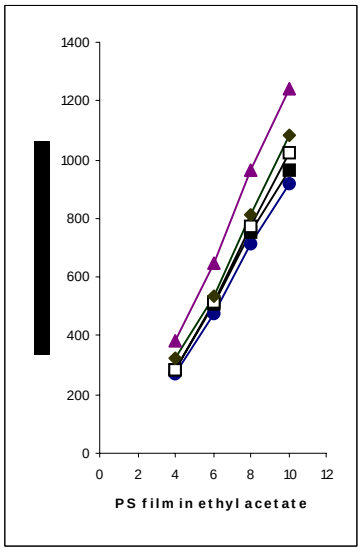
Results and discussion

Disintegration test of different sets of tablets coated with varying concentration of polymers and plastizers in different solvents was performed. From the data obtained, It was evident that ,the two plastizers have shown appreciable effect in altering the properties of polymeric films and there by disintegration rates have been changed.

Fig 1 shows the data for the batch of tablets coated with polystyrene films in ethyl acetate. It was evident that disintegration time increased with the addition of plastizers than the plain polystyrene films. However liquid paraffin showed better plasticizer effect than castor oil. It was also interesting to note that with the increase in plastizers concentration, there was decrease in

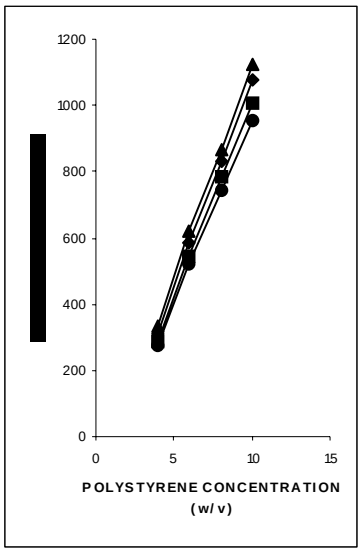
disintegration time. It was also observed that coating of the tablets at different temperatures has a very little effect Fig 2.

Fig 1: The data for the batch of tablets coated with Polystyrene films in Ethyl acetate solvent (Single solvent system)



▲0.5% liquid paraffin, ◆plain polystyrene, □1.0% liquid paraffin, ■ 0.5% castor oil, ●1.0% castor oil

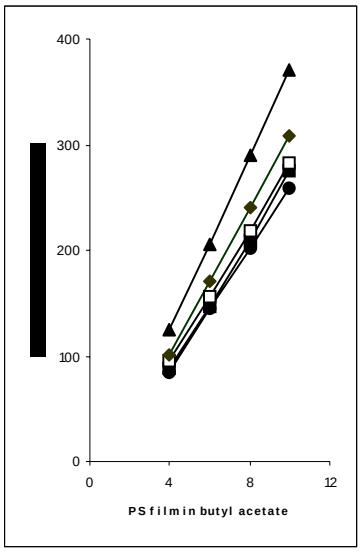
Fig 2: The coating of the tablets with polystyrene films at different temperatures



▲ at 65^{o}C, ◆ at 45^{o}C, ■ at 35^{o}C, ● at room temperature

Fig 3 shows the data for the batch of tablets coated with polystyrene films in butyl acetate. It was evident from the data that the effect of plastizers on the polystyrene films made of butyl acetate has shown similar effects as that of tablets coated with polystyrene films in ethyl acetate. Hence one should be very careful in selecting the plasticizers and its concentration.

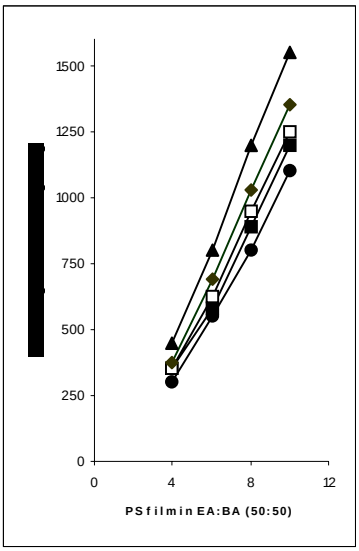
Fig 3 The data for the batch of tablets coated with Polystyrene films in Butyl acetate solvent (Single solvent system)



▲0.5% liquid paraffin, ◆plain polystyrene, □1.0% liquid paraffin, ■ 0.5% castor oil, ●1.0% castor oil

Fig 4 shows the data for the batch of tablets coated with polystyrene films in ethyl acetate and butyl acetate (50:50) mixture solvent. It was surprising that liquid paraffin and castor oil had greater plastizer effect in mixed solvent system than in single solvent system which can be attributed to the high solubility of polymer in mixture solvent because of co-solvency effec6t and thereby the viscosity of the solution was increased.

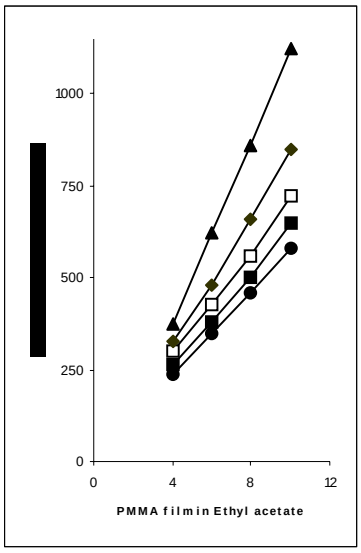
Fig 4 The data for the batch of tablets coated with Polystyrene films in Ethyl acetate and Butyl acetate solvent (50:50) (Mixed solvent system)



▲0.5% liquid paraffin, ◆plain polystyrene, □1.0% liquid paraffin, ■ 0.5% castor oil, ●1.0% castor oil

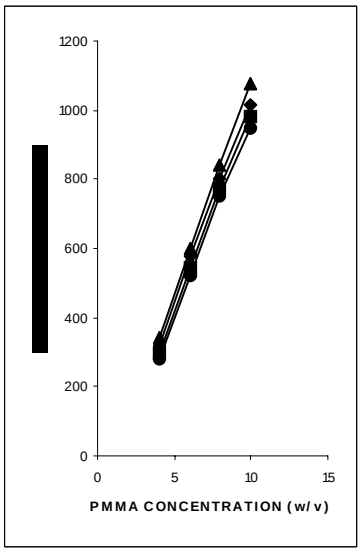
Fig 5 and 6 shows the data for the batch of tablets coated with poly methyl methacrylate (PMMA) films in ethyl acetate. The disintegration time in case of PMMA is low compared to polystyrene films, however concentration of liquid paraffin has increased the disintegration time, furthermore coating of the polymer at different temperatures has shown an appreciable improvement in disintegration time.

Fig 5 The data for the batch of tablets coated with Poly methyl methacrylate films in Ethyl acetate solvent (Single solvent system)



▲1.0% castor oil, ◆0.5% liquid paraffin, □ plain PMMA, ,
■ 1.0% liquid paraffin, ● 0.5% castor oil

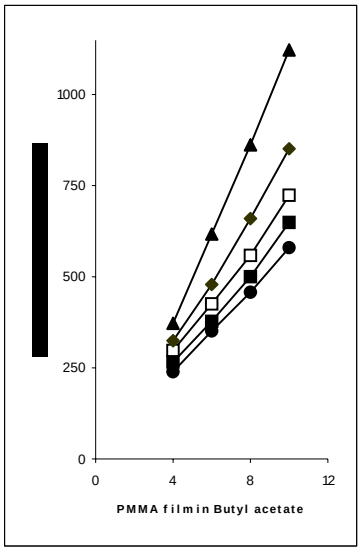
Fig 6: The coating of the tablets with PMMA films at different temperatures



▲ at 65^{o}C, ◆ at 45^{o}C, ■ at 35^{o}C, ● at room temperature

Fig 7 represents the data for the batch of tablets coated with poly methyl methacrylate (PMMA) films in butyl acetate. Here it was interesting to note that the effect of castor oil was much better than that of liquid paraffin and with the increase in castor oil concentration, there was increase in disintegration time, while it was reverse with the case of liquid paraffin.

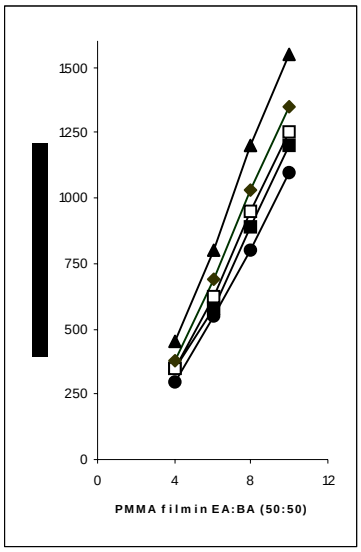
Fig 7 The data for the batch of tablets coated with Poly methyl methacrylate films in Butyl acetate solvent (Single solvent system)



▲0.5% liquid paraffin, ◆plain polystyrene, □1.0% liquid paraffin, ■ 0.5% castor oil, ●1.0% castor oil

Fig 8 shows the data for the batch of tablets coated with poly methyl methacrylate films in ethyl acetate and butyl acetate (50:50) mixture solvent. In this case castor oil had better effect than liquid paraffin where as coating at higher temperature has little effect.

Fig 8 The data for the batch of tablets coated with Poly methyl methacrylate films in Ethyl acetate and Butyl acetate solvent (50:50) (Mixed solvent system)



▲0.5% liquid paraffin, ◆plain polystyrene, □1.0% liquid paraffin, ■ 0.5% castor oil, ●1.0% castor oil

Conclusion

From the experimental results it can be concluded that among all the films, polystyrene films were found to have good film forming properties than PMMA films which can be attributed to the crystalline nature of polystyrene. Among the solvent systems mixed solvent system showed better solubility of polymer than single solvent system which could be due to the co-solvency effect but when single solvent system was considered ethyl acetate was better solvent than butyl acetate. Plastizers had variable effects which deepened upon the type of polymer, concentration and coating temperature. Liquid paraffin was a better plasticizer in polystyrene films whereas castor oil was better suited in PMMA films. Plasticizers at low concentration were found to be optimum and showed high disintegration time. The process of coating at high temperature does not show much effect on disintegration time. There is a negligible effect on the tablet hardness between the tablets coated with plain polymer and the one in presence of plasticizers. Thus from the above observations we can conclude that the effect of plasticizers will vary according to the

nature of polymer, solvent and coating conditions. Hence while selecting the plasticizers it is necessary not only to know the properties of the material involved in coating but also to know the coating conditions.

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