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Effect of Adjuvants on Tackiness of Polyvinylpyrrolidone Film Coating

ABU S. ALAM* and EUGENE L. PARROTT▲

Abstract □ Two formulations were developed using polyvinylpyrrolidone for the film coating of tablets by the pan-coating method. The addition of ethylcellulose and shellac eliminated the tackiness sometimes associated with polyvinylpyrrolidone coating due to the hygroscopicity of the film former. The film coats increased the resistance of the tablet to mechanical stress, did not significantly increase the weight of the tablet, and were physically acceptable after storage at 2 and 45°. The film coats did not interfere with the disintegration and dissolution of the tablet since the film coats were rapidly removed from the tablet in water, simulated gastric fluid, and simulated intestinal fluid.

Keyphrases □ Polyvinylpyrrolidone film-coated tablets—addition of ethylcellulose and shellac to eliminate tackiness, dissolution □ Tablets, film coated—elimination of tackiness in polyvinylpyrrolidone coatings □ Pan-coating method—polyvinylpyrrolidone film-coating formulations

Since the first commercial film-coated tablet was marketed in 1954, the use of polymeric substances, such as polyvinylpyrrolidone, for the film coating of tablets has become widely accepted (1). Ellis *et al.* (2) adequately described the advantages and process of film coating. Banker (3) discussed the theory and recent developments in film-coating technology.

Although many polymeric substances have been investigated for use in film coating, the use of hydroxypropylmethylcellulose (4), hydroxyethylmethylcellulose (5), ethylcellulose (6), hydroxypropylcellulose (7), sodium carboxymethylcellulose (8), polyethylene glycols (9, 10), and polyvinylpyrrolidone has been most acceptable.

Polyvinylpyrrolidone possesses many of the desired characteristics of a polymer to be used in film coating; however, because polyvinylpyrrolidone is hygroscopic, in a humid atmosphere the film coat may be tacky and cause the tablets to adhere (11). Ahsan (12) reported that this disadvantage could be overcome by the addition of acetylated monoglycerides to the coating solution.

This study was conducted to determine the effect of various adjuvants on moisture uptake and tackiness of polyvinylpyrrolidone film-coated tablets.

EXPERIMENTAL

Tableting and Coating Procedure— The tablets to be coated were prepared by the wet granulation method using a 20% by weight acacia solution. Each tablet contained 298.2 mg. of lactose, 8.1 mg. of acacia, and 3.7 mg. of magnesium stearate. The tablets were compressed to a hardness of 5.5 ± 0.5 kg. by means of 1.08-cm. ($^{13}/_{32}$-in.) standard concave punches and dies in a rotary tablet machine[1].

The pan-coating method was used to coat the tablets. One thousand tablets were placed in a 20.3-cm. (8-in.) coating pan. While the pan was rotating at 25 r.p.m., 10 ml. of the coating solution was applied to the tablets. The tablets were stirred by hand to ensure distribution of the coating solution. After 2 min., a stream of air at room temperature was directed into the pan for 2–3 min. The pan was stopped, and a stream of air at room temperature was allowed to flow onto the tablet bed for 10 min. Successive applications of 5, 3, 3, 3, and 3 ml. of coating solution were made. For the acceptable formulations, six applications provided a smooth and uniformly colored coating. Polishing was accomplished by placing 1000 coated tablets in a 15.24-cm. (6-in.) canvas-lined pan, which had been impregnated with a molten mixture of carnauba wax, white wax, and paraffin (8:1:1), and by rotating it at 20 r.p.m. for 2 hr.

Coating Solutions—In the initial design of the project, it was decided to use a coating solution containing 5% of polyvinylpyrrolidone as the film-forming agent and 0.1% FD&C Red No. 3 as a colorant, which would facilitate visual evaluation of the uniformity of the coating. Isopropanol, acetone–alcohol (1:1), and 70, 75, 80, 85, and 95% alcohol were tested as solvents. It was found that the coating was least tacky and most uniform if 75% alcohol was used as the solvent.

Polyvinylpyrrolidone K 29–32 and K 90 were used in combination in 75% alcoholic solutions containing 0.1% FD&C Red No. 3 in the following percentages: 3.75 and 1.25, 3.33 and 1.67, 2.50 and 2.50, 1.67 and 3.33, and 1.25 and 3.75, respectively. The coating solution containing 2.5% polyvinylpyrrolidone K 29–32 and 2.5% polyvinylpyrrolidone K 90 appeared to be least tacky and to warrant

[1] Stokes model B-2.

Table I—Moisture Uptake by Polyvinylpyrrolidone K 29–32 upon Exposure to Various Humidities at Room Temperature

Initial Weight, g.	Weight after 1 Week, g.	Moisture Uptake, %
	20% R.H.	
0.9332	0.9405	0.78
0.9342	0.9415	0.78
	40% R.H.	
0.9456	0.9966	5.39
0.9460	0.9971	5.40
	60% R.H.	
0.9564	1.0787	12.79
0.9570	1.0793	12.78
	80% R.H.	
0.9333	1.1701	25.37
0.9328	1.1695	25.38

further study. Various adjuvants—polyvinylpolypyrrolidone[2], ethylcellulose 10 cps.[3], shellac 3-pound cut[4], glyceryl monostearate[5], stearic acid[6], hydrogenated castor oil[7], *n*-butyl stearate[8], and sorbitan monooleate[9]—were added in various concentrations to this coating solution. The addition of ethylcellulose and shellac made the coating less tacky and easier to apply.

As a result of this preliminary examination, it was decided to evaluate polyvinylpyrrolidone coating solutions to which ethylcellulose and shellac had been added. Two percent diethyl phthalate[10] was added as a plasticizer, which imparts flexibility to the film coat (3, 13). The complete formulations were as follows:

Coating Solution I	
Polyvinylpyrrolidone K 29-32	1.25%
Polyvinylpyrrolidone K 90	1.25
Ethylcellulose, 10 cps.	2.50
Diethyl phthalate	2.00
Colorant	*q.s.*
Alcohol, 75%	*q.s.* 100

Coating Solution II	
Polyvinylpyrrolidone K 29-32	1.25%
Polyvinylpyrrolidone K 90	1.25
Shellac, 3-pound cut	2.50
Diethyl phthalate	2.00
Colorant	*q.s.*
Alcohol, 75%	*q.s.* 100

Evaluation of Film Coating—*Moisture Uptake*—Relative humidities of 20, 40, 60, and 80% were maintained in desiccators by means of sulfuric acid and water solutions (14). Polyvinylpyrrolidone K 29–32 powder was dried in a vacuum oven for 48 hr. at 80° before it was exposed in thin layers to various humidities. The moisture uptake after 1 week of exposure is shown in Table I. Tablets that were film coated with polyvinylpyrrolidone K 29–32, Coating Solution I, and Coating Solution II were dried in an oven (Colton) for 24 hr. using air at room temperature. The percent relative humidity of the drying area was 50 ± 5 at 20°. Ten accurately weighed, coated tablets, which could be individually identified, were stored at various humidities for 6 weeks; then the moisture uptake was determined by the gain of weight.

Dissolution of Film Coating—The dissolution or removal of the film coat from the tablet was determined by measuring spectrophotometrically the amount of a dye that had dissolved from the coat. The tablet, which had been coated with a solution containing

[2] Polyclar AT, registered trademark of GAF Corp., New York, N. Y., for a high molecular weight, crosslinked form of polyvinylpyrrolidone.
[3] Ethocel, 10 cps., The Dow Chemical Co., Midland, Mich.
[4] Confectioner's glaze, Gillespie-Roger-Pyatt Co., Inc., Attleboro, Mass.
[5] Purified, Fisher Scientific Co., Fair Lawn, N. J.
[6] USP, Mallinckrodt Chemical Works, New York, N. Y.
[7] Castorwax, Baker Castor Oil Co., Bayonne, N. J.
[8] Practical, Eastman Kodak Co., Rochester, N. Y.
[9] Span 80, Atlas Powder Co., Wilmington, Del.
[10] Purified, Fisher Scientific Co., Fair Lawn, N. J.

Table II—Average Weight of 10 Tablets Coated with Polyvinylpyrrolidone K 29–32 after Exposure to Various Humidities at Room Temperature

Initial Weight, g.	Weight after 1 Week, g.	Weight after 6 Weeks, g.
	20% R.H.	
0.3158 ± 0.0065[a]	0.3158 ± 0.0064	0.316 ± 0.0064
	40% R.H.	
0.3140 ± 0.0085	0.3141 ± 0.0085	0.3141 ± 0.0085
	60% R.H.	
0.3162 ± 0.0102	0.3166 ± 0.0102	0.3168 ± 0.0102
	80% R.H.	
0.3124 ± 0.0059	0.3133 ± 0.0059	0.3136 ± 0.0059

[a] Standard deviation programmed with Wang calculator.

0.3% FD&C Red No. 2, was placed in a USP dissolution apparatus operating at 150 r.p.m. in 100 ml. of distilled water, simulated gastric fluid without pepsin, and simulated intestinal fluid without pancreatin at 37° in a 150-ml. beaker (15). At given time intervals, a 10-ml. sample was removed by pipet, and the absorbance of the sample was measured using a blank of the dissolution medium. The absorbance was measured in distilled water, simulated gastric fluid, and simulated intestinal fluid at 520, 522, and 520 nm., respectively. The concentration of FD&C Red No. 2 was obtained by means of a standard absorbance-concentration curve. A correction for cumulative amount was made for the previously removed samples (16). The dye was allowed to dissolve completely, and the total concentration was determined. The percent dissolved at each time interval was calculated based on the total assayed dye.

Physical Stress—The coated tablets were subjected to mechanical stress by rotating a 4-oz. square bottle, half filled with coated

Table III—Average Weight of 10 Film-Coated Tablets after Exposure to Various Humidities at Room Temperature

Initial Weight, g.	Weight after 1 Week, g.	Weight after 6 Weeks, g.
	Using Coating Solution I	
	20% R.H.	
0.3088 ± 0.0082[a]	0.3101 ± 0.0082	0.3100 ± 0.0082[b]
0.3141 ± 0.0096[c]	0.3145 ± 0.0096	0.3143 ± 0.0096
	40% R.H.	
0.3107 ± 0.0107[a,c]	0.3113 ± 0.0108	0.3110 ± 0.0108
0.3112 ± 0.0082	0.3120 ± 0.0082	0.3117 ± 0.0083
	60% R.H.	
0.3097 + 0.0068[a]	0.3106 ± 0.0068	0.3103 ± 0.0068
0.3161 + 0.0077[c]	0.3173 ± 0.0077	0.3169 ± 0.0076
	80% R.H.	
0.3128 ± 0.0125[a]	0.3141 ± 0.0126	0.3136 ± 0.0126
0.3087 ± 0.0089[c]	0.3103 ± 0.0090	0.3095 ± 0.0090
	Using Coating Solution II	
	20% R.H.	
0.3053 ± 0.0064[a]	0.3057 ± 0.0064	0.3053 ± 0.0065
0.3076 ± 0.0079[c]	0.3080 ± 0.0080	0.3075 ± 0.0079
	40% R.H.	
0.3025 ± 0.0100[a]	0.3031 ± 0.0100	0.3039 ± 0.0100
0.3076 ± 0.0114[c]	0.3082 ± 0.0114	0.3078 ± 0.0114
	60% R.H.	
0.3023 ± 0.0087[a]	0.3033 ± 0.0088	0.3029 + 0.0087
0.3071 ± 0.0102[c]	0.3082 ± 0.0102	0.3075 + 0.0102
	80% R.H.	
0.3034 ± 0.0101[a]	0.3048 ± 0.0102	0.3044 ± 0.0102
0.3098 ± 0.0107[c]	0.3112 ± 0.0107	0.3104 ± 0.0108

[a] With 0.3% FD&C Red No. 2. [b] Standard deviation programmed with Wang calculator. [c] With 0.3% FD&C Yellow No. 5 Lake.

Table IV—Number of Applications of Coating Solution I and Average Weight of 10 Film-Coated Tablets

Number of Applications	Weight, g.
0	0.3115 ± 0.0091
1	0.3082 ± 0.0067
2	0.3111 ± 0.0077
3	0.3088 ± 0.0097
4	0.3114 ± 0.0078
5	0.3161 ± 0.0073
6	0.3145 ± 0.0147
7	0.3121 ± 0.0092
8	0.3171 ± 0.0063
9	0.3170 ± 0.0105
10	0.3159 ± 0.0128
11	0.3191 ± 0.0041
12	0.3123 ± 0.0139
13	0.3084 ± 0.0075
14	0.3122 ± 0.0145
15	0.3116 ± 0.0085
16	0.3158 ± 0.0100
17	0.3121 ± 0.0098
18	0.3106 ± 0.0074
19	0.3159 ± 0.0113
20	0.3122 ± 0.0115

[a] Standard deviation programmed with Wang calculator.

tablets, for 4 hr. at 25 r.p.m. The weight loss was determined by use of an analytical balance. Coated tablets were stored in 4-oz. square bottles at 2 and 45° for 4 weeks. These tablets were examined for overall physical appearance, cracking, and tackiness.

RESULTS AND DISCUSSION

Preliminary experiments showed that a 5% solution containing equal quantities of polyvinylpyrrolidone K 29–32 and K 90 in 75% alcohol could be readily applied by the pan-coating method to produce a smooth and uniform coating. Because polyvinylpyrrolidone K 29–32 is hygroscopic, it could produce a tacky film coat in an improper formulation. Several adjuvants—glyceryl monostearate, *n*-butyl stearate, hydrogenated castor oil, polyvinylpolypyrrolidone, sorbitan monooleate, and stearic acid—were added in various concentrations to the polyvinylpyrrolidone coating solution; however, the resulting coatings were tacky and not uniform. Coating solutions containing equal quantities of polyvinylpyrrolidone K 29–32 and K 90, from 0.63 to 1.69%, and of ethylcellulose or shellac, from 1.67 to 3.75%, produced uniform and nontacky coatings. Ethylcellulose and shellac as used in Coating Solutions I and II greatly decreased the tackiness of the polyvinylpyrrolidone coating.

Although the data in Table I clearly demonstrate the hygroscopicity of polyvinylpyrrolidone, the moisture uptake by tablets coated with polyvinylpyrrolidone K 29–32 is small as shown in Table II. Similar results are shown in Table III for film coatings applied by Coating Solutions I and II. When the tablets coated with polyvinylpyrrolidone K 29–32 were held in the hands of the authors in an air-conditioned room, they were tacky. When the tablets coated with Coating Solutions I and II were held in the hand, they were not tacky. In these cases, one could distinguish between an acceptable and an unacceptable film coating by touch but not by a weight change upon exposure to high humidities. This is understandable in view of the small weight of polyvinylpyrrolidone which comprises the thin film coating.

An advantage of film coating is the minute weight that it contributes to the weight of the coated tablet. Twenty applications of FD&C Red No. 2 and FD&C Yellow No. 2 Lake in Coating Solutions I and II were applied to tablets. After each application had dried, 10 tablets were weighed and the average weight was calculated. There was no significant change of weight after 20 applications. Typical data are shown in Table IV and indicate no tendency toward a steady gain in weight as the number of applications is increased. This may be due to the manual method and the small number of tablets per batch. Since six applications of coating solution were sufficient to coat the tablets, these formulations did not add any significant weight to the tablet.

The application of FD&C Red No. 2 and FD&C Yellow No. 5 Lake in Coating Solutions I and II to the tablets demonstrated

Table V—Dissolution of FD&C Red No. 2 from Film-Coated Tablets Prepared by Use of Coating Solution I

Minutes	Percent Dye Dissolved A	B	C	Dissolution Time, min.[a] $t_{1/2}$	$t_{2/3}$
	Distilled Water				
2	56.1	62.4	62.1		
5	66.4	69.6	67.6		
10	68.7	75.4	74.1		
20	73.5	80.6	80.1		
				0.9	4.3
	Simulated Gastric Fluid				
2	60.8	49.1	57.6		
5	66.6	58.6	71.0		
10	73.3	65.5	76.7		
20	80.0	76.5	89.7		
				1.7	6.2
	Simulated Intestinal Fluid				
2	59.9	55.7	56.2		
5	69.7	66.9	65.2		
10	75.7	73.8	71.6		
20	81.5	75.5	76.8		
				1.3	4.6

[a] Read from graph of dissolution profile.

that both soluble and insoluble colorants could be satisfactorily applied with these solutions.

Coating Solutions I and II were applied to tablets engraved with "I." The coating did not interfere with the sharpness of the design. The coated tablets could be readily polished to a high gloss in a canvas-lined pan impregnated with a waxy mixture.

Mechanical stress was applied to uncoated tablets by rotating a bottle that was half filled with tablets for 4 hr. at 25 r.p.m. The weight loss of the uncoated tablets was 0.18%. Tablets coated by Coating Solutions I and II were subjected to the same test and had a weight loss of 0.004%. Because the coatings showed good resistance to chipping and attrition at room temperature, the tablets were stored for 4 weeks at 2 and 45°. The coatings did not crack or become brittle at 2° and did not soften or become tacky at 45°.

Although the film coating applied by Coating Solutions I and II possessed most of the advantages of a good film coating, it is essential that a film coating be rapidly dissolved or removed from the tablet so that disintegration of the tablet and dissolution of the drug are not hindered. It is visually impractical to observe exactly when a coating has been removed from a tablet; therefore, 0.3% of FD&C Red No. 2 was added to Coating Solutions I and II. The removal of the coating from the tablet could be determined by measuring the

Table VI—Dissolution of FD&C Red No. 2 from Film-Coated Tablets Prepared by Use of Coating Solution II

Minutes	Percent Dye Dissolved A	B	C	Dissolution Time, min.[a] $t_{1/2}$	$t_{2/3}$
	Distilled Water				
2	62.1	52.9	59.3		
5	69.6	64.1	71.4		
10	76.5	77.0	82.5		
20	89.2	84.6	91.8		
				1.3	4.2
	Simulated Gastric Fluid				
2	52.3	56.8	60.4		
5	71.5	70.7	74.6		
10	87.4	86.2	83.8		
20	97.3	94.4	95.6		
				1.6	3.6
	Simulated Intestinal Fluid				
2	62.7	66.8	68.5		
5	76.7	76.7	78.6		
10	84.4	86.4	83.4		
20	91.8	87.5	96.1		
				0.8	2.1

[a] Read from graph of dissolution profile.

amount of dye that had dissolved from the coating at various intervals of time. The dissolution of the coating was determined in distilled water, simulated gastric fluid without pepsin, and simulated intestinal fluid without pancreatin (Tables V and VI). In all dissolution media, two-thirds of the dye and, presumably, the coating was dissolved within 7 min. Thus, the film coating would not hinder disintegration and dissolution.

Visual examination of the tablets coated with shellac and polyvinylpyrrolidone revealed that the coat was completely removed from the tablet in all dissolution media. All coated tablets dissolved within 25 min. Examination of tablets coated with ethylcellulose and polyvinylpyrrolidone showed that the coating was ruptured and that small fragments of the coating were attached to the tablet. This did not interfere with the release of the drug because all tablets coated with ethylcellulose and polyvinylpyrrolidone dissolved within 50 min. in all dissolution media. In addition, the dissolution of the ingredients of a tablet and subsequent dialysis through a membranelike sac were reported from intact ethylcellulose films (6).

SUMMARY

Two formulations containing polyvinylpyrrolidone were developed for the film coating of tablets by the pan-coating method.

The addition of ethylcellulose and shellac in the film coating modified the hygroscopicity of polyvinylpyrrolidone so that a nontacky coating was obtained.

The physical characteristics of the coatings were evaluated.

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* Present address: Warren-Teed Pharmaceuticals, Inc., Columbus, OH 43215

▲ To whom inquiries should be directed.

Physical Properties of Coarse Suspensions

EVERETT N. HIESTAND

Abstract □ The probable mechanism of the control of floc structure by polymeric materials is developed from theory of polymer stabilization of disperse systems. Techniques that provide some insight into the nature of the floc are described. In predicting shelf-life, these concepts shift the emphasis away from the evaluation of sedimentation and caking to a study of potential structural changes of the floc.

Keyphrases □ Suspensions, coarse—stability, physical properties, structure-controlling factors □ Flocculated systems—use in coarse suspensions, structure

Coarse suspensions must be distinguished from colloidal dispersions because peptized particles of the former sediment during the usually desired shelflife of commercial products while the latter do not. With larger particles, settling produced by the gravitational field dominates the very mild mixing produced by ambient thermal fluctuations. Sedimented, peptized particles form hard cakes in the bottom of the container. Consequently, flocculated systems are used with coarse particles to prevent caking. Numerous reports provide a broader understanding of suspensions (1–6) than is given here. This discussion is limited to a few selected topics in an attempt to explain the structure-controlling factors in a flocculated suspension.

Pourable vehicles with sufficient structure to hold particles trapped in a three-dimensional, vehicular assembly are rarely encountered and are not discussed. Because the common viscosity builders and vehicle-structuring agents nearly always adsorb onto solid particles, they seldom act independently of the solid. The adsorbed material participates in the structure of the suspension by affecting the particle–particle interactions in a manner that may determine the floc structure. If the structure of a flocculated suspension is controlled adequately, inelegance and caking are not problems.