Ankara Ecz. Fak. Mec.
4. 16 (1974)

J. Fac. Pharm. Ankara
4. 16 (1974)

Film Coating of Tablets by Tragacanth
Kitre Zamkı ile Tabletlerde Filim Kaplama

Şükran GEÇGİL,* Günsel BAYRAKTAR — ALPMEN*

The use of tragacanth as a film coating material on medicinal tablets has been investigated in this study. Different methods and materials have been used for the coating of medicinal tablets. Tablets are coated for various reasons. Some of these are; the ability of coatings to mask unpleasant taste and odor and to protect from atmospheric gases, to control the disintegration site of tablets and provide sustained release action, to prevent incompatibilities between the ingredients, to facilitate product identification and to improve product appearance.

Because of certain drawbacks of sugar coating, studies on compression and film coating have been carried out. The aim of film coating is to provide coating which disintegrates in the gastric or in the intestinal fluid. The subject of our study is film coating which disintegrates in the gastric fluid. Film coated tablets are more resistant than sugar coated tablets and retain their original shape and emblems. Increase in weight, volume and weight variation, increase in disintegration time between coated and uncoated tablets are small. In different pharmacopeias disintegration time of coated tablets is given between 30 - 120 minutes.

Coating thickness of film coated tablets should not be more than the coating thickness of sugar coated tablets. Most of the reasons for sugar coating tablets can be satisfied with just a few coats of a suitable film coating material, saving in labor and coating solution. There are several criteria which a material to be used in tablet coating must meet. The material should be nontoxic,

Redaksiyona verildiği tarih : 19 Şubat 1974

(*) Farmasi ve Teknolojisi Kürsüsü, Eczacılık Fakültesi, İstanbul Üniverşitesi

white or colorless, pratically tasteless and colorless, solid and stable to air, light, heat and humidity, easily applied, chemically unreactive, rapidly applicable, soluble in the fluids of the gastro-intestinal tract and in solvents.

Hydroxyethylcellulose and sodium carboxymethylcellulose are used as alternatives for sugar coating of tablets (1). Polyethylene glycol (carbowax 6000) (2), polyvinylpyrrolidone (3), silicone resins (4), hydroxypropyl methylcellulose and ethylcellulose (5), cellulose acetate phthalate with carbowax 6000 (6) are widely used tablet coating materials or coating compositions. Zein (7) and gliadin (8) are two natura products and Eudragit E is a synthetic compound which is a cationic polymer of dimethyl amino - ethyl methacrylate and another neutral methacryl acid ester (9) which have been used for film coating.

The solubility of the film forming subtance in the solvent is the main factor in the selection of the solvent. Methylene chloride, chloroform, methanol, ethanol, ethanol mixtures with acetone or ethyl acetate are solvents used in film coating compositions (10). Aqueous dispersion of Eudragit E 30D has been used (11).

This investigation presented in this paper is about the film coating properties of tragacanth for tablets. Tragacanth used was identified and standarts were determined according to B.P. (12).

Tragacanth is one of the native drugs of Anatolia. It is known by the name of «Geven» and exported from İzmir (Smyrna) (13). Tragacanth is a pseudo emülsifying agent and a very useful substance in the pharmaceutical industry. It consists principally of two components in carbohydrate nature: (a) — Bassorin, which is the 60 - 75 percent of the gum, does not dissolve in water but swells. It gives neutral reactions and contains L - arabinose and D - galactose. Its average molecular weight is more than 100.000. (b) — Tragacanthin is a soluble constituent of the drug and gives slight acidic reactions which is caused by free hydroxyl groups. It contains L - fucose, D - xylose, D - galactose and D - galacturonic acid. Average molecular weight of Tragacanthin is about 10.000. It has no emülsifying properties.

Tragacanth gives pseudoplastic systems in preparations by increasing the viscosity. The most stable pH values are between 5-7.5 (14). The pH values of the mucilages which contain 0.1-2 percent tragacanth calculated on dried gum are between 0.5-5.90 (15). Heat, preparation method and other substances in the formula affect the swelling time and the viscosity of the gum. Decrease in viscosity has been determined, if the tragacanth powder is heated at 105°C for more than one hour before preparation. The mucilages after heating in a water-steam for one hour have optimum viscosity (16) and the swelling time is descreased by the addition of the substances as glycerol, ethanol, sorbitol etc. which are «polyol» nature (17). If they are in high concentration, the viscosity decreases by dehydratation (18).

Our attention was called to the fact that tragacanth mucilages have shown film forming properties with Tweens and Spans, during the experiments about the effects of the surface active agents on the swelling time and rheological properties of tragacanth (19).

EXPERİMENTAL

MATERIALS

Tablets: The tablets coated were starch - lactose placebos (weight 0.194 g. diameter 8.485 mm, thickness 3.568 mm) compressed in a rotary tablet machine and have a hardness of 2.1 Kg. by Monsanto hardness tester.

Disintegration Test Fluid: Distilled water containing 2 g. sodium chloride, 3.2 g. pepsin, 80 ml. N hydrochloric acid in 1000 ml.

Taragacanth: Flaky taragacanth was first comminuted in a bronze mortar and then in Cullati and Alpine mills, the powder was sieved through a No. 120 sieve (B. P. 1968). Moisture content of the powdered tragacanth is 11.62 %.

APPARATUS

Glass coating pan: With a diameter of 8 cm, revolving at a speed of r. p. m.

Disintegration Device (Carlo Erba) : Raising and lowering the basket in the immersion fluid at a constant frequency rate between 28 cycles per minute through a distance of not less than 1 cm. and not more than 6 cm.

Micrometer (Mauser) : Measures with 0.001 mm. sensitivity.

Oven (Ender) : Adjusted to 105°C ($\mp$ 1°C)

Viscometer : Redwood No. 1 viscometer.

Mills : Culatti (Type DF 148) Tour 5000 - Amp. 0.7 - No. 25500 Alpine Stiftmühle Type 680 u/m 25000.

METHODS

Determination of the Rheological Properties of Tragacanth :

0.4 % mucilage of accurately weight tragacanth, calculated on the dried sample, was prepared according to B. P. 1968. Viscosity of the mucilage was determined by the use of Redwood viscometer No. 1 and corrected efflux time was found 444.2.

Preparation of the coating Formula :

Film forming properties of tragacanth in combination with Tween 20, Tween 60 and Span 20 were investigated.

Sample IA - IB : Tragacanth - Tween 20 (1 : 1)

Sample IIA - IIB : Tragancth - Tween 60 (1 : 1)

Sample IIIA - IIIB - : Tragacanth - Span 20 (1 : 1)

Tragacanth is mixed thoroughly in equal portions with Tween 20 or Tween 60 or Span 20. Samples IA, IIA, IIIA have been heated in a water bath at 100°C for 30 minutes and samples IB, IIB, IIIB in an autoclave at 120°C for 30 minutes.

Solubility studies of the samples in isopropyl alcohol, chloroform, acetone, ether and ethyl alcohol (70°, 96°) have been carried out. Addition of cholesterol and sodium lauryl sulphate up to 25 % was made to increase the solubility. Samples gave colloidal dispersions but not true solutions in these solvents. After the

evaporation of the dispersions, the film properties of the residues were studied. Good results were obtained with sample IIIA and this sample has been the subject of our film coating study.

Coating dispersion is as follows :

Tragacanth - Span 20 (1 :1)	2.5 g.
Water	22.5 ml.
Talc	0.6 g.
Lactose	1.25 g.
Dye (FD & C Red No. 2)	0.01 g.
Propylene glycol	0.25 g.
Ethanol (70 % w/w) q s. p.	100 g.

Tragacanth and Span 20 were mixed thoroughly and was heated in a water bath at 100°C for 30 minutes. Water was added to the mixture and a homogenous mucilage was prepared. After the addition of ethanol, colloidal dispersion was formed. Talc, lactose, propylene glycol and dye were added and volume was made up to 100 ml with ethanol.

Application of tragacanth - coating dispersion :

The tablets were screened, 50 g of tablets were weighed and placed in the pan ready for coating. 90 g fluid was applied in a thin stream along the top of the tumbling tablets, providing the warm air (90 - 100°C) is directed onto the tablets. In 30 minutes every tablet is evenly coated with a very thin coating of the fluid.

Tablet Disintegration Test :

Disintegration tests were performed on coated and uncoated tablets using the prescribed apparatus. In the disintegration fluid uncoated tablets disintegrated in 300 minutes and tablets with tragacanth dispersion with the given procedure disintegrated in 40 minutes.

RESULTS AND DISCUSSION

Tablets are film coated with an alcoholic dispersion of tragacant. To increase the solubility properties, tragacanth - Span

20 mixture (1 : 1) was used. Lactose tablets were coated in a glass coating pan. In 30 minutes every tablet is evenly coated a very thin coating of the fluid. Average weight, diameter and thickness of coated and uncoated tablets are given on Table 1. Tablets are coated with a film 190 μ thick and show a weight increase of 8 mg/cm². Uncoated tablets disintegrated in 30 minutes and tables coated with tragacanth dispersion disintegrated in 40 minutes.

Table 1

	Uncoated Tablets	Coated Tablets	Difference
Weight (g)	0.178	0.194	0.016
Diameter (mm)	8.292	8.485	0.193
Thickness (mm)	3.378	3.568	0.190

The most commonly used materials for film coating are cellulose derivatives (1) (5) (6), high molecular weight polyethylene glycols (2) (6), vinly derivativers (3) silicone resins (4), acrylics and methacrylics (9) various copolymers of these materials. Zein and gliadin are two prolamins used for film coating (7) (8). In this study we obtained very good film coating properties by use of tragacanth which has all the properties for a good coating material.

For film coating by the known methods organic solvents such as alcohols, ketones, chlorinated hydrocarbons (10) haven been used in coating solutions or dispersions. By the use of organic solvents drying of the coated tablets are very quick but organic solvents are expensive and cause problems for productions safety, hygiene of the work places and protection of the environment. Aqueous coating dispersions of Eudragit E 30D have been used for the application as a film coating (11). By the use of water and ethanol (70 % w/w), we prepared dispersion of tragacanth and obtained good results in coating of by providing warm air onto the tablets continuously.

SUMMARY

Lactose tablets are film coated with an alcoholic dispersion or tragacanth. Tablets are coated with a film 190 μ thick and show weight incease of 8 mg/cm². The difference in the disintegration time between coated and uncoated tablets was about ten minutes.

ÖZET

Bu çalışmada kitre zamkının alkollü dispersiyonunun tabletletlerde film kaplama gayesi ile kullanılabileceği tesbit edilmiştir. 0.194 g. ağırlığındaki, «rotary» tablet makinesinde basılmış, 2,1 Kg. Monsanto sertlik derecesi gösteren tabletler 190 μ. kalınlığında bir filmle kaplanmış ve 8 mg/cm² bir ağırlık göstermiştir. Dağılma kontrolünde kaplanmış ve kaplanmamış tabletler arasında on dakikalık bir fark meydana gelmektedir.

ACKNOWLEDGEMENTS

We wish to expers our thanks to Prof. Dr. K. Münzel for his sincere help and giving a place to one of us (Ş.G.) in the Galenical Research Department of Hoffmann La - Roche, Switzerland (Basel) to carry out studies on the rheological properties of tragacanth and for the financial assistance of the firm. We are also thankful to Pharm. Vildan Çiftçi for her technical assistance.

REFERENCES

1 — Doerr, D. W., Serles, E. R., Deardorff. D. L. : J. Amer. Pharm. Ass., Sci. Ed., **43**, 433 (1954)

2 — Gans, E. H., Chavkin, L. : Ibid., **43**, 483 (1954)

3 — Rotteglia, E. : Boll. chim., farm., **95**, 238 (1956) Ref. : Münzel, K., Pharm. Acta Helv., **38**, 65 (1963)

4 — Neuhoff, E. W. : Pharm. Ind., **20**, 548 (1958)

5 — Mody, D. S., Scott, M. W., Lieberman, H. A. : '. Pharm. Sci. **53**, 949 (1964)

6 — Gross, H. R., Endicott, C. J. : Drug Cosmetic Ind., **86,** 170 (1960)

7 — Winters, E. P., Deardorff, D. L. : J. Amer Pharm, Ass, Sci. Ed., **45,** 125 (1956). Ibid. **47,** 608 (1958)

8 — Bayraktar, G. : Doktora Tezi, İstanbul Üniversitesi, Eczacılık Fakültesi (1964)

9 — Flack, W., Rothgang, G. : Pharm. Ind., **22,** 441 (1960)

10 — Hess, H., Janssen, H. J : Pharm. Acta Helv. **44,** 581 (1969)

11 — Rothe, W., Groppenbächer, G. : Pharm. Ind., **34,** 892, (1972)

12 — British Pharmacopeia p. 1027, The Pharmaceutical Press, London (1968)

13 — Baytop, T. : Türkiye'nin Tıbbî ve Zehirli Bitkileri p. 211, İsmail Akgün Matbaası, İstanbul (1963)

14 — Shewarz, T. W., Gerhard, L., Kawagoe, H. H. : J. Amer. Pharm. Ass. Sci. Ed., **47,** 695 (1958)

15 — Geçgil, Ş. : Doçentlik Tezi, İstanbul Üniversitesi, Eczacılık Fakültesi (1965)

16 — Vogel, H. U. : Doktora Tezi, Diss. ETH, Zurich (1954

17 — Münze, K., Büchi, J., Schultz. O-T. : Galenisches Practicum, p. 298, Wissenschaftlische, Verlagsgesellschaft, Stuttgart (1959)

18 — Schaub, K. : Pharm. Acta Helv. **33,** 797 (1958)

19 — Geçgil, S. : Unpubliched.