lene" we have a suppository medium whose physical properties render more likely the fulfilment of theoretical considerations of this type of medication, while providing many minor points of distinct advantage to both maker and user.

SUMMARY.

A new suppository base is suggested—propylene glycol stearate. The substance melts within body temperature range, is self emulsifying in water, forming soft, bulky, unguentous, hydrophilic and non-irritant emulsions particularly suitable for rectal treatment.

Its properties allow of medicament diffusion and absorption of water-soluble drugs irrespective of melting range, while insoluble substances are emulsified and kept in intimate local contact with mucosal tissue.

Other advantages include freedom from greasiness and leakage in use, while retaining firmness, ease and rapidity of molding, and better storage qualities.

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THE USE OF CETYL ALCOHOL AS AN ENTERIC COATING MATERIAL.*,[1]

BY LUCILLE M. MILLS.

The first reference to the passage of pills through the stomach undissolved was made by Proctor (1), in 1862, who ascribed the occasional failure of the pills to disintegrate either to the condition of the patient or the composition of the pill, rather than the nature of the coating. Wruble (2), in 1930, did some work on enteric coating materials; he stated, as a practical specification that an enteric coated tablet should withstand the gastric fluids for a period of four hours and then be deprived of its coat within one-half hour after entering the intestinal tract. Lozenski and Diver (3), used the fluoroscopic method to determine the point of disintegration. In their work they gave one tablet of barium sulfate and another of sodium salicylate, both having the same enteric coating. It was assumed that both tablets left the stomach at the same time; later this was shown to be a fallacy by Bukey and Brew (4).

The purpose of this study was to determine the value of cetyl alcohol, cetyl alcohol and shellac, and cetyl alcohol and mastic as possible enteric coating materials. Cetyl alcohol was chosen because of its similarity to some other coating materials which have been previously used with some success.

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* Scientific Section, A. PH. A., Dallas meeting, 1936.

[1] Study from the laboratories, College of Pharmacy, University of Nebraska.

EXPERIMENTAL PROCEDURE.

In these studies compressed tablets of barium sulfate were used. The granulation mass was made as follows:

Barium sulfate	50%
Starch	30%
Acacia	10%
Sugar	10%

This mass was then sent to a manufacturer who compressed it into tablets. Barium sulfate was used to render the tablets opaque to X-rays.

The tablets to be coated were placed in a rotating metallic hopper and a small amount of the coating material was sprayed on the side of the hopper so as not to moisten the tablets. As the tablets rotated they were coated. More coating was added from time to time, as the coating dried due to the evaporation of the solvent. A small amount of purified talc was added to give body to the coat and when the coating was uniform the tablets were removed from the hopper and allowed to dry.

The cetyl alcohol, or the various combinations of cetyl alcohol and other materials used, were dissolved in acetone so that the material could be sprayed over the tablets.

The coated tablets were administered to students, and the time and point of disintegration was determined by means of radiographs. The students were chosen at random so that a cross section of various types of individuals could be studied. Since tablets are given for various reasons and under widely differing conditions we were endeavoring to find a material suitable for enteric tablets which might be given for any condition for which the physician wished to prescribe.

The first series of tablets were coated with a cetyl alcohol coating; other tablets were coated with a cetyl alcohol-shellac coating and still others with a cetyl alcohol-mastic coating. The following chart gives the number of grams of the ingredients used.

TABLE I.

Ingredients.	Group I.	Group II.	Group III.
Cetyl alcohol	10 Gm.	10 Gm.	10 Gm.
Shellac		10 Gm.	
Mastic			10 Gm.
Acetone	100 cc.	100 cc.	100 cc.

The shellac was added to the cetyl alcohol as it was thought that it would give body to the coating. Shellac had been previously studied and found unsatisfactory as a coating material when used alone. Wruble (2) suggested that the value of shellac as a coating material might be due to the fact that it is produced from an animal source (*Tachardia lacca*).

EXPERIMENTAL DATA.

The following abbreviations and symbols are used in the charts. *S*, stomach; *S. I.*, small intestine; *A. C.*, ascending colon; *T. C.*, transverse colon; and *D. C.*, descending colon. *Loc.* unknown, exact point of disintegration is unknown.

The calculations used in determining the efficiency of the enteric coating were made as follows. The number of tablets for which the point of disintegration was unknown was deducted from the total number of tablets given, and this value used as the denominator in the efficiency factor. The numerator was determined by subtracting from the total number of tablets used those disintegrating in the stomach, the number remaining in the stomach at the end of the experiment, and those in which the point of disintegration was unknown.

CETYL ALCOHOL COATING.

TABLE II.

Time and Point of Disintegration.

Hours.	4.	5.	6.	7.	8.	10.	11.	12.	Total.
S.	2		2	3				1	8
S. I.	3	1	1	5			3		13
A. C.	1	1	2	1	1	3	13		22
Loc. unknown						4	4		8
Total									51

Location and Time of Those Tablets Not Disintegrating.

S.			1	2				6	9
S. I.			7	1	1		7		16
A. C.			1	9	4		5	1	20
T. C.						2			2
Total									47

Total number of tablets used was 98.
Number of subjects was 25.
Efficiency was 81.11 per cent.

TABLE III.—CHART FOR DETERMINING EFFICIENCY OF COATINGS.

For Denominator.	Cetyl Alcohol Coating.	Cetyl Alcohol-Shellac Coating.	Cetyl Alcohol-Mastic Coating.
Total number tablets	98	85	47
Disintegration point unknown	8	3	0
Total	90	82	47
For Numerator.			
Disintegrating in *S*	8	11	0
Not disintegrating in *S*	9	16	1
Loc. unknown	8	3	0
Total not considered	25	30	1
Total number tablets	98	85	47
Total not considered	25	30	1
Total	73	55	46
Efficiency	$\frac{73}{90} \times 100 =$ 81.11%	$\frac{55}{82} \times 100 =$ 70.73%	$\frac{46}{47} \times 100 =$ 97.98%

It will be noted that nine tablets remained in the stomach at the time when the last radiograph was taken. Some of these may have passed into the intestinal tract but as no definite evidence could be obtained it was thought best to omit this number. It is obvious that the efficiency might be greater than the value reported. The tablets in the disintegration chart marked location unknown have no bearing on the value since it was deducted from both numerator and denominator.

CETYL ALCOHOL-SHELLAC COATING.

TABLE IV.

Time and Point of Disintegration.

Hours.	4.	5.	6.	8.	11.	Total.
S.	1	6	2	2		11
S. I.	16	13	11	3	2	45
A. C.		4	2			6
Loc. unknown	1		2			3
Total						65

Location and Time of Those Tablets Not Disintegrating.

S.	2	14	16
S. I.		4	4
Total			20

Total number of tablets used was 85.
Number of subjects was 20.
Efficiency was 70.73 per cent.

In making the calculations for the efficiency of this coating the same procedure was used as in the previous study. For calculations see Table III.

CETYL ALCOHOL-MASTIC COATING.

TABLE V.

Time and Point of Disintegration.

Hours.	4.	5.	6.	7.	8.	10.	11.	12.	Total.
S.									0
S. I.									0
A. C.	1			1			1	4	7
Total									7

Location and Time of Those Tablets Not Disintegrating.

S.						1		1
S. I.		4	1	3		1		9
A. C.			6	5	4	5	5	25
T. C.							2	2
D. C.							3	3
Total								40

Total number of tablets used was 47.
Number of subjects was 13.
Efficiency was 97.87 per cent.

The calculations were made in the same manner as the preceding. See Table III.

CONCLUSIONS.

From this study the following conclusions may be drawn:

(1) That cetyl alcohol as an enteric coating material was 81.11 per cent efficient.

(2) That cetyl alcohol-shellac as an enteric material was 70.73 per cent efficient.

(3) That cetyl alcohol-mastic as an enteric coating material was 97.87 per cent efficient.

(4) That in the case of cetyl alcohol-mastic coating the highest percentage of the tablets disintegrated in the ascending, the transverse and descending colon.

(5) That the efficiency of the cetyl alcohol-mastic coating can be increased by decreasing the amount of mastic used in the preparation of the coating mixtures.

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