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EVALUATION OF MALTODEXTRIN AS BINDING AGENT

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ABSTRACT

Different types of maltodextrin were evaluated as binding agents in wet granulation process. Maltodextrins were added during wet granulation process in the dry form or as a solution. The granulation was performed in a planetary and a high shear mixer. Lactose monohydrate and dicalcium phosphate dihydrate were used as bulk materials. This study showed no difference in binding capacity between the different types of maltodextrin. Maltodextrins did not show any advantage as binding agent in comparison to native starch.

INTRODUCTION

Starch is one of the most commonly employed granulating agents in the preparation of solid dosage forms. Different types of starches and products derived from starches have received much attention

from investigators regarding their used as binding agents. Nasipuri (1 & 2) evaluated the use of cassava starch and cocoyam starch as binding agents while the use of sorghum starch was studied by Garr and Bangudu (3). Recently, thermally modified and/or crosslinked modified waxy-corn starches were investigated as binders in both the conventional and high shear granulation (4,5 & 6).

Maltodextrin which is a mixture of purified nutritive saccharides obtained by hydrolysis of starch has been widely used in the food industry. It is important as moisture conditioner, food plasticizer, crystallization inhibitor, stabilizer, carrier and bulking agent (7). The micromeretic properties of maltodextrin were recently studied by Li and Peck with the intention to develop a maltodextrin product for direct compression (8). In this study, the potential use of different types of maltodextrin were evaluated as binding agents. The study was performed in a conventional and a high shear granulation using soluble and insoluble bulk materials.

MATERIALS

Six different types of maltodextrin with respect to the DE (dextrose equivalent) value were evaluated as binding agents in wet granulation process. The maltodextrins were produced and provided by Cerestar (Vilvoorde, Belgium). The type and composition of these maltodextrins are summarized in Table 1. Dicalcium phosphate dihydrate (Emcompress, Edward Mendell, New York, U.S.A.) and lactose monohydrate

TABLE 1

Composition and dextrose equivalent of Maltodextrins

Composition	Types of Maltodextrin 1906	1908	1910	1912	1915	1921
DE	4-6	8-10	11-14	15-17	17-19	20-23
Dextrose	<1	<1	<1	<1	<1	<1
Maltose	2	2	3	5	5	6
Maltotriose	2	4	7	9	10	13
Higher Saccharides	95	94	90	86	84	80

(Pharmatose 200M, DMV, Veghel, The Netherlands) were used as bulk materials.

METHODS

Granulation

Wet granulations were performed in a planetary mixer (Hobart K45SS, Troy, OH, U.S.A.) or in a high shear mixer (Gral 10, Machines Collette, Wommelgem, Belgium) and by the addition of maltodextrin in the dry form and as a solution. All granulations were performed in triplicate on each sample. The procedures were described in a previous study (Visavarungroj et al., 1990a).

Granule evaluation

Sieve analysis and granule friability were determined in triplicate as previously described (Visavarungroj et al., 1990a).

Results and Discussion

There is no difference in size distribution and average size of lactose granules prepared by adding maltodextrins in the dry form or as a solution. No variation in size distribution between lactose granules prepared with different types of maltodextrins was observed. With all maltodextrins used, the average size of lactose granules prepared with a planetary mixer was about 0.85-0.90 mm and those prepared with a high shear mixer was about 1.10 mm (Fig.1). When dicalcium phosphate dihydrate was used as bulk material instead of lactose monohydrate, an identical observation was obtained (Fig.2). The average size of dicalcium phosphate granules prepared with a planetary mixer was about 0.50 mm and about 0.6 mm for those prepared with a high shear mixer.

The size distribution of the lactose granules prepared with the maltodextrins as binders was similar to the distribution of granules produced by corn or waxy-corn starch (4 & 5), while some differences in size distribution of dicalcium phosphate dihydrate granules were observed (6). Using a planetary mixer with corn or waxy-corn starch as dry binders, dicalcium phosphate granules were produced with an average size of about 0.20 mm, the paste addition method produced an average granule size of 0.65 mm. The maltodextrins produced dicalcium phosphate granules with the average size of about 0.50 mm independent on the type of addition method. A similar observation was made with the high shear granulator. This can be attributed to the excellent solubility of the maltodextrins used. As all maltodextrins were

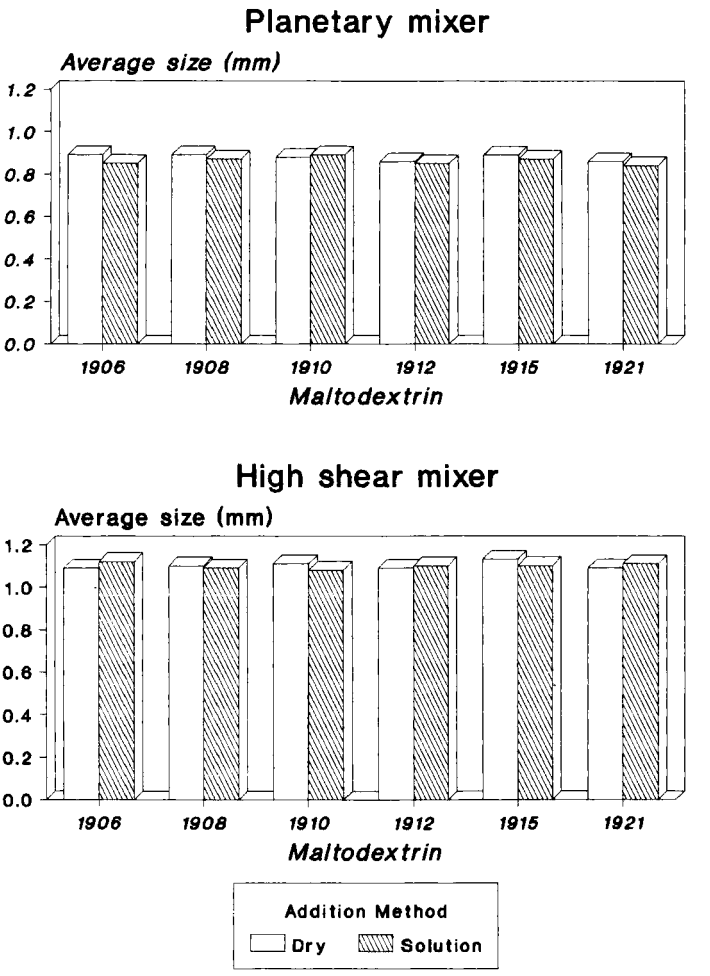

FIGURE 1

Average size of lactose granules.
(SD ≤ 0.04, n = 3)

easily dissolved in water, no important difference in the distribution of maltodextrins in the agglomeration of granules were expected.

The results from the friability studies showed the same trend as the size distribution analysis. No difference in friability was observed for granules

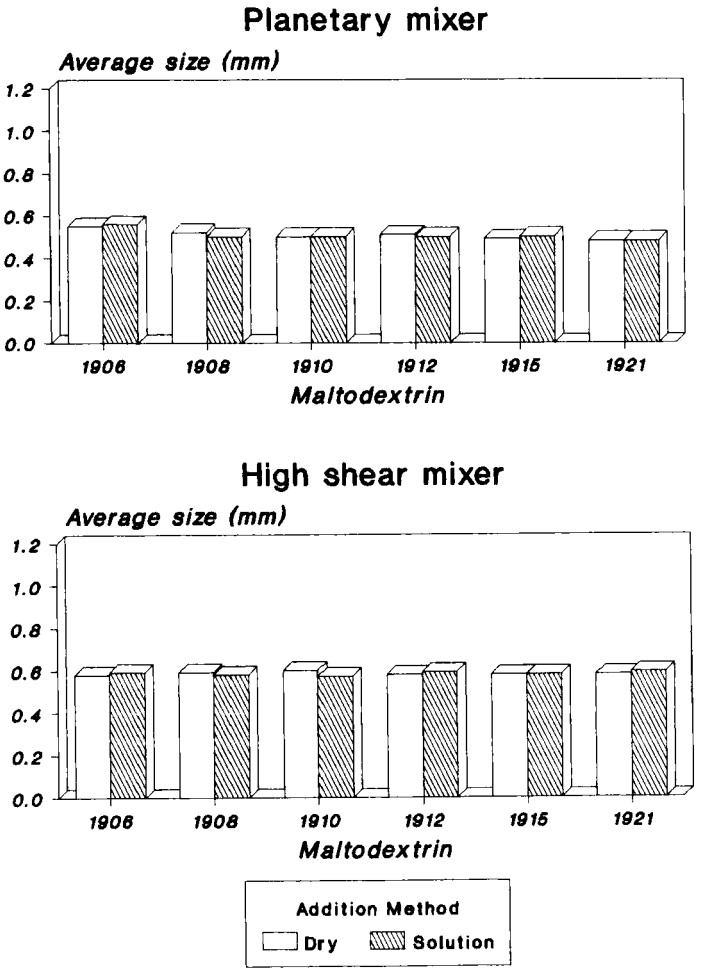

FIGURE 2

Average size of dicalcium phosphate dihydrate granules. (SD ≤ 0.04, n = 3)

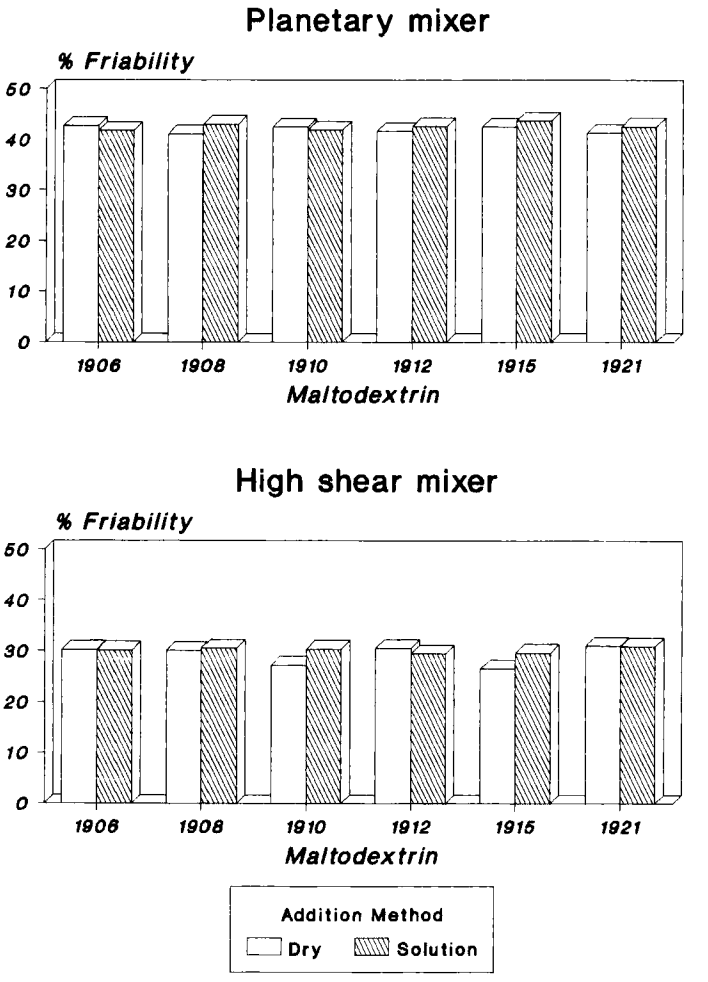

FIGURE 3

Friability of lactose granules.
(SD ≤ 2.5, n = 3)

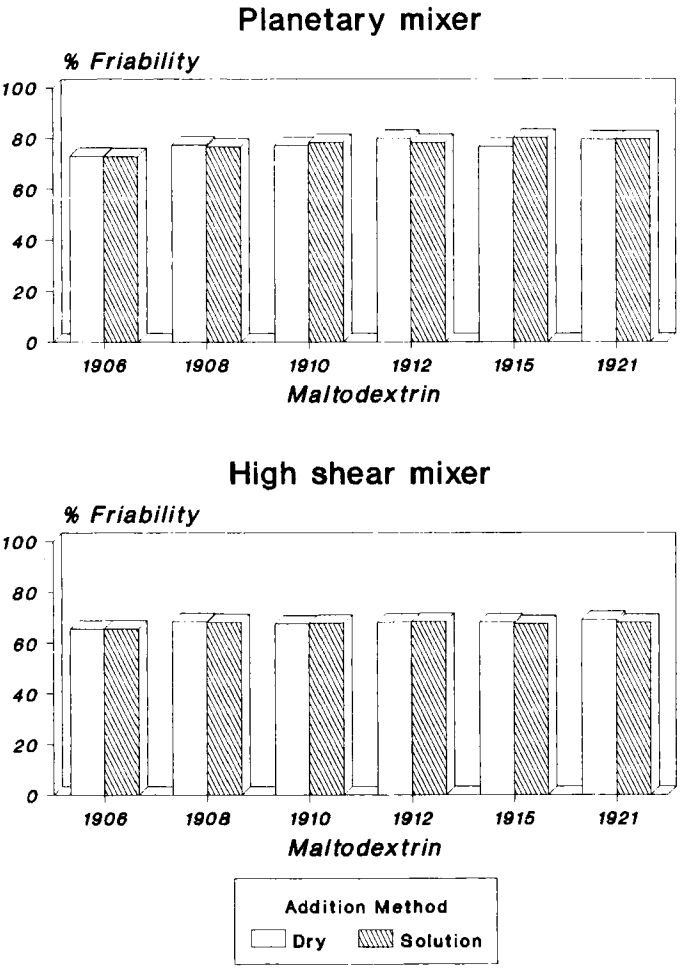

FIGURE 4

Friability of dicalcium phosphate dihydrate granules. (SD ≤ 2.5, n = 3)

produced by different methods of binder addition or with different types of maltodextrin (Fig.3 and 4). Granulation performed with a high shear mixer produced less friable granules in comparison to those produced with a planetary mixer. Conventional granulation with maltodextrins, either in dry form or as a solution, produced lactose granules with a friability of 40-45% which was lower than those using the dry addition method of corn (75%) and waxy-corn starches (78%). The paste addition method of corn starch produced lactose granules with a higher friability (57%) while those using waxy-corn starch paste produced about the same friability (45%) in comparison to maltodextrins.

With the high shear mixer and a waxy-corn starch paste, the same friability (30%) of lactose granules was obtained as for the maltodextrins. Corn starch paste produced lactose granules with a higher friability (40%) in comparison to maltodextrins (30%) in a high shear mixer. This confirms that amylopectin seem to be the important fraction in providing binding strength for granules.

Dicalcium phosphate dihydrate as an insoluble substance does not show an ability in improving the bonding strength of granules. Dicalcium phosphate granules prepared with maltodextrins, either dry or solution addition, showed a similar granule friability as those produced with dry corn or waxy-corn starches (70-75%). Less friable dicalcium phosphate granules were obtained with a corn or waxy-corn starch paste.

In conclusion, one might say that maltodextrins with a DE value between 4-23 did not show any advantage as binding agent in wet granulation compared to native corn starch or waxy-corn starch.

Acknowledgements

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