Biosciences, Biotechnology Research Asia Vol. **4**(2), 639-644 (2007)

Effect of starch over sodium starch glycolate in dispersible tablet

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(Received: September 22, 2007; Accepted: October 18, 2007)

ABSTRACT

Our work aims to find the optimum concentration of the diluent –starch with sodium starch glycolate (SSG) for the fast dispersion for the dispersible tablet. We had formulated four formulations of varying proportions of starch (0.05 %,0.1 %,0.2 % and 0.15%) with sodium starch glycolate at a concentration of 4%. The tablet were formulated with SSG in relation to that of starch and evaluating their physical characteristics such as hardness , weight variation and their disintegrating efficiency. The fast dispersible tablets with an acceptable hardness and desirable taste could be prepared within the optimum starch concentration. The formulation and its characterization of the dispersible tablets showed that the formulation A (0.05 %) of starch gave a faster dispersibility than the other formulation including the market sample. Hardness due to compaction force plays a vital role in the dispersion of the tablet. Thus a concentration of 0.05 % of starch would be optimum at a hardness of 1.6 kg/cm^2 would be optimum to have a faster disintegration time.

Key words: Sodium starch glycolate, dispersible tablet, starch and compaction.

INTRODUCTION

Oral administration has been the most versatile and commonly employed recite of drug delivery indeed for the instant release system. Development of a successful oral controlled release drug delivery dosage form requires relevant knowledge on GI physiology, the required physio chemical characteristics of the drug, relevant dosage form characteristics. To successfully modulate a delivery system for maximal GI absorption of the drugs, one needs to have a fundamental understanding of the anatomical and physiological characteristics of the human gastro intestinal tract. Remarkable improvements can often be achieved by novel formulation for well known and established drugs. Absorption can be facilitated by formulation techniques and the unnecessary dose can be reduced but its efficacy and the duration of the effect can be prolonged and the desirable side effects can be suppressed / minimized and so forth. By suitably modifying the dosage delivery system. Since ever increasing safety requirement for new drugs and other factors have dramatically increased, the registration expenses and the number of new drugs entities introduced per year had dropped down considerably in recent years. On the other hand, novel formulation techniques applied to drugs and compound that have been known for sometime or have been successfully applied already may open up new fields of application[1]. Drugs administered orally in solid dosage form must first dissolve in gastro intestinal fluids before they are absorbed. Thus absorption of drugs becomes principally dissolution rate limited. Disintegration, deaggregation and dissolution may occur from the tablets simultaneously only with the release of drugs from the dosage form.[2].

The dissolution rate of the solid drug is the rate controlling step in absorption of drugs which get impaired for the drug which has poor water solubility[3], since it is the slowest of the various stages involved in the release of the drug from its dosage form and in to systemic circulation. So any factor influencing the dissolution and dispersion rate controls the onset , intensity and duration of the biological responses. Thus taking in to consideration the dissolution and the dispersibility of the tablet formulation, various formulations of the tablets have been tried out. In our study, sodium starch glycolate have been included along with the various proportion of the starch to evaluate the economicity and the efficiency of the formulation of dispersible tablets. The Dispersible tablets were uncoated or film-coated tablets intended to be dispersed in water before administration giving a homogeneous dispersion[4]

Sodium starch glycolate is widely used in oral pharmaceuticals as disintegrant in capsules [5] and tablets[6] formulations. They are used in tablets prepared by direct compression[7] and also by wet granulation process[8]. The usual concentration of SSG employed in a formulation ranges between 2%w/w and 8%w/w with optimum concentration of about 4%w/w. Disintegration occurs by rapid uptake of water followed by rapid and enormous swelling[9]. It is been observed that the effectiveness of many disintegrants are affected by hydrophobic excipients, like lubricants but the disintegration ability of sodium starch glycolate was unimpaired[10]. Increasing the tablet compression pressure can also have nil effect in disintegration time of sodium starch glycolate[11]. Sodium starch glycolate is commonly and efficiently used in oral pharmaceutical formulation and are generally defined as a non toxic and non irritant material. The excipients such as spray dried lactose, HPMC, SSG , microcrystalline cellulose and osmotic agent – sodium chloride with the drug diclofenac are used to formulate the composition of the inner core tablet[12]. The results indicated that the drug released from all the compression coated tablets was characterized by a distinctive lag of time followed by a faster drug release that depend on the types of excipients , drug and the osmotic agent that are used in the inner core tablet. These findings can affect while formulating moisture sensitive drugs. In a study of fast dispersible tablets ibuprofen tablet, the fast dispersible tablet disintegrate more rapidly in water to form a stabilized suspension or disperse instantaneously in the mouth to be swallowed without the help of water. A direct compression method was used to prepare these two types of tablets containing ibuprofen[13] .The properties of the water dispersible tablet such as porosity, hardness, disintegration time and increase in viscosity after dispersion was investigated for its influence in the disintegration process and proved to have influence over the dispersion. Therefore the fast dispersible tablets with an acceptable hardness and desirable taste could be prepared within the optimum concentration of Starch and SSG. The above literature citing confirms various works conducted on SSG. The effect of another conventional and economic disintegrant – starch has been planned to formulate the fast dispersible tablets along with SSG.

MATERIAL AND METHODS

The drug chosen was aspirin (gift sample form medopharm , India) , sodium starch glycolate (gift sample from medispan pharmaceuticals, India), starch (Reachem laboratory chemicals, India, Lactose (Nice Chemicals-India), Talc (Burgeon chemicals-India), Magnesium stearate (Burgeon chemicals-India) and other chemicals and reagents of laboratory grade. The equipments used were single punching machine (Cadmach machinery ,ahmedabad, India), Pfizer tablet hardness tester (Shreji chemicals instruments, India), Tablet Friabiliator (Shreji chemicals instruments ,India) etc. For the dissolution of formulated tablets the dispersability is the main criterion in our work. We had tried to formulate the dispersible tablets in competitive with the maket samples using SSG. Our work concentrates to find the optimum concentration of the diluent-starch with SSG for the fast dispersion. We had formulated four formulations of varying proportions of starch (0.05 %, 0.1 %, 0.2 % and 0.15%) with sodium concentration (4%). The methods were planned to carry out the work after formulating the tablets with SSG in relation to that of starch and evaluating their physical characteristics such as hardness, weight variation and then its disintegrating efficiency.

Formulation

The ingredients – SSG, starch, magnesium stearate, lactose, and drug- aspirin) were formulated

using wet granulation technique[14] using starch mucilage as the binding solution. The ingredients used is tabulated in the table 1.

Table 1: Formula for the dispersible tablet

Ingredients	Formulation			
	A	B	C	D
Drug (aspirin)*	10	10	10	10
SSG	4	4	4	4
Lactose[$]	77	72	80	67
Starch	5	10	2	15
Talc	2	2	2	2
Magnesium stearate	2	2	2	2

*Drug (aspirin) concentration was adjusted to get the total average weight of the tablet

[$] Lactose concentration were adjusted minimally to achieve the total average weight of the tablet

In the wet granulation process SSG ,lactose are mixed intimately. The starch mucilage (2%w/w) was added little by little with continuous trituration until a coherent mass was obtained .It is then balled between the fingers and passed through the sieve no 10 and the granules were dried at 60 ^{0}C in an hot air oven. The dried granules were then passed through sieve number 22 and again dried at the same temperature. Then the dried granules were mixed with talc and magnesium stearate .It is then compressed to a tablet an average weight of 200 mg.

Weight variation[15]

Twenty tablets were taken and weighed individually .Then the average weight is calculated by adding all the tablet weight and dividing the same by twenty. The pharmacopoeial requirement is that not more than two tablets differ from the average weight by more than than the percentage listed in the tablets and no tablets should differ in weight by more than double the percentage unit. The result was tabulated in Table 2.

Hardness[16]

Hardness can be defined as the force required to break a tablet in a diametric direction. A tablet was placed between two anvils of the Pfizer tablet hardness tester and the crushing strength that causes the tablet to break was recorded. Hardness is thus the tablet's crushing strength. The result was tabulated in Table 2.

Friability Test[17]

About ten tablets were weighed and placed in a friabilator that were made to rotate of about 25 rpm. During the rotation, the tablets were made to drop from the height of about 6 inches .The chamber was allowed to rotate for about 100 rotations. Then the tablets were removed, dedusted and weighed. The result is tabulated in Table 1. The difference in the weight calculated should not be more than 1 % w/w.

Dispersion time and fineness of the dispersion[18]

Disintegration - Dispersible tablets disintegrate within 3 min when examined by the test for disintegration of tablets and capsules using *water* at 15°C to 25°C.Fineness of dispersion is found by Placing 2 tablets in 100 ml of *water* and stir until completely dispersed. A smooth dispersion is produced, which passes through a sieve screen with a nominal mesh aperture of 710 µm.

RESULTS AND DISCUSIONS

The weight variation, friability, hardness , dispersion time and the uniformity of the dispersion were tabulated in the Table 2.

The work that we have done on the dispersible tablets gave us some idea about the interaction of the starch with that of the SSG over its dispersibility. The formulation and its characterization of the dispersible tablets showed that the formulation A (0.05%) gave a faster dispersibility than the other formulation including the market sample. The hardness and friability of the formulation were comparably equivalent to that of the standard market sample. The formulation D (0.15%) showed more hardness than the other formulation which was reflective in the dispersion by having more time to disperse. Thus the effect of hardness (compaction force) played a vital role in the dispersion of the tablet. Thus a concentration of 0.05 % of starch would be optimum at a hardness of 1.6 would be optimum to have a faster disintegration time.

Table 2: Physical characterization for the formulation

Formulation	Weight variation (±S.D.)	Hardness (Kg/cm2) (±S.D.)	Friability (±S.D.)	Dispersion time seconds (±S.D.)	Uniformity of the dispersion
A(0.05%)	0.8 ± 0.11	1.6 ± 0.55	0.4 ± 0.15	24 ± 0.54	All the formu
B(0.1%)	0.7 ± 0.25	1.5 ± 0.45	0.42 ± 0.25	44.4 ± 0.25	lation passed
C(0.2%)	0.6 ± 0.31	1.8 ± 0.33	0.51± 0.0.31	71.6 ± 0.34	of the tests
D(0.15)	0.6 ±0.21	2 ± 0.21	0.44 ± 0.41	87.4 ± 0.31	
Market sample control	0.5±0.22	1.6 ±0.11	0.41 ± 0.44	41 ± 0.31	

* Dispersion time –calculated from the mean value using ten tablets for dispersion tests .

As concluding remarks, in our study we hoped to give the formulator an idea about the effect of SSG over the concentration of starch in designing dispersible tablets and thus would economize their formulation procedures. This work is a worthy tool in pilot scale up process and further work may be carried out to get the real data's of how the interaction of SSG with that of starch.

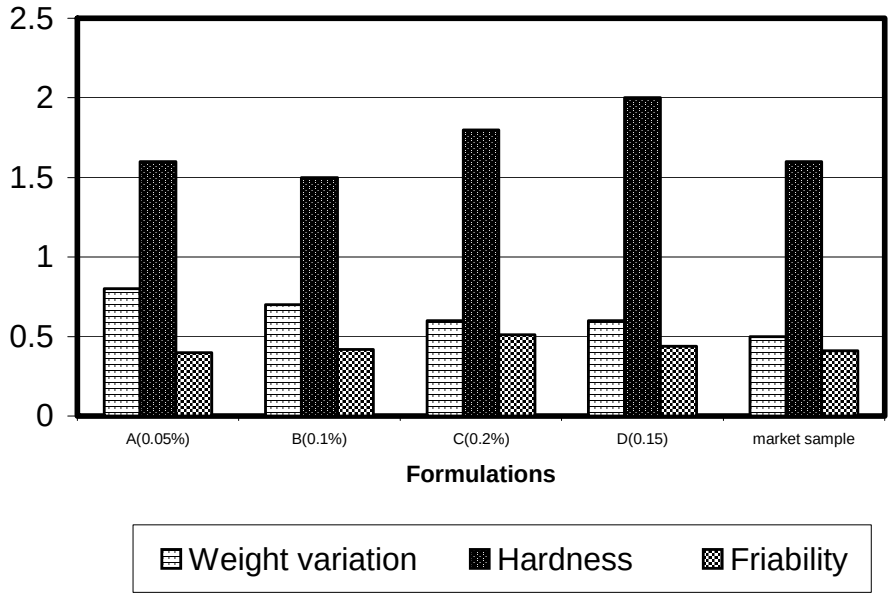
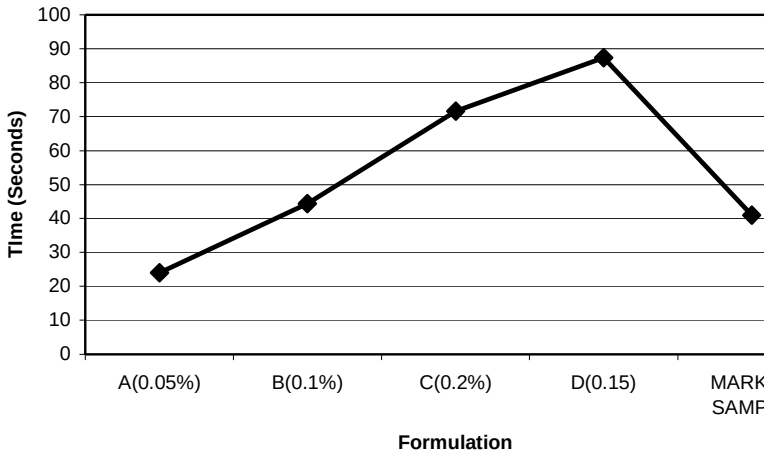


Fig. 1: Respective scales of weight variation, hardness and friability of the formulation

Fig. 2. Disintegration time

ACKNOWLEDGEMENTS

We sincerely thank our Chairman Dr. Ishari K. Ganesh, Vels college of Pharmacy, Chennai for providing facilities to undertake the present project work.



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