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Study On Characterization And Comparative Evaluation Of Spray Dried Garadu Powder (Sdgp) As A Binder For Direct Compression Tablets

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ABSTRACT

The in-depth characterization of excipients is a prerequisite for their safe application in pharmaceutical products. In case of excipients, this task can be a challenge, since many industrial products are mixtures of variable composition. In this paper, a directly compressible form of Spray dried Garadu powder (SGDP) is introduced as filler and binder for direct compression. An attempt was made to provide cheaper, indigenous directly compressible tapioca starch. The SEM of the SGDP AND Starch 1500 samples were obtained using a Hitachi S-4000 microscope It was characterized by evaluating physicochemical, binding and disintegrating properties. The studies indicated that this SGDP is qualitatively comparable to Garadu powder as also the rheological and swelling characteristics. Paracetamol (600mg) tablets prepared using corn and Garadu powder met the requirements of uniformity of weight, assay, friability and hardness. These tablets also conformed to the disintegration and dissolution specifications of I.P. Garadu powder showed adequate binding and disintegrating characteristics. Garadu powder was reported to have rheological and swelling characteristic comparable to corn starch. it was reported to perform multiple function as a filler, binder and disintigrant.

Key words :Garadu Powder, Paracetamol, Dissolution, Binding and disintegrating properties.

INTRODUCTION

Solid dosage forms like tablets and capsules are the most popular and preferred drug delivery systems because they have high patient compliance, relatively easy to produce, easy to market, accurate dosing, good physical and chemical stability Tablet dosage form is mainly composed of the drug and excipients such as a diluent, a binder, a lubricant, a disintegrant, and a glidant. Lubricant is an important excipient to improve the quality and manufacturing efficiency of tableting process[1]. As formulators demand more functionality and performance from their pharmaceutical excipients, these ingredients play a critical role in achieving stability, reducing costs, and improving manufacturing. Starch is one of the most widely used excipients in the manufacture of solid dosage forms. Author have tried to develop botanical SGDP for use as binders and disintegrants in tablet formulations. One objective of this research was to study the

basic physico-chemical properties of the SGDP. A SGDP was shown potential as binding agents and/or disintegrants in tablet formulations. Bindeing properties of starch was investigated in paracetamol – tablet formulation using tablet physical properties, Hardness and disintegration time.[2] In this article, the effects of SGDP on a paracetamol tablet formulation's compressional characteristics and mechanical properties are compared with those of official starch1500.

EXPERIMENTAL

Material:- The Garadu was procured from loca market mandsaur,M.P.India. Garadu powder were obtained from natural source. Corn starch BP, Paracetamol BP were obtained from Asoj soft caps P.Ltd Varoda Gujrat India. All other chemical were analytical grade obtained from Kasliwal brother Indore India.

Physicochemical properties

Garadu powder and Corn Starch were studied (table no.1)for microscopic characteristics, loss on drying, Acidity, pH, ash value, Bulk density, angle of repose and compressibility index.[4,5]

Rheological studies of starch mucilage's

Starch mucilages (2.5% and 5%) of Garadu powder and Corn starch were prepared. The rheological characteristics of mucilages were evaluated by using Brookfield viscometer.[3]

The intrinsic viscosity of the starch was 91.01 mL/g in distilled water at 25°C. Its rheological properties were dependent on shear rate, starch concentration, temperature, and pH.

Moisture content

The moisture content of starch has also been determined by Loss on drying (LOD).

The sample **Tapioca starch** (2gram) is dried at 120°C for 4 hour.

% LOD = 100 X wt. of water in sample **/** Total wt. of wet sample

pH - value

Slurry of Garadu powder and water is prepared in a nonmetallic container and agitated Continuously for 5 min. the pH is measured immediately to the nearest 0.1 unit.

For cornstarch value between 4.5 and 7.0 should be obtained. pH – value of Garadu powder determined by pH meter.

2% slurry of Garadu powder and water is prepared in a nonmetallic container and agitated Continuously for 5 min.

Ash value

To determining ash value, the powdered sample is incinerated so as to burn out all organic matter. Ash value is a criterion to judge the identity or purity of sample.

The weight of the residue cannot exceed 0.5% on a 2 g sample. Sample (Garadu powder) was incinerated for 45 min at 60° temperature.

Bulk density

Bulk density of powder is defined as the ratio of the mass of the powder and its bulk of volume.

Bulk density = mass of the powder / bulk volume.

Bulk volume is determined by the amount of sample required to fill 3/4th volume of a 10 –ml capacity graduated cylinder.

Tapped density

The tapped volume is determined by tapping the measuring cylinder 100 times from a

height of about 1.5 inches.

% Compressibility:

% Compressibility is expressed as a ratio of difference between bulk and tapped density.
% Compressibility = 100 X tapped density - Bulk density / tapped density.

Swelling characteristics

Explanation for disintegration properties is the swelling of the Garadu powder granules when exposed to water and it has been proposed that amylose is the component responsible for disintegration properties of starch due to swelling.

One gram of the material was mixed each with water and liquid paraffin. The sample was centrifuge for 20 min.at 2000 rpm.

% Swelling capacity = (D.S. X 100) / Volume in oil

where D.S. = difference in sediment volume.

One gram sample and add 10 ml of water, centrifuge at 2000 rpm for 20 min.

Sediment volume = 2.5 ml.

One gram sample and add 10 ml of liquid paraffin, centrifuge at 2000 rpm for 20 min.

FORMULATION OF TABLETS

Preparation of Paracetamol (500mg) tablets containing 4%, 6%, 8% and 10% of Garadu powder and corn starch as a disintegrant were prepared using 10%w/w paste of corn starch as well as Garadu powder by wet granulation method. Lubricated were compressed by Automatic eight station tablet punch machine (Cadmach, Ahemdabad India). After preparation of tablet, were stored over silica gel for 24 hour to elastic recovery and hardening.[7]

Test for friability and flow properties of granules

Paracetamol tablet prepared with Garadu powder and corn starch were tested for friability and flow properties. Friability testing was carried out using Roche friabilator. Friability was calculated from the following formula [8]

$$\%\text{Friability} = (1-W1/W2) \times 100$$

Where, W1 = weight of granules after test.
W2 = weight of granules before test.

Flow properties of granules were tested by determining angle of repose: $\tan \theta = h/r$

Where,θ is the angle of repose,h is the height of the heap of powder and r is the radius of the base of the heap of powder.

Evaluation of tablets:
Hardness and friability test

Using Monsanto hardness tester and Roche friabilator respectively carried out hardness and Friability testing. A Monsanto hardness tester (Monsanto Chemical, USA) was used at room temperature to determine the load required to diametrically break the tablets (crushing strength) into two equal halves. Tablets with signs of lamination or capping were not used. The percent friability of the tablets was determined using a Roche friabilator (Erweka Apparatebau, germany) operated at 25 rev. min–1 for 4 minutes. Ten tablets were used at each relative density. The average of three determinations was taken for the crushing strength and friability values.

Disintegration test

All the formulations were tested for disintegration time as per method prescribed in I.P. for uncoated tablets. Tablet disintegration time (*DT*) was determined in distilled water at 37 ±0.5 ^{o}C in a disintegration test unit. Six tablets were tested at each relative density and the results were expressed as an average of three determinations.

Uniformity of weight

The weight variation test of the tablets was performed as per I.P. Twenty tablets of each type were weighed and the average weights were calculated.

Dssolution studies

Dissolution studies were performed as per procedure given in I.P. the sampling time specified in I.P. was modified instead of withdrawing a sample after 30 minutes serial sampling was done at 5,10,15,20,25,and 30 minutes.

RESULTS AND DISCUSSION

Garadu powder was found larger in size than of corn starch. They were oval and polygonal in shape. Loss on drying is less than of corn starch. The bulk density, angle of repose and compressibility index, pH values, ash value and acidity of both starches were comparable in (table no.1).[10] Thermo gravimetric analysis of Garadu powder was showing melting point at 307.33 ^{o}C. Paracetamol was used as model drug because of its poor compactability as evidenced during this study by the low tablet tensile strength (0.38 and 0.67 MPa at a compression pressure of 74 and 111 MPa, respectively) as well as capping and lamination problems after compaction of pure spray dried Paracetamol. This behaviour was due to the formation of monoclinic acetaminophen crystals during spray drying, exhibiting a relatively high elastic deformation [11]. Therefore, Paracetamol was compressed with water Garadu powder to improve tablet tensile strength and to overcome capping and lamination problems.

Table no.1

Sr.No.	Properties	Tapioca starch	Corn starch
1.	Average Grain Size (micron)	145	23.48
2.	Loss on drying (%)	4.25	10.08
3.	Acidity(ml of 0.01 m Na OH)	0.4	0.3
4.	pH value	5.59	6.35
5.	Ash value (%)	.005	0.298
6.	Bulk Density (g/c.c)	0.55	0.50
7.	Angle of repose(Degree)	33	37.34
8.	Compressibility index (%)	8.97	9.09
9.	Swelling capacity	750%	350-450%

Table 02 :-Hardness and Friability of Paracetamol Tablets and Granules.

Product	Friability (%)	Hardness (Kg/sq.cm)
Paracetamol Granules		
T	2.86±1.22	4.5±1.25
C	1.93±1.91	4.0±0.025
Paracetamol Tablets		
P	0.98±0.075	6.84±1.25
C	0.593±0.078	7.00±0.025

Where, T-Containing Garadu powder as binder and disintegrant.
C – Containing corn starch as binder and disintegrant.

Fig No. 01 weight and weight variation of different formulation of tablets :

W.T= weight of tablet W.V. % = weight variation in %

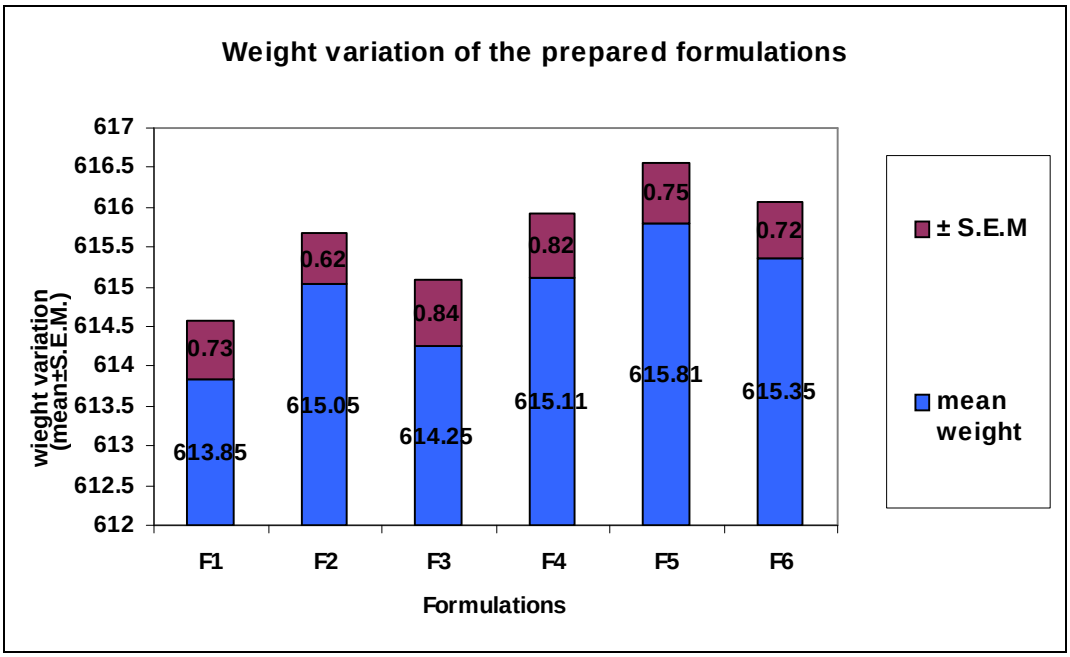

Fig No.02:- Thickness of different prepared formulations

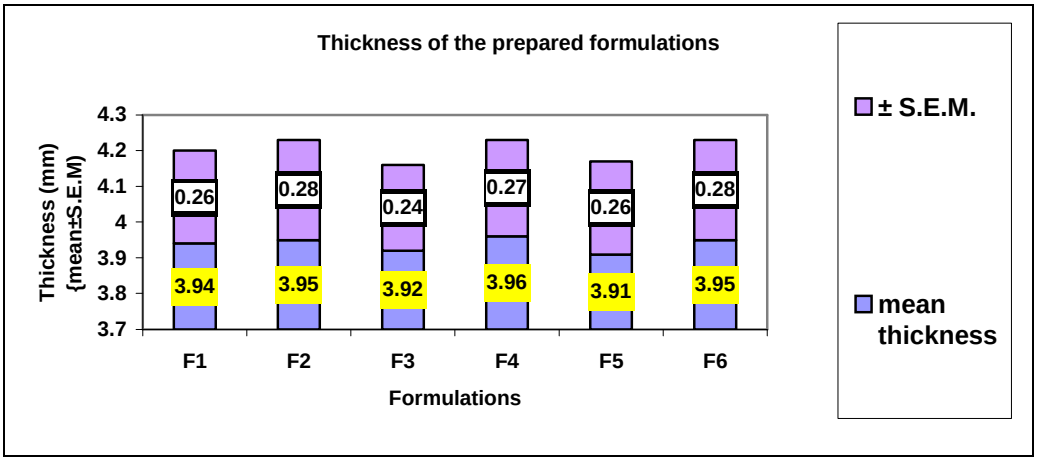

Table no.03: Disintegration time for Paracetamol Tablets (n =3)

Paracetamol tablets	% Disintegrant	Disintegration Time (sec.)
T	10 8 6 4	123±2.1 153±0.89 213±2.6 268±2.3
C	10 8 6 4	159±1.2 190±1.0 270±3.1 349±2.3

Where, T-Containing Garadu powder as binder and disintegrant.

C – Containing corn starch as binder and disintegrant.

CONCLUSION

This article provides insight into the effects of the Garadu powder on paracetamol tablet formulation's compressional characteristics and mechanical properties. The results indicate botanical starches could be useful to produce tablets with desired mechanical properties for specific purposes depending on whether stronger or softer tablets are required in cases such as chewable or disintegrating tablets. This study show that a special free flowing form of Garadu powder is an effective filler binder for tablet, wet granulation/direct compression. The binding properties of this product are much better than those of cornstarch. In contrast to cornstarch, Garadu powder can be used as single filler binder in tablet preparation. And does not need a second filler binder such a cornstarch or MCC. According to the result of this study Garadu powder is a promising filler binder of tablet for pharmaceutical purpose. As it showed adequate binding and disintegration properties.

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