



EVALUATION OF THE TABLET BINDING PROPERTIES OF BARLEY (*HORDEUM VULGARE*) STARCH

H.MUSA, S.N. OCHU AND P.G.BHATIA

Department of Pharmaceutics and Pharmaceutical Microbiology, Ahmadu Bello University, Zaria, Nigeria. Email: hassanmusaf@yahoo.com

Received: 20 April 2010, Revised and Accepted: 18 Jun 2010

ABSTRACT

The binding properties of the starch obtained from Barley (*Hordeum vulgare*) crop was evaluated. The starch from the crop was extracted, evaluated and its binding ability compared with gelatin B.P in paracetamol 500mg tablets formulation produced by wet granulation method of massing and screening, was studied.

The results showed that granule and tablet properties of paracetamol produced using 0% to 12%w/v Barley (*Hordeum vulgare*) starch mucilage produced hard and good quality tablets comparable in Crushing strength, weight variation, Dissolution rate and Disintegration rate with gelatin B.P mucilage binder at most of the concentration tested. The study revealed that the mucilage of Barley (*Hordeum vulgare*) starch when used as binder produced tablets of standard pharmaceutical quality.

Keywords: Evaluation, , Binding Properties, Barley (*Hordeum vulgare*) starch, paracetamol.

INTRODUCTION

Binders are agents used to impart cohesive qualities and structural strength to powdered materials in tablet formulations. A good binder ensures that tablets remain intact after compression and can withstand handling during transportation and packaging processes (Garr, 1988). Binders are mostly employed in the wet granulation methods of tablet production. In this process, a binder solution previously prepared is used in wetting the dry power mix to form a damp mass, kneaded and screened to give granules. The quantity of binder used has considerable influence on the characteristic of the compressed tablets. Generally increasing the binder concentration invariably causes a corresponding increase in the disintegration times of tablets (Udeala and Chukwu, 1985; Mgbahurike and Igwilo, 1991).

Examples of materials commonly used as binders are starch, gelatin, sugar, acacia sodium alginate, methyl-cellulose, microcrystalline cellulose, polyethylene glycol, waxes and water.

The aim of this study is to investigate on the tablet binding properties of Barley (*Hordeum vulgare*) starch in paracetamol tablets.

MATERIALS AND METHODS

Paracetamol (May and Baker (Nigeria), Maize starch and Talc (B.D.H. Laboratories, U.K) and magnesium stearate (Hopkin and Williams, U.K.) were used as obtained.

Collection of *Hordeum vulgare*

Hordeum vulgare cereal was purchased from sabon – gari market Zaria and taken to Department of Biological science Ahmadu Bello University Zaria, Nigeria for authentication and certification at the herbarium.

Extraction of starch

This is in accordance with the standard method described by Musa et al, 2008.

Preparation of granules

The granules for the macro-dose tablet paracetamol were prepared by wet granulation method of massing and screening using the formulae on Table 1.

Initial mixing

The paracetamol powder, lactose and barley starch, or, maize starch as the case may be and the maize starch and lactose, or, barley

starch as the case may be were carefully weighed as stated in the formular. They were dry mixed using a Z blade mixer for five minutes. The disintegrants were first incorporated into the drug in geometrical proportions there after the diluent was incorporated with the powders in like manner.

Wet mixing

As shown in Table 1, varying concentrations of binder solutions (barley starch and maize starch) were prepared. This is done by dissolving the appropriate weights of binder in small quantities of water in a beaker then making up to the 100ml mark with hot boiling water.

Small volumes of the binder solution were added to the dry powder mix gradually until a moist mass was formed. The quantity of binder solution used was noted. The wet mass was then screened through a 1.7mm mesh using a spatula. The resulting granules were dried in a hot air oven at 40°C for 30mins after which they were re-screened through a 1.6mm mesh size and further dried for another 30mins. They were allowed to cool and over sized granules were discarded.

Lubrication of granules

The stated weights of extragranular excipients as shown in the working formulae were carefully weighed in each case. They were first dry mixed manually using a mortar and pestle then incorporated into the dry granules in geometrical proportions.

Analysis of granules

Sieve analysis

30g of the granules were used for the analysis. Six sieves of aperture sizes 500µm, 250µm, 150µm, 125µm, 90µm, and 75µm were used. They were arranged in a stack with the largest pore size sieve at the top and the smallest pore size sieve at the bottom. The stack was mounted on an Endecotts test sieve shaker. The weighed amount of granules was placed on the top sieve and shaken for 15mins. The weight of granules retained on each sieve and the fines collected were taken.

Moisture content

One gram of the granules were weighed in a crucible and put into a hot air oven which was set at 105 °C for 4hours. The crucible was transferred to a dessicator to cool and then re-weighed. The

procedure was repeated until consistent weight was achieved. The BP 1980 states that it should not lose more than 15% of its weight.

Flow rate of granules

This was obtained using an Erweka flowability tester. It measured the time required for 30g of granules to pass through the orifice.

Bulk density

30g of each of the starch granules was gently poured through a short stemmed glass funnel into a 100ml graduated glass cylinder. The volume occupied by granules was read and the bulk density calculated.

Tapped density

A graduated cylinder containing 30g of the granules was tapped 50 times on a bench to obtain a constant volume. This volume was recorded and the tapped volume calculated in g/ml.

Carr's index

The difference between the tapped and bulk density divided by the tapped density was calculated and the ratio expressed as a percentage.

Compression of granules

The batches were compressed into tablets after incorporation of the stated weights of extragranular excipients as shown in tables 3.2, 3.3 and 3.5 using a single punch tablet press (Erweka AR 400 Germany). The punch diameter used for the compression was 12mm while the compression pressure was 7.5mT.

Quality standards of the tablets produced

Weight uniformity test

Twenty tablets from each batch of formulation were weighed individually; on a mettler balance (Type 163, mettler instruments A.G Switzerland). From the mean tablet weight, the deviation of each tablet from the mean weight was calculated, the standard deviation was then found.

Tablet thickness test

Tablets thickness was determined using the micrometer screw gauge. Ten (10) tablets were picked randomly from each batch. Each tablet was placed in between the micrometer screw gauge, spindle and the thickness reading was obtained in millimeters. The mean tablet thickness and the standard deviation (SD) were calculated.

Hardness test

The hardness of the tablet given as the crushing strength was determined using mosanto hardness tester. A tablet was held between a fixed anvil and a moving jaw and the load gradually increased until the tablet just fractured. The value of the load at this point gives a measure of the tablet hardness in Kg force. For each batch, the hardness of four (4) tablets was determined from which the average was obtained.

Friability Test

Ten (10) tablets were randomly picked from each batch, brushed carefully and lightly until any surface powder was removed. The ten tablets were weighed (W1) accurately with the mettler balance. They were placed inside the Erweka (TA - 3R Germany) friabilator and operated for 4 minutes at a speed of 25rpm, removed, dusted and reweighed (W2). From the two weight values, the friability (F) for each batch of tablets was determined.

$$F = 100 (1 - W2 / W1) \quad (1)$$

Disintegration time

The time required for six tablets per batch of 120 tablets to disintegrate was determined using a device mentioned in United States Pharmacopoeia (USP) adopted in British pharmacopoeia B.P. (1993). Erweka disintegration tester (type ZT3 Germany) distilled water thermostatically maintained at 37 °C was used as the

disintegration medium. The disintegration apparatus was calibrated to operate at thirty cycles per minutes. The time taken for the last tablet or its fragment to pass through the mesh into the disintegration medium was recorded. The mean of five such determinations was calculated to be the disintegration time.

Tablet particle density determination

The tablet particle density was determined in a similar way as was done in the case of determination of true density of the starches described previously.

Tablet packing fraction and porosity determinations

Tablet packing fraction and porosity were determined by the following method;

$$\text{Packing fraction (Pf)} = \frac{\text{Bulk density of tablets}}{\text{Particle density of tablets}} = D_B / D_t \quad (2)$$

Where Bulk density of tablet (D_B) = $(4W / \pi d^2 h)$ g/cm³

h = thickness of tablets (cm)

W = Weight of tablets (g)

d = Diameter of tablet (cm)

The tablets porosity was determined from the formular

$$\begin{aligned} \text{Tablets porosity} &= 1 - \text{packing fraction (Pf)} \\ &= 1 - \frac{\text{Bulk density of tablets}}{\text{Particle density of tablets}} \\ &= 1 - 4W / \pi r d^2 \quad (3) \end{aligned}$$

DISCUSSION

Both hordeum vulgare and gelatin when used as binders gave tablets whose crushing strength increased with increase in binder concentration (Fig 1). This implies an increase in hardness (Jacob and Plein 1968, Musa et al 2004) this might be due to the fact that the more the concentration of the binder the more the viscosity and stronger the bridges and tablet binding mechanism such binding forces includes mechanical interlocking, plastic deformation, molecular forces, van der waal forces, electrostatic forces, solid and liquid bridges. Similarly friability of the tablets was found to decrease with increase in binder concentration Fig 2) due to increase in tablet hardness. (Esezobo and Ambujam 1982). Disintegration time was found to increase with increase in binder concentration for both binders (Fig 3). The interacting forces and bonds between the particles and the binder present are responsible for the strength of the tablets; those forces were also responsible for the increase in disintegration time of the tablets, Nasipuri R.N. and Akala E.O. (1986)

York and Pipel (1973) found that the hardness of tablets, depend on the compression force and the amount of binding agent present. The compression force used was same for all the batches therefore the increase in tablet hardness observed can be attributed to the amount and type of binding agents.

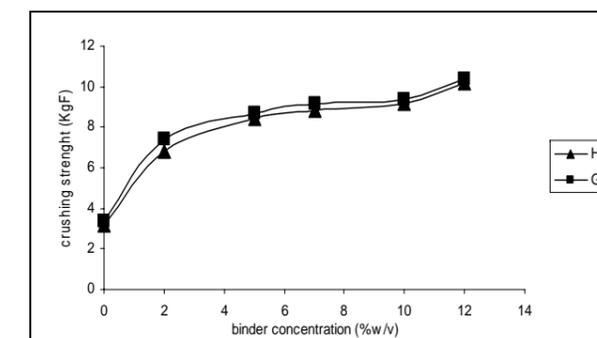


Fig. 1: Plots of mean crushing strength (KgF) against binder concentration (%w/v) in paracetamol tablets produced from Hordeum vulgare (Hv) and Gelatin (G) as binders

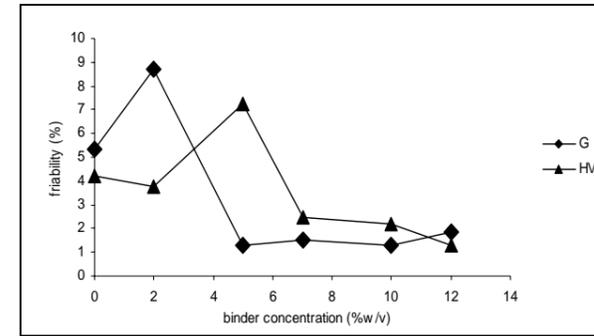


Fig. 2: Plots of Friability (%) against Binder concentration (%w/v) in paracetamol tablets produced using Hordeum vulgare and Gelatin as binders

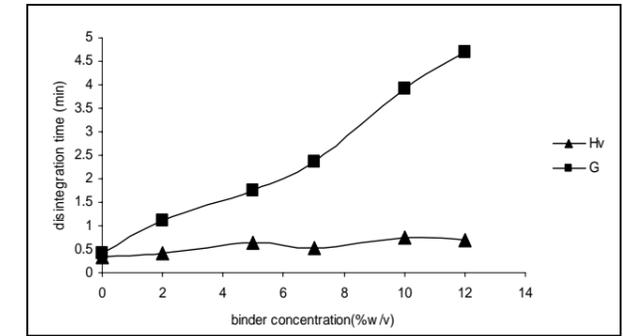


Fig. 3: Plots of disintegration time (min) against binder concentration (%w/v) produced from Hordeum vulgare (Hv) and Gelatin (G) as binders

Table 1: Table shows the working formular for studying the binding properties of *Hordeum vulgare* starch compared with gelatin in paracetamol tablets

Components	Quantity / tablet	Quantity / batch
Paracetamol	500mg	60g
Lactose	50mg	6g
Disintegrant:		
Maize starch	5%w/w	5%w/w
Binder solution:		
Gelatin /barley starch	0, 2, 5, 7, 10, 12%w/w	0, 2, 5, 7,10, 12%w/w
Extragranular excipient:		
Maize starch	7.8%w/w	7.8%w/w
Lubricant / glidant:		
Dried talc	2.0 %w/w	2.0 %w/w
Dried mg stearate	0.2%w/w	0.2%w/w

Table 2: Table shows Granule Properties for *Hordeum vulgare* compared with gelatin used as binder at varying concentration in paracetamol tablets

Granule Properties	Binder type											
	Hordeum vulgar			Hordeum vulgare			Gelatin		Gelatin		Gelatin	
Binder concentration (%w/w)	0	2	5	7	10	12	0	2	5	7	10	12
Flow rate (g/sec)	3.89	4.21	3.90	3.83	4.00	3.71	3.87	4.41	4.08	4.07	3.40	4.04
MoistureContent (%w/w)	2	2	1	1	2	2	3	3	3	2	1	2
Bulk densities (g/ml)	0.44	0.45	0.48	0.50	0.46	0.46	0.44	0.44	0.50	0.48	0.47	0.48
Tapped densities (g/ml)	0.53	0.54	0.55	0.56	0.53	0.53	0.53	0.51	0.56	0.54	0.54	0.55
Carr's Index (%)	16.98	16.67	12.73	10.71	13.21	13.21	16.98	13.73	10.71	11.11	12.96	12.73
Angle of repose (°)	30.1	32.3	25.59	26.6	29.4	28.1	36.6	28.7	31.1	22.9	24.7	23.2
Hausner ratio	1.21	1.2	1.15	1.12	1.15	1.15	1.21	1.16	1.12	1.13	1.15	1.15

Table 3: Table shows results of varying binder type / concentration on paracetamol tablet properties produced by wet granulation method

Tablet Properties	Binder type											
	Hordeum vulgare						Gelatin					
Binder Conc. (% w/w)	0	2	5	7	10	12	0	2	5	7	10	12
Crushing strength (kgf)	6.43	6.5	10.2	5.54	7.06	10.87	6.5	10.93	11.1	9.03	10.6	8.93
Friability (% w/w)	20.55	3.76	7.26	2.44	2.20	1.32	21.84	8.69	1.27	1.54	1.29	1.87
Disintegration time (min)	0.34	0.43	0.63	0.54	0.75	0.69	0.43	1.11	2.61	1.89	4.11	4.64
Weight Variation (% w/w)	631.1	618.7	649	647.5	637.9	649.5	606.1	614.5	566.2	633.7	618.9	555.3
Tablet thickness (mm)	5.1	5.4	5.3	5.7	5.6	5.6	5.4	5.4	5.3	5.6	5.4	4.7
Porosity (%)	0.409	0.301	0.394	0.315	0.363	0.346	0.347	0.374	0.387	0.357	0.346	0.330

CONCLUSION

From the results of the study conducted above it can be inferred that starch extracted from Barley (*Hordeum vulgare*) may be suitability used as binder to formulate paracetamol tablets. Also the paracetamol granules obtained from the extracted starch have similar physicochemical properties with that of paracetamol granules prepared with maize starch B.P.

The Barley (*Hordeum vulgare*) starch has been compared with maize starch as a binder at various concentrations and was found to be as good as maize starch in the formulation of paracetamol tablets.

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