Acta Poloniae Pharmaceutica – Drug Research, Vol. 66 No. 4 pp. 433–438, 2009 ISSN 0001-6837
Polish Pharmaceutical Society

PROPERTIES OF DELONIX REGIA SEED GUM AS A NOVEL TABLET BINDER

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Abstract: The mechanical and disintegration properties of paracetamol tablets formulated using *Delonix regia* seed gum (DRSG) as a binder have been studied in this work. Acacia BP (ACG) and tragacanth BP (TRG) were used as official gum standards. The mechanical properties, i.e. tensile strength (TS) and brittle fracture index (BFI), showed that with an increase in concentration of the gum binder, the tensile strength increased while the BFI was reduced. The crushing strength – friability/disintegration time ratio used to analyze the disintegration properties gave a rank order: tablets containing DRSG > tablets containing ACG > tablets containing TRG at 1%, w/w binder concentration while for higher binder concentrations, the rank order is: tablets containing ACG > tablets containing TRG > tablets containing DRSG. The results suggest that while *Delonix regia* seed gum may be useful as a binder, its use at a low concentration will improve the balance between the binding and disintegration properties of tablets when a faster disintegration is desired, while its use at a high concentration could serve the desire for a modified or sustained release tablet formulation.

Keywords: *Delonix regia* seed gum, gum binder, tensile strength, brittle fracture index, crushing strength – friability/disintegration time ratio

Binders are employed in pharmaceutical tablet formulation to provide adequate mechanical properties by promoting the bonding properties existing between the different components of a powder mix in a formulation (1). Various natural, semi-synthetic and/or synthetic substances like starches, cellulose and gums have been employed in pharmaceutical tablet formulation as binders (2). Gums are an example of hydrophilic substances employed in pharmaceutical solid dosage formulation mainly as binders.

In this work delonix gum (DRSG) obtained from the seed of *Delonix regia* (Bojer ex Hook) Raf., family: Fabaceae, was evaluated for its activity as a binder in a paracetamol tablet formulation in comparison with two standard gum binders: acacia BP and tragacanth BP using the mechanical properties of tensile strength and brittle fracture index, and the crushing strength – friability/disintegration time ratio. Paracetamol powder was chosen due to its poor compression properties which therefore, requires a binding agent in order to form good quality tablets.

The tensile strength (*T*) and brittle fracture index (*BFI*) are two mechanical properties which have been used in assessing the usefulness of new binders in a formulation (3, 4).

The crushing strength – friability/disintegration time ratio (*CSFR*/*DT*) of a tablet formulation is an index of measuring tablet quality which measures tablet strength (crushing strength) and weakness (friability), and simultaneously evaluates any negative effects of these parameters on disintegration time, *DT* (5). This index is also used to assess the usefulness of binders in a formulation.

EXPERIMENTAL

Materials

The materials used were: corn starch BP (BDH Chemicals Ltd., Poole, U.K.), lactose (AB Knight and Co., London, U.K.), paracetamol powder BP (supplied by Gawo Pharmaceuticals Ltd., Lagos, Nigeria), tragacanth powder B.P. (Kimpton Brothers Ltd., London, U.K.), acacia gum (Hopkin and Williams Ltd., Chadwell Heath, Essex, England), *Delonix regia* seed gum extracted from the seed of unripe but matured pods of *Delonix regia* (Bojer ex Hook) Raf., family Fabaceae, as described (6) in our

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laboratory, and ethanol 99.8 % (Sigma-Aldrich Laborchemikalien GmBH, D-30926 Seelze, Germany).

Methods

Determination of swelling capacity of the gums

The method described by Bowen and Vadino (7) was used. Two grams of each powdered gum was poured gently into a 100 mL measuring cylinder and the bulk volume (V_0) measured. Distilled water was added to disperse the gum (at room temperature), and subsequently, made up to the 100 mL mark. The dispersion was allowed to stand for 24 h when the volume (V_1) of the swollen gum was read. The swelling capacity was calculated as V_1/V_0. Determinations were done in triplicate.

Preparation of granules

Batches (300 g) of a basic paracetamol – lactose formulation (84.75 : 15.25 %, w/w) were dry-mixed for 5 min in a planetary mixer (Hobart model N50 planetary mixer, Hobart, Canada). The mixture was moistened with sufficient quantity of distilled water or appropriate amounts of gum mucilage to produce granules containing various concentrations of gum. Massing continued for 5 min, the wet masses were granulated manually by passing them through a 16-mesh sieve (1000 μm), dried in a hot air oven for 18 h at 50°C, and re-sieved through a 16-mesh sieve (1000 μm). The granules were stored in air-tight containers before use. The granular density of each batch was determined by the pycnometer method with acetone as the displacement fluid. This same procedure was repeated for batches containing tragacanth and acacia gum binders.

Preparation of tablets

Tablets (590 mg) were prepared from the granules by compressing them using a 12.5 mm die and flat faced punches for 30 s with predetermined loads on a model C, hydraulic hand press (Carver Inc., Menomonee Falls, USA). Tablets with a hole (1.5 mm diameter) at their center were made using an upper punch with a hole and a lower punch with a pin (4). After ejection, the tablets were stored in a desiccator for 24 h to allow for elastic recovery and hardening in order to prevent false low yield values. The tablets' weights and dimensions were determined to within ± 1 mg and 0.01 mm, respectively, and their relative densities (D) were calculated using the equation:

$$D = m / V_t \rho_s \qquad \text{Eq. 1.}$$

where V_t is the volume (cm^3) of the tablet volume (including the hole when present) and ρ_s is the particle density of the solid material.

The volume reduction, which increased with an increase in compression pressure led to variable relative density.

Determination of the mechanical properties of the tablets

The tensile strengths (T) of the normal tablets and apparent tensile strength (T_0) of those containing a hole were determined at room temperature by diametral compression (8) using a Monsanto hardness tester and by applying the equation:

$$T \text{ (or } T_0) = 2F/\pi dt \qquad \text{Eq. 2.}$$

where T (or T_0) is the tensile strength of the tablet ($MN \times m^{-2}$), F is the load (MN) needed to cause fracture, d is the tablet diameter (M) and t is the thickness (m). The results were taken from tablets that split clearly into two halves without any sign of lamination. All results were expressed as the mean of triplicate determinations.

The BFI of the tablets were calculated using the following equation:

$$BFI = 0.5\ (T/T_0 - 1) \qquad \text{Eq. 3.}$$

Friability test

This was determined using an Erweka friabilator (Erweka Apparatebau, Offenbauch/Main, Germany). Ten weighed tablets were placed inside the drum and allowed to tumble for 4 min at a speed of 25 rpm, the tablets were then weighed and the loss in weight was expressed as a percentage of the initial weight. Determinations were done in triplicate.

Crushing strength

The load required to break the tablet (crushing strength) at room temperature into two equal halves was determined by the application of a diametrical force using the Monsanto hardness tester (Monsanto Chemical, USA). Tablets with signs of lamination or capping were not used. The results were expressed as the mean of three determinations.

Disintegration test

Tablet disintegration time (DT) was determined in distilled water at 37 ± 0.5°C in a BP Manesty (Manesty Machines, U.K.) disintegration test unit. Six tablets were tested at each relative density and the results were expressed as the mean of three determinations.

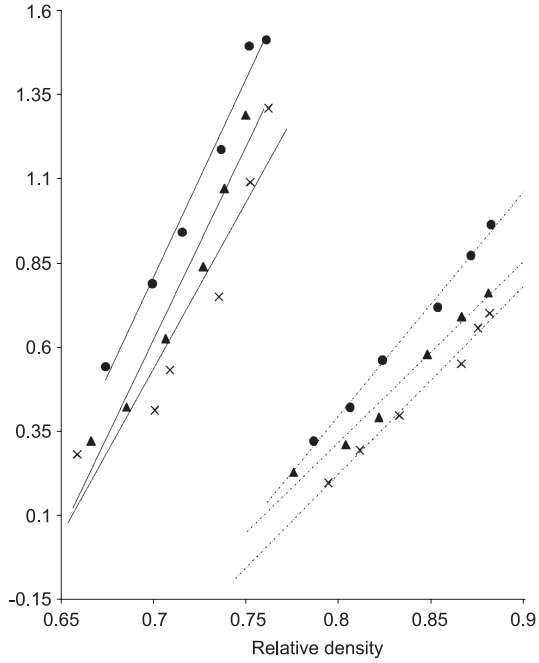

Figure 1. Plot of Log tensile strength versus relative density for paracetamol tablets containing 2 % w/w of DRSG (●), TRG (▲) or ACG (×). Tablets without a hole (_____), tablets with a hole (- - -).

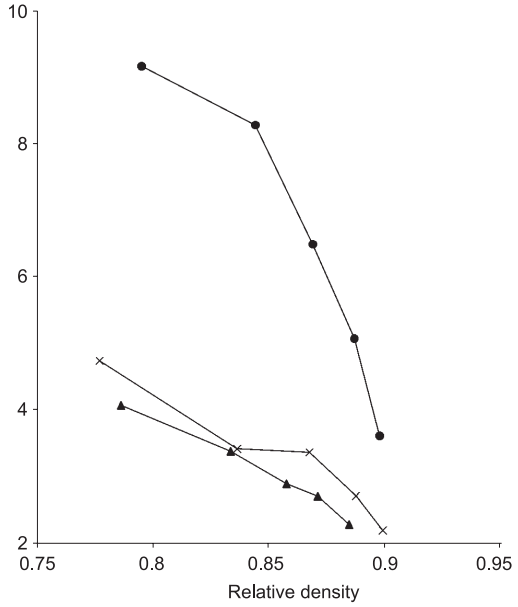

Figure 3. Effect of relative density on friability of paracetamol tablets containing 2% w/w of *Delonix regia* seed gum (-●-), acacia gum (-×-), and tragacanth gum (-▲-).

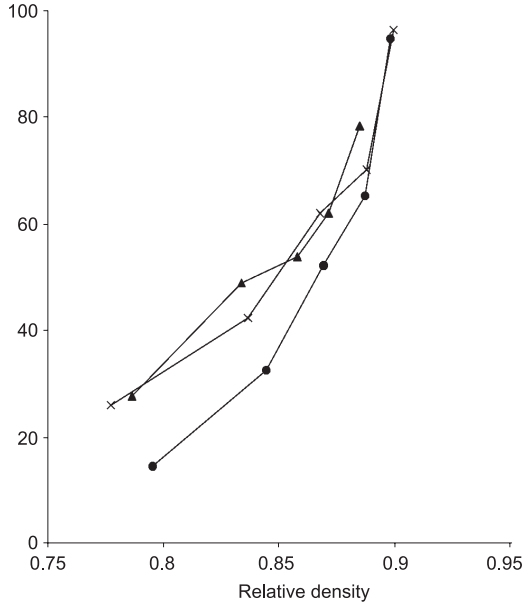

Figure 2**.** Effect of relative density on crushing strength of paracetamol tablets containing 2% w/w of *Delonix regia* seed gum (-●-), acacia gum (-×-), and tragacanth gum (-▲-).

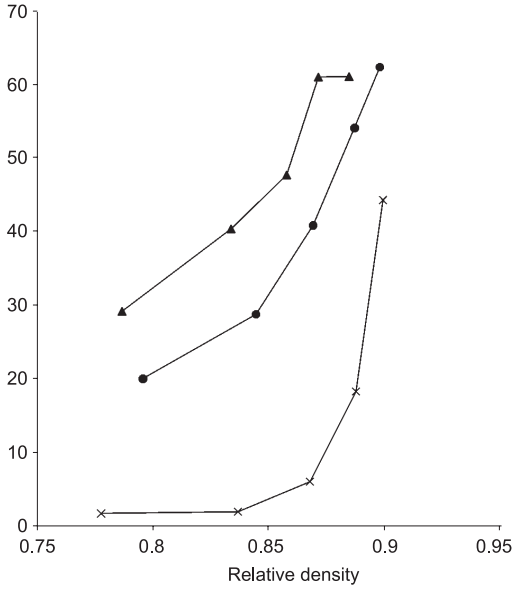

Figure 4. Effect of relative density on disintegration time of paracetamol tablets containing 2% w/w of *Delonix regia* seed gum (-●-), acacia gum (-×-), and tragacanth gum (-▲-).

Table 1. Swelling index values of the gums

Delonix regia seed gum	Tragacanth gum	Acacia gum
17.840 ± 0.601	13.630 ± 0.687	Soluble

the mean ± SEM, n = 3

Table 2. Tensile strength and brittle fracture index for paracetamol tablet formulations containing different concentration of ACG, TRG, or DRSG at 0.90 relative density

Gum Binder	Conc. (% $^{w}/_{w}$)	T (MNm^{-2})*	T_0 (MNm^{-2})*	*BFI*
Control	0.0	0.792 ± 0.087	0.285 ± 0.034	0.891
ACG	1.0	1.748 ± 0.133	0.854 ± 0.060	0.524
	2.0	2.148 ± 0.075	1.106 ± 0.090	0.471
	3.0	2.788 ± 0.079	1.534 ± 0.066	0.408
	4.0	3.050 ± 0.034	1.990 ± 0.003	0.267
	5.0	3.110 ± 0.100	2.204 ± 0.137	0.206
TRG	1.0	1.964 ± 0.059	0.874 ± 0.068	0.623
	2.0	2.686 ± 0.040	1.208 ± 0.035	0.612
	3.0	2.968 ± 0.062	1.637 ± 0.006	0.407
	4.0	3.063 ± 0.207	1.940 ± 0.065	0.289
	5.0	3.403 ± 0.181	2.302 ± 0.064	0.239
DRSG	1.0	1.459 ± 0.074	0.681 ± 0.035	0.571
	2.0	2.890 ± 0.157	1.464 ± 0.108	0.487
	3.0	3.071 ± 0.079	1.791 ± 0.006	0.357
	4.0	3.239 ± 0.070	2.121 ± 0.001	0.263
	5.0	3.330 ± 0.191	2.292 ± 0.001	0.226

*the mean ± SEM, n = 3. T – tensile strength of tablets without a hole. T_0 – tensile strength of tablets with a hole. *BFI* – brittle fracture index.

Statistical analysis

Statistical analysis was done to compare the effects of *Delonix regia* seed gum and those of the official gums (acacia and tragacanth) employed as standards in this study using the *t*-test. At 95% confidence interval, the p value lower than or equal to 0.05 was considered the limit of significance.

RESULTS AND DISCUSSION

The results of the tensile strength tests on the paracetamol tablets were found to fit the general equation:

$$\text{Log } T \text{ (or } T_0) = AD + B \qquad \text{Eq. 4.}$$

with a correlation coefficient = 0.956. A and B are the constants that depend on the type and concentration of the gum binder present in the formulation and on whether the tablet has a hole in it or not, and D is the relative density of the tablets. Representative plots for tablets made from formulations containing 2% w/w of the binder are presented in Fig. 1.

The tensile strength of a tablet with a hole was less than that of the same tablet without a hole at all the relative densities considered, the hole acting as a stress concentrator (3). The plot the effect of gum binder type on the T shows that tablets prepared with DRSG had higher T than those containing TRG or ACG in that order. This observation is in agreement with previous reports (2, 4, 9), and could be due to the fact that the inclusion of DRSG in a tablet formulation would produce a higher amount of total plastic deformation during compression as shown in an earlier report (6), this in effect would result into the formation of stronger tablets.

The tensile strength values of tablets without a hole (T) and tablets with a hole (T_0) for paracetamol formulations at a relative density of 0.90 which is representative of commercial tablets containing different concentrations of the gum binder (ACG, TRG or DRSG) are presented in Table 2. The values of T (T_0) are seen to generally increase with an increase in binder concentration. It has been established that the presence of high concentration of plasto-elastic binding agent leads to an increase in plastic defor-

Table 3. Effect of gum binder on the crushing strength, disintegration time (DT), friability and crushing strength – friability/disintegration time ratio (CSFR/DT) of paracetamol tablets at 0.90 relative density

Gum	Conc. (% w/w)	Crushing strength (N)*	Friability (%)*	DT (min)*	CSFR/DT
Control	0.0	39.028 ± 0.749	7.666 ± 0.139	0.524 ± 0.045	9.716
ACG	1.0	67.948 ± 1.021	4.302 ± 0.006	1.463 ± 0.406	10.798
	2.0	83.539 ± 0.567	2.404 ± 0.006	27.063 ± 2.950	1.284
	3.0	83.954 ± 0.566	1.856 ± 0.007	33.730 ± 2.090	1.341
	4.0	87.759 ± 0.283	1.483 ± 0.008	45.815 ± 10.535	1.292
	5.0	90.430 ± 0.749	1.435 ± 0.005	47.287 ± 12.454	1.333
TRG	1.0	72.771 ± 0.491	2.717 ± 0.006	8.978 ± 3.659	2.984
	2.0	79.080 ± 0.283	2.128 ± 0.005	66.247 ± 7.291	0.561
	3.0	89.399 ± 0.491	1.859 ± 0.009	83.308 ± 4.147	0.577
	4.0	111.362 ± 1.723	1.260 ± 0.002	96.305 ± 4.821	0.918
	5.0	128.192 ± 1.499	1.146 ± 0.004	98.678 ± 9.560	1.134
DRSG	1.0	70.028 ± 0.567	3.937 ± 0.013	1.031 ± 0.021	17.263
	2.0	81.298 ± 1.234	4.350 ± 0.004	58.229 ± 1.983	0.321
	3.0	96.436 ± 0.566	2.455 ± 0.007	84.552 ± 0.986	0.465
	4.0	107.449 ± 0.566	1.531 ± 0.004	90.896 ± 1.319	0.772
	5.0	116.146 ± 1.499	1.458 ± 0.003	97.029 ± 5.084	0.821

* the mean ± SEM, $n = 3$.

mation of the formulation and consequently to the formation of more solid bonds with an increase in tablet strength and resistance to fracture (2, 9). Many reasons have been adduced to this effect such as the melting of the asperities and of the binding agents due to the generation of heat during compression. These asperities would solidify on cooling to form strong solid bonds between the particles. The degree of bonding would therefore depend on the amount of the binding agent present (10). Also, being soft and plasto-elastic, binders undergo plastic and elastic deformation under high compression pressure and are forced into the interparticulate spaces. This increases the area of contact between particles due to further densification and formation of more solid bonds (4, 11).

The *BFI* values at a relative density of 0.90 (Table 1) indicate that as the concentration of binder increases, the *BFI* values decrease. This implies that with the increase in concentration of gum binder, there is an increased reduction in the propensity to cap or laminate by the tablets. This could be due to the presence of binder at interparticulate junctions which would facilitate plastic deformation for the relief of localized stresses (4, 11).

The crushing strength values for paracetamol tablets containing different concentrations of gum binder (ACG, TRG or DRSG) at a relative density of 0.90 is presented in Table 3. The result shows a general increase in the crushing strength value as the concentration of the gum binder in the tablet increases. This could be due to the fact that there exists more particle – particle contact points, particularly with the particles of the gum, which help to create more solid bonds hence, higher crushing strength values were obtained. It was also observed that as the relative density increased, the crushing strength of the tablets increased (Fig. 2). This could be due to the decrease in intra-granular and inter-granular voids (porosity) and a subsequent increase in the number of contact points, which would lead to an increase in the degree of bonding between the particles (11, 12). It is well known that friability tends to decrease with an increase in the crushing strength and relative density of tablets, as shown in Table 3 and Fig. 3, and could be due to the reasons for an increase in crushing strength.

The effect of the concentration of gum binder (ACG, TRG or DRSG) on the disintegration time (*DT*) of the tablet is shown in Table 3 for relative density of 0.90. An increase in concentration led to an increase in the disintegration time. Also, increasing the relative density of the tablets led to an increase in the disintegration time (Fig. 4). Similar observations have already been reported (5). The increase in *DT* with increasing gum binder concentration could be due to the formation of a thick film of gum mucilage as the tablet comes into contact with the disintegrating fluid. This film would be converted into a mucilaginous viscous barrier. Also,

the decrease in porosity as the relative density of the tablet increases due to the promotion of interparticulate bond by the gum binder, coupled with the mucilaginous barrier formed by the swelling gum could slowdown water penetration by capillary flow of the disintegrating fluid into the tablets. Consequently, swelling and development of the active mechanism of disintegration would be reduced (12, 13).

Generally, except for tablets containing the gum binder (ACG, TRG or DRSG) at a concentration of 1 % w/w, other tablets containing 2 % w/w and higher concentrations of the gum gave disintegration times that were higher than the official limit of less than 15 min. for uncoated tablets. The observed sharp increases in the disintegration time of the tablet as the concentration of the gum binder increased from 1% w/w is a result of an increase in bond formation with an increase in binder concentration (10). The high *DT* values recorded at the higher gum binder concentrations and the swelling capacity result (Table 1) suggest the probable usefulness of DRSG in the formulation of a sustained/modified release tablet dosage form.

The *CSFR*/*DT* increased with an increase in gum concentration (Table 3) except for those tablets containing tragacanth for which no trend was observed. However, tablets containing 1% w/w of the gum – binder (ACG, TRG or DRSG) had the highest *CSFR*/*DT* value. The rank order of *CSFR*/*DT* values for the tablets containing 1% w/w was: tablets containing DRSG > tablets containing ACG > tablets containing TRG, thus implying that DRSG will improve the balance between binding and disintegration of the tablets more than those of ACG and TRG. The low *DT* and high *CSFR*/*DT* values obtained at 1% w/w concentration of the gum binder could be due to the high concentration of the diluent, lactose, whose concentration in the formulation decreases as the concentration of gum binder increases. Lactose is soluble in water, its presence in the tablet formulation would facilitate water permeation into tablet capillaries as it gets dissolved in the medium and therefore, promoting faster disintegration by annihilation of the hydrogen bonding existing between particles (10).

CONCLUSION

The results obtained in this work indicate that the use of DRSG in paracetamol tablet formulation would serve the purpose of a binder because the results of the mechanical property compares favorably well with those of tablets containing ACG or DRSG. The study also shows that the use of the gums (acacia, tragacanth or DRSG) at a lower concentration of 1% w/w gave better quality tablets in terms of the balance between the binding and disintegration properties of the tablets as shown by the *CSFR*/*DT* values obtained. Finally, the result obtained from this study suggests that DRSG would serve as a suitable alternative binder to the two official gums used as standard.

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Received: 16. 12. 2008