EVALUATION OF BUCHANANIA COCHINCHINESIS GUM AS A BINDER IN FORMULATION DEVELOPMENT OF PARACETAMOL TABLETS

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ABSTRACT

Objective: An attempt was made to investigate the binding efficacy of Chirauli nut tree gum in tablet formulation in comparison with standard binders such as acacia and polyvinyl pyrrolidone (PVP K-30).

Methods: The paracetamol granules were prepared with different concentration of the gum as a binder by wet granulation method. The granules were evaluated and found to be satisfactory for preparing compressed tablets. The tablets were prepared by compression machine and evaluated for volume of tablet, apparent density, porosity, packing fraction, percentage elastic recovery, tablet physical stability, content uniformity, weight variation, hardness, friability, disintegration time, in vitro dissolution studies. Effect of diluents (Microcrystalline cellulose pH 101, Di-calcium Phosphate) and disintegrants (Croscarmellose sodium, Sodium Starch Glycolate and Crospovidone) of gum were also studied using optimized concentration of gum.

Results: Formulations containing the minimum concentration of 2.5% of gum as a binder showed good physico-chemical properties and dissolution profile.

Conclusions: formulation development of paracetamol tablets using diluents and disintegrants like lactose (Pharmatose 200M), dicalcium phosphate and sodium starch glycolate, croscarmellose sodium can be used respectively, using 2.5% optimized concentration of chirauli nut tree gum

Keywords: Buchanania Cochinchinesis; Chirauli Gum; Binding efficacy; Paracetamol

INTRODUCTION

Binders are agents used to impart cohesive qualities to the powdered material during the production of tablets. They impart cohesiveness to the tablet formulation, which ensures that the tablet remain intact after compression as well as improving the free-flowing quality. Binders have been used as solutions and in dry form depending on the other ingredients in the formulations and method of preparation. The choice of a particular binding agent depends on the binding force required to form granules and its compatibility with the other ingredients, particularly active drug [1]. A number of binding agents are available for tablet formulations. However, different binding agents can be useful in achieving various tablets mechanical strength and drug release properties for different pharmaceutical purposes. Thus, the development of new excipients for potential use as binders continues to be of interest, and a number of plant gums have been used as binding agents in tablet formulation. They have been found useful in producing tablets with different mechanical strength and drug release properties for different pharmaceutical purposes. The fact that these gums are non-toxic and widely available has made them of continuing interest [2-12].

Chirauli nut tree gum is obtained from the incised trunk of the tree Buchanania cochinchinesis (Family: Anacardeaceae). This study investigated the efficacy of Chirauli nut tree gum as a binding agent for paracetamol tablets to determine their physical properties, mechanical strength and release profiles. Here, acacia and polyvinyl pyrrolidone (PVP K-30) was used as standard binders. Effect of diluents (Microcrystalline cellulose pH101, Di-calcium Phosphate) and disintegrants (Croscarmellose sodium, Sodium Starch Glycolate and Crospovidone) were also studied using optimized concentration of Chirauli nut tree gum as a binder. Paracetamol, a drug with known capping and lamination problems that normally require a binder and disintegrant to form satisfactory tablets, was used as the model substrate.

MATERIALS AND METHODS

Materials

Crude Chirauli nut tree gum was collected from various places of Maharashtra (India). Paracetamol was obtained from Tablets India Ltd, (Chennai, India). Cornstarch, acacia were supplied by SD Fine Chemicals (Chennai, India). Lactose (Pharmatose 200M) was supplied by DMV-Fonterra Excipient GmbH & Co., Germany. Microcrystalline cellulose pH 101, Di-calcium Phosphate, Croscarmellose sodium, Sodium Starch Glycolate were supplied by Signet Chemicals (Mumbai, India). Polyvinyl pyrrolidone (PVP K-30), Crospovidone (Polyplasdone XL) was supplied by BASF Chemical Company, Germany. All chemicals used in the study were of analytical grade.

Methods

Isolation of water-soluble fraction of Chirauli nut tree gum

The collected crude Chirauli nut tree gum (100g) was ground by using mortar and pestle. The ground gum was dissolved in water (300 ml). The solution was filtered through several folds of muslin cloth, and the filtrate was collected. The filtrate was centrifuged at 3000 rpm for 10 minutes and the supernatant fluid was collected and remaining insoluble portion was separated. The supernatant fluid was collected, evaporated and dried to obtain the solid mass, which was ground. This mass was passed through sieve no. 80 and stored in an airtight container for further studies.

Characterization of gum

The gum was characterized for surface analysis, pH, surface tension and viscosity. The surface analysis was determined by scanning electron microscope (SEM, Hitachi S-2400, Japan). The gum was evaporated with carbon and then sputtered with gold to make the sample electrically connected. Carbon was layered to a thickness of approximately 10nm and gold was layered to approximately 25nm. The pH of the gum solution (1%w/v solution) was determined using digital pH meter (pH system 361, Systronics, Mumbai). The surface tension of the gum solution (1%w/v solution) was determined by drop count method, using stalagmometer. The viscosity of the gum (1%w/v) was determined using RVDV II+ viscometer (Brookfield Engineering India, Mumbai). Prior to the study, the sample was filled in the sample adapter and allowed to stand for 24h undisturbed for complete relaxation of the sample [13]. Viscosity was determined using spindle 62, at 50 rpm using a constant temperature bath maintained at 20°C.
The difference was calculated by mass/volume of tablet. Tablet weight and dimensions were taken. The relative density or packing fraction (Pf) was calculated using weight of tablet/volume of tablet × density of granules [17]. Percent porosity was calculated according to the following formula:

\[
\text{Percent porosity} = \left( \frac{V_b - V_t}{V_b} \right) \times 100
\]

where, \(V_b\) is the apparent tablet volume calculated from tablet dimensions, and \(V_t\) is the true volume calculated from the true density of the material. The difference \(V_b - V_t\) represents the void volume. The percentage elastic recovery was assessed using equation:

\[
\text{ER} = \left( \frac{h_c - h}{h_c} \right) \times 100
\]

where, \(h\) is the thickness of tablet after 24 h and \(h_t\) is the thickness of tablet after ejection. Tablet physical stability of tablet was calculated by using hardness/disintegration × friability ratio [17]. The hardness of the tablets was determined using a Monsanto hardness tester (Cadmach, Ahmedabad, India). The percentage of friability of the tablets was determined using Roche tablet friabilator (Indian Equipment Corporation, Mumbai, India) operated at 25 rpm for 4 min [19]. Disintegration time was determined in distilled water at 37±0.5°C using the disintegration apparatus (Veejo Equipments, Mumbai, India). The rate of dissolution of paracetamol from the tablets was studied in a rotary paddle USP (XXIII) apparatus II (Lab India DS 8000, Mumbai, India) operated at 50 rpm. The dissolution medium was the 900ml phosphate buffer at pH 5.8 at 37±0.5°C. At specified time intervals, 5ml samples were withdrawn and immediately replaced with 5ml samples of fresh buffer solution maintained at the same temperature. The amount of paracetamol in each sample was analyzed spectrophotometrically with UV/visible spectrophotometer (Cyberlab UV-100, USA) at 284nm. All parameters were made in triplicate.

### Table 1: Formulation of different batches of paracetamol tablets

<table>
<thead>
<tr>
<th>Batch Code</th>
<th>F1*</th>
<th>F2*</th>
<th>F3*</th>
<th>F4*</th>
<th>F5*</th>
<th>F6*</th>
<th>F7*</th>
<th>F8*</th>
<th>F9*</th>
<th>F10*</th>
<th>F11*</th>
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<td>Drug</td>
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<td>100</td>
<td>100</td>
<td>100</td>
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<td>100</td>
<td>100</td>
<td>100</td>
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<td>100</td>
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<tr>
<td>Chirauli Gum</td>
<td>5</td>
<td>10</td>
<td>15</td>
<td>15</td>
<td>-</td>
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<tr>
<td>PVP K-30</td>
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<td>-</td>
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<td>5</td>
<td>5</td>
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<td>Crosscarmellose Sodium</td>
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<td>Polypasdone XL</td>
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<td>73</td>
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<tr>
<td>Dicalcium Phosphate</td>
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<tr>
<td>Titration</td>
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<td>2</td>
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<td>2</td>
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<td>2</td>
<td>2</td>
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<tr>
<td>Total (mg/tablet)</td>
<td>200</td>
<td>200</td>
<td>200</td>
<td>200</td>
<td>200</td>
<td>200</td>
<td>200</td>
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<td>200</td>
</tr>
</tbody>
</table>

*Formulation batches F1, F2, F3, F4 contains Chirauli nut tree gum with 2.5%, 5%, 7.5%, 10% binder respectively.

*Formulation batch F5 contain PVP K-30 with 2.5% binder.

*Formulation batch F6 contain Acacia with 2.5% binder.

*Formulation batch F7 contain Chirauli gum with 2.5% binder and Microcrystalline Cellulose (MCC PH 101) as diluent.

*Formulation batch F8 contain Chirauli gum with 2.5% binder and Dicalcium Phosphate as diluent.

*Formulation batch F9 contain Chirauli gum with 2.5% binder and Sodium Starch Glycolate as disintegrant.

*Formulation batch F10 contain Chirauli gum with 2.5% binder and Crosscarmellose Sodium as disintegrant.

*Formulation batch F11 contain Chirauli gum with 2.5% binder and Polypasdone XL as disintegrant.

### Preparation and evaluation of granules

The different batches F1 to F6 (100g) of paracetamol granules were prepared using different concentration of gum, acacia, and PVP K-30 by wet granulation technique using the formula as shown in table 1. Here, acacia and PVP K-30 were used as standard binders for comparison. The desired quantities of paracetamol, lactose and cornstarch were dry mixed for 5 min using mortar and pestle, then moistened with the appropriate amount of binder solution, which was prepared with different concentration of gum and with the selected standard binders massed separately with the sufficient amount of water. Massing was continued for 5 min and the wet mass was granulated by passing it manually through a mesh 16/22 sieve and dried in a hot air oven at 50°C. Dried granules were sieved through a mesh 16/22 sieve and granules were collected, which were passed through 22 sieve for further studies. The granules were evaluated for bulk density, tap density, true density, apparent density, particle size distribution, porosity, Carr’s index, Hausner ratio. The bulk density of the sample was calculated by Mass of powder / bulk volume of powder. A given quantity of the sample was transferred to a measuring cylinder and was tapped mechanically, using a bulk density apparatus (Electrolab, Mumbai, India) until a constant volume was obtained, which was referred as bulk volume (Vb). True density of the sample was determined by using the liquid displacement method, and xylene was used as the liquid for displacement. The particle size distribution was determined by sieve analysis[14]. The percentage porosity of the granules was calculated by (bulk density−true density/bulk density) × 100. Carr’s index was calculated by initial volume-tapped volume/tapped volume) × 100 [15]. The Hausner ratio was determined by bulk tapped density/bulk loose density [16]. All experiments were made in triplicate.

### Evaluation of binding efficacy of gum

Tablets (200 mg) were prepared from the prepared granules by compressing those using 8 mm flat faced punch tooling on a rotary tablet compression machine (Shakti press, Ahmadabad, India). After ejection, the tablets were stored over the silica gel for 24 h to allow for hardening and elastic recovery. The prepared tablets were evaluated for volume of tablet, apparent density, porosity, packing fraction or relative density, percentage elastic recovery, tablet physical stability, content uniformity, weight variation, hardness, friability, disintegration time, in vitro dissolution studies. Apparent density was calculated by mass/volume of tablet. Tablet weight and dimensions were taken. The relative density or packing fraction (Pf) was calculated using weight of tablet/volume of tablet × density of granules [17]. Percent porosity was calculated according to the following formula:

\[
\text{Percent porosity} = \left( \frac{V_b - V_t}{V_b} \right) \times 100
\]

where, \(V_b\) is the apparent tablet volume calculated from tablet dimensions, and \(V_t\) is the true volume calculated from the true density of the material. The difference \(V_b - V_t\) represents the void volume. The percentage elastic recovery was assessed using equation:

\[
\text{ER} = \left( \frac{h_c - h}{h_c} \right) \times 100
\]

where, \(h\) is the thickness of tablet after 24 h and \(h_t\) is the thickness of tablet after ejection. Tablet physical stability of tablet was calculated by using hardness/disintegration × friability ratio [17]. The hardness of the tablets was determined using a Monsanto hardness tester (Cadmach, Ahmedabad, India). The percentage of friability, disintegration, content uniformity and dissolution were performed by following the official method given in USP [18]. The percentage of friability of the tablets was determined using Roche tablet friabilator (Indian Equipment Corporation, Mumbai, India) operated at 25 rpm for 4 min [19]. Disintegration time was determined in distilled water at 37±0.5°C using the disintegration apparatus (Veejo Equipments, Mumbai, India). The rate of dissolution of paracetamol from the tablets was studied in a rotary paddle USP (XXIII) apparatus II (Lab India DS 8000, Mumbai, India) operated at 50 rpm. The dissolution medium was the 900ml phosphate buffer at pH 5.8 at 37±0.5°C. At specified time intervals, 5ml samples were withdrawn and immediately replaced with 5ml samples of fresh buffer solution maintained at the same temperature. The amount of paracetamol in each sample was analyzed spectrophotometrically with UV/visible spectrophotometer (Cyberlab UV-100, USA) at 284nm. All parameters were made in triplicate.

### Effect of diluents using optimized concentration of gum

The two batches F7 and F8 (100g) of paracetamol granules were prepared using optimized concentration of gum, microcrystalline cellulose (MCC PH 101) and dicalcium phosphate by wet granulation technique using the formula as shown in table 1.
microcrystalline cellulose (MCC PH 101) and dicalcium phosphates were used as diluents. Granules were prepared and evaluated. Tablets (200 mg) were prepared from the prepared granules by compressing those using 8 mm flat faced punch tooling on a rotary tablet compression machine (Shakti press, Ahmadabad, India) and evaluated. Effect of disintegrants using optimized concentration of gum as a binder on in-vitro drug release was evaluated.

Effect of disintegrants using optimized concentration of gum

The three batches F9 and F11 (100g) of paracetamol granules were prepared using optimized concentration of gum, sodium starch glycolate, croscarmellose sodium and Polyplasdone XL by wet granulation technique using the formula as shown in table 1. Here, sodium starch glycolate, croscarmellose sodium and polyplasdone XL were used as disintegrants. Granules were prepared and evaluated. Tablets (200 mg) were prepared from the prepared granules by compressing those using 8 mm flat faced punch tooling on a rotary tablet compression machine (Shakti press, Ahmadabad, India) and evaluated. Effect of disintegrants using optimized concentration of gum as a binder on in-vitro drug release was evaluated.

RESULTS

The gum was purified using water as solvent. The yield was 82 % w/w. Water-soluble portion was separated from purified gum. The water soluble gum was characterized for surface characters by SEM, pH, viscosity, surface tension to assess the gum as an excipient (binder) for developing paracetamol tablets. The scanning electron microscopy microphotograph showed that the gum was smooth and crystalline in nature as shown in figure 1.

Fig. 1: Microphotograph depicting SEM Chirauli nut tree gum at X3000 magnification

The pH of the gum solution (1%w/v) was 7.8. Viscosity and surface tension of the gum was 5.2 Ns/m² and 32.5 dyne/cm respectively. The water-soluble gum was used as a binder for developing paracetamol oral uncoated solid dosage form. The eleven batches F1 to F11, each batch of 100g of granules was prepared to use the formula as shown in the Table 1 by wet granulation method. The results for granule’s evaluation are shown in table 2.

Table 2: Evaluation of paracetamol granules

<table>
<thead>
<tr>
<th>Batch</th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
<th>F4</th>
<th>F5</th>
<th>F6</th>
<th>F7</th>
<th>F8</th>
<th>F9</th>
<th>F10</th>
<th>F11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Untapped Bulk Density (g/ml)</td>
<td>0.52±0.000</td>
<td>0.487±0.000</td>
<td>0.488±0.000</td>
<td>0.501±0.001</td>
<td>0.476±0.000</td>
<td>0.426±0.000</td>
<td>0.400±0.000</td>
<td>0.385±0.000</td>
<td>0.416±0.000</td>
<td>0.444±0.000</td>
<td>0.435±0.000</td>
</tr>
<tr>
<td>Tapped Bulk density (g/ml)</td>
<td>0.534±0.000</td>
<td>0.588±0.000</td>
<td>0.572±0.000</td>
<td>0.626±0.001</td>
<td>0.555±0.000</td>
<td>0.521±0.000</td>
<td>0.455±0.000</td>
<td>0.555±0.000</td>
<td>0.526±0.000</td>
<td>0.555±0.000</td>
<td>0.666±0.000</td>
</tr>
<tr>
<td>True density (g/ml)</td>
<td>0.468±0.002</td>
<td>0.439±0.001</td>
<td>0.389±0.000</td>
<td>0.362±0.000</td>
<td>0.477±0.000</td>
<td>0.484±0.000</td>
<td>0.356±0.001</td>
<td>0.525±0.001</td>
<td>0.424±0.001</td>
<td>0.389±0.000</td>
<td>0.499±0.000</td>
</tr>
<tr>
<td>Porosity (%)</td>
<td>12.359±0.002</td>
<td>25.349±0.013</td>
<td>31.967±0.038</td>
<td>42.178±0.004</td>
<td>14.054±0.004</td>
<td>7.106±0.004</td>
<td>21.753±0.004</td>
<td>5.405±0.005</td>
<td>19.392±0.003</td>
<td>29.913±0.003</td>
<td>25.078±0.003</td>
</tr>
<tr>
<td>Particle size distribution (mm)</td>
<td>0.459±0.000</td>
<td>0.479±0.000</td>
<td>0.440±0.000</td>
<td>0.450±0.000</td>
<td>0.426±0.000</td>
<td>0.522±0.000</td>
<td>0.446±0.000</td>
<td>0.489±0.000</td>
<td>0.478±0.000</td>
<td>0.439±0.000</td>
<td>0.454±0.001</td>
</tr>
<tr>
<td>Hausner Ratio</td>
<td>1.015±0.001</td>
<td>1.207±0.002</td>
<td>1.171±0.000</td>
<td>1.251±0.002</td>
<td>1.166±0.001</td>
<td>1.224±0.001</td>
<td>1.137±0.001</td>
<td>1.444±0.001</td>
<td>1.264±0.001</td>
<td>1.250±0.000</td>
<td>1.533±0.000</td>
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<tr>
<td>Carr’s index (%)</td>
<td>15.184±0.085</td>
<td>17.178±0.129</td>
<td>14.598±0.025</td>
<td>20.083±0.133</td>
<td>14.260±0.058</td>
<td>18.273±0.069</td>
<td>12.031±0.041</td>
<td>30.736±0.055</td>
<td>20.863±0.040</td>
<td>20.031±0.060</td>
<td>34.789±0.005</td>
</tr>
</tbody>
</table>

All values are expressed as mean ± SEM (n=3)

Particle size distribution of granules was within size range of 0.426-0.522 mm. The average particle size of granules was 0.462 mm. According to literature data, excellent flow properties had seen for granules with a Carr’s index between 5 to 15 % and a Hausner ratio below 1.25 [19]. All the formulations had a Carr’s index between 12.031 to 20.863 % except F8 and F11. Carr’s index of batches F8 and F11 were 30.736 and 34.789 respectively. Hausner ratios were between 1.015-1.264 except F8 and F11. Hausner ratio of batches F8 and F11 were 1.444 and 1.533, which indicated poor flow of granules.
Volume of tablet results showed better consolidation of granules producing more cohesive tablet compact. Apparent densities of tablet were similar except F2, F8, F9 and F11. Percentage porosity of tablets was in between 78.396-87.031. Formulations containing chirauli nut tree gum (F1) showed similar values as that of formulations containing PVP K-30 (F5) and acacia (F6). This indicates that formulations containing gum 2.5% of gum exhibited a similar degree of packing in the die because of better die filling. Packing fractions of all the formulations were in between 2.402-3.274. Percentage elastic recoveries of tablets were between 1.161-1.826, which indicates best binding efficacy resulting in best compressibility and tabletability. Hardness/disintegration x friability ratio has been identified as a better index of tablet quality than has the traditional hardness-friability ratio. This index not only assesses the tablet strength (i.e. hardness) and weakness (i.e. friability), but it simultaneously evaluates any negative effects of these parameters on disintegration. The content uniformity and weight variation of all batches F1 to F11 of tablets was within the specified USP limits. The hardness of the tablets was increased with an increase in percentage of gum. The friability values decreased with an increase in percentage of gum. However, overall friability values were less than the specified limits of USP. Friability is especially important because the tablet subjected to various abrasive motions during production and subsequent use. Increasing the concentration of plastoelastic binding agents leads to increase in plastic deformation of formulation during compression and consequently, to the formation of more solid bonds in the resulting tablets to provide more resistant to tablet fracture and abrasion [20]. This suggests that at 2.5% concentration gum should be able to provide adequate protection for the tablets against abrasive motions during handling. Disintegration time was increased with an increase in concentration of binder. The disintegration time was delayed, which might be reasoned that the gum facilitated extensive plastic deformation, which would lead to an increase in the area of contact between particles, reducing the rate of fluid penetration into interstitial void spaces. This results in the swelling of the disintegrants and disruption of the tablet reduced, which prolonged disintegration [20]. Rank-order effect of disintegrants on disintegration time was sodium starch glycolate>croscarmellose sodium>crospovidone(Polyplasdone XL)>corn starch. This suggests that sodium starch glycolate and croscarmellose sodium can be used as disintegrants using 2.5% of gum as a binder. The figure 2 shows comparative in-vitro dissolution profiles of batches F1, F2, F3, F4 to see the effect of binder concentration on in-vitro drug release. As the binder concentration was increased in-vitro drug release was decreased. This was because of a sticky film of hydration on the surface, which might have reduced the diffusion of the drug.

![Fig. 2: Comparative In-vitro Dissolution profile of batch F1-2.5% Chirauli gum, F2-5% Chirauli gum, F3-7.5% Chirauli gum, F4-10% Chirauli gum as binder. In-vitro study was performed in phosphate buffer of pH 5.8 using USP (XXIII) apparatus II.](image1)

The figure 3 shows comparative in-vitro dissolution profiles of tablets containing 2.5% of gum(F1),PVP K-30(F5),acacia(F6).Tablets with gum as a binder produced comparable dissolution profiles with PVP K-30 and acacia.

![Fig. 3: Comparative In-vitro Dissolution profile of batch F1-2.5% Chirauli gum, F5-2.5%Polyvinyl Pyrrolidone (PVP K-30), F6-2.5%Acacia as binder. In-vitro study was performed in phosphate buffer of pH 5.8 using USP (XXIII) apparatus II at 50 RPM.](image2)
Figure 4 shows comparative in-vitro dissolution profiles of tablets containing lactose (Pharmatose 200M) F1, microcrystalline cellulose (MCC PH101) F7, dicalcium phosphate F8 as diluents. Dissolution profiles of batches F1 and F8 were comparable. Microcrystalline cellulose (MCC PH101) showed the slightly higher drug release initially but was comparable later. Insoluble, non-hydrating dicalcium phosphate provides a slow-release profile. Lactose (Pharmatose 200M) had shown intermediate release behavior. Microcrystalline cellulose (MCC PH101), which is hydrophilic and swellable but insoluble, displayed the fastest release profile.

![Figure 4: Comparative In-vitro Dissolution profile of batch F1, F7, F8 containing Lactose (Pharmatose 200M), Microcrystalline Cellulose (MCC PH101) and Di-calcium Phosphate as diluents. In-vitro study was performed in phosphate buffer of pH 5.8 using USP (XXIII) apparatus II at 50 RPM.]

Figure 5 shows comparative in-vitro dissolution profiles of tablets containing corn starch (F1), sodium starch glycolate (F9), croscarmellose sodium (F10), crospovidone Polyplasdone XL (F11) as disintegrants.

![Figure 5: Comparative In-vitro Dissolution profile of batch F1, F9, F10, F11 containing Corn Starch, Sodium Starch Glycolate, Croscarmellose Sodium and Polyplasdone XL as disintegrants respectively. In-vitro study was performed in phosphate buffer of pH 5.8 using USP (XXIII) apparatus II at 50 RPM.]

Dissolution profiles of F9 and F10 batches were higher than that of F1 and F11. This may be due to super disintegrating property of sodium starch glycolate and croscarmellose sodium. It was evidenced from the in-vitro percent dissolution at 30 minutes as shown in table 3.

<table>
<thead>
<tr>
<th>Table 3: Physical qualities and in vitro availability parameters of paracetamol tablets</th>
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<tr>
<td>Batch</td>
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<tr>
<td>Volume of tablet</td>
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<td>Apparent density (%)</td>
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<td>Porosity</td>
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<tr>
<td>Packing fraction</td>
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<td>Percenta ge elastic recovery</td>
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<td>Tablet physical stability</td>
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In-vitro study was performed in phosphate buffer of pH 5.8 using USP (XXIII) apparatus II at 50 RPM.
By considering all the granule and tablet evaluation results in 2.5% of gum was selected as an ideal concentration for tablet production to meet all pharmacopeial limits.

**DISCUSSION**

Chirauli nut tree gum exhibits fairly regular, elongated with rugged appearance. The near neutral pH of chirauli nut tree gum implies that when used in uncoated tablets, it may be less irritating to the gastrointestinal tract. It may also find useful application in formulation of acidic, basic, and neutral drugs. Knowledge of the pH of an excipient is an important parameter in determining its suitability in formulations since the stability and physiological activity of most preparations depend on pH [21]. The lower viscosity and surface tension of gum probably enabled better penetration and spreading over paracetamol powder during wet massing, thereby producing more porous granules. The characterized gum was selected as an excipient for preparing tablets to find out the binding efficacy associated with paracetamol. The gum was selected from natural sources as a binder due to its distinguished characters such as low cost, abundant availability, ease of isolation, stickiness, surface tension and viscosity. The binding efficacy of the gum was compared with standard binders such as, acacia and PVP K-30 using different concentrations such as 2.5, 5, 7.5, and 10% w/w. The granules were evaluated for bulk density, tap density, true density, apparent density, particle size distribution, porosity, Carr’s index, Hausner ratio. There was no significant difference in their untapped bulk densities, tapped bulk density and true densities in all the prepared granules. Porosity of granules was increased as the concentration of chirauli gum was increased. Porosity of granules of batches F1 and F5 were comparable; however, batch F6 showed less porosity. Porosity of granules of batches F7, F9, F10 and F11 was more than that F1. Batches F6 and F8 showed less porosity than batch F1. As per values indicated in table 2 granules showed more intimate packing, better die filling during compression, which was further evidenced by Carr’s index and Hausner ratio. Percentage porosity of tablets was decreased as the concentration of gum increased. The values of relative densities or packing fraction, which represents the degree of initial packing in the die as a result of die filling, increased with increased concentrations of the binders. Effect of diluents (Microcrystalline cellulose pH 101, Di-calcium Phosphate) and disintegrants (Crosscarmellose sodium, Sodium Starch Glycolate and Crospovidone(Polyplasdone XL)) were also studied using optimized concentration of Chirauli nut tree gum as a binder. figure 2 showed comparative in-vitro dissolution profiles of batches F1, F2, F3, F4 to see the effect of binder concentration on in-vitro drug release. The rank-order effect of binders on tablet quality values was acacia> gum>PVP-K30 [20]. Figure 4 showed the rank-order effect of diluents on tablet quality values as lactose (Pharmatose 200M)>microcrystalline cellulose (MCC PH101)>di-calcium Phosphate. Lactose and MCC PH101 can be used as diluents using gum as binder. The rank-order effect of disintegrants on tablet quality values was sodium starch glycolate> crosscarmellose sodium > corn starch> crospovidone (polyplasdone XL). This concludes that sodium starch glycolate is better suited as disintegrants. Based on the investigation Chirauli nut tree gum can be used as an excipient (binder) for developing paracetamol tablets.

**CONCLUSION**

The results of the present study show that formulations with the minimum concentration of 2.5% Chirauli nut tree gum as a binding agent show short disintegration and fast dissolution including good physico-mechanical properties. These suggest that formulation development of paracetamol tablets using diluents and disintegrants like lactose (Pharmatose 200M), di-calcium phosphate and sodium starch glycolate, crosscarmellose sodium can be used respectively; using 2.5% optimized concentration of chirauli nut tree gum.

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**REFERENCES**