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Evaluation of *Araucaria heterophylla* Gum as a Binder in Tablet Formulations

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ABSTRACT

Introduction: *The present study was focused on the isolation and purification of natural gum from the bark exudates of Araucaria heterophylla tree. Polysaccharides were isolated by precipitation method and purified. Tablets were formulated by wet granulation technique with various concentrations of the gum using Aceclofenac as a model drug. The formulation blend was subjected to drug excipient compatibility. Three batches of the formulations F1, F2 and F3 were prepared using 5%, 7.5% and 10%, gum concentrations respectively.*

Materials and methods: *Gum was isolated from the bark of Araucaria heterophylla tree and purified. Aceclofenac drug was obtained as a gift sample from Micro labs Pvt Ltd, Hosur. All other chemicals used were obtained from SD fine chemicals Mumbai. 1) Extraction and Purification of the gum 2) Phytochemical and physicochemical investigation of the gum.*

Results and Discussion: *The granules were evaluated for pre-compressional parameters such as bulk density, tapped density, compressibility index, Hauser ratio and angle of repose. The tablets were evaluated for weight variation, hardness, friability, disintegration time and in vitro dissolution studies.*

Conclusion: *As the concentration of the gum increased the disintegration time increased. Also, the dissolution time enhanced as the proportion of the gum was increased indicating the binding efficiency was directly proportional to the concentration of the gum.*

Keywords: Natural binder, *Araucaria heterophylla* gum, Tablet, Aceclofenac, AHG binder.

INTRODUCTION

Industrial demand for pharmaceutical excipients is increasing day by day. Natural gums are always preferred due to local accessibility, eco-friendliest and cost effectiveness [1]. Impetus is being given to natural polymers due to their diverse application in pharmaceutical industry such as diluents, binders, disintegrants, thickeners, suspending agents, gelling agents and semisolid bases [2]. *Araucaria heterophylla* popularly known as Christmas tree is native of pacific countries but spread throughout the world [3]. The gum was isolated from the bark exudates of the tree and purified. Their physiochemical properties were analyzed using suitable methods [4]. Present study deals with the formulation of tablets with the isolated gum and thereby, establishing it as binder.

MATERIALS AND METHODS

Materials

Gum was isolated from the bark of *Araucaria heterophylla* tree and purified. Aceclofenac drug was obtained as a gift sample from Micro labs Pvt Ltd, Hosur. All other chemicals used were obtained from SD fine chemicals Mumbai.

Extraction and Purification of the gum

The bark exudates of the *Araucaria heterophylla* tree were collected, dried and pulverized. The powder was dispersed in demineralized water using an impeller for 4 hours. The impurities were removed by filtration through muslin cloth. The extract was treated with aliquots of acetone to precipitate the gum. The precipitate was separated and dried in a vacuum desiccator at 50ºC for 48 hours. The dried gum was pulverized using a laboratory blender, passed through sieve number 80 and stored in air tight container [5].

Phytochemical and physicochemical investigation of the gum

The dried gum was screened for its phyto constituents like Carbohydrates, Reducing sugars, Mucilage, Polysaccharide, Alkaloids, Glycosides, Tannins, Steroids, Terpinoids, Proteins and Amino acids by subjecting to chemical tests. Physicochemical evaluation such as solubility, melting point by DSC, average particle size, surface morphology SEM, loss on drying, total ash value, pH, Swelling index,viscosity as well as micromeritic characterisation like Angle of repose, Bulk density, Tapped density, Carr's index and Hausner ratio were determined using standard procedures [6].

Drug Excipient compatibility studies

Drug excipient compatibility studies were performed to determine the compatibility of the drug with the gum using FTIR.

Formulation of tablets

Tablets were formulated with aceclofenac as a model drug using *Araucaria heterophylla* gum in concentrations 5%, 7.5% and 10% as a binding agent (Table 1). The tablets were prepared by wet granulation method. The ingredients such as drug, binder and diluents of various batches were blended properly using mortar and pestle and passed through # 40 sieves separately [7]. Then the blends were mixed thoroughly by adding water as granulating agent to get a coherent mass which was screened through #16 sieve to obtain coarse granules, followed by drying of the granules for 1 hour at 40°C. The dried granules were then passed through the #20 sieve.

Table 1: Composition of aceclofenac tablets.

S. No	Ingredients in mg	Formulation code		
		F1	**F2**	**F3**
1.	Drug	100	100	100
2.	Gum	10 (5%)	15 (7.5%)	20 (10%)
3.	Micro Crystalline cellulose	86	81	76
4.	Magnesium stearate	2 (1%)	2 (1%)	2 (1%)
5.	Talc	2 (1%)	2 (1%)	2 (1%)

Evaluation of precompressional characteristics

The dried granules were subjected to precompressional studies such as compressibility index, Hauser ratio and angle of repose [8]. Compressibility Index and Hauser ratio were determined from the values of bulk density and tapped density. Angle of repose was determined by funnel method. The reports were an average of three determinations.

Preparation of tablets

Tablets were prepared by compressing the granules them using 8mm die and flat bottom punches with eight station rotary tablet press (Shakti). After ejection the tablets were stored in a desiccator for 24 hrs to allow for elastic recovery and hardening [9].

Evaluation of the tablets

The prepared tablets were evaluated for various parameters like physical appearance, weight variation, hardness, friability and disintegration time according to the USP 29 requirements. Twenty tablets were weighed and the average weight was calculated, the percentage weight deviation of each tablet from average weight was calculated. The tablets were evaluated for hardness by using Monsanto hardness tester. The values were reported in average of three measurements. Twenty tablets were weighed and placed in a friabilator. After 100 revolutions, the percentage weight loss was determined. The disintegration test was performed in distilled water at 37°C. The disintegration time reported is an average of three determinations [10,11].

***In vitro* dissolution studies**

The dissolution rate of the Aceclofenac tablets was determined according to USP XXIV type I rotating basket (Lab India) apparatus using 900 ml of Phosphate buffer 7.5 as the dissolution medium. The dissolution test was performed at 50 RPM at a temperature of 37 ± 0.5°C. Five-milliliter samples were removed at predetermined time intervals and replaced with equal volumes of fresh dissolution medium at the same temperature. Sampling were done at an interval of 10 min upto 1 hour [12,13]. The absorbance of the samples withdrawn were determined spectrophotometrically (UV Spectrophotometer Shimadzu 1800) at 275 nm, and the concentration of drug in each sample was determined from the Beer–Lambert plot of pure Aceclofenac. The drug release was reported as an average of three determinations.

RESULTS AND DISCUSSION

Araucaria heterophylla gum obtained was pure and found to be white, amorphous, mucilageous and odorless powder with a yield of 67.4% with the characteristics of polysaccharide. The bulk density was 0.53 g/cm^3 indicating its compactness. The swelling index was 13.4% capable of increasing viscosity in aqueous solutions. Total ash value, water soluble ash and acid soluble ash were found to be 2%, 1.24% and 1% respectively. Microbial analysis show the gum was devoid of pathogens (Table 2).

Table 2: Phytochemical characterization.

Chemical properties	Test	Observations
Carbohydrates	Molish Test	+
Reducing Sugars and aldehydes	Fehling's and Benedict's test	+
Mucilage	Ruthenium red	+
Starch	Iodine test	-
Alkaloids	Dragendroff's test	-
Glycosides	Keller killani test	-
Phenols and Tannins	Ferric Chloride test	-
Steroids	Libermann Buchards test	-
Proteins and amino acids	Ninhydrin test	-
Flavanoids	Shinoda test	-
Terpenoids	Acetic anhydride test	-

Table 3: Physicochemical evaluations of the gum.

Physicochemical parameters	Inference
Organoleptic properties	White amorphous mucilageous and odourless
Solubility	Soluble in water
	Insoluble in acetone, ethanol, chloroform, and otherorganic solvents
Loss on drying (%)	3%
Swelling index (%)	13.9%
Bulk density	0.53 g/cm^3
Angle of repose in degrees	57.70º
pH	6.1
Total ash value (%)	2%
Water soluble ash (%)	1.24%

Acid insoluble ash (%)	1%
Viscosity (1% w/v solution)	1.12 cps
Total Microbial (Load) count	
Bacteria: (CFU/g)	Nil
Fungi: CFU/g)	Nil

The FTIR spectrum of the drug, excipient, and mixture showed no appreciable change in the characteristics bands indicating that there was no interaction between the drug and excipient were compared in Figures 1, 2 and 3.

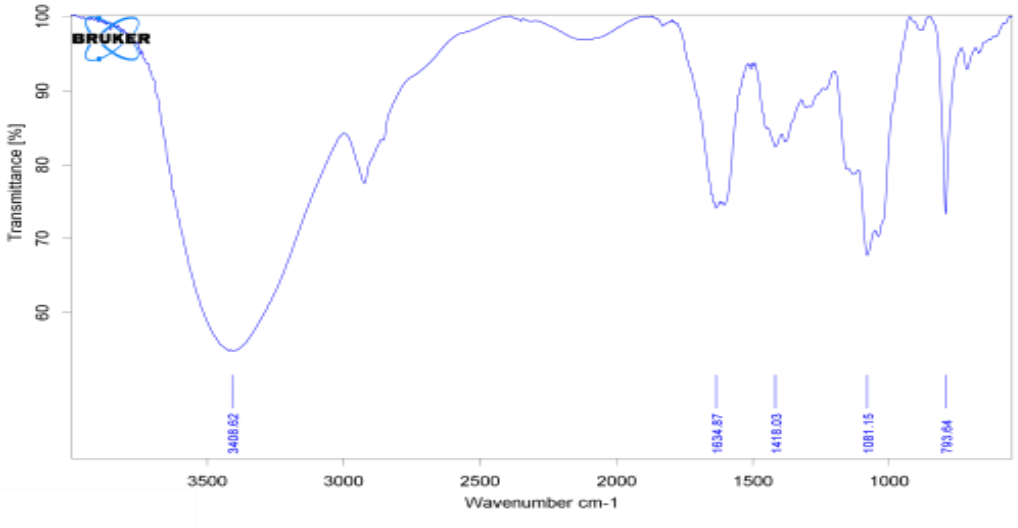

Figure 1: FTIR spectrum of *Araucaria heterophylla* gum.

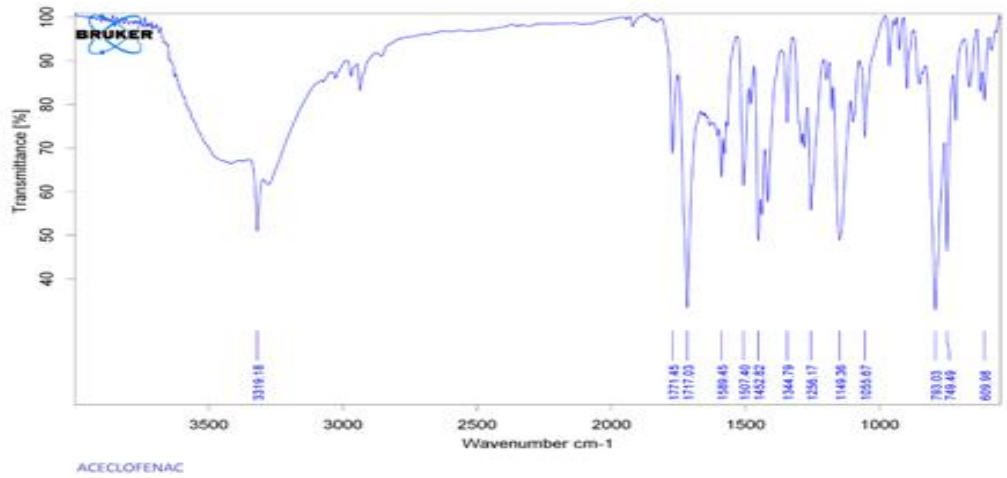

Figure 2: FTIR spectrum of Aceclofenac drug.

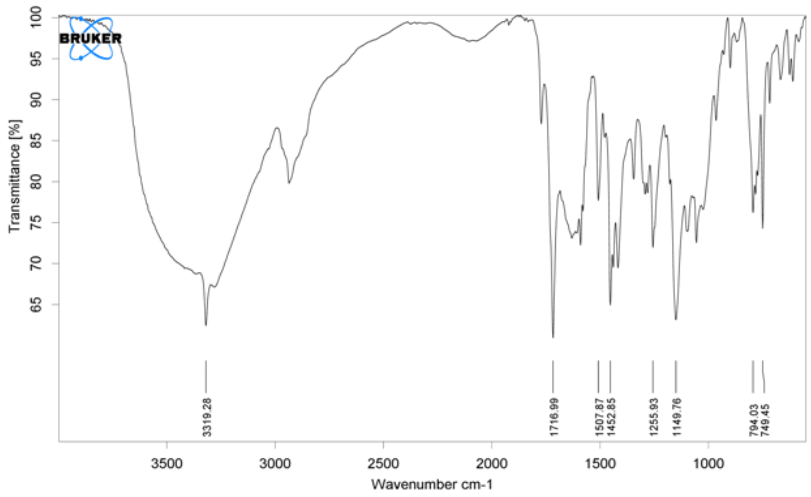

Figure 3: FTIR spectrum of Aceclofenac drug and *Araucaria heterophylla* gum.

Bulk density values were 0.562 ± 0.04, 0.552 ± 0.01 and 0.531 ± 0.02 gm/cc for the formulations F1, F2and F3 showed a satisfactory result. Hausner ratio for formulation with gum concentrations of 5%, 7.5% and 10% were found to be 1.160 ± 0.01, 1.217 ± 0.01, 1.258 ± 0.01 and compressibility index 13.8 ± 0.01, 17.8 ± 0.02 and 20.50 ± 0.02 respectively. This indicates the reduction in the quantity of fines during the granulation process with an increase in concentration from 5% to 10%. Angle of repose for all the formulations were below 30° which is desirable for good flow as observed in Table 4.

S. No	Parameters	F1	F2	F3
1	Bulk Density (gm/cc)	0.562 ± 0.04	0.552 ± 0.01	0.531 ± 0.02
2	Tapped Density (gm/cc)	0.652 ± 0.03	0.662 ± 0.03	0.678 ± 0.03
3	Hausner's Ratio	1.160 ± 0.01	1.217 ± 0.01	1.258 ± 0.01
4	Compressibility Index	13.8 ± 0.01	17.8 ± 0.02	20.50 ± 0.02
5	Angle of repose (ɵ)	28°44″ ± 0.23	28°32″ ± 0.14	26°14″ ± 0.13
Note: ± SD for n=3				

Table 4: Pre-compressional characteristics of the granules.

Mechanical characters like weight variation, friability, and hardness were within the limits, when the concentration of the gum was increased from 5% to 10%. The friability value showed a significant reduction from 1.4% to 0.65% and again reduced to 0.32%. When the gum concentration was increased to 10%. Hardness increased with increase in the concentration of the gum for all the three formulations indicating the good binder effect of the gum. The drug content of all the

formulations were above 90%. Another good interpretation of the binding effect of the gum was that the disintegration time was directly proportional to the concentration of the gum as shown in Table 5.

Table 5: Evaluation of pre-compression characteristics of the granules.

S. No	Parameters	F1	F2	F3
1	Weight Variation (%)	2.3 ± 0.033	2.2 ± 0.013	2.5 ± 0.031
2	Hardness (kg/cm^2)	5.5 ± 0.01	6 ± 0.04	6.5 ± 0.05
3	Friability (%)	1.4 ± 0.06	0.65 ± 0.01	0.32 ± 0.02
4	Drug Content (%)	95.26 ± 0.22	94.21 ± 0.12	96.87 ± 0.33
5	Disintegration time (min)	4 ± 0.05	5.5 ± 0.03	6.5 ± 0.02
Note: ± SD for n=3				

Formulation F1 with % gum ratio gave drug release of 90.28% within 40 mins and F2 with 7.5% gum showed 93.78% release on 50 mins. Formulation F3 where the gum concentration was increased to 10% could sustain the release up to 60mins and the release was 92.21%. In general, the amount of drug release decreases as the gum concentration increased indicating the binding effect of *Araucaria heterophylla* gum shown in Table 6 and Figure 4. All the formulations possessed sufficient mechanical characteristics that are required for tablet formulations

Table 6: *In vitro* drug release profile for the various concentration of the gum.

S. No	Time	% Drug Release		
	(mins)	F1	F2	F3
1	10	34.31 ± 1.71	20.31 ± 0.91	12.63 ± 1.52
2	20	60.31 ± 1.26	40.25 ± 0.96	30.33 ± 1.11
3	30	77.28 ± 1.17	60.13 ± 0.96	45.27 ± 1.46
4	40	90.28 ± 1.17	79.91 ± 1.4	60.3 ± 1.37
5	50	-	93.78 ± 0.32	75.85 ± 1.3
6	60	-	-	92.21 ± 1.56

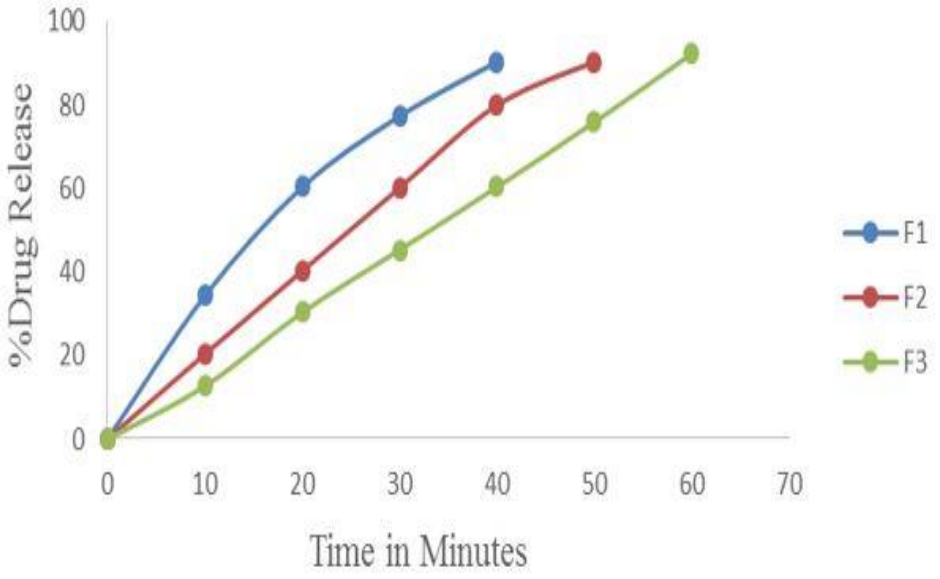

Figure 4: *In vitro* cumulative % drug release of Aceclofenac tablets using various concentrations of *Araucaria heterophylla* gum as binder

CONCLUSION

It is evident from the physiochemical properties of the gums that the isolated gum was pure and exhibits the qualities required for a pharmaceutical excipient. The parameters namely hardness and dissolution time increased when the concentration of the gum increased indicating the gum has a good binding property. Also, it can be concluded from the drug release studies that the *Araucaria heterophylla* gum exhibits good binding property at the concentration as low as5% and can be used as a binder for tablets formulations.

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