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EFFECT OF NATURAL ALMOND GUM AS A BINDER IN THE FORMULATION OF DICLOFENAC SODIUM TABLETS

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ABSTRACT

The present study was undertaken to find out the potential of gum from Almond gum to act as a binder and release retardant in tablet formulations. No significant work has been reported to use it as a tablet binder. The effect of almond gum and pvp on the release of diclofenac sodium was studied. The FT-IR spectroscopic studies of drug, gum and mixture indicated no chemical interaction. Seven formulations were prepared by wet granulation method containing Microcrystalline cellulose as diluents, diclofenac sodium as model drug using 2%,4%,6%,8% and 10% w/v of almond gum solution and 2%,4% w/v of pvp gum solution. This was carried out to find out the difference between synthetic and natural gum and whether synthetic gum can be replaced by natural gums. Physical and technological studies of granules and tablets like flow rate, carr's index, Hausner's ratio, angle of repose, friability and disintegration time were determined and found to be satisfactory. The drug release increased with almond gum when compared to synthetic gum concentration of 2% and 4%. The values of release exponent were found to be less than 0.5. This implies that the release mechanism is non-fickian diffusion. Tablet at 2% w/v binder concentration showed optimum results as tablet binder. The Almond gum was found to be useful for the preparation of uncoated tablet dosage form. Further this work can be extended to investigate on novel sustained release formulations.

INTRODUCTION: Almond gum is obtained from the tree Prunus communis which is a water soluble gum extrudes from the wounds on almond trees. The constitution of almond gum includes aldobionic acid, L-arabinose, L-galactose, D-mannose etc. It contains different components which have emulsifier, thickener, suspending pharmaceutical, adhesive, glazing agent and stabilizer. Gum is a bye product obtained as a result of metabolic mechanism of plants. Natural gums are either water soluble or absorb water to form a viscous solution. Natural gums are economic, easily available and found useful as tablet binder[1].

MATERIALS AND METHODS: Micro crystalline cellulose (Indian research products), Diclofenac (Rankem Pvt Ltd.), Fresh gum of prunus communis and all other materials used in this study were of AR grade.

Purification of Almond Gum [2]: The gum was taken and well dried and powered in a mortar and passed through sieve No.100. The gum was solubilised in distilled water and heated for some time and then cooled. The concentration solution was precipitated in ethanol with ice cold condition. The precipitate was separated and dried at 60ºC. The gum was powdered and stored in tightly closed container.

Characterization of Gum:

Ash Value: One gram of gum was accurately weighed and evenly distributed and dried at 105ºC for one hour and ignited in muffle furnace at 600±25ºC. Percentage ash content was found to be less than 3%.

pH: The gum was analyzed for determining the P_H and it was found to be in the range of 6-7 [3].

Preformulation Studies of Gum

Water Absorption Test: Polymeric discs of almond gum were prepared directly by compressing 100 mg of dried gum in the hydraulic press. The prepared discs are placed on the surface of agar gel plates and incubated at 37ºC until constant weight was obtained. The initial and final weight of the discs was noted and the mean for the determination were taken to represent the uptake volume. The water absorption ratio was found to be 85.6% w/v over 4 hours period [4].

Swelling Index: Gum (1g) was reduced to fines and introduced into a 25 ml of glass stoppered measuring cylinder. 25ml of water was added and was shaken thoroughly for every 10min. for 1 hour at room temperature. Then the volume in one occupied by plant material, including sticky material was measured. Swelling index was found to be 83.33% [5].

Preparation and Evaluation of Granules: Wet granulation method was used to prepare granules of drug. The formulation was developed by using diclofenac sodium as model drug. Binder solution of gum prepared by dissolving it in distilled water. The binder concentration used was 2,4,6,8 and 10 w/w & PVP 2 and 4 % w/w. Binder level was adjusted by lowering the level of microcrystalline cellulose in the formula. All ingredients were dry mixed manually

in the mortar. Binder solution was slowly added into mixture. The wet mass was granulated by passing through 14 sieves. Granules were dried at 60ºC in oven and then pass through set of sieves (18 & 44). The granules were evaluated for bulk density, tapped density and angle of repose. The tablet formulation of 2% tablets was shown in the table No.1[6, 7, 8].

Table 1: Formula table

Ingredients	A1	A2	A3	A4	A5	B1	B2
	2%	4%	6%	8%	10%	P-2%	P-4%
Diclofenac sodium	50	50	50	50	50	50	50
Microcrystalli-ne cellulose	171	166	161	156	151	171	166
Almond gum	5	10	15	20	25	-	-
PVP	-	-	-	-	-	5	10
Mg.stearate	6	6	6	6	6	6	6
Aerosil	8	8	8	8	8	8	8
Sodium starch glycolate	10	10	10	10	10	10	10

Preparation and Evaluation of Tablets: The tablets were compressed by using rotary punching machine of 250mg. The batch size prepared was of 30 tablets. The prepared tablets were stored in a closed container for 15 days. No significant evidence of chemical change was prepared. The tablets were evaluated for weight variation, hardness, friability, disintegration test and the dissolution study [9]. Dissolution was carried out in 900ml of P_H 6.8 phosphate buffer using paddle type dissolution test apparatus. The dissolution was carried out at 37± 2ºC and 50 rpm as the paddle speed. The suitable volume of sample (10ml) was withdrawn for every 10 min for 60 min. 10ml of buffer was replaced to maintain the sink condition. Absorbance was measured at 274 nm using spectrometer. The dissolution data was fitted to different models and to find out the drug follows which order of kinetics and mechanism of action of drug[10].

RESULT AND DISCUSSION: The binder gum is natural and has P_H between 6- 7. The prepared granules are evaluated for the bulk density tapped density; angle of repose and the result are tabulated in table No.2. The flow property of granules was determined by angle of repose and it was found that values were between 23º 60´ - 32º 33´. All the batches showed good flow property. Then the granules were compressed to tablets and the tablets were evaluated for weight variation, hardness, and friability and disintegration time. The results are indicated in table No.3. All the batches of tablets exhibited good uniformity in content. The hardness was within the range of 5 to 6 kg/cm^2, with the increase in binder concentration, the increase in hardness of tablets was found. The friability of the tablet was found well with the approved range less than 0.5 to 1 % in all the formulations. The disintegration time for natural gum was found to be less when compared to synthetic gum tablets and all the tablet complies within IP limits(i.e.) for 15 min.

Table 2: Preformulation Characteristics of Blend of all Formulations

Parameters	A1 2%	A2 4%	A3 6%	A4 8%	A5 10%	B1 PVP 2%	B2 PVP 4%
Bulk density (g/m)	0.33	0.2857	0.277	0.2631	0.25	0.32	0.294
Tap density (g/m)	0.4166	0.3571	0.333	0.303	0.2941	0.466	0.3571
Compress-ibility Index	20.096	19.994	16.8168	13.168	14.96	22.74	17.642
Hausners ratio	1.25	1.249	1.202	1.15	1.17	1.29	1.214
Angle of repose	23.6	26.67	28.83	31.04	32.33	25.45	27.69

Table 3: Post Formulation Studies of Diclofenac Sodium Tablets

PARAMETERS		A1 2%	A2 4%	A3 6%	A4 8%	A5 10%	B1 PVP-2%	B2 PVP-4%
Weight variation	+ve	1.6	1.6	2	1.6	2	1.6	1.6
	-ve	0.8	0.8	0.8	1.2	0.8	1.2	0.8
Hardness kg/(m^2)		5	5.5	5.5	6	6	5.5	6
Friability (%)		0.96	0.65	0.89	0.65	0.97	0.98	0.65
Disintegration test (min)		1 min 5sec	1 min 40 sec	2 min 5 sec	2 min 28 sec	8 min 24 sec	1 min 30 sec	1 min 50 sec

The in- vitro dissolution profile is given in fig.1 and fig2. Dissolution study showed that the drug release from the tablets containing 2 to 10 % w/w of almond and 2, 4 % of pvp was more than 70% in 60 min. The tablets at 2 % w/w concentration show more optimum results as tablet binder. The drug release from the tablets decreased with the increased in binder concentration. The dissolution data of all the formulations containing 50mg per tablets was fitted to different mathematical order. The correlation coefficient (R^2) values were calculated using the linear regression analysis to find out the best fitted model and in order to have an idea about the kinetic mechanism of drug release. The order of drug release was found to be first order as the R^2 value close to 0.99; the R^2 value shows that the drug release is by diffusion mechanism rather than erosion as the value better fitted to the korsemeyer- peppas model. The diffusion coefficient (n) was found to be less than 0.5 which indicates that the drug follows nonfickian diffusional release mechanism as shown in fig 3 & 4.

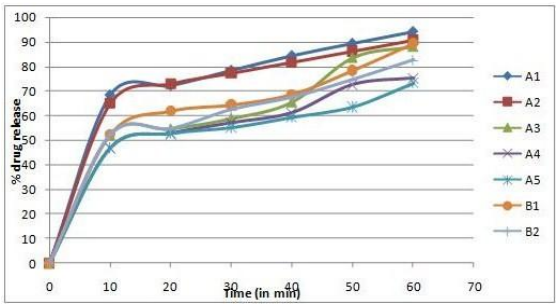

Figure 1: In- vitro drug release profile of Diclofenac Sodium Tablets for all formulations

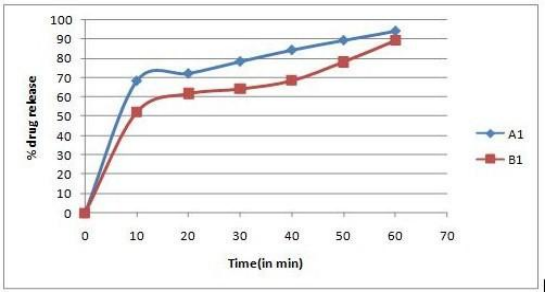

Fig 2: In- vitro drug release profile of diclofenac sodium tablets for the best formulations [A1-B1]

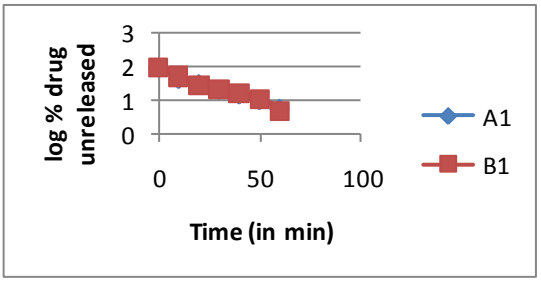

Fig 3: First Order Kinetics

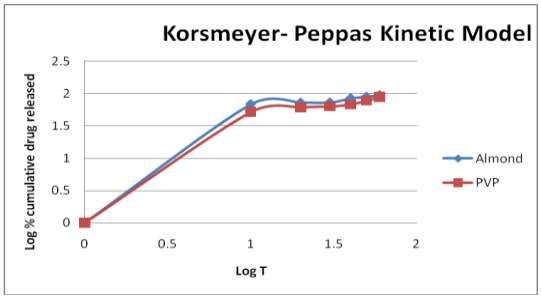

Fig 4: Korsemeyer- Peppas Model

Effect of 2 % Almond gum & PVP on korsemeyer – Peppas Kinetic Model of diclofenac sodium Tablets.

CONCLUSION: The 2% of almond gum showed optimum results. The almond gum exhibited good binding properties for the uncoated tablets. The increased concentration of gum showed small retardation in drug release from tablet.

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