OPEN ACCESS

Saudi Journal of Medical and Pharmaceutical Sciences
Abbreviated Key Title: Saudi J Med Pharm Sci
ISSN 2413-4929 (Print) |ISSN 2413-4910 (Online)
Scholars Middle East Publishers, Dubai, United Arab Emirates
Journal homepage: https://saudijournals.com

Original Research Article

Assessment of *Prunus amygdalus* Gum for Functionality of Tablet Excipient

Sivakumar R[1*], Komala M[2], Athira C[2], Fathima A. F[2], Rinseena M. G[2], Reshma Fathima K[2]

[1]Professor, Department of Pharmaceutics, Grace College of Pharmacy, Palakkad – 678004, India
[2]Vels Institute of Science Technology and Advanced Studies, Chennai – 600 117, India

DOI: 10.36348/sjmps.2021.v07i05.001 | **Received:** 14.03.2021 | **Accepted:** 19.04.2021 | **Published:** 04.05.2021

***Corresponding author:** Dr. R. Sivakumar

Abstract

The aim of the research work is to assess the *Purnus amygdalus* gum for the potentiality of tablets binder / disintegrant excipient and potato starch was used as standard excipients. The gum was assessed for various tests. Ibuprofen was used as a model drug for the preparation of tablets. Totally eight batches were developed using various compositions. Pre-formulation and post formulation study were performed for the tablets. Also the tablets qualities were compared with innovator tablet. FTIR studies ruled out the drug excipient interaction. The hardness of the tablets were in the acceptable range. Disintegration time was ~4 minutes. Dissolution were between 70 – 89%. The results of the study describe that the *Purnus amygdalus* gum *(PA)* could be alternative tablet excipients for potato starch.

Keywords: *Prunus amygdalus* gum, Ibuprofen, FTIR studies.

INTRODUCTION

Various formulation and excipients strategies have been investigated to improve the quality of the formulation. These strategies include use of different excipient, Complexation, the use of co-solvents, solubilization by surfactants and formulation of solid drug solutions / dispersion. Excipients are non drug components of a formulation / pharmaceutical ingredients and are added to ensure acceptability, physiochemical stability during the shef life, uniformity of composition, better bioavailability and functionality of the drug product. Excipients used in the pharmaceutical industry include diluents fillers, binders, disintegrant and flavors. All the excipients used in the pharmaceutical industry should be acceptable to regularity agencies, chemically stable, and free from microorganism. Starch is a polysaccharide, widely used as binder, diluents, glidants and disintegrating agent in oral dosage form. Commercially starch obtained from maize, potato, rice, and wheat. Many scientists working on various sources for alternative excipients for starch. The research work report the usage of *Prunus amygdalus* gum for the design of immediate release tablet [1].

Prunus amygdalus (Rosaceae) is a small tree indigenous to regions around the Mediterranean Sea. The edible portion of PA is its nuts, commonly known as almonds or badam and is a popular nutritious food. Nuts of PA are found to possess various pharmacological properties, such as antistress, antioxidant, immunostimulant, lipid lowering [2-6]. The aim of the research work was to develop ibuprofen tablets using *Prunus amygdalus* gum to assess the sutability of disintegrant and binder.

MATERIALS AND METHODS

Ibuprofen (Yarrow chem. Products Mumbai) Lactose (Prowess lab chemicals) Almond Gum, Starch, Mannitol, Talc, Magnesium stearate (Spectrum reagents and chemicals, Cochin). All other chemicals used were of reagent grade.

Assessment of *Prunus amygdalus* gum

All the results are shown in Table 1-4. The P.amygdalus gum was evaluated for Solubility, Loss on drying, ash value and total ash as described by Indian pharmacopoeia.

Bulk and tapped density

Micromeritcs property was assed for PA gum and the starch powder. Bulk density is the ratio of the total mass of powder and the bulk volume of powder. It was measured by pouring the weighed powder into a graduated measuring cylinder and the volume was recorded. Bulk density = Mass of powder / bulk volume of powder.

Tapped density is the ratio of the total mass of powder to the tapped volume of powder. The tapped

volume was measured by tapping the powder to a constant volume. Tapped density = Mass of powder / tapped volume of powder [8].

Flow property

The static angle of repose "Ɵ" was measured according to the fixed funnel and free standing cone method. It is the maximum angle possible between the surface of a pile of powder and the horizontal plane. The funnel was clamped with its tip 2 cm above a paper placed on a flat horizontal surface. The gum powder was poured through the funnel until the apex of the cone, thus formed just reached the tip of the funnel. The mean diameters of the base of the powder cones were determined and the tangent of the angle of repose calculated using the equation.Hausners ratio is calculated as the ratio of tapped density to the bulk density [9].

Viscosity Study

The viscosity of 1% solution of a P. Amygdalus gum and Potato starch is carried out by using Brookfield viscometer.

Compatibility Study

Compatibility study of drug with polymer was determined by FT-IR spectroscopy using Shimadzu spectrophotometer. The pellets were prepared by gently mixing 200mg of Potassium bromide with 1mg of Sample. The prepared pellets were analyzed for individual drug, for individual polymers and for drug polymer mixture. The drug and polymer interaction were analyzed by comparing IR spectra of Drug Sample (Fig 1& 2).

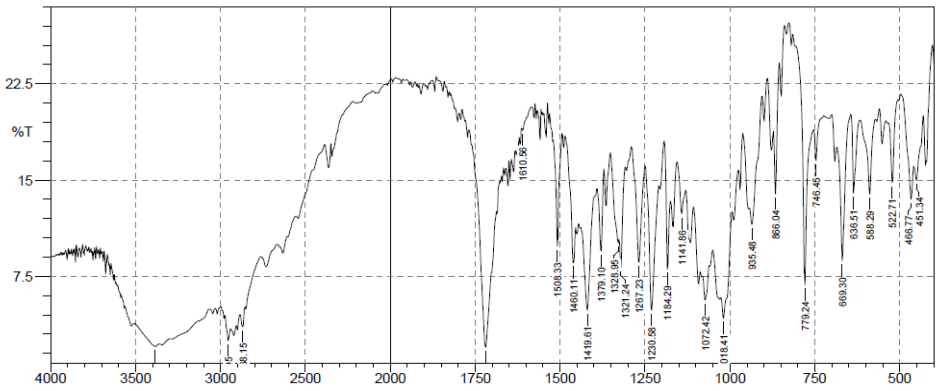

Fig-1: FTIR Spectrum for Pure Ibuprofen drug

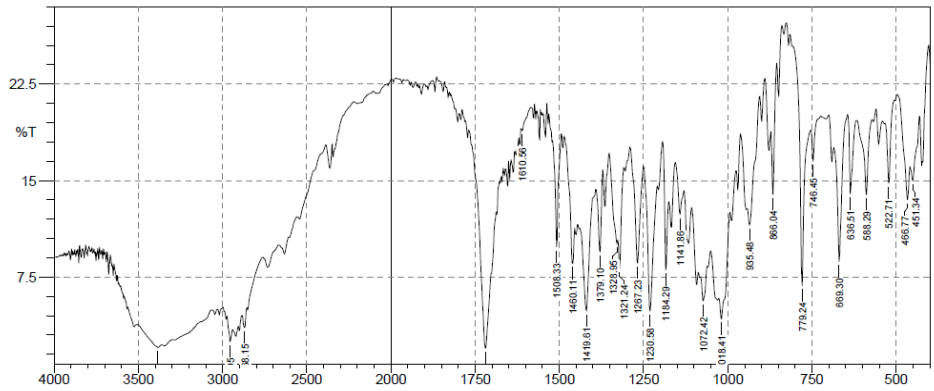

Fig-2: FTIR for the drug and excipients

Table-1: Evaluation of P. amygdalus gum

Parameters	Results
Source	*Prunus amygdalus*
Common Name	Almond gum
Odour	Odorless
Colour	Yellowish brown
Taste	Tasteless
Size	20µm
Shape	Irregular
Solubility	Soluble in water
Loss on drying (%)	17.3
Swelling index (%)	66.6
Ash value (%)	9.0

Table-2: Precompression parameters for P.Amygdalus gum and Potato starch

Parameter	PA Gum	Potato Starch
Bulk density (g/cm^3)	0.78	0.53
Tapped density(g/cm^3)	0.98	0.66
Angle of repose (º)	39.1	35.37
Hausners ratio	1.2	0.8
Viscosity (Centipoise)	72	100

Table-3: Composition Ibuprofen Tablets

S. No	INGREDIENTS	F1	F2	F3	F4	F5	F6	F7	F8
1	Ibuprofen	200	200	200	200	200	200	200	200
2	Lactose	64	64	64	64	64	64	64	64
3	Mannitol	30	30	30	30	30	30	30	30
4	Talc	4	4	4	4	4	4	4	4
5	Potato starch	40	35	30	25	20	15	50	-
6	*Prunus amygdalus* gum	10	15	20	25	30	35	-	50
7	Magnesium stearate	2	2	2	2	2	2	2	2
	Total weight	350	350	350	350	350	350	350	350

Note: All Ingredient quantities are expressed in mg.

Table-4: Results of evaluation tests for Ibuprofen Tablets

Parameters	F1	F2	F3	F4	F5	F6	F7	F8	Innovator
Hardness(kg/cm^2)	4.0	4.5	4.3	3.5	3.0	4.9	4.2	4.8	4.6
Friability (%)	1.3	1.4	1.6	1.5	1.8	1.7	1.2	0.9	0.5
Weight variation	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Drug content %	97	96	95	97	95	96	95	96	99
Disintegration(mts)	4.1	3.3	3.7	3.2	4.5	3.2	4.1	3.8	4.0
Wetting time(s)	12	13	14	17	21	26	22	60	120

Procedure for Formulation of Ibuprofen Tablets

All the ingredients were mixed together in pestle motor (in decreasing order of their quantity used). Then this mixture was triturated and the mixture was passed through sieve No.10. After passing through a sieve, the powder was compressed by direct compression method to form tablets.

Post compression parameters [10-1 2]

Hardness

Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. The hardness of the tablet was determined by Monsanto type hardness tester. Samples were randomly picked and the hardness of the tablets was determined.

Weight variation test

Twenty tablets from each formulation weighed individually and the test was performed according to the official method.

Friability test

The friability of tablets was determined using Roche Friabilator. It is expressed in percentage (%). 10 tablets were initially weighed (W_i) and transferred into friabilator and was operated at 25 rpm for 4 min or run up to 100 revaluations. Then the tablets were weighed

again (W_f). Friability (%) = (initial weight (W_i) – final weight (W_f))/ Initial weight X 100.Percentage friability of tablet less than 1% are considered acceptable.

Wetting time [13]

A piece of tissue paper folded double was placed in a Petriplate (internal diameter 7 cm) containing 7ml of water. The tablet was placed on the paper and the time for complete wetting was measured in minutes.

Dissolution Study [14]

The dissolution test for the tablet was conducted in USP Type I dissolution apparatus using 900 ml of phosphate buffer. The set condition was 37.5 ± 0.5^0C, 50 rpm, 1h. Aliquots were collected diluted suitably with pH 6.8 phosphate buffer and analyzed at 268 nm in UV Visible spectrophotometer. The drug concentration was calculated using calibreation curve.

RESULTS AND DISCUSSION

Prunus amygdalus gum is a yellowish in colour less powder with no taste and odor. The granules are irregular or ovoid or pear shaped. Swelling index was 66%. Total ash value was 9%. The gum was soluble in water. The *Prunus amygdalus* gum and potato starch were assessed for bulk density, true density, Hausner ratio and angle of repose. The un tapped bulk density and tapped density were higher for the *Prunus amygdalus* gum when compared with potato starch. The angle of repose and Hausners ratio give qualitative assessment of the internal cohesiveness and frictional effects. Under low levels of external loading as might be applied in powder mixing or in the table die filling operation. The results were tabulated in Table 8. The results obtained were slightly greater than potato starch. The viscosity of 1% solution of *Prunus amygdalus* gum and potato starch were assessed using brook field viscometer using spindle size 63 at various upto 100 rpm. Both the dispersion following psedoplastic flow. The viscosity of *Prunus amygdalus* gum is lower than the potato starch. *Prunus amygdalus* gum possess suitable rheological and micromeritics property,permitting its use in compression technology. There by design of ibuprofen tablets using *Prunus amygdalus* gum and Potato starch in varying composition as binder, disintegrant was performed. The tablets were evaluated for weight variation, friability, hardness and disintegration test as per the Indian pharmacopoeia and the results were compiled. It is evident that the weight variation content compiles the weight variation tolerance for un coated tablets. Similarly, the percentage friability of all the formulation was within the limits of 1 % and the hardness was within the scope of 3 – 4 kg /cm^2. Disintegration time ranged from. ~~3 to 4 minutes, indicate the formulation showed excellent disintegration property. The overall dissolution time indicated that the tablet prepared from *Prunus amygdalus* gum not significantly difference with the tablets prepared with the potato starch. The innovator formulation (Tablet Brufen 200mg) showed comparable dissolution property than the prepared formulation. It may be due to particle size of drug and excipients might lower than the test formulation. Also the gum has similar property to that of potato starch. Thus the gum could be alternative for potato starch.

CONCLUSION

Prunus amygdalus gum was evaluated as an alternative natural excipient along with potato starch following the isolation gum from *Prunus amygdalus* gum. The battery of tests done on *Prunus amygdalus* nearly similar to potato starch. Following this, the preformulation studies results suggest that *Prunus amygdalus* as a similar property like potato starch.Based on the study results F8 formulation quality similar to the reference product. The study conclude *Prunus amygdalus* gum could be used as alternative excipient for potato starch.

REFERENCES

1. Venkatesh, S., Babashankar, G., Latha, K., Reddy, M. B., & Mullangi, R. (2011). Evaluation of Caralluma attenuata Starch as an Alternative Tablet Excipient to Potato and Maize Starch: Assessment by Preformulation and Formulation Studies. Indian Journal Of Pharmaceutical Education And Research, 45(3), 218-224.
2. Agunbiade, S. O., & Olanlokun, J. O. (2006). Evaluation of some nutritional characteristics of Indian almond (*Prunus amygdalus*) nut. Pakistan journal of nutrition. 5:316–8.
3. Bansal, P., Sannd, R., Srikanth, N., & Lavekar, G. S. (2009). Effect of traditionally designed nutraceutical on stress induced immunoglobulin changes at Antarctica. African Journal of Biochemistry Research, 3(4), 084-088.
4. Pinelo, M., Rubilar, M., Sineiro, J., & Nunez, M. J. (2004). Extraction of antioxidant phenolics from almond hulls (*Prunus amygdalus*) and pine sawdust (Pinus pinaster). Food Chemistry, 85(2), 267-273.
5. Puri A, Sahai R, Singh KL, Saxena RP, Tandon JS, Saxena KC. Immunostimulant activity of dry fruits and plant materials used in Indian traditional medical system for mothers after child birth and invalids. J Ethnopharmacol. 2000;71:89–92.
6. Spiller, G. A., Jenkins, D. A., Bosello, O., Gates, J. E., Cragen, L. N., & Bruce, B. (1998). Nuts and plasma lipids: an almond-based diet lowers LDL-C while preserving HDL-C. Journal of the American college of nutrition, 17(3), 285-290.
7. Pinnamaneni, S., Das, N. G., & Das, S. K. (2002). Formulation approaches for orally administered poorly soluble drugs. Pharmazie, 57(5), 291-300.

8. Baliga, S. B., & Manjula, B. P. (2017). Formulation and evaluation of microspheres based orodispersible tablets of sumatyiptan succinate. Indian Drugs, 54(3):28-37.
9. Perioli, L., Nocchettib, M., Glannellia, P., & Pagano, C. (2013). Hydrotalchite composites for for an effective fluoride buccal administration: A new technology approach. Int J Pharm, 454, 259 - 68.
10. Venkatesh, S., Babashankar, G., Latha, K., Reddy, M. B., & Mullangi, R. (2011). Evaluation of Caralluma attenuata Starch as an Alternative Tablet Excipient to Potato and Maize Starch: Assessment by Preformulation and Formulation Studies. Indian Journal Of Pharmaceutical Education And Research, 45(3), 218-224.
11. Singh, S., Ahmad, A., & Bothara, S. (2014). Formulation of oral mucoadhesive tablets using mucilage isolated from Buchanania lanzan spreng seeds. International Journal of Pharmaceutical Sciences and Nanotechnology, 7(2), 2494-2503.
12. Sarojini, S., Kunam, D. S., Manavalan, R., & Jayanthi, B. (2010). Effect of natural almond gum as a binder in the formulation of diclofenac sodium tablets. International Journal of Pharmaceutical Sciences and Research (IJPSR), 1(3), 55-60.
13. Tavakoli, N., Ghasemi, N., & Hamishehkar, H. (2010). Evaluation of okra gum as a binder in tablet dosage forms. Iranian Journal of Pharmaceutical Research, (Supplement 2), 47-47.
14. Rahim, H., & Khan, M. A. (2014). Comparative studies of binding potential of Prunus armeniaca and Prunus domestica gums in tablets formulations. Acta Pharmaceutica Sciencia, 52: 254-262.