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Research Article

COMPARATIVE EVALUATION OF POTATO STARCH AND BANANA POWDER AS DISINTEGRATING AGENTS IN ACECLOFENAC TABLET FORMULATION

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ABSTRACT

Objective: The main objective of this research was to introduce and evaluate disintegrant property of natural excipients like potato starch and banana powder in tablet formulation. Pharmaceutical excipients developed from natural sources are economic.

Methods: Dehydrated banana powder and potato starch were prepared and physicochemical properties like solubility, iodine test, angle of repose, bulk density, tapped density, carr's index, hausner's ratio and melting point were evaluated. The interaction between the excipcents and aceclofenac was also studied through FTIR spectroscopy. Tablets were then prepared by direct compression method using different disintegrants and the disintegration time of the tablets formulated was determined. Dissolution study was conducted to characterize release mechanism from the tablet system and data were fitted to various kinetic models.

Results: It was found that tablets with banana powder and potato starch disintegrate more rapidly than the tablets with microcrystalline cellulose. The prepared formulations were passed the evaluation test that is weight variation, hardness, friability and content uniformity. The mechanism of drug release from tablets was found to be non-Fikian, anomalous transport.

Conclusion: Results from various evaluations suggested that banana powder and potato starch could be used as disintegrants in tablet formulation.

Keywords: Potato starch, Banana powder, Natural excipients, Disintegrant, Aceclofenac.

INTRODUCTION

Researches are being carried out to reduce the patient compliance and for an effective therapy. The most widely utilized route of administration is oral drug delivery among all the routs that have been explored for the systemic delivery of drugs. This is because that, the popularity involved in the case of administration and the traditional belief that by oral administration the drug is as well absorbed as the food stuffs are ingested daily[1]. Appropriate design and formulation of a dosage form need consideration in the physical, chemical and biologic characteristics of the drug substances. Excipients help the formulation design and perform a wide range of functions to obtain desired properties in the finished drug product. Excipients are the additives used to convert pharmacologically active compounds in to pharmaceutical dosage forms suitable for administration to patients. Present day researches are looking for natural excipients as they believe that anything natural will be more safe and devoid of side effects. Advantage of natural excipients are low cost and natural origin free from side effects, biocompatibility & bioacceptance, renewable source, environment friendly processing, local availability, better patient tolerance as well as public acceptance, they comprise the natural economy by providing inexpensive formulation to people[2].

In the present context the focus was the study of natural excipients. For most tablets, the first important step is break down of tablets in to smaller particles or granules, a process is known as disintegration. Disintegration test is provided to determine whether tablet disintegrate within the prescribed time when placed in liquid medium as specific experimental condition. Starches are used extensively in pharmaceutical industries as disintegrants, binders and lubricants in tablet formulation. Starches are believed to extent its disintegrating property by absorption of moisture and spelling of the grain followed by rapture of tablet core[3]. Banana fruit is economically one of the most important fruit produced and consumed in the world. The soft and sweet fruit of this tropical plant is enjoyed by the people from around the world. The main objective of this study was to utilize banana powder [musa accuminata] as a pharmaceutical excipient and evaluate its disintegrating properties in comparison with the other disintegrating agents. The dehydrated Banana powder is a natural commonly used as nutritional supplement as it contains many essential nutritional including minerals. It is considered to be good for treatment of gastric ulcer and diarrhea because they contain vitamin A[4].

METERIALS AND METHODS

Materials

Aceclofenac was received as a gift sample from Macsur Pharma India Pvt Ltd, Puducherry, India. Dehydrated Banana powder (Banatone industies, Thiruvanathapuram), Lactose (Spectrum reagent & chemicals Pvt.Ltd), Microcrystalline cellulose (Chemdyes co, Rajkot), Acacia (Nice chemicals Pvt.Ltd), Talc (Spectrum reagent & chemicals Pvt.Ltd), Magnesium stearate (Otto chemicals, Mumbai) were used as tablet excipients.

Methods

Extraction of Potato Starch

Potato was thoroughly washed and all foreign materials were removed. The potato was peeled, weighed and washed. The washed potato was pulverized using a blender. Enough quantity of water was added to the pulp which then passed through a sieve. The filtrate was allowed to settle and 0.1 N sodium hydroxide was added to separate the starch and proteinous materials as well as to neutralize the prevailing slight acidity. Excess sodium hydroxide was removed by washing several times with distilled water. The clear supernatant fluid was poured away while sedimented starch was collected on a tray and air-dried on a table at room temperature[5].

Characterization of Dehydrated banana powder and Potato starch [6,7]

Solubility Test

The solubility of the banana powder and potato starch in cold water was determined and the results recorded.

Iodine Test

1g of banana powder and potato starch was boiled with 15mls of water. After cooling to 1ml of the mucilage, 2drops of 0.1N iodine solution was added and the colour change noted.

Angle of repose

A 30 g sample was poured into a plugged glass funnel with the tip, 10 cm above the flat surface of the bench. The granules were allowed to flow freely through the orifice of the funnel to form a heap whose height and diameter were determined.

The angle of repose was calculated using the equation below:

Tan θ = h/r

Where h = height and r = radius of circular heap

Bulk Density

A 30g weight of each of the banana powder and potato starch to be used as carrier was weighted and poured in to a 100ml measuring cylinder and the volume was recorded. The bulk density was then calculated.

Bulk Density (BD) = M / V

Where M is mass and V is volume

Tapped Density

A 30g weight of each of the banana powder and potato starch was weighted and poured into a 100ml measuring cylinder and tapped on a hard surface 30 times from about 2cm height and the volume was recorded.

Tapped Density (TD) = M / V

Where M is mass and V is volume

Carr's Index

Carr's Index (%) was determined using the following relationship

C.I. = (TD – BD/ TD) x 100

Hausner's ratio

Hausner's ratio was determined using the following relationship

H.R=TD/BD

Where TD is Tapped density, BD is Bulk density

Swelling capacity

The tapped volume occupied by 10g of each banana powder and potato starch (*Vd)* in a 100ml measuring cylinder was noted. The powder was then dispersed in 85ml of distilled water and the volume made up to 100ml with more water. After 18hours of standing, the volume of the sediment, (*Vw)* was estimated and the swelling capacity was computed as;

Swelling capacity= *Vw – Vd*

Moisture Content

A 3g weight of each banana powder and potato starch was heated at 1350C using moisture analyzer (Sartorius, Germany); and the reading was recorded.

Compatibility study

Before formulation of a drug substance into a dosage form, it is essential that it should be chemically and physically characterized. Compatibility studies give the information needed to define the nature of the drug substances and provide a frame work for the drug combination with pharmaceutical excipients in the fabrication of a dosage form. One of the requirements for the selection of suitable excipients or carrier for pharmaceutical formulation is its compatibility. Therefore in the present work, a study was carried out by using Shimadzu FTIR spectrometer to find out if there is any possible chemical interaction between aceclofenac and excipients respectively. The samples were powdered and intimately mixed with dry powdered potassium bromide. The powdered mixture was taken in a diffuse reflectance sampler and the spectra recorded by scanning in the particular wavelength region (4000-400 cm^{-1}) using Shimadzu FTIR spectrometer. The IR spectrum of drug was compare with that of the physical mixture of the drug and excipients used to check for any possible drug-excipients interaction.

Formulation of Aceclofenac Tablet

Four different batches of tablets each containing 100mg of aceclofenac were formulated and evaluated. In all four bathes the tablets were formulated employing aceclofenac alone and lactose as diluents and direct compression method. In all the bathes acacia (2%) as binder, talc (2%) and magnesium stearate (2%) as lubricants were used. In formulation F1 Potato starch (5%), F2 banana powder & Potato starch (2.5% &2.5%), F3 banana powder (5%) and F4 Microcrystalline cellulose [MCC] (5%) as disintegrent were used. In each batch 100 tablets were prepared.

Table 1: It shows the composition of different batches of Aceclofenac tablets.

Ingredient mg/Tablet	Formulation F1	F2	F3	F4
Aceclofenac	100	100	100	100
Lactose	291.6	291.6	291.6	291.6
Potato starch	22	11	-	-
Banana powder	-	11	22	-
Microcrystalline cellulose	-	-	-	22
Acacia	8.8	8.8	8.8	8.8
Talc	8.8	8.8	8.8	8.8
Magnesium stearate	8.8	8.8	8.8	8.8
Total weight of tablet (mg)	440	440	440	440

Evaluation of Tablets[8,9,10]

Weight variation

The USP weight variation test was performed by taking 20 tablets from a batch. Then 20 tablet, were weighed and the average weight was taken. Then each tablet was weighed individually. The percentage deviation can be determined by using the following formula.

$$\%\,Deviation = \frac{Average\ weight - Individual\ weight}{Average\ weight} X\,100$$

Hardness Test

Pfizer hardness tester was used for measuring the hardness of the formulated aceclofenac tablets. From each batch five tablets were taken at random and subjected to test. The mean of these five tablets were given in the table.

Friability

It is a measure of tablet strength. The friability was determined by using Roche Friabilator. 10 tablets were taken and their weight determined. Then they were placed in the friabilator and allowed to make 100 revolutions at 25rpm. The tablets were then dusted and reweighed. The percentage weight loss was calculated by using the following formula.

$$F = 100X(1 - w/w_o)$$

Where, w_o = Weight of tablets before friability

w = Weight of tablets after friability

Drug content Uniformity

The prepared tablets containing aceclofenac was tested for drug content uniformity. Tablets were dissolved in 100 ml of phosphate buffer (pH 6.8) in 100 ml volumetric flask which was previously clean and dry. This solution after suitable dilution was measured for absorbance at 274 nm in a UV visible spectrophotometer.

Disintegration Test

Six tablets were taken in disintegration apparatus. Six glass tubes that are 3 inches long open at the top and held against a 10 mesh screen at the bottom end of the basket rack assembly. To test the disintegration time one tablet was placed in each tube, and the basket rack was positioned in a 1litre beaker of water at 37^0C ± 2^0C such that the tablets remain2.5 cm from the bottom of the beaker. A standard motor driver device was used to move the basket assembly up and down through a distance of 5-6cm at a

frequency of 28-32 cycles per minute. To meet the USP standard all particles of tablet must pass through 10 mesh screen in the time specified.

Dissolution

Dissolution was carried out using USP dissolution apparatus II (paddle apparatus). Dissolution of tablets was carried out in 900ml-dissolution medium. The dissolution medium for aceclofenac tablet was pH 6.8. The temperature of dissolution medium was maintained at 37ºC ± 2ºC. The agitation intensity was 100rpm. The samples of dissolution medium were withdrawn through a filter at different time intervals. Equal volume of fresh medium having same temperature was replaced at each time. The samples were suitably diluted and the amount of active ingredient was determined spectrophotometry with respect to the reported methods.

Dissolution Kinetics

To study the release kinetics, data obtained from *in vitro* drug release studies were plotted in various kinetic models: Zero order (cumulative amount of drug released vs time), First order (log cumulative percentage of drug remaining vs time), Higuchi's model (cumulative percentage of drug released vs square root of time), Hixon-Crowell (cube root of amount remained to be absorbed vs time) and Korsmeyer's (log cumulative percentage of drug released vs. log time).

Stability studies

To study the effect of temperature and humidity on the tablets, they were stored at 400c and 75% RH in Stability chamber (LabTop Instruments Pvt.Ltd.). After three months disintegrating time, drug content and FTIR spectrum were recorded to observe any effect on the tablets by the exposure to humidity and temperature.

RESULTS AND DISCUSSION

Compatibility study

FRIR spectroscopy was performed to assess the compatibility of aceclofenac with excipients. Analysis of aceclofenac structure reveals that few intense peaks which are characteristic (3918.64, 3701.69, 3661.19, 3477.99, 3275.5, and 2916.16) of the drug, the similar peaks were observed in all formulations. The results clearly indicate no shifting of peaks was significantly found, indicating the stability of the drug during tablet formulation. Thus the IR study indicates stable nature of aceclofenac in the tablet formulations. This also confirmed that the drug and polymer does not interact.

Table 2: It shows the physicochemical properties of starch powder.

Properties	Potato starch	Banana powder
Iodine test	Positive	Positive
Solubility	Insoluble	Soluble
Angle of repose(0)	38.13±0.12	35.83±0.25
Bulk density (g/ml)	0.46±0.1	0.68±0.12
Tapped density (g/ml)	0.54±0.12	0.77±0.1
Carr's index (%)	14.81±0.22	11.68±0.20
Hausner's ratio	1.17±0.16	1.13±0.12
Melting point (ºC)	72	78

Banana powder is soluble in water where Potato starch is practically insoluble in water. The powders also turn blue black on addition of iodine solution which confirmed the presence of starch. An angle of repose 35.83,and 38.13 were obtained for banana powder and potato starch respectively which all fall with the required range for pharmaceutical powders which is 25- 450, that of the banana powder which is lower and indicates a better flow property. Angle of repose has been used to characterize the flow properties of powders, it also related to inter particulate friction or resistance to movement between particles.

Table 3: It shows the physical evaluation of tablets

Formulation	Hardness (kg/cm²)	Average Weight Variation (%)	Friability (%)	Drug Content (mg)	Disintegration Time (sec)
F1	5.6±0.12	2.5±0.13	0.48	98.64	44
F2	5.8±0.14	3.8±0.10	0.62	99.18	91
F3	5.7±0.12	2.8±0.25	0.52	98.74	51
F4	6.1±0.20	2.5±0.35	0.58	99.21	148

The hardness values ranged from 5.6 to 6.1 kg/cm² for all formulations (Table 3). The entire tablets passes weight variation test as the average % weight variation was the pharmacopoeial limit of 5% (Table 3). The friability values were found to be within the limit (Table 3). The drug content of aceclofenac determined at 274nm ranges from 98.64 to 99.21 and complies with IP standard. In the study, potato starch and banana powder was employed as disintegrant and its effect was compared with microcrystalline cellulose. Tablets produce from the potato starch and banana powder show a relative lower disintegration time compared to that of the microcrystalline cellulose (Table 3).

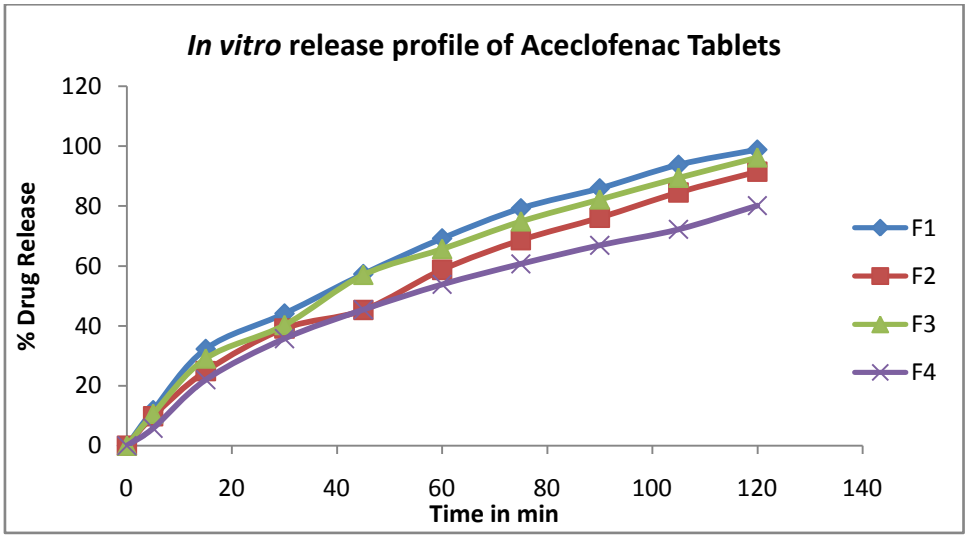

Fig. 1: It shows the *In vitro* release profile of Aceclofenac Tablets.

The dissolution process of a tablet depends upon the wetting followed by disintegration of the tablet. It was observed that the tablets containing banana powder and potato starch exhibited a higher percentage release in comparison with tablet containing microcrystalline cellulose. *In vitro* data obtained for tablets containing aceclofenac were used to determine the dissolution kinetics. The drug release data of aceclofenac were fitted to various kinetic models. The data were processed for regression analysis using MS-EXCEL statistical functions. Evaluation of release kinetics and application of best fit by correlation coefficient shows that the drug release following Higuchi square root kinetics. The release exponent 'n' calculated from the Korsemeyer-Peppas equation, shows that in all the batches, the 'n' values were between 0.45 and1. It can be suggested that the release mechanism was non-Fickian, anomalous transport where release dependent on both drug diffusion as well as polymer relaxation.

Stability studies

The results of accelerated stability studied indicated that there was no significant change in the tablets. The drug content was found to be within 100±5% for all the formulations at the end of 90 days. FTIR analysis suggested that there was no significant degradation or changes taking place in the tablets during the study period.

CONCLUSION

The present study was aimed at evaluating the disintegration property of and compares it with other synthetic disintegrant in the preparation of orally disintegrating tablets. The study showed that the banana powder and potato starch have a better disintegrant property than the microcrystalline cellulose. It was concluded that banana powder and potato starch were having excellent superdisintegrant property which can be used as natural disintegrant in the tablet formulation.

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REFERENCE

1. Dhara B.Patel, Madhabhai M.Patel. Natural excipient in controlled Drug Selivery Systems. J. Pharmacy Res., 2009, 2(5); 900-907
2. Prabakaran.L,Senthil.D. Formulation development of patient friendly dosage form: All in one natural excipient as binder, diluents and disintegrant. Int J Pharmacy and Pharm Sci. Vol.2, Suppl.2, 2011, 97-102.
3. Jaminet F, Delalatre L, Golfriaux C. Mechanism of action of starch as a tablet disintegrants. J Pharm. Sci. 1967; 60: 1235.
4. Haas S V. The value of the Banana in the Treatment of Celiac Disease. Am J Dis Child 1924; 28: 421.
5. Kokate, C.K., A.P. Purohit and S.B.Gokhale. Pharmacognosy, 38th edition, Nirali Prakashan. 2007. pp: 160-162.
6. Hadkar, U.B., Handbook of practical physical pharmacy and physical pharmaceutics. Nirali Prakashan. 2008. pp: 85(88): 92-93.
7. Jubril, J. Muazu and G. T. Mohammed. Effects of Phosphate Modified and Pregelatinized Sweet Potato Starches on Disintegrant Property of Paracetamol Tablet Formulations. Journal of Applied Pharmaceutical Science 02 (02); 2012: 32-36.
8. Lachman, H.A. Lieberman and J.L Kanig. The Theory and Practice of Industrial Pharmacy, Third edition Lea and febiger, Philadelphia. 1990. pp: 296-303: 336-342.
9. The Indian Pharmacopoeia. Volume I, the controller of publication, Ministry of Health and Family Welfare, Government of Indian, 2007 pp: 175-184.
10. Allen, L.V., N.G. Popovich and H.C. Ansel,. Pharmaceutical dosage forms and drug delivery systems. Eighth edition, Wolters Kluwers lippincott Williams & Wilkins Philadelphia. 2008. pp: 148-50: 227-259.
11. Jain, N.K., 2006. Pharmaceutical product development. First edition, CBS publishers and distributors, New Delhi and Bangalore, reprient 2008, pp: 100.
12. Muazu J, Musa H, Isah AB, Bhatia PG, Tom GM. Extraction and characterization of Kaffir Potato Starch: A potential Source of pharmaceutical raw material. *J. Nat. Prod. Plant Resour*, 2011, 1 (2): 41-49.
13. Leon Sharge/Andrew B C Yu; Biopharmaceutic considerations in Drug product Design, Applied biopharmaceutic and pharmacokinetics, NewDelhi, Mc Graw-Hill (Medical publishing Division), Fourth Edition, 2002; 284-288, 332-336.
14. Bankar, G.S. and C.T. Rhodes,. Modern Pharmaceutics, Third Edition revised and expanded, Marcel Dekker. New York, 1996. pp: 385.
15. Satyam Gangwar, Shivani Singh, Garima Garg, Vipin Garg, P.K.Sharma. To compare the disintegrating property of papaya starch and sago starch in paracetamol tablets. Int J Pharmacy and Pharm Sci. Vol.2, Suppl.2, 2010, 148-151.
16. Martin A; Micromeritics. In: Martin A, ed. Physical pharmacy. Baltimore, MD: Lippincott. Williams & Wilkins. 2001; 423.
17. Bi Y, Sunda H, Yonezawa Y, Danjo K. Evaluation of rapidly disintegrating tablets prepared by a direct compression method. Drug Dev Ind Pharm 1999; 25; 571-581.
18. EsezoboS. Evaluation of Sweet potato starch as a binder and disintegrant for paracetamol tablets. Nig. J. Pharm. Sci. 1986, 2(2): 44 – 51.
19. Gennaro, A.R., 1995, Remington. The science and practice of pharmacy, volume-II, Nineteenth edition, Mack Publishing Company, pp: 1635.
20. Guyot-Hermann, A. M. The disintegration and disintegrating agent; S.T.P. Pharmaceutical Science: 1992, 2(6): 445-462.
21. Hamid A. Merchant, Harris M. Shoaib, Jaweria Tazeen, AAPS PharmSciTech 2006; 7 (3) Article 78.
22. Cooper J and Gunn C; Tutorial Pharmacy; Powder flow and compaction; In: Carter Sj. Eds, New Delhi, India: CBS Publication. 1986; 211.
23. Mital, H. C. and Ocran, J.Cassava and Yam starches as tablet binder and disintegrant.*Pharm. Acta.Helv*. 1968, 43:493.
24. Musa, H. A Comparative Disintegrant Action of Pregelatinized maize starch on physical characteristic of low granules and tablets, Nig. J. Pharm. Res. 2005, 4 (2): 59 – 67
25. Olayemi O. J., Oyi A. R. and Allagh T .S. Comparative Evaluation of Maize, Rice and Wheat Starch Powders as Pharmaceutical Excipients, Nig. Journ.of Pharm. Sci. 2008, 7(1): 131– 138.
26. Yie W Chien. Oral drug delivery systems. In: Novel Drug Delivery Systems, 2nd edn, Drugs and the pharmaceutical sciences 1992; 50-139.
27. Prabakaran.L, Sendhil.D. Formulation development of patient friendly dosage form: All in one natural excipient as binder, diluent and disintegrant. Int J Pharmacy and Pharm Sci. Vol.3, Suppl.2, 2011, 97-102.