Indian Journal of Novel Drug Delivery

IJNDD

An Official Publication of Karnataka Education and Scientific Society

Research Article

Development and Evaluation of Banana Pulp Powder as a Pharmaceutical Excipient

RAVINDRA R PATIL*, YUVRAJ S PAWARA, NAYANA MAHAJAN, HITENDRA S MAHAJAN

R. C. Patel Institute of Pharmaceutical Education and Research, Shirpur Dist. Dhule 425 405 Maharashtra, India.

ARTICLE DETAILS

Article history:
Received on 7 September 2017
Modified on 15 February 2018
Accepted on 20 February 2018

Keywords:
Novel excipient,
Antimicrobial drug,
Suspending agents,
Suspension

ABSTRACT

The study was aimed extraction of banana powder from banana pulp; The presence of carbohydrate was confirmed by phytochemical analysis. The drugs and extract were found to be compatible as confirmed by IR spectral studies. The banana powder was evaluated for its micromeritic properties viz. suspending properties, Sedimentation volume, redispersibility, pH measurement, viscosity measurement and particle size. The formulations were prepared using Musa Paradisiacal pulp powder and other excipient. Suspension prepared by using Musa Paradisiacal pulp powder were found to be easily redispersible than other suspensions. Studies indicate that the pulp of Musa paradisiacal may be used as a pharmaceutical adjuvant and as a suspending agent at 2-4%w/v, concentration. This study confirmed that the banana pulp can be used as an effective release retardant and can be successfully used in commercial products. Ofloxacin suspension was prepared by using musa paradisiacal pulp powder as suspending agent and the suspension was evaluated for its various parameters and dissolution studies

INTRODUCTION

Banana is a tropical fruit of the banana tree. The banana obtained from *musa paradisiacal*, having family *Museace* [1]. The banana is the most commonly eaten fresh fruit worldwide. It believed to be rich of nutritional source, containing many vitamins, iron calcium, magnesium, sugar, protein, amino acid, fats, fatty acid, minerals and dietary fibbers, which aid in digestion and intestinal health [2]. Raw banana 10% with has 200 calories and about half the vitamin C found in banana [3]. It also contains more vitamin A, D, E, K, and B12 than most fruits. The mature banana can be recognized when it has a characteristic fragrance and smooth and soft skin [4]. The color of banana is pale yellow. Likes another popular fruits, banana can be eaten raw as fruit or can be processed to various products such as Snapple, [5]. The food becomes stable to both microbial and chemical deterioration [6]. The modern techniques such as spray drying, freeze drying and so on can be applied for this method [7].

Author for Correspondence:
Email: rrp2003@hotmail.com

MATERIALS AND METHODS

Materials

The Banana fruit was obtained local market (shirpur. Maharashtra) Ofloxacin obtained as gift sample from Alkem laboratories. Ltd, (Mumbai). Glycerin obtained from loba chemical (Mumbai), aspartame Vishal chemical (Mumbai), Manitol Loba chemical (Mumbai), Zinc oxide Rankem laboratory (Mumbai), Ttragacanth Rankem laboratory (Mumbai), Sodium cmc Rankem laboratory (Mumbai), Benzoic acid Rankem laboratory (Mumbai), Potassium dihydrogen phosphate Rankem laboratory (Mumbai), Sodium hydroxide Loba chemical (Mumbai India) Hydrochloric acid Loba chemical (Mumbai India) Methanol Loba chemical (Mumbai India) Distilled water rcpiper Shirpur All others chemical used were of analytical grade.

Preparation of Banana Fruit Pulp Powder

The Banana fruits were collected from the local market, washed through water and Peels were removed from pulp and cut into small pieces with the help of knife. The Banana pulp was homogenized by using mixer grinder and mechanical stirrer. The homogenized Banana juice was added 5% Manitol and frozen in defreeze. The frozen Banana pulp was kept in

freeze dryer at - 45°C. The frozen sample was allowed to sublime at - 75°C under vacuum. This process was continued up to 48 hr. up to getting dry Banana powder [1, 8-9].

Formulation of Suspension

All ingredients were passed from sieve number 100. Ofloxacin and glycerin were triturated together with 1:1 ratio. DBP was added and triturated by using mortar and pestle. About 30mg of aspartame was added as a sweetener. 0.1% benzoic acid was added as a preservative. All suspensions were deflocculated. For measurement of degree of flocculation, potassium dihydrogen phosphate (0.001mol) was added separately for measurement of degree of flocculation. The Ofloxacin suspension was prepared using different concentrations of DBP as suspending agent. The suspensions were prepared as mentioned in Table 1.

Table 1: Composition of Ofloxacin formulation

Sr. no	Content's	F-1	F-2	F-3	F-4	F-5
1	Ofloxacin (mg)	1230	1230	1230	1230	1230
2	Glycerin (ml)	2	2	2	2	2
3	Banana Powder(mg)	300	450	600	750	900
4	Aspartame (mg)	30	30	30	30	30
5	Benzoic Acid (mg)	0.03	0.03	0.03	0.03	0.03
6	Water up to (ml)	30	30	30	30	30

Evaluation of Lyophilized Banana powder

Phytochemical Examination

Molisch's test was performed to confirm the presence of Polysaccharide.

Procedure: To 2-3 ml. aqueous mixture of powder, add few drops of alpha naphthol solution in alcohol, shake and add conc. H_2SO_4, from sides of the test tube. Violet ring is formed at the junction of two liquids

Micromeritic Properties of Banana Powder

Bulk density, tap density, angle of repose, Hausner's ratio and Carr's index were determined.

Bulk Density: Apparent bulk density was determined by placing excipients blend into a graduated cylinder and measuring the volume (V) and weight (M) "As it is''. [10]

$$\textbf{Bulk Density} = \frac{\textbf{Mass of powder (M)}}{\textbf{Bulk volume of the powder (V)}} \ldots . (1)$$

Tapped Density: The measuring cylinder containing a known mass of blend was tapped for a fixed number of taps. The minimum volume (Vt) occupied in the cylinder and the weight (M) of the blend was measured. The tapped density (ρt) was calculated using following formula.

$$\textbf{Tapped Density} = \frac{\textbf{Weight of powder (M)}}{\textbf{Tapped Volume of the powder (Vt)}} \ldots\ldots (2)$$

Angle of Repose: the angle of repose was determined by the funnel method. The blend was poured through a funnel that can be raised vertically until maximum cone height 2 cm. (h) was obtained. Radius of the heap (r) was measured and angle of repose (q) was calculated using the following formula. [11]

$$q = Tan^{-1} h/r \ldots . (3)$$

Hausner's Ratio

Hausner's ratio was determined by following equation [14]

$$\textbf{Hausner's ratio} = \frac{\textbf{TBD}}{\textbf{LBD}} \ldots . (4)$$

Where,

TBD= Tapped Bulk density

LBD= Loose Bulk density

Carr's index

The compressibility index of all ingredients was determined by following equation [12]

$$\textbf{Carr's index} = \frac{\textbf{TBD} - \textbf{LBD}}{\textbf{TBD}} x100 \ldots (5)$$

Loss on Drying: Loss on drying was carried out as per method mentioned in I.P.2007 [13].

Fourier Transform Infrared Spectroscopy (FTIR)

The FTIR study of BPP was carried out to identify the functional group present in Material. For FTIR spectroscopy, BPP and dried KBR were mixed in ratio 1:100. Then small fraction of mixture was compressed on Automatic IR Press (Kimaya Engg. Thane, India), at pressure 10 tones, to form transparent pellet. Then the IR

spectrum of pellet was taken on FTIR spectrophotometer.

Thin Layer Chromatography
Aluminium backed silica gel 60 F254 HPTLC plates (10cm × 20 cm, layer thickness 0.2mm) as a stationary phase and mobile phase consisting of n- butanol: ammonia: triethylamine (4:2:4:0.5). Rf value of Ofloxacin was found to be 0.72 which was found to be same value as that on standard one.

Differential Scanning Calorimetry
The DSC thermogram of plain drug, drug-excipient physical mixture are shown in Figure. 2. the thermogram of Ofloxacin exhibited sharp endothermic peak at 267.87ºc indicated melting point which is reported in literature. Ofloxacin shows endothermic peaks in drug excipient physical mixture. This indicates no interaction between ofloxacin and DBP. DSC thermogram of DBP + Ofloxacin physical mixture is shown in Figure. 2.

Scanning Electron Microscopy
Extracted banana pulp powder is subjected for SEM studies to understand its surface morphological characters.

Evaluation of Formulation
Appearance
The tests are Physical observations of finalized formulation carried out during the manufacturing of suspension to ensure a stable, safe and quality product. These include:

pH Values
The pH of suspensions was measured, using calibrated pH meter, by dipping electrode in the suspension and value was noted.

Sedimentation Volume
Each suspension (50 ml) was placed in a 100 ml measuring cylinder and stored for 7 days at room temperature. The volume of the sediment at every hour for 7 hr and then every 24 hr for 7 days was noted. Marketed product IMOL was selected for comparison. The sedimentation volume of different suspensions was calculated by the equation [8].

$$\mathbf{F = Vu / V_0} \ldots (6)$$

Where
F is the sedimentation volume.
Vu is the ultimate volume of the sediment and
Vo is the original volume of the of suspension.

Redispersibility
The bottles containing suspension were held up right between the fingers and rotated clockwise upside down through 180º in a semicircular path and back in the anti-clock wise direction (one-cycle). This process was repeated continuously until the sediment was completely redispersed

Viscosity
The viscosity of suspension was measured, using Brookfield viscometer (Brookfield Engineering labs. INC. Middleboro, USA)

Particle Size Measurement
The particle size distribution of Ofloxacin in the suspension was determined using optical microscope. The suspensions were mixed thoroughly and a drop of the suspension was taken on a slide and spread into a thin film. A total of 100 particles were counted and their size was determined.

Degree of Flocculation
The degree of flocculation was determined from the following equation

$$\mathbf{\beta = F/F\infty} \ldots (7)$$

Where
F is the ultimate sedimentation volume in the flocculated suspension.
F∞ is the ultimate sedimentation volume in the deflocculated suspension.

Dissolution Test
In vitro dissolution studies on prepared suspension was carried out in 900 ml of pH 1.2 phosphate buffer using USP type II (paddle) apparatus at 50 rpm and maintain the temperature for both at 37 ±0.5ºC. Test sample (5 ml) was withdrawn at particular time interval and replaced with fresh dissolution medium maintained at 37 ± 0.5ºC. The samples were then filtered (membrane filter, 0.45µm) and analyzed using UV spectrophotometer at λmax294 nm for Ofloxacin respectively against the blank solution i.e. buffer 1.2pH.

Stability Study
The stability studies of the optimized suspension were carried out according to International Conference on Harmonization (ICH) Q1A (R2) guide lines. the optimized formulation was packed in amber colored glass vial and sealed with rubber caps after that vials were kept under ambient temperature and moisture condition (40±2ºc and 75±5% RH) for a period of 3 months

in stability chamber (Remi Lab., Bombay). Samples were withdrawn at 1 month, 2 months and 3 months intervals and evaluated for drug content, in vitro release and sedimentation value.

Evaluation of Suspensions

RESULT AND DISCUSSION

Phytochemical characterization of banana powder results indicates presence of carbohydrates and reducing sugar in the banana powder. Negative results were shown for alkaloids, tannins, glycosides, proteins and amino acids. As per physico chemical characterization banana powder was soluble in water and insoluble in acetone and other organic solvents. Total ash, water soluble ash and acid insoluble ash (%) was 0.64 and 0.89, respectively. FT-IR spectra for pure ofloxacin, banana pulp powder, and optimized ofloxacin suspension formulation F1 are shown in the Figure 1. There is a no changes in the absorption peaks of drug in the final formulation was observed. Hence, there is no interaction of the drug with the banana pulp powder as well as other excipients used. SEM photos of banana pulp powder shown in Fig. 3. The banana pulp powder particles are asymmetric and smooth surface observed. Particle size of the all suspension formulations were range of 10 - 50 µm determined by microscopic method. Drug content of suspension formulations prepared with banana pulp powder was found to be in the range 95.78 96.15 % shown in Table 4. Sedimentation studies percentage sedimentation volume of ofloxacin suspensions was directly proportional to suspending agent concentration. However, in each suspension percentage sedimentation volume inversely proportional to time in days. In case of F1 formulation as the time increased from zero to 45 days the percentage sedimentation volume decreased from 50 to 15 (Table 5).Whereas formulation F3 shows 70 % sedimentation volume. Hence, F1 was selected as an optimized formulation. Redispersibility and pH was found to be in the range of 7.2-7.8 [Table 4]. In vitro release studies of suspension showed that 85.71 % drug released within 15 minutes in case of formulation F3. Whereas formulation F1 released 96.15 % within 60 minutes, formulation F1 & F3 released 98.72 and 99.39 % within 22 and 24 minutes. As percentage of banana peel mucilage powder increased in the formulation increase amount of time taken to release about 98 % of the drug from different suspension formulations. Formulation F9 is optimized even though formulation F6, F7 & F8 released 98 % of the drug earlier to the formulation F9 because formulations F6, F7 & F8 did not show enough percentage sedimentation volume. Release kinetics of optimized tablet and suspension formulations was followed zero order kinetics and non fickian model. The stability studies for optimized formulations were carried for 3 months. There was no significant change in the physical property and drug content during the study period.

Physicochemical Characterization of DBP (Banana Pulp Powder)

The results of physicochemical properties of DBP are shown in Table 2. The powder was slightly soluble in maximum solvents except boiling water. The loss on drying, ash values and microbial load all were within official limits. The results are shown in following Table 2.

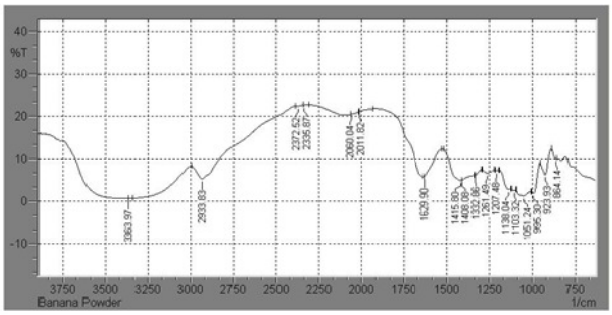
Table 2: Specification of DBP

Sr.No.	Parameter	Result (DBP)
1	**Solubility**	Slightly soluble in water, NaOH, HCL, ethanol
2	**Loss on drying (%)**	7.9
3	**Total ash (%)**	5.94
4	**Acid insoluble ash**	0.64
5	**Microbial load (micro-organis m/gram)**	Not more than – 103 Not more than – 102
6	**Angle of repose (θ)**	28.6± 2.6
7	**Density** **a. Bulk density (g/cc)** **b. Tapped density (g/cc)**	 0.27±1.1 0.36±0.03
8	**Carr`s index (%)**	12.13±1.2
9	**Hausner`s ratio**	1.33±0.03
10	**Specific gravity**	1.34
11	**Swelling index**	128%
12	**Moisture content**	2.13±1.1
13	**pH**	7.8

Infrared Spectroscopy

The IR spectrum of novel excipient is presented in Figure 1. Observed peaks are shown in Table 3. From the FTIR spectra it was observed that, the DBP showed some characteristic bands between 4000-700 cm-1. Range like the broad band between 3363.97 cm-1, sharp peak at 2933.83cm-1, 1629cm-1, which identifies

presence of free OH, C-H Stretching, C=O Stretching respectively.



Figu1: IR spectra of DBP

Table 3: IR ranges for DBP

Peak (cm-1)	Chemical group
3363.97	O-H (stretch)
2933.83	C-H (stretch)
1629.90	C=O

Differential Scanning Calorimetry

The melting point of DBP was detected by capillary method and differential scanning calorimetry at scan rate of 10ºc/min. It was observed that by capillary method DBP melts at 165ºc and by DSC it was shown that the material does not shows melting up to the 240ºc instead of this it was charred at 165.97ºc-221.02ºc. DSC of material shows maximum peak since glass transition temperature (Figure. 2)

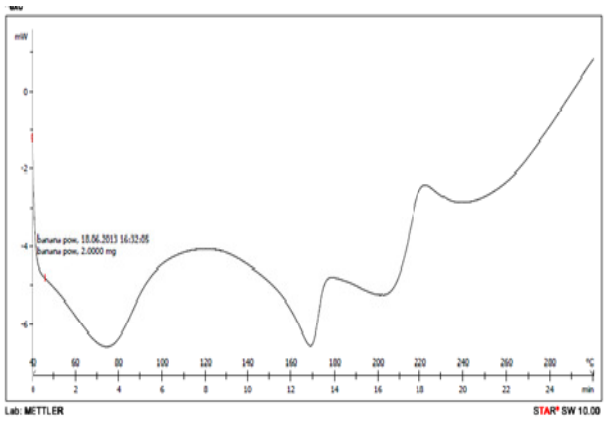


Figure 2: DSC thermogram of DBP

Scanning Electron Microscopy

The mucilaginous nature of the DBP is evident from their SEM photomicrographs. As can be seen in the photomicrograph, there are some pores and in the powder. In SEM photomicrograph of DBP it can be seen that the particles of powder appears irregular in shape having film like structure. The material appears in the form of aggregated particles with fluffy nature which shows its mucilaginous nature (Figure. 3).

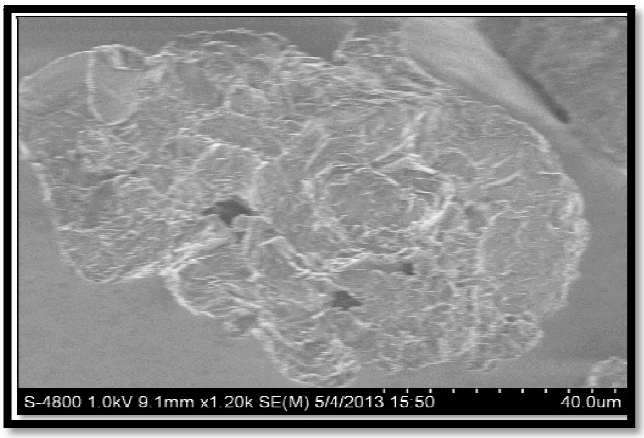


Figure 3: SEM an**alysis DBP**

Table 4: Evaluation parameter

Parameter	S1	S2	S3	S4	S5
PH	7.26	7.7	7.40	7.36	7.22
Viscosity (cp)	90	90	110	115	120
Drug content %	96.15	94.05	95.78	95.23	95.64

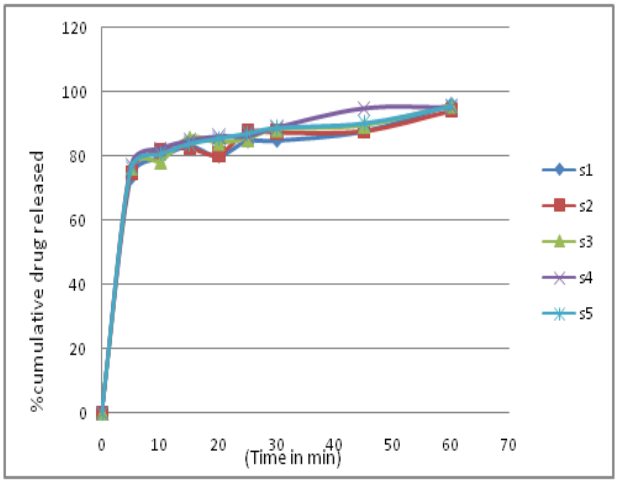


Figure 4: Dissolution profile of Ofloxacine suspension in buffer 1.2 pH

The release profiles of the freshly prepared suspensions are shown in Figure .4. The order of percentage cumulative drug release (%CDR) at 60 min were S1>S3>S5>S4>S2 with values of 96.15, 95.78, 95.64, 95.23, 94.05 %. From the dissolution study, it was concluded that DBP in the formulation does not affects on the dissolution profile of drug. Increase in the concentration of DBP does not interfere with dissolution of drug.

Table 5: Stability Studies

Evaluation parameters	Before stability storage	After 1 month	After 2 month	After 3 month
Drug content (%)	98.56±0.13	98.01±0.83	98.12±0.16	98.36±0.56
In-vitro drug release	95.23±0.15	95.01±0.23	95.32±0.32	95.76±0.54
PH	7.32	7.03	7.13	7.20
Sedimentation volume (F)	1	0.7	0.5	0.5

Stability Study of Suspension

Sedimentation studies showed that the sedimentation volume of S4 & S5 batches was above 0.9 after 1 hour. The batch S4 contains less amount of suspending agent than batch S4. So, the S4 batch was selected as optimized batch. After storage of formulation (S4) it was analysed for various physical parameters. No major difference was found between evaluate parameters before and after storage and all are in acceptable limits (Table. 5)

During the stability studies it was found that, presence of banana pulp powder in the formulation does not interferes with the drug content, pH of the formulation and drug release. The sedimentation volume (F) of the suspension decreases as increase in time. Up to 2 months it gets decreases but after that it remains same.

ACKNOWLEDGEMENT

Authors are thankful to Dr. S. J. Surana principal, R. C. Patel institute of pharmaceutical education & research for the providing necessary facilities to carry out research work.

REFERENCE

[1] Dr. Khandelwal K. R. 'Practical Pharmacognosy Techniques and experiments', Nirali prakashan, pp 25.1-25.9

[2] Roos, Y.H. and Karel, M. 1991. Phase transition of amorphous sucrose and sucrose solution. J. Food Sci. *56*, 38–49.

[3] Roos, Y.H. 1995. Glass transition-related physicochemical changes in foods. Food Technol. *10*, 97–102

[4] Ranadheer Reddy V; Ravindrakullai Reddy M. Vol. 2 (4) Oct-Dec 2013, "Evaluation of musa paradisiacal (Banana peel) Mucilage as pharmaceutical excipient", international journal of pharmaceutical and chemical sciences Vol. 2 (4) page 2057.

[5] Pifferi G, and restani p. 2003, the safety of pharmaceutical excipient

[6] Baldric P, 2000, pharmaceutical excipient develops [meant: the need for clinical guidance, regal, toxicol, pharmacol, PP. 32-210.

[7] Anroop, B, Bhatnagar SP, Ghosh P, 2005, 'Studies on Ocimum gratissimum Seed mucilage: evaluation of suspending properties', Ind. J.Pharm. Sci., vol 67(2), pp.206-209

[8] Baldrick, P 2000, 'Pharmaceutical excipient development: the need for clinical guidance', Regul. Toxicol. Pharmacol, pp. 32-210.

[9] Crowley, P & Martini, C 2001, 'Drug excipient interactions', *Pharmaceutical Techn. Europe*, pp. 26-34.

[10] Lachman, L, Lieberman HA, Kanig JL 1990, *The Theory and Practice of Industrial Pharmacy*, 3 rd ed. Bombay, Varghese Publishing House, pp.67-68.

[11] Butchko, HH et al 2002, 'Aspartame: review of safety', Regul. Toxcol. Pharmacol, vol. 35(2), pp.70-93.

[12] British Pharmacopoeia, British Pharmacopoeia commission, 2002, 1247

[13] Indian Pharmacopoeia, The Indian Pharmacopoeia commission, Ghazibad, 2010 vol 1, pp.1808, 2095.