ORIGINAL ARTICLE

Enhancement of dissolution rate and formulation development of irbesartan tablets by employing starch phosphate: A new modified starch

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The objective of the present study is to prepare, characterize, and evaluate starch phosphate as a carrier in solid dispersions for enhancing the dissolution rate of irbesartan (IRB). The feasibility of formulating solid dispersions of IRB in starch phosphate into compressed tablets with enhanced dissolution rate was also investigated. Starch phosphate prepared by reacting starch with di-sodium hydrogen orthophosphate anhydrous at elevated temperatures was insoluble in water and has good swelling (400%) property without pasting or gelling when heated in water. Solid dispersions of IRB in starch phosphate prepared by solvent evaporation method employing various weight ratios of drug: Starch phosphate gave rapid and higher dissolution of IRB when compared to pure drug. The 19.92- and 39.98-fold increase in the dissolution rate (K_1) of IRB was observed with solid dispersions ISD4 and ISD5, respectively. The dissolution efficiency up to 30 min (DE_{30}) was also increased from 10.58% in the case of IRB pure drug to 81.77% and 88.28% in the case of ISD4 and ISD5, respectively. IRB tablets formulated employing its solid dispersions in starch phosphate also gave rapid and higher dissolution rate and DE_{30} when compared to plain and commercial tablets. The 33.82- and 59.66-fold increase in the dissolution rate (K_1) was observed with formulations IBTF2 and IBTF3 when compared to formulation IBTF1. Starch phosphate could be used as a carrier to enhance the dissolution rate of IRB from its solid dispersions as well as tablet formulations.

Key words: *Irbesartan, solid dispersions, starch phosphate, tablets and modified starches*

INTRODUCTION

Irbesartan (IRB), used orally for the treatment of hypertension, is a nonpeptide, specific competitive antagonist of the Angiotensin II receptor (AT1 subtype).[1,2] The drug is lipophilic and practically insoluble in water. The low aqueous solubility and slow dissolution may lead to irreproducible clinical response or therapeutic failure.[3] Improvement of aqueous solubility in such cases shall lead to improved therapeutic efficacy of the drug. Several techniques[4] such as micronization, cyclodextrin complexation, use of surfactants and solubilizers, solid dispersion in water soluble and dispersible carriers, use of salts, prodrugs, and polymorphs, which exhibit high solubility, microemulsions, and self-emulsifying micro and nano-disperse systems have been used to enhance the solubility, dissolution rate, and bioavailability of poorly soluble drugs. Among the various approaches, solid dispersions in water dispersible excipients are a simple, industrially useful approach for enhancing the solubility, dissolution rate, and bioavailability of poorly soluble drugs.

Starch phosphate is one of the modified starches used in the frozen food industry.[5,6] It is produced by phosphorification of free hydroxyl groups of anhydroglucose units of the starch molecule. They are esterified with phosphate reagents. Phosphate reagents

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Access this article online

Quick Response Code:

Website: www.asiapharmaceutics.info

DOI: 10.4103/0973-8398.139180

for starch phosphate monoester are orthophosphate salts.[7] We have earlier reported[8,9] starch phosphate, a new modified starch, as an efficient carrier in solid dispersions for enhancing the dissolution rate of poorly soluble drugs.

The objective of the present study is to prepare, characterize, and evaluate starch phosphate as a carrier in solid dispersions for enhancing the dissolution rate of IRB. The feasibility of formulating solid dispersions of IRB in starch phosphate into compressed tablets with enhanced dissolution rate was also investigated.

MATERIALS AND METHODS

Materials

Irbesartan was a gift sample from M/s Dr. Reddys Pvt. Ltd., Hyderabad, Starch phosphate was prepared in the laboratory, Methanol (Qualigens), potato starch (S.D Fine Chemicals), di-sodium hydrogen orthophosphate anhydrous (S.D Fine Chemicals), crospovidone lactose, talc, magnesium stearate, and acacia were procured from commercial sources.

Methods

Preparation of starch phosphate

Starch phosphate was prepared based on the method of Sung *et al*.[10] with some modifications. Potato starch (100 g) and di-sodium hydrogen orthophosphate anhydrous (30 g) were suspended in 100 ml of water and continuously stirred for 20 min. This starch slurry was then filtered, and the wet starch mixture was conditioned for 12 h at room temperature (28°C). To enhance phosphorylation, this mixture was heated in a forced air oven at 130°C for 3 h. The product obtained was ground and sized.

Characterization of starch phosphate

The starch phosphate prepared was evaluated for the following.

Solubility

Solubility of starch phosphate was tested in water, aqueous buffers of pH 1.2, 4.5, and 7.4 and organic solvents such as alcohol, dichloromethane, chloroform, acetone, and petroleum ether.

pH

The pH of 1% w/v slurry was measured.

Melting point

Melting point was determined by using melting point apparatus.

Viscosity

Viscosity of 1% dispersion in water was measured using Ostwald viscometer.

Swelling Index

Starch phosphate (200 mg) was added to 10 ml of water and light liquid paraffin taken in two different graduated test tubes and mixed. The dispersion in the tubes was allowed to stand for 12 h. The volumes of the sediment in the tubes were recorded. The swelling index of the material was calculated as follows.

$$S.I\ (\%) = \frac{\text{Volume of sediment in water} - \text{Volume of sediment in light liquid paraffin}}{\text{Volume of sediment in light liquid paraffin}} \times 100$$

Test for gelling property

The gelling property (gelatinization) of the starch and starch phosphate prepared was evaluated by heating 7% w/v dispersion of each in water at 100°C for 30 min.

Moisture absorption

The hygroscopic nature of starch phosphate was evaluated by moisture absorption studies in a closed desiccator at 84% relative humidity and room temperature.

Particle size

Particle size analysis was performed by sieving using standard sieves.

Density

Density (g/cc) was determined by liquid displacement method using benzene as liquid.

Bulk density

Bulk density (g/cc) was determined by three-tap method in a graduated cylinder.[11]

Angle of repose

Angle of repose was measured by fixed funnel method.[12]

Compressibility index

Compressibility index (CI) was determined by measuring the initial volume (V_o) and final volume (V) after hundred tapings of a sample of starch phosphate in a measuring cylinder. CI was calculated using equation[13]

$$CI = \frac{V_o - V}{V_o} \times 100$$

Preparation of solid dispersions of irbesartan in starch phosphate

Solid dispersions of IRB and starch phosphate were prepared in 3:1 (IBSD-1), 2:1 (IBSD-2), 1:1 (IBSD-3), 1:2 (IBSD-4), and 1:3 (IBSD-5) ratios of drug: carrier by solvent evaporation method. IRB (1 g) was dissolved in methanol (10 ml) in a dry mortar to get a clear solution. Starch phosphate (1 g) was then added and mixed. The thick slurry was triturated for 30 min for complete evaporation of methanol and then dried

at 55°C until dry. The dried mass was pulverized and sieved through mesh no. 100.

Characterization of irbesartan solid dispersions in starch phosphate

Fourier transform infrared spectroscopy

Fourier transform infrared spectroscopy (FTIR) spectra of the IRB, starch phosphate, and its solid dispersions (ISD3 and ISD4) were recorded on Perkin Elmer spectrophotometer using KBr discs. The instrument was operated under dry air purge, and the scans were collected at scanning speed of 2 mm/s with resolution of 4 cm^{-1} over the region of 4000-400 cm^{-1}.

X-ray diffraction

Powder X-ray diffraction (XRD) patterns of the IRB, starch phosphate, and its solid dispersions (ISD3 and ISD4) were recorded using Phillips *P* Analytical X'Pert PRO powder X-ray diffractometer (the Netherlands) using Ni-filtered, CuKα radiation, a voltage of 45 kV, and current of 40 mA. The scanning rate employed was 1°C/min and samples were analyzed between 2θ angles of over 5-45°.

Differential scanning calorimetry (DSC) analysis

Differential scanning calorimetry (DSC) scans of the IRB, starch phosphate, and its solid dispersions (ISD3 and ISD4) were recorded using Mettler Toledo DSC-823 DSC module controlled by STAR SW 9.01 software (Mettler, Switzerland). The samples (5-8 mg) were accurately weighed in crimped aluminum pans before heating under nitrogen flow (40 ml/min) at a scanning rate of 10°C/min over the temperature range of 30-300°C. An empty aluminum pan was used as a reference.

Scanning electron microscopy

The surface morphology of the IRB, starch phosphate, and its solid dispersions (ISD3 and ISD4) were examined by a JEOL/EO/JSM-6610scanning electron microscope (Japan). The samples were fixed on a brass stub using double-sided tape and made electrically conductive by coating with a thin layer of platinum. The photographs were taken at an electric voltage of 10 kV.

Formulation of irbesartan tablets

Four different batches of tablets each containing 50 mg of IRB were formulated and evaluated. The formulae of tablets prepared are given in Table 1. In batch IBF1, the tablets were formulated employing IRB alone and lactose as diluent and prepared by wet granulation method using water as granulating fluid. In batch IBF2, the tablets were formulated employing IRB-starch phosphate (1:2) solid dispersion and the tablets were prepared by wet granulation method employing water as granulating fluid. In batch IBF3, the tablets were formulated employing IRB-starch phosphate (1:3) solid dispersion and the tablets were prepared by wet granulation method employing water as granulating fluid. In all the batches, acacia (2%) as the binder, crospovidone (5%) as disintegrant, talc (2%), and magnesium stearate (2%) as lubricants were used. In each batch, 100 tablets were prepared.

Table 1: Formulae of irbesartan tablets formulated employing irbesartan alone and its solid dispersions in starch phosphate

Ingredient (mg)/tablet	Formulation		
	IBTF1	IBTF2	IBTF3
Irbesartan	50	50	50
Starch phosphate	-	100	150
Lactose	155.8	55.8	5.8
Crospovidone	11	11	11
Acacia	4.4	4.4	4.4
Talc	4.4	4.4	4.4
Magnesium stearate	4.4	4.4	4.4
Total weight of tablet (mg)	230	230	230

Preparation of irbesartan tablets by wet granulation method

Compressed tablets each containing 50 mg of IRB were prepared by wet granulation method employing IRB alone (IBTF1) and its solid dispersions in starch phosphate (IBTF2 and IBTF3). The required quantities of IRB or IRB-starch phosphate solid dispersions, lactose, and acacia were mixed thoroughly in a mortar by following geometric dilution technique. The granulating fluid, water was added and mixed thoroughly to form dough mass. The mass was passed through mesh no 12 to obtain wet granules. The wet granules were dried at 60°C for 2 h. The dried granules were passed through mesh no 16 to break the aggregates. Crospovidone and the lubricants (talc and magnesium stearate) were passed through mesh no 100 on to dry granules and blended in a closed polyethylene bag. The tablet granules were compressed into tablets on a Cadmach 16-station rotary tablet punching machine (M/s Cadmach Engineering Co. Pvt. Ltd., Mumbai) to a hardness of 6 kg/cm^2 using 9 mm round and flat punches.

Evaluation of tablets

All the tablets prepared were evaluated for content of active ingredients, hardness, friability, disintegration time, and dissolution rate as per official (IP) methods. Hardness of tablets was tested using Monsanto Hardness tester. Friability of the tablets was determined in a Roche friabilator. Disintegration time was determined in a Labindia tablet disintegration test machine (Model: DT 1000) using water as test fluid.

Estimation of drug content in the tablets

From each batch of tablets prepared, 20 tablets were accurately weighed and powdered. Tablet powder equivalent to 50 mg of drug was taken for assay into a 100 ml conical flask and extracted with 3 ml × 20 ml quantities of methanol. The methanolic extracts were filtered and collected into a 100 ml volumetric flask, and the volume was made up to

100 ml with methanol. The solution was then suitably diluted with 0.1N hydrochloric acid. The absorbance of the solution was measured at 230 nm. Drug content of the tablets was calculated using the standard calibration curve.

In vitro drug release study

Dissolution rate of IRB as such and from its solid dispersions and tablets prepared was studied in 0.1N hydrochloric acid (900 ml) employing USP 8-station Dissolution Rate Test Apparatus (M/s Labindia Disso 8000) with a paddle stirrer at 50 rpm. IRB or its solid dispersions equivalent of 100 mg of IRB and one tablet containing 50 mg of IRB was used in each test. A temperature 37°C ± 1°C was maintained in each test. Samples of dissolution medium (5 ml) were withdrawn through a filter (0.45 µ) at different time intervals and assayed for IRB at 230 nm. For comparison, dissolution of IRB from one commercial brand was also studied. All the dissolution experiments were conducted in triplicate ($n = 3$).

RESULTS AND DISCUSSION

Starch phosphate was prepared by reacting starch with di-sodium hydrogen orthophosphate anhydrous at elevated temperatures. The reactions involved are shown in Figure 1. Starch phosphate prepared was found to be white, crystalline, and nonhygroscopic powder and can easily be ground to different sizes. Powder which passes through mesh no. 80 and retained on mesh no. 120 was collected. This powder has an average particle size of 152 µm. The starch phosphate prepared was characterized by determining various physical properties. The properties of starch phosphate prepared are summarized in Table 2.

When tested for mp, it was charred at 210°C. Starch phosphate prepared was insoluble in water, aqueous fluids of acidic and alkaline pH, and several organic solvents tested. In water, it exhibited good swelling (400%). No gelling/pasting was observed with starch phosphate when its aqueous dispersion was heated at 100°C for 30 min, whereas potato starch formed a paste/gel during the above heat treatment. In the micromeritic evaluation, the angle of repose and CI values revealed the excellent flow characteristic of starch phosphate prepared.

As starch phosphate, a chemically modified starch was found to be insoluble in water and has good swelling property without pasting or gelling when heated in water

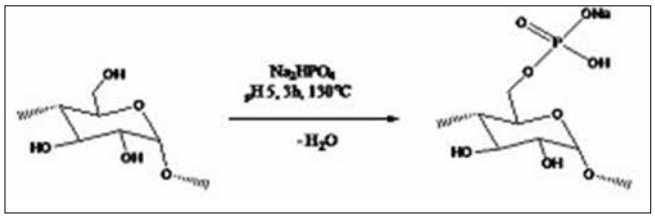

Figure 1: Phosphorification of potato starch to produce starch phosphate

it is considered as a promising carrier for solid dispersions for enhancing the dissolution rate of poorly soluble drugs. Solid dispersions of IRB in starch phosphate were prepared by solvent evaporation method employing various weight ratios of drug: Starch phosphate. All the solid dispersions prepared were found to be fine and free flowing powders with an angle of repose in the range 15-20°. Low CV (<1.0%) in the percent drug content indicated uniformity of drug content in each batch of solid dispersions prepared.

Fourier transform infrared spectroscopy

The compatibility of IRB with starch phosphate and other excipients used in the study was evaluated by FTIR spectra. FTIR spectrum of pure drug and mixtures is shown in Figure 2. Infrared (IR) spectrum of IRB was characterized by strong absorption peaks at 1731 and 1622 cm^{-1} assigned to C = O

Table 2: Physical properties of the starch phosphate prepared

Property	Result
Solubility	Insoluble in all aqueous and organic solvents tested
pH (1% w/v aqueous dispersion)	7.25
Melting point	Charred at 210°C
Viscosity (1% w/v aqueous dispersion)	2.11 cps
Swelling index	400
Gelling property	No gelling and the swollen particles of starch phosphate separated from water. Whereas in the case of starch, it was gelatinized and formed gel
Moisture absorption	<4.0%
Particle size	152 µm (80/120 mesh)
Density	1.667 g/cc
Bulk density	0.534 g/cc
Angle of repose	20.04°
Compressibility index	11.01%

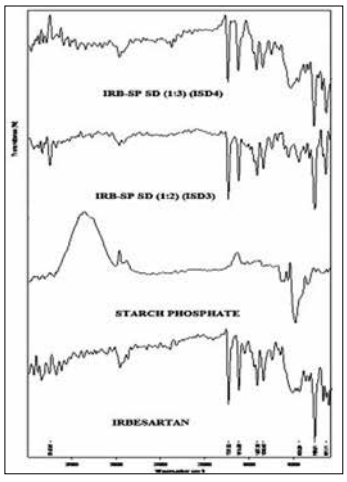

Figure 2: Fourier transform infrared spectroscopy spectra of pure drug and its solid dispersions in starch phosphate

and C-N stretch, respectively. From the spectral study, it was observed that there was no significant change in the IR absorption peaks of pure drug and mixtures. Hence, there was no drug-excipient interaction between the pure drug and other excipients used in the study.

Differential scanning calorimetry

The DSC curve for IRB alone and its mixture with the starch phosphate and other excipients used in the study is shown in Figure 3. The thermal curve of IRB showed a sharp melting endothermic peak at 180.52°C corresponding to the melting point of the drug. The DSC thermogram of IRB-starch phosphate solid dispersion showed a sharp melting endothermic peak at 178.81°C. In the thermal curve of solid dispersions of drug in starch phosphate, the endothermic peak for drug is slightly broadened.

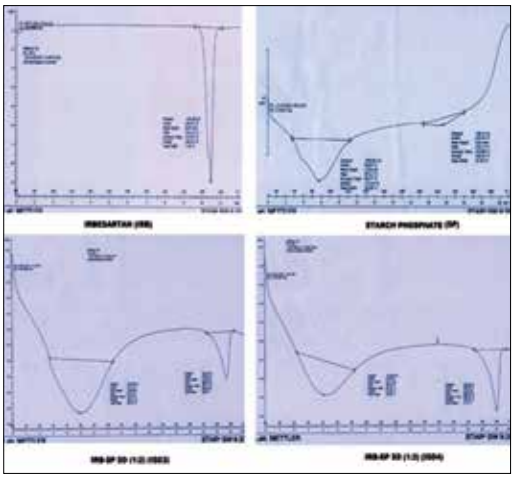

Figure 3: Differential scanning calorimetry thermograms of pure drug and its solid dispersions in starch phosphate

X-ray diffraction

The powder diffraction patterns of IRB and its solid dispersions (ISD3 and ISD4) are shown in Figure 4. The XRD pattern of drug was characterized by presence of sharp peaks at 4.7°, 12.40°, 20.4°, and 24.0° (2θ) indicative of the crystalline nature of drug. The crystalline nature of starch phosphate was evident from the presence of sharp peaks at 16.9°, 20.10°, 24.0°, and 33.11° (2θ). The solid dispersions of IRB in starch phosphate were characterized by presence of combined peaks of drug as well as starch phosphate, however, with slightly reduced intensities. The sharpness of peaks as well as the number of sharp peaks existing with plain drug was found to be significantly reduced in case of solid dispersions which may mainly be due to the existence of drug in a totally different form other than crystalline form.

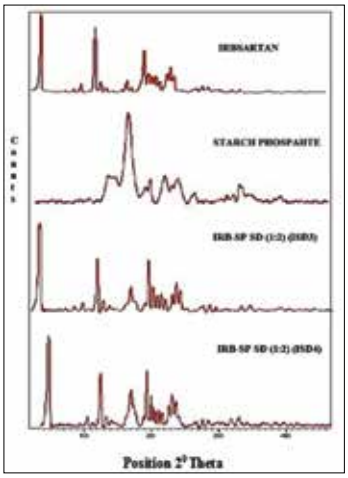

Figure 4: X-ray diffraction spectra of pure drug and its solid dispersions in starch phosphate

Scanning electron microscopy

The scanning electron microscopy (SEM) photographs of IRB and its solid dispersions (ISD3 and ISD4) are shown in Figure 5. From SEM spectra as seen in Figure 5a, pure IRB particles appeared as irregular shaped large particles, starch phosphate particles [Figure 5b] consisted of crystals of round sizes. Microscopic examination of IRB-starch phosphate solid dispersion (ISD3) [Figure 5c] showed the presence of IRB crystals mixed and adhered on the surface of starch phosphate particles. In the case of IRB–starch phosphate solid dispersion (ISD4) as shown in Figure 5d, showed small and irregular pieces with a change from crystalline to amorphous nature and uniformly coated on the surface of the starch phosphate.

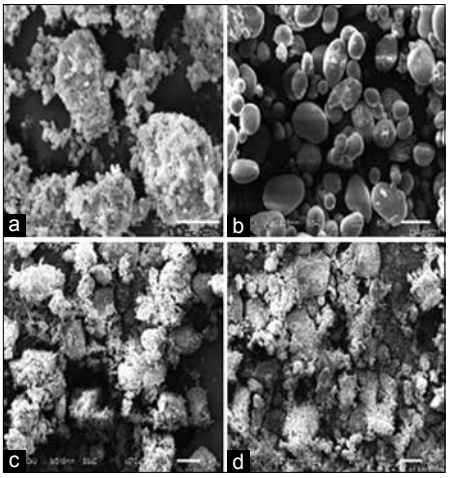

Figure 5: Scanning electron microscopy photographs of (a) irbesartan, (b) starch phosphate, (c) irbesartan: Starch phosphate (1:2), and (d) irbesartan: Starch phosphate (1:3)

In vitro drug release study

The dissolution rate of IRB alone and from its solid dispersions was studied in 0.1N hydrochloric acid (pH 1.2). All the solid dispersions prepared gave rapid and higher dissolution of IRB when compared to pure drug. The dissolution data were analyzed as per zero order and first order kinetics in each case. The R^2 values were higher in the first order model than in the zero order model indicating that the dissolution of IRB as such and from

its solid dispersions followed first order kinetics. The corresponding dissolution rate (K_1) values of various products were estimated. DE_{30} values were calculated as described by Khan:[14]

$$DE_T = \frac{\int_0^T y_t . dt}{y_{100} . T}$$

Where DE_T is dissolution efficiency at time T, y_t is percent of drug dissolved at any time t, y_{100} denotes 100% dissolution, and the integral represents the area under dissolution curve between time zero and T. The time T in this study was 30 min. The dissolution parameters of IRB and its solid dispersions are given in Table 3. Solid dispersions of IRB showed superior dissolution properties when compared to IRB pure drug. Both dissolution rate (K_1) and DE_{30} values were much higher in the case of solid dispersions when compared to IRB pure drug. The dissolution rate (K_1) and DE_{30} values increased as the proportion of starch phosphate were increased. The number of folds of increase in dissolution rate (K_1) and DE_{30} observed with various solid dispersions are shown in Table 3. The 19.92- and 39.98-fold increase in the dissolution rate (K_1) of IRB was observed with solid dispersions ISD4 and ISD5, respectively.

The DE_{30} was also increased from 10.58% in the case of IRB pure drug to 81.77% and 88.28% in the case of ISD4 and ISD5, respectively. Thus, solid dispersions of IRB prepared employing starch phosphate as carrier showed marked enhancement in the dissolution rate (K_1) and DE_{30} of IRB. The feasibility of formulating IRB solid dispersions in starch phosphate into tablets retaining their rapid and higher dissolution rates was also investigated. IRB (50 mg) tablets were prepared employing IRB alone and its solid dispersions ISD4 and ISD5 by wet granulation method and were evaluated. All the IRB tablets prepared were found to contain the IRB within 100% ±2% of the labeled claim. Hardness of the tablets was in the range 6-7 kg/cm^2. Percentage weight loss in the friability test was <0.47% in all the cases. Tablets formulated employing solid dispersions disintegrated rapidly within 1.0 min. Tablets formulated employing IRB pure drug disintegrated within 8 min. As such, all the IRB tablets prepared were of good quality with regard to drug content, friability, hardness, and disintegration time and fulfilled the official (IP) specifications of uncoated tablets.

The dissolution parameters of the prepared tablets are given in Table 4. Dissolution of IRB from all the tablets prepared followed first-order kinetics with correlation coefficient $R^2 > 0.989$. IRB tablets formulated employing its solid dispersions in starch phosphate (IBTF2 and IBTF3) gave rapid and higher dissolution rate and DE_{30} when compared to plain (TF1) and commercial tablets. The 33.82- and 59.66-fold increase in the dissolution rate (K_1) was observed with formulations IBTF2 and IBTF3 when compared to formulation IBTF1. The 1.52- and 2.64-fold increase in the dissolution rate (K_1) was observed with formulations IBTF2 and IBTF3 when compared to the commercial formulation. Thus, solid dispersions of IRB in starch phosphate could be formulated into compressed tablets retaining their fast dissolution characteristics and fulfilling official standards.

CONCLUSION

Starch phosphate prepared by reacting starch with di-sodium hydrogen orthophosphate anhydrous at elevated

Table 3: Dissolution parameters of the solid dispersions of irbesartan prepared employing starch phosphate as a carrier

Formulation	PD_{10} (%)	T_{50} (min)	DE_{30} (%)	Increase in DE_{30} (number of folds)	K_1 (min^{-1})	Increase in K_1 (number of folds)
Irbesartan	8.61	>60	10.58	-	0.0079	-
ISD1	36.99	22.0	40.70	3.84	0.0168	2.12
ISD2	55.64	<5	64.15	6.06	0.0629	7.96
ISD3	67.82	<5	73.01	6.90	0.0862	10.91
ISD4	82.45	<5	81.77	7.70	0.1574	19.92
ISD5	95.75	<5	88.28	8.34	0.3159	39.98

Ratio of drug: Starch phosphate in solid dispersions: ISD1 (3:1); ISD2 (2:1); ISD3 (1:1); ISD4 (1:2); ISD5 (1:3), PD_{10}: Percent dissolved in 10 min, T_{50}: Time for 50% dissolution, DE_{30}: Dissolution efficiency up to 30 min, K_1: First order dissolution rate

Table 4: Dissolution parameters of irbesartan tablets formulated employing irbesartan alone and its solid dispersions in starch phosphate

Formulation	PD_{10} (%)	T_{50} (min)	DE_{30} (%)	Increase in DE_{30} (number of folds)	K_1 (min^{-1})	Increase in K_1 (number of folds)
IBTF1	17.20	>60	20.13	-	0.009	-
IBTF2	89.60	<5	86.73	4.30	0.304	33.82
IBTF3	99.53	<5	90.17	4.47	0.537	59.66
Commercial	71.82	8.0	70.92	3.52	0.203	22.56

IBTF1: Tablets formulated employing irbesartan alone and using lactose as diluent, IBTF2: Tablets formulated employing irbesartan solid dispersion ISD4, IBTF3: Tablets formulated employing irbesartan solid dispersion ISD5, DE_{30}: Dissolution efficiency up to 30 min

temperatures was insoluble in water and has good swelling (400%) property without pasting or gelling when heated in water. Solid dispersions of IRB in starch phosphate prepared by solvent evaporation method employing various weight ratios of drug: starch phosphate gave rapid and higher dissolution of IRB when compared to pure drug. Dissolution followed first-order kinetics. The 19.92- and 39.98-fold increase in the dissolution rate(K_1) of IRB was observed with solid dispersions ISD4 and ISD5, respectively. The DE_{30} was also increased from 10.58% in the case of IRB pure drug to 81.77% and 88.28% in the case of ISD4 and ISD5, respectively. IRB tablets formulated employing its solid dispersions in starch phosphate also gave rapid and higher dissolution rate and DE_{30} when compared to plain and commercial tablets. The 33.82- and 59.66- fold increase in the dissolution rate (K_1) was observed with formulations IBTF2 and IBTF3 when compared to formulation IBTF1. The 1.52- and 2.64- fold increase in the dissolution rate (K_1) was observed with formulations IBTF2 and IBTF3 when compared to the commercial formulation. Solid dispersions of IRB prepared employing starch phosphate as carrier showed marked enhancement in the dissolution rate (K_1) and DE_{30} of IRB. These solid dispersions could be formulated into compressed tablets retaining their fast dissolution characteristics and fulfilling official (IP) standards.

ACKNOWLEDGMENTS

The authors are thankful to University Grants Commission, New Delhi for providing financial assistance in the form of UGC JRF to Veeraiah Enturi. Authors are thankful for Advanced Analytical Laboratory, Andhra University for Providing X-RD, SEM, and FTIR facility.

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How to cite this article: Enturi V, Chowdary BY, Chowdary K. Enhancement of dissolution rate and formulation development of irbesartan tablets by employing starch phosphate: A new modified starch. Asian J Pharm 2014;8:171-7.

Source of Support: Nil. **Conflict of Interest:** None declared.