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Review Article

AN OVERVIEW ON TECHNIQUES IMPLEMENTED FOR DISSOLUTION ENHANCEMENT OF ACECLOFENAC

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Abstract

Aceclofenac is aceclofenacum (O-(2, 6-dichloroaniline) phenyl] acetate glycolic acid ester, 2-(2, 6-dichloroaniline) phenyl acetoxy acetic acid. Aceclofenac is a Non- Steroidal Anti Inflammatory drug. It is used in the management of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. Aceclofenac when taken orally shows gastrointestinal disturbances such as GI discomfort, nausea, diarrhea due to its low solubility, in some patient's peptic ulceration and severe gastrointestinal bleeding may also occur. Thus various approaches have been used to overcome problems like gastric irritation and other side effects that are frequently experienced with NSAID drug therapy. Aceclofenac is practically insoluble in water leading to poor dissolution and variable bioavailability upon oral administration. Aceclofenac needs enhancement of solubility and dissolution rate to improve its oral bioavailability and therapeutic efficacy. In order to improve solubility and dissolution of poorly water-soluble drug several methods are used. Enhancing the bioavailability of poorly water-soluble drug, selection of the carriers is of the most challenging aspect of drug development. Now a days different techniques are available to enhance the solubility of drug like co-solvent, solid dispersion, chemical modification of drug, liquid solid technique etc. The review article comprises of the research materialized in the field of solubility and dissolution enhancement of aceclofenac.

Keywords: Aceclofenac, Dissolution Enhancement, Solubility, Solid Dispersion

INTRODUCTION

Solubilization is the process by which the apparent solubility of poorly water soluble substance is increased. Solubilization techniques include addition of a co solvent, salt formation, pro-drug design, complexation, particle size reduction, and the use of surface active agents (Micellization). Use of solvate and hydrates, polymorphs, hydro trophy, use of absorbents, pH adjustment, solubilizing vehicles, etc. are the some other physicochemical approaches to enhancing oral absorption of poorly water soluble drugs. A drug substance is considered highly soluble when the highest dose strength is soluble in < 250 ml water over a pH range of 1 to 7.5. A drug substance is considered highly permeable when the extent of absorption in humans is determined to be > 90 % of an administered dose, based on mass-balance or in comparison to an intravenous reference dose. A drug product is considered to be rapidly dissolving when > 85 % of the labeled amount of drug substance dissolves within 30 minutes using USP apparatus I or II in a volume of < 900 ml buffer solutions¹. Aceclofenac, a phenyl acetic acid derivative is an NSAID. It is used in the management of osteoarthritis rheumatoid arthritis and ankylosing spondylitis. The usual dose of aceclofenac is 100 mg given twice daily by mouth.

The initial dose should be reduced to 100 mg daily in patients with hepatic impairment. Aceclofenac is a white or almost white crystalline powder, with a melting point: 149°C to 150°C. It is practically insoluble in water, soluble in alcohol and methyl alcohol, freely soluble in acetone and dimethyl formamide. Aceclofenac suffers from low aqueous solubility (0.058 µg/ml), leading to poor dissolution and insufficient oral bioavailability. The biopharmaceutical classification system (BCS) divides all drug candidates into four different groups, according to their solubility and permeability. Aceclofenac is an example of BCS class II compound (Highly Permeable and Low Soluble); its oral bioavailability is determined by dissolution rate in the gastro intestinal tract². The mode of action of aceclofenac is largely based on the inhibition of prostaglandin synthesis. Aceclofenac is a potent inhibitor of the enzyme cyclooxygenase (COX), which is involved in the production of prostaglandins. The mean plasma elimination half-life is around 4 hours. Aceclofenac is highly protein bound > 99 %, aceclofenac circulates mainly as unchanged drug. Aceclofenac when taken orally shows gastrointestinal disturbances such as GI discomfort, nausea and diarrhea. In some patients, peptic ulceration and severe gastrointestinal bleeding may also occur. Hypersensitivity:

Leukocyto elastic vasculitis, a type-III hypersensitivity reaction with lung hemoptysis has been reported in patients following therapy with aceclofenac³.

Techniques of Solubility Enhancement

There are many techniques which are used to enhance solubility of poor water soluble compounds some of which are as, solid dispersion, particle size reduction (micronization), nano suspension, salt formation, precipitation, use of precipitation inhibitors, spray freezing into liquid, evaporative precipitation into aqueous solution, selective adsorption on insoluble carriers, solvent deposition, eutectic mixtures, modification of the crystal habit, solubilization by surfactants, drug dispersion in carriers, co solvency, liquid-solid techniques, pH adjustment, hydro trophy, super disintegrates supercritical fluid technology, inclusion complex formation techniques, floating granules⁴.

Research Materialized for Solubility and Dissolution Rate Enhancement of Aceclofenac

The poor solubility causes decreased absorption of the drug. The bioavailability thus depends on the solubility makes the solubility as rate limiting step. The solubility of the drug can be increased by several techniques. The research arises in the enhancement of the solubility and dissolution of aceclofenac is as follows:

Gavhane YN et al. 2013, investigates and compares the feasibility of Chitosan and water soluble Chitosan derivative to enhance Aceclofenac dissolution. Aceclofenac was size reduced and polymer was precipitated on it. Drug-polymer compatibility was accessed using Infrared spectroscopy and Differential Scanning Calorimetry (DSC). Effect of polymer aqueous solubility and polymer: drug ratios on solubility enhancement of drug were studied. Aceclofenac micro particles were subjected to micromeritic properties including angle of repose, bulk density, tapped density, Carr's index, Hausner's ratio and particle size determination. Micro particles were subjected to *in vitro* drug release and solubility analysis. Results were assayed statistically using one way analysis of variance (ANOVA). The prepared micro particles were white, free-flowing and crystalline in nature. Micro particles of both the polymers had shown very good flow property and compression behavior at all ratios. The particle size of drug was drastically reduced during formulation. The dissolution studies demonstrated a marked increase in the dissolution rate in comparison with pure drug. Result was more significant for Chitosan chlorhydrate than the Chitosan. DSC showed reduction in melting enthalpy of formulation. DSC results were statistically higher for Chitosan chlorhydrate than Chitosan. The considerable improvement in the dissolution rate of Aceclofenac from prepared micro particles was due to decreased drug crystallinity, altered surface morphology and micronization. Significant higher effect of Chitosan chlorhydrate than the Chitosan might be attributed to its higher wetting property⁵.

Rathi PB et al, 2013, reported the solubility parameter of aceclofenac in different blends of dioxane-water. Experimental values obtained were compared with the theoretical values obtained by molar volume method and Fedor's group substitution method. Dioxane and water were selected based on their Hildebrand value received: Aceclofenac is a non-steroidal anti-inflammatory drug and it is poorly soluble in water- thus has low bioavailability on oral administration. One of the important methods to improve

the solubility and bioavailability of a less water-soluble drug is by the use of co solvents. The solubility enhancement produced by binary blends with a co solvent (dioxane) was studied against the solubility parameter of solvent blends (δ_1) to evaluate the solubility parameter of drug (δ_2). Solubility parameter of drug (δ_2) was evaluated in blends of dioxane-water system. The results obtained were compared with the δ_2 values obtained using Molar Volume Method and Fedor's Group Substitution Method. The binary blend water-dioxane (10:90) gave maximum solubility with an experimental δ_2 value of 11.34 (Cal/cm³)^{0.5} that was comparable to the theoretical values of 11.34 (Cal/cm³)^{0.5} determined by Molar Volume Method and 12.08 (Cal/cm³)^{0.5} when determined by Fedor's Group Substitution Method, which is still in good agreement with solubility measurement method. Determination of δ_2 as the varying blends of these provided a range of 10.00-23.40 (Cal/cm³)^{0.5} of δ_1 . The peak solubility (X2) of 1.2929167 g/ml for aceclofenac was observed in a solvent blend of water: dioxane (10:90) with δ_1 of 11.34 (Cal/cm³)^{0.5}. Thus, the solubility parameter for aceclofenac can be defined as 11.34 (Cal/cm³)^{0.5}.

Reddy BV et al. 2012, prepared solid dispersions of Aceclofenac from polyethylene glycol 8000 (PEG 8000) and study its effect on *in vitro* dissolution of drug. Initial studies were carried out using physical mixtures of the drug and carrier. Solid dispersions were prepared by the dropping method. Aceclofenac was formulated as physical mixtures and solid dispersions (dropping method) using 1:2, 1:4, 1:6 and 1:8 ratios of drug and carrier (PEG 8000). Saturation solubility study for pure drug, physical mixtures and solid dispersions were carried out in water and pH 6.8 phosphate buffer solutions (PBS). The *in vitro* dissolution studies were carried in pH 6.8, higher *in vitro* dissolution of solid dispersions was recorded compared to their corresponding physical mixtures and the pure drug. The prepared solid dispersions showed marked increase in the saturation solubility and dissolution rate of Aceclofenac than that of pure drug. PEG 8000 in 1: 8 drug to carrier ratio exhibited the highest drug release (98.83 %) formulated as solid dispersions using dropping method. The FT-IR shows the complexation and there were no interactions. Finally maximum increase in dissolution rate was obtained with Aceclofenac: PEG 8000 solid dispersion with a weight ratio of 1:8. PEG 8000 dispersion by dropping method showed faster dissolution rate when compared with that of physical mixtures of various concentrations and pure drug⁷.

Reddy BV et al. 2012, enhance the oral bioavailability and dissolution rate of aceclofenac by solid dispersions using polyethylene glycol (PEG-6000) as a carrier and to study the effect of carrier on dissolution rate. Initial studies were carried out using physical mixtures of the drug and carrier. Solid dispersions were prepared by fusion technique using dropping method. Aceclofenac was formulated as physical mixtures and solid dispersions (dropping method) using 1:2, 1:4, 1:6 and 1:8 ratios of drug and carrier (PEG 6000). Saturation solubility study for pure drug, physical mixtures and solid dispersions were carried out in water and pH 6.8 phosphate buffer solutions (PBS). The *in vitro* dissolution studies were carried in pH 6.8, higher *in vitro* dissolution of solid dispersions was recorded compared to their corresponding physical mixtures and the pure drug. The prepared solid dispersions were observed that increased in the saturation solubility and dissolution rate of aceclofenac than that of pure drug. PEG 6000 in 1: 8 drug to carrier ratio

exhibited the highest drug release (98.69 %) formulated as solid dispersions using dropping method. The FT-IR study shows that drug was stable in solid dispersions and there were no interactions. It is concluded that dissolution rate was improved by solid dispersion of aceclofenac: PEG 6000 prepared as 1:8 ratio by dropping method showed excellent physicochemical characteristics and was found to be described by dissolution release kinetics and was selected as the best formulation⁸.

Samal HB et al. 2012, investigates the enhancement of drug dissolution rate of aceclofenac using its solid dispersions (SDs) with β -Cyclodextrin. Inclusion complex of Aceclofenac with β Cyclodextrin was prepared by physical mixture, co-grinding and kneading method at 1:1 w/w ratio. It was clear that kneading method would be the best method for the preparation of inclusion complex of aceclofenac with β -CD. Hence Kneading method was selected for further study (K1, K2, K3 and K4 in 1:0.5, 1:1, 1:1.5 and 1:2 ratios respectively). Phase solubility study was conducted to evaluate the effect of polymer on aqueous solubility of Aceclofenac. Solid state characterization was evaluated by Fourier transform infrared spectroscopy and differential scanning calorimetry. *In vitro* dissolution study was performed in phosphate buffer at pH 6.8. *In vitro* dissolution rate of Aceclofenac from solid dispersion (SD) was significantly higher compared to pure Aceclofenac. This article justifies the success of kneading method of aceclofenac with β -Cyclodextrin².

Dhamat K et al. 2012, reported that the Aceclofenac is partially insoluble in water and aqueous fluid and as such it exhibits poor variable oral bioavailability. Aceclofenac needs enhancement of solubility and dissolution rate to improve its oral bioavailability and therapeutic efficacy. Among the various approaches to enhance the solubility and dissolution rate of poorly soluble drugs complexation with cyclodextrin is an effective and industrially accepted technique. In the present investigation, Complexation of aceclofenac with β -CD was carried out by using various techniques like physical mixture, kneading method, co precipitate method and solvent evaporation method. From the various characterization studies like drug content, production yield and *in vitro* dissolution study, batch abc-6 by kneading method was selected as optimized batch⁹.

Senthilkumar KL et al. 2011, reported that the various compositions of aceclofenac solid dispersions prepared by fusion and meting methods to enhance the solubility and dissolution rate of with 3 different ratio of PEG 6000. Such as ACF: PEG6000-1:1, 1:2 and 1:4 by fusion method or melting method. The percentage of drug release of Aceclofenac from solid dispersions ACF: PEG 6000-1:1, 1:2 and 1:4 was 59.65 %, 84.75 %, 98.34 % respectively in 180 minutes. Out of the three formulations prepared, the formulation ACF: PEG 6000 – 1:4 showed better release of aceclofenac than the formulation of ACF: PEG 6000 – 1:2, and ACF: PEG 6000 – 1:1. It indicates that an increase in the polymer concentration may increase the dissolution rate. This justifies the enhancement of solubility and dissolution rate of aceclofenac with PEG 6000¹⁰.

Tiwari BK et al. 2011, explore the application of different solubilization technique in the water- insoluble drugs and to reduce concentration of hydrotropic agent produce its own toxicity. In case of synergistic effect in solubility due mixing of hydrotropic agent, say, the toxic level of individual can further be lowered because still less concentration of the

hydrotropic agents shall be sufficient for a desired enhancement in solubility. Equilibrium solubility of aceclofenac in different media was determined by excess solute method and the solubility enhancement ratios were calculated. From the results of the solubility data it was concluded that the aqueous solubility of aceclofenac was increased more than 250 times in hydrotropic blends except blend A (73.44), 5 and 25 times in 30 % sodium citrate and 30 % urea, respectively. It is concluded that the solubility of aceclofenac increases synergistically by mixed hydrotropy¹¹. **Aejaz A et al. 2010**, reported that the various compositions of aceclofenac solid dispersions prepared by physical mixing, fusion and solvent evaporation methods using PVP, PEG 6000, mannitol and urea as carrier to enhance the solubility and dissolution rate of aceclofenac. Three ratios of drug and polymer prepared 1:1, 1:3 and 1:4. The formulation evaluated for drug content, *in vitro* dissolution study and also characterized by IR and DSC studies. 1:3 show the greater dissolution than others. This justifies the enhancement of solubility and dissolution rate of aceclofenac with various polymers¹².

Apparao B et al. 2010, investigates the enhancement of drug dissolution rate of aceclofenac using lactose, mannitol and urea with solvent evaporation method to increase its aqueous solubility. Aceclofenac solid dispersion was prepared in 9:1, 7:3 and 4:1 ratios of the drug to polymer. *In vitro* release profiles of all SDs (F-1 to F-9) were comparatively evaluated and also studied against pure aceclofenac. Faster dissolution was exhibited by solid dispersion containing 9:1 ratio of drug: lactose. The increase in dissolution rate of the drug may be due to increase in wettability, hydrophilic nature of the carrier and due to reduction in drug crystallinity. The crystallinity of the drug was reduced in solid dispersion formulation with polymers i.e. urea. Results from IR spectroscopy concluded that there was no well-defined interaction between aceclofenac and carriers. Finally it could be concluded that solid dispersion of aceclofenac using hydrophilic polymers would improve the aqueous solubility, dissolution rate and thereby enhancing its systemic availability¹³.

Derle DV et al. 2010, develop the solvent deposition system for solubility enhancement of aceclofenac by adsorbing poorly water soluble drug over lactose particles exposing fine particles of drug in dissolution media. The principle of solvent deposition technique is deposition of the drug in “minuscule form” from an organic solvent on to the surface of an inert excipient. Due to micronization the surface area of drug increases which in turn improves dissolution rate. This solvent deposition system was formulated as oro dispersible tablet through wet granulation, using camphor as subliming agent and sodium starch glycolate as super disintegrate. The formulations were evaluated for weight variation, hardness, friability, drug content, wetting time, *in vitro* dispersion time and *in vitro* dissolution. All the formulations showed variation with *in vitro* dispersion time less than 40 seconds and rapid *in vitro* dissolution. Fine particles of drug absorbed over lactose and porous nature of tablet gave higher drug dissolution and hence rapid drug release. The formulation F4 showed good release profile with maximum drug being released at all time intervals (99 % drug release within 35 minutes). The present study demonstrated that Solvent deposition system of aceclofenac can be successfully formulated into mouth dissolving tablet in order to improve

disintegration/dissolution of the drug in oral cavity and hence better patient compliance and effective therapy¹⁴.

Dua K et al. 2010, investigates the effect of various water soluble carriers like urea, mannitol, PVP and PVP/VA-64 on *in vitro* dissolution of aceclofenac from solid dispersions. Aceclofenac binary solid dispersions (SD) with different drug loadings were prepared using the melting or fusion method. *In vitro* dissolution of pure drug, physical mixtures and solid dispersions were carried out. Solid dispersion of aceclofenac with all four carriers (urea, mannitol, PVP and PVP/VA-64) showed considerable increase in the dissolution rate in comparison with physical mixture and pure drug in 0.1 N HCl, p^H 1.2 and phosphate buffer p^H 7.4. Solid dispersions containing PVP showed maximum dissolution rate in comparison to formulation containing urea, mannitol and PVP/VA-64. Amorphous nature of the drug in solid dispersion was confirmed by scanning electron microscopy and a decrease in enthalpy of drug melting in solid dispersion compared to the pure drug. FT-IR spectroscopy and differential scanning calorimetry studies indicated no interaction between aceclofenac and carriers in solid dispersions in solid state. Dissolution enhancement was attributed to decreased crystallinity of the drug and to the wetting, eutectic formation and solubilizing effect of the carrier from the solid dispersions of aceclofenac. Thus it is concluded that dissolution of aceclofenac can be enhanced by the use of various hydrophilic carriers like urea, mannitol, PVP and PVP/VA-64¹⁵.

Maheshwari RK et al. 2010, investigates the effect of hydro tropes such as urea and sodium citrate and blends (urea + sodium citrate) on the solubility of aceclofenac. The enhancement in the solubility of aceclofenac was more than 5 and 25 folds in 30 % sodium citrate solution and 30 % urea solution, respectively, as compared to its solubility in distilled water. The enhancement in the solubility of aceclofenac in a mixed hydrotropic solution containing ≥ 20 % urea and 10 % sodium citrate solution was more than 250 folds (compared to its solubility in distilled water). This proved a synergistic enhancement in solubility of a poorly water-soluble drug due to mixed hydrotrophy. Synergistic combination of hydrotropic agents can minimize the amount of hydrotropic agents employed, minimizing the chances of their toxicities. Aqueous injection of aceclofenac, using the mixed hydrotropic solubilization technique, was developed and by using the lyophilization method, the problem of inadequate stability of aceclofenac in aqueous solution was overcome. The developed formulation was studied for physical and chemical stability. Thus, this study opens the chance of preparing aqueous formulations of poorly-water soluble drugs, if chemical stability of the drug remains unaffected¹⁶.

Shinde SS et al. 2010, prepared solid dispersions of aceclofenac by solvent evaporation method and compared the effectiveness of hydrophilic polymer such as PVP-K30, HPMC E-5 and Aerosil 200. The resultant complexes were evaluated for drug content, FT-IR, XRD and dissolution studies. The present study was successfully utilized the solvent evaporation method for preparation of stable, amorphous SDs of aceclofenac by encapsulation with hydrophilic carrier with adsorbents agent. The results revealed that batch prepared at 1:1:2 ratios of drug: PVPK30: aerosil showed maximum release in phosphate buffer of pH 6.8. The study revealed that optimum levels of hydrophilic carriers and hydrophilic porous adsorbents ensure a prompt

and complete dissolution of aceclofenac from solid dispersions that are used in oral pharmaceutical formulations¹⁷.

Shakeel F et al, 2009, reported that improvement of solubility and *in vitro* dissolution of the poorly soluble drug aceclofenac using various nanocarriers which would further enhance biological performance of dosage form. Solubility and dissolution enhancement of the lipophilic drug aceclofenac carried out using three nanocarriers namely nano emulsion, solid lipid nano suspension and polymeric nano suspension. The solubility of aceclofenac in distilled water and different nanocarriers was determined using the UV spectrophotometer method at the wavelength of 274 nm. Dissolution studies of pure aceclofenac suspension and its nanocarriers were performed using USP dissolution apparatus in distilled water. The highest solubility (198.53 mg/ml) as well as % dissolution (99.5) of aceclofenac was obtained with nanoemulsion formulation as compared to lipid and polymeric nano suspension. The results of solubility and dissolution were highly significant in nanoemulsion as compared to lipid and polymeric nano suspension ($P < 0.01$). Dissolution profile of aceclofenac in lipid and polymeric nano suspension was significant as compared to pure aceclofenac suspension ($P < 0.05$). These results indicated that nanoemulsion is a promising nano carrier as compared to lipid and polymeric nano suspension for solubility and dissolution enhancement of aceclofenac¹⁸.

Vadher HA et al., 2009, enhance the dissolution of poorly water-soluble BCS-class II drug aceclofenac by co-grinding with novel porous carrier neusilin US2. Neusilin US2 has been used as an important pharmaceutical excipient for solubility enhancement. Co-grinding of aceclofenac with neusilin US2 in a ratio of 1:5 was carried out by ball milling for 20 h. Samples of co ground mixtures were withdrawn at the end of every 5 h and characterized for X-ray powder diffraction, differential scanning calorimetry, and Fourier-transform infrared spectroscopy. The analysis revealed the conversion of crystalline aceclofenac to its amorphous form upon milling with neusilin US2. Further, *in vitro* dissolution rate of aceclofenac from co ground mixture was significantly higher compared to pure aceclofenac. The accelerated stability study of co-ground mixture was carried out at 40°C/75 % RH for 4 weeks, and it showed that there was no reversion from amorphous to crystalline form. The results indicate that neusilin enhances the dissolution of aceclofenac and also provides physical stability by preventing reversion of drug from crystalline state to amorphous state after co-grinding. This approach can be further extended for dissolution enhancement of other BCS class II drugs¹⁹.

Venkatesh DN et al. 2009, attempt to improve the solubility and dissolution rate of aceclofenac by complexing with β -cyclodextrin (β -CD). The characterization of the drug, β -CD and complex was done by using differential scanning calorimetry (DSC), FTIR and X-ray powder diffractometry (XRD). *In vitro* aqueous solubility and dissolution rate studies were performed on the complex. Phase-solubility profile indicated that the solubility of aceclofenac was significantly increased in the presence of β -CD and was classified as AL-type, indicating the 1:1 stoichiometric inclusion complexes. Physical characterization of the prepared systems was carried out by differential scanning calorimetry (DSC), X-ray diffractometry (XRD) and IR studies. Solid state characterization of the drug in the β -CD binary system using XRD, FTIR and DSC revealed distinct

loss of drug crystallinity in the formulation, ostensibly accounting for enhancement of dissolution rate. The study shows that the dissolution rate of aceclofenac can be enhanced to a greater extent by solid dispersion technique using an industrially feasible kneading method. The solid dispersion complex of drug gave better dissolution profile as compared to pure drug. This in turn, can lead to a reduction in dose related adverse effects and improved bioavailability²⁰. Mahaparale PR *et al*, 2007, studied the absorption maximum of aceclofenac in methanol diluted with glass distilled water and was found to be 274.5 nm. Beer's law was obeyed in the concentration range 2 to 20 µg/ml. The method allows rapid analysis of pharmaceutical formulations with accuracy. The results were validated statistically and by recovery studies and were found to be satisfactory²¹.

CONCLUSION

To achieve the immediate effect in severe panic disease the drug availability must be ensured in the body. The tablet with improved rate of dissolution certainly provides therapeutic effectiveness of the drug at the earliest time after administration. The immediate release formulation attempted with different investigators mentioned above may be used commercially. Aceclofenac is a BCS class II (low soluble high permeable) drug, thus dissolution is the rate limiting step. With an improvement in the dissolution in the formulation the availability of drug can be improved. Thus the area of the improvement in dissolution of the drug is widely exploited in case of drug with low solubility and high permeability. Further there is desperate requirement in the development of the immediate release formulations of the aceclofenac to improve the dissolution and bioavailability and the immediate release formulation also reduce side effect occurred due to low solubility of aceclofenac like gastric irritation therefore.

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