Literature Review
3. Literature review on work on Telmisartan

J.Kausalya, K.Suresh, et al, Solubility and Dissolution Enhancement Profile of Telmisartan using various techniques.

Telmisartan is Angiotensin II Receptor Antagonist, which is used in the prevention and treatment of Hypertension. Telmisartan belongs to class II drug in BCS classification i.e. low solubility and high permeability. One of the major problems with this drug is its low solubility in biological fluids, which results into poor bioavailability after oral administration. In order to improve the aqueous solubility and dissolution rate of the telmisartan solid dispersions of drug using different methods were prepared and investigated. Enhancement of solubility of Telmisartan was observed with solid dispersion of drug using carriers such as Poly vinyl pyrrolidonek30, Poly ethylene glycol-4000 and β-Cyclodextrin. The observed results showed the solid dispersion of drug almost three times greater than the pure drug.


Telmisartan (TLM) is an angiotensin II receptor antagonist used in the treatment of hypertension. According to BCS, (biopharmaceutical classification system) telmisartan belongs to class II drug, and it is practically insoluble in water and it shows low dissolution profile and poor absorption. The present study is to improve the solubility of telmisartan by forming complexation with HP- β CD by using three convenient methods viz physical mixing method, kneading method, and solvent evaporation method at different molar ratios of 1:1, 1:2 and 1:3. In vitro dissolution studies were carried out in 7.5 pH phosphate buffer. The cyclodextrin complexes formulated by employing 1:3 (drug: complexing agent) with kneading technique showed higher drug release compared to other techniques and other ratios. Significance difference was observed in IR spectra of pure drug and complex containing telmisartan so it conform the formation of complex. In X-RD the pure drug was observed in crystalline form after complexing with HP- β CD it was observed in amorphous form.

Polyethylene glycol 6000 (PEG 6000)-based SDs were prepared after adding 9 different alkalizers in ethanol solution. The dissolution test was performed according to the USP paddle method in water, gastric (pH 1.2) and intestinal fluid (pH 6.8), respectively. The structural behaviors of drug were also characterized by instrumental methods such as differential scanning calorimetry (DSC), powder X-ray diffraction (PXRD) and infrared spectroscopy (IR). Results. The incorporation of alkalizers in the ternary SDs could enhance the release of telmisartan in intestinal fluid and water. The incorporation of alkalizers in SDs enhanced drug release in water, gastric and intestinal fluid due to their pH modifying activity. Most of all, MgO, NaOH, KOH and Na2CO3 significantly increased the drug dissolution rate. IR spectra were also changed, in which the frequency of C=O was decreased and the O-H broad band disappeared. DSC thermograms showed that distinct drug melting point disappeared in the SDs. The PXRD also showed the lack of distinct drug peak when some alkalizers like MgO, NaOH, KOH and Na2CO3 were present, possibly due to the formation of an amorphous structure. Conclusion. The incorporation of alkalizers in the SDs containing drug with pH dependent solubility like telmisartan could provide an alternative to enhancing dissolution.

S. Bankey, G. G Tapadiy et al, Simultaneous Determination of Ramipril, Hydrochlorothiazide and Telmisartan by Spectrophotometry

A simple, fast and precise multicomponent mode analysis method has been developed for simultaneous determination of Ramipril (RMP), Hydrochlorothiazide (HCT) and Telmisartan (TEL) in tablet formulation. The wavelengths selected for these drugs were 218nm, 271nm and 296nm respectively using methanol as solvent. The linearity for these drugs at all the selected wavelengths lies between 0.5-3.5 µgml−1 for RP, 1.25-8.75 µgml-1 for HCT and 4-28 µgml-1 for TEL. The concentrations of these drugs were evaluated in laboratory mixture and marketed formulation. Accuracy was determined by recovery studies from tablet dosages forms and ranges from 99.09-99.52%. Precision of method was find out as repeatability, day to day and analyst to analyst variation and shows the values within acceptable limit (R.S.D ≤ 2 percent).
3.1. Literature review on work on cyclodextrin complexation


The effect of β-cyclodextrin on the aqueous solubility and dissolution rate of celecoxib was investigated. The possibility of molecular arrangement of inclusion complexes of celecoxib and β-cyclodextrin were studied using molecular modeling and structural designing. The results offer a better correlation in terms of orientation of celecoxib inside the cyclodextrin cavity. Phase-solubility profile indicated that the solubility of celecoxib was significantly increased in the presence of β-cyclodextrin and was classified as AL-type, indicating the 1:1 stoichiometric inclusion complexes. Solid complexes prepared by freeze drying, evaporation, and kneading methods were characterized using differential scanning calorimetry, powder x-ray diffractometry, and scanning electron microscopy. *In vitro* studies showed that the solubility and dissolution rate of celecoxib were significantly improved by complexation with β-cyclodextrin with respect to the drug alone. In contrast, freeze-dried complexes showed higher dissolution rate than the other complexes.

*Maria Letizia Manca et.al.* (46) Described the diclofenac β-cyclodextrin binary systems: physicochemical characterization and *in vitro* dissolution and diffusion studies.

The aim of the work was to study the influence of β-cyclodextrin (β-CD) on the biopharmaceutic properties of diclofenac (DCF). To this purpose the physicochemical characterization of diclofenac-β-cyclodextrin binary systems was performed both in solution and solid state. Solid phase characterization was performed using differential scanning calorimetry (DSC), powder x-ray diffractometry (XRD), and Fourier transform infrared spectroscopy (FTIR). Phase Solubility analysis and in vitro permeation experiments through a synthetic membrane were performed in solution. Moreover,
DCF/β-CD interactions were studied in DMSO by 1H nuclear magnetic resonance (NMR) spectroscopy. The effects of different preparation methods and drug-to-β-CD molar ratios were also evaluated. Phase solubility studies revealed 1:1 M complexation of DCF when the freeze-drying method was used for the preparation of the binary system. The true inclusion for the freeze-dried binary system was confirmed by 1H NMR spectroscopy, DSC, powder XRD, and IR studies. The dissolution study revealed that the drug dissolution rate was improved by the presence of CDs and the highest and promptest release was obtained with the freeze-dried binary system. Diffusion experiments through a silicone membrane showed that DCF diffusion was higher from the saturated drug solution (control) than the freeze-dried inclusion complexes, prepared using different DCF-β-CD molar ratios. However, the presence of the inclusion complex was able to stabilize the system giving rise to a more regular diffusion profile.

Thorsteinn Loftsson et al. (47) Described the evaluation of cyclodextrin solubilization of drugs.

Aqueous solubility of 38 different drugs was determined in pure aqueous solution, aqueous buffer solutions and aqueous cyclodextrin solutions, and the apparent stability constant (K1:1) of the 1:1 drug/cyclodextrin complexes calculated by the phase-solubility method. For poorly soluble drugs (aqueous solubility <0.1 mM) the intrinsic solubility (S0) is in general much larger than the intercept of the phasesolubility diagram (Sint) resulting in non-linearity of otherwise linear (AL-type) phase-solubility diagram. This can lead to erroneous K 1:1 value. A more accurate method for determination of the solubilizing efficiency of cyclodextrins is to determine their complexation efficiency (CE), i.e. the concentration ratio between cyclodextrin in a complex and free cyclodextrin. CE is calculated from the slope of the phase-solubility
diagrams, it is independent of both $S_0$ and $S_{\text{int}}$, and more reliable when the influences of different pharmaceutical excipients on the solubilization are being investigated.

*Matt S. Duana, Nelson Zhaoa et.al.* (48) Described the cyclodextrin solubilization of the antibacterial agents - triclosan and triclocarban: formation of aggregates and higher-order complexes. The effects of cyclodextrins, 2-hydroxypropyl-$\beta$-cyclodextrin (HP-$\beta$-CD) and randomly methylated $\beta$-cyclodextrin (RM-$\beta$-CD) on the aqueous solubility of triclosan and triclocarban were investigated. The phase-solubility profiles were all of type AP indicating formation of higher-order complexes or complex aggregates. Addition of lysine and other excipients enhanced the RM-$\beta$-CD solubilization of triclocarban. NMR spectroscopic studies, including 2D ROESY and 1D GROESY techniques, indicated that HP-$\beta$-CD and RM-$\beta$-CD, as well as their complexes, form aggregates of two to three cyclodextrin molecules. The critical concentration for the aggregate formation was determined to be 5.4% (w/v). Lysine, poly vinyl pyrrolidone and magnesium ions formed non-inclusion complexes resulting in formation of multiple component cyclodextrin complexes in aqueous solutions with triclocarban.

*G. Zingone et.al.* (49) Described the preformulation study of the inclusion complex warfarin-$\beta$-cyclodextrin.

Inclusion complex between warfarin and $\beta$-cyclodextrin was obtained to improve the in vitro bioavailability of the drug in acidic media. Inclusion complexation in solution was studied by phase solubility technique. The apparent stability constant was influenced by the pH of the medium ranging from $633.26 \text{ M}^{-1}$ (at pH 1.2, where the drug was in unionized form) to $99.81 \text{ M}^{-1}$ (at pH 7.4, where the drug was in ionized form). Phase solubility study showed an AL-type diagram indicating the formation of an inclusion complex in 1:1 molar ratio. Solid binary mixtures of the drug with $\beta$-cyclodextrin were
prepared by several methods (physical mixing, kneading, co-evaporation, freeze-drying). Physicochemical characterizations were performed using differential scanning calorimetry, powder X-ray diffractometry and dissolution studies. Preparation method influenced the physicochemical properties of the binary mixtures. An inclusion complex was obtained by freeze-drying, and it showed a high solubility and drug dissolution rate. The physical stability of the complex was also studied. After one year storage in glass container at room temperature no significant changes were detected in the diffractogram, thermogram and dissolution profile of the freeze-dried product.

*Kora Pattabhi Ramaiah Chowdary et.al. (50) Described the influence of hydrophilic polymers on celecoxib complexation with hydroxypropyl β-CD.*

Complexation of celecoxib with hydroxypropyl β-cyclodextrin (HP-β-CD) in the presence and absence of 3 hydrophilic polymers - polyvinyl pyrrolidone (PVP), hydroxypropyl methylcellulose (HPMC), and polyethylene glycol (PEG) was investigated with an objective of evaluating the effect of hydrophilic polymers on the complexation and solubilizing efficiencies of HP-β-CD and on the dissolution rate of celecoxib from the HP-β-CD complexes. The phase solubility studies indicated the formation of celecoxib HP-β-CD inclusion complexes at a 1:1M ratio in solution in both the presence and the absence of hydrophilic polymers. The complexes formed were quite stable. Addition of hydrophilic polymers markedly enhanced the complexation and solubilizing efficiencies of HP-β-CD. Solid inclusion complexes of celecoxib-HP-β-CD were prepared in 1:1 and 1:2 ratios by the kneading method, with and without the addition of hydrophilic polymers. The solubility and dissolution rate of celecoxib were significantly improved by complexation with HP-β-CD. The celecoxib HP-β-CD (1:2) inclusion complex yielded a 36.57-fold increase in the dissolution rate of celecoxib. The addition of hydrophilic polymers also markedly enhanced the dissolution rate of celecoxib from HP-β-CD complexes: a 72.60-, 61.25-, and 39.15-fold increase were
observed with PVP, HPMC, and PEG, respectively. Differential scanning calorimetry and X-ray diffractometry indicated stronger drug amorphization and entrapment in HP-β-CD because of the combined action of HP-β-CD and the hydrophilic polymers.

*Sarasija Sures et al.* (51) Described the effect of β-cyclodextrin complexation on the solubility and dissolution rate of carbamazepine from tablets.

Carbamazepine was complexed with β-Cyclodextrin in an attempt to enhance the solubility features of the drug. Phase solubility studies revealed a linear relationship between carbamazepine solubility and β-Cyclodextrin concentration, the value of solubility constant (405.42 M⁻¹) calculated from the phase solubility diagram indicates that the complexes were adequately stable. Carbamazepine β- Cyclodextrin complexes prepared by kneading method were used to produce dispersible tablets. A 23 factorial design was employed to investigate the effect of factors such as amount of binder, hardness and type of disintegrate on the tablet disintegration time and dissolution rate. Mathematical models containing only the significant factors influencing each response were generated using multiple linear regression and analysis of variance. The three main factors studied had a significant influence on both the response parameters. In addition to the main factor the two-way interaction factors also showed a significant effect on the release rate. Type of disintegrate emerged as the main effect with the highest statistical significance affecting both the responses. Two formulations with a combination of factor within the experimental domain were developed and evaluated to validate the mathematical models. The predicted values were found to agree with the experimental values confirming the forecasting ability of multi-linear regression and ANOVA.
K.P.R. Chowdary and G. Kamalakara Rao (52) Described the complexes of nifedipine with β- and hydroxypropyl β-cyclodextrin in the design of nifedipine sustained release tablets.

Complex formation of nifedipine with β-cyclodextrin and hydroxypropyl β-cyclodextrin was studied. The possibility of improving the solubility and dissolution rate of nifedipine via complexation with the above cyclodextrins and the feasibility of employing nifedipine cyclodextrins inclusion complex in the design of mucoadhesive tablet for sustained release were also investigated. The phase solubility studies indicated the formation of a nifedipine β-cyclodextrin (1:1M) and nifedipine-hydroxypropyl-β-cyclodextrin (1:1 M) inclusion complexes with a stability constant of 121.9 M⁻¹ and 253.7 M⁻¹ respectively. The solubility and dissolution rate of nifedipine were markedly enhanced by complexation with β-cyclodextrin (1:3) gave the highest enhancement (44.8 fold) in the dissolution rate of nifedipine. Mucoadhesive tablets formulated employing nifedipine alone gave very low dissolution. Whereas those formulated employing nifedipine β-cyclodextrin and nifedipine-hydroxypropyl-β-cyclodextrins complexes gave slow, controlled and complete release spread over a period of 12h. Drug release from those tablets followed zero order kinetics up to 85-90% release and the release was diffusion controlled. Good sustained release two layered tablet formulation of nifedipine satisfying the theoretical sustained release need based on its pharmacokinetics, were developed using nifedipine β-cyclodextrin and nifedipine hydroxypropyl-β-cyclodextrin inclusion complexes.
A.M. Sanoferjan et.al. (53) Described the formulation and evaluation of β-cyclodextrin complexes of tenoxicam.

β-Cyclodextrin complexation of Tenoxicam was attempted to enhance the solubility features of the drug. The stoichiometry and complex stability was determined by the phase solubility studies. The complex was characterized by infrared spectroscopy and X-ray diffraction studies. The complexes prepared in 1:1M ratio by various techniques were evaluated for its dissolution profile, thermal stability and photo stability. The complex prepared by neutralization method was found to yield very reliable and best results over that of the common solvent and kneading method.

Sanjula Baboota et.al. (54) Described the inclusion complexation of meloxicam with β-cyclodextrin.

Inclusion complexes of meloxicam with β-cyclodextrin were prepared by various methods like grinding, kneading, solid dispersion and freeze-drying. The prepared complexes were evaluated by FTIR, X-ray diffraction, differential scanning calorimetry and scanning electron microscopy. The in vivo dissolution rate of drug β- cyclodextrins complexes were faster compared to the drug alone.

Jennifer L. H. Johnson et.al. (55) Described about improving cyclodextrin complexation of a new antihepatitis drug with glacial acetic acid.

The purpose of this study was to develop and evaluate a solid non-aqueous oral dosage form for a new hepatitis C drug, PG301029, which is insoluble and unstable in water. Hydroxypropyl-β-cyclodextrin (HP-β-CD) and PG301029 were dissolved in glacial acetic acid. The acetic acid was removed by rotoevaporation such that the drug exists primarily in the complexed form. The stability of formulated PG301029 was determined upon dry storage and after reconstitution in simulated intestinal fluid (SIF), simulated gastric fluid (SGF), and water. Formulated PG301029 was found to be stable upon storage and can be reconstituted with water to a concentration 200 times that of the intrinsic solubility. Once reconstituted, the powder dissolves rapidly and
PG301029 remains stable for 21 hours in SGF, SIF, and water. The unique use of acetic acid and HP-β-CD results in a solid dosage form of PG301029 that is both soluble and stable in water.

*Indranil Nandi et.al. (56) Described the synergistic effect of peg-400 and cyclodextrin to enhance solubility of progesterone*

In the study PEG-400, polysorbate 80, and 2 CDs (Trappsol HPB and Captisol) were used in an attempt to improve the aqueous solubility of a model hydrophobic drug, progesterone. The aqueous solubility of progesterone improved significantly from 0.007 mg/mL by the addition of PEG-400, CDs, and polysorbate 80. In systems containing various amounts of PEG-400 and 3% Trappsol HPB in water (% wt/wt), the theoretical solubility was calculated by adding the solubilities in the individual systems. The observed solubility values were up to 96% higher than the theoretical values. The effect of synergism was significant in 5% to 50% PEG-400/water systems containing Trappsol HPB. Systems containing Captisol did not show such synergistic effects. In general, the addition of polysorbate 80 to the PEG-400/water systems containing CDs affected synergism negatively.

*Alka Pravin Mukne and MS Nagarsenker (57) Described triamterene-β-cyclodextrin systems: preparation, characterization and in vivo evaluation.*

This study presents the formulation of solid dispersions of triamterene with β- cyclodextrin by co-grinding, kneading, and co-evaporation, using low pH conditions and their characterization, evaluation of improvement in dissolution profiles, and in vivo advantage. Phase solubility studies indicated complex with possible stoichiometry of 1:1 and a stability constant of 167.67M -1. The solid dispersions were characterized by Fourier trans-form infrared spectroscopy, nuclear magnetic resonance, x-ray diffraction, and differential scanning calorimetry studies. The characterization studies confirmed inclusion of the phenyl ring of triamterene within the non polar cavity of β-cyclodextrin in the coevaporate. Remarkable improvement in in-vitro drug release profiles in 0.1N HCl and pH 6.8 phosphate buffer was observed with all dispersions, especially the coevaporate. The coevaporate, when administered orally in rats, also exhibited
improved in-vivo activity, as measured by net sodium ion excretion, as compared with triamterene powder. Thus, coevaporation of the drug and β-cyclodextrin from acidified alcohol provide the optimum condition for inclusion complexation to give a binary system with remarkable improvement in in-vitro drug release profile and in-vivo performance.

*Mamdouh M. Ghorab et al. (58) Described tablet formulation containing meloxicam and β-cyclodextrin: mechanical characterization and bioavailability evaluation*

The purpose of this research was to evaluate β-cyclodextrin (β-CD) as a vehicle, either singly or in blends with lactose (spray-dried or monohydrate), for preparing a meloxicam tablet. Aqueous solubility of meloxicam in presence of β-CD was investigated. The tablets were prepared by direct compression and wet granulation techniques. The powder blends and the granules were evaluated for angle of repose, bulk density, compressibility index, total porosity, and drug content. The tablets were subjected to thickness, diameter, weight variation test, drug content, hardness, friability, disintegration time, and in vitro dissolution studies. The effect of β-CD on the bioavailability of meloxicam was also investigated in human volunteers using a balanced 2-way crossover study. Phase-solubility studies indicated an AL-type diagram with inclusion complex of 1:1 molar ratio. The powder blends and granules of all formulations showed satisfactory flow properties, compressibility, and drug content. All tablet formulations prepared by direct compression or wet granulation showed acceptable mechanical properties. The dissolution rate of meloxicam was significantly enhanced by inclusion of β-CD in the formulations up to 30%. The mean pharmacokinetic parameters (Cmax, KE, and area under the curve [AUC](0-∞)) were significantly increased in presence of β-CD. These results suggest that β-CD would facilitate the preparation of meloxicam tablets with acceptable mechanical properties using the direct compression technique as there is no important difference between tablets prepared by direct compression and those prepared by wet granulation. Also, β-CD is particularly useful for improving the oral bioavailability of meloxicam.
Sanjula Baboota et al. (59) Described physico-chemical characterization, in vitro dissolution behavior, and pharmacodynamic studies of rofecoxib-cyclodextrin inclusion compounds: preparation and properties of rofecoxib hydroxypropyl β-cyclodextrin inclusion complex.

An inclusion complex of rofecoxib and HP-β-CD was prepared successfully by the spray-drying method in a molar ratio of 1:1. The inclusion complex was found to have improved in vitro drug release compared with the pure drug. The solubility profile of complexes of rofecoxib prepared using HP-β-CD as the complexing agent in a molar ratio of 1:1 by the spray-drying method in pH 1.2 and pH 7.4 indicated that the acid solubility of rofecoxib was enhanced considerably by formation of an inclusion complex with HP-β-CD. The results also clearly demonstrated a significant decrease in the gastric ulcerogenic activity of rofecoxib through complexation with cyclodextrins. Even though the physical mixture of rofecoxib with cyclodextrins reduced ulcer formation, it was the spray-dried complex formation approach that minimized gastric ulceration. These findings are extremely important from a commercial point of view as the prepared complex removes a major drawback for rofecoxib in therapy.

Margarita Valero et al. (60) Described about ternary naproxen: β-cyclodextrin: polyethylene glycol complex formation.

The presence of different proportions of PEG, in the 0–1% (w/w) range, systematically lowers Kapp of the formation of the naproxen: β-CD inclusion complex. The reason for the decrease in the complexed drug is the presence of other competing equilibria, the first one is an interaction of the polymer with the β-CD, which in turn reduces the amount of free CD available for including the naproxen, and the second is the formation of a naproxen: β-CD: PEG ternary complex with lower affinity than the binary complex. The binding constant of these processes are $K_2 = (4.5 \pm 1.0) \times 105 \text{ M}^{-1}$ and $K_3 = 870 \pm 19 \text{ M}^{-1}$, respectively. In addition the presence of the PEG produces an important change in the driving force of the complex formation. In this case the process is enthalpically unfavoured and entropically favoured; these are typical characteristics of processes governed by hydrophobic interactions.
3.2. Literature review on work on PEG-6000.

Verheyen S, Blaton N, Kinget R, Van den Mooter G. Mechanism of increased dissolution of diazepam and temazepam from polyethylene glycol 6000 solid dispersions.

Solid dispersion literature, describing the mechanism of dissolution of drug-polyethylene glycol dispersions, still shows some gaps; (A). only few studies include experiments evaluating solid solution formation and the particle size of the drug in the dispersion particles, two factors that can have a profound effect on the dissolution. (B). Solid dispersion preparation involves a recrystallisation process (which is known to be highly sensitive to the recrystallisation conditions) of polyethylene glycol and possibly also of the drug. Therefore, it is of extreme importance that all experiments are performed on dispersion aliquots, which can be believed to be physico-chemical identical. This is not always the case. (C). Polyethylene glycol 6000 (PEG6000) crystallises forming lamellae with chains either fully extended or folded once or twice depending on the crystallisation conditions. Recently, a high resolution differential scanning calorimetry (DSC)-method, capable of evaluating qualitatively and quantitatively the polymorphic behaviour of PEG6000, has been reported. Unraveling the relationship between the polymorphic behavior of PEG6000 in a solid dispersion and the dissolution characteristics of that dispersion, is a real gain to our knowledge of solid dispersions, since this has never been thoroughly investigated. The aim of the present study was to fill up the three above mentioned gaps in solid dispersion literature. Therefore, physical mixtures and solid dispersions were prepared and in order to unravel the relationship between their physico-chemical properties and dissolution characteristics, pure drugs (diazepam, temazepam), polymer (PEG6000), solid dispersions and physical mixtures were characterised by DSC, X-ray powder diffraction (Guinier and Bragg-Brentano method), FT-IR spectroscopy, dissolution and solubility experiments and the particle size of the drug in the dispersion particles was estimated using a newly developed method. Addition of PEG6000 improves the dissolution rate of both drugs. Mechanisms involved are solubilisation and improved wetting of the drug in the polyethylene glycol rich micro-environment formed at the surface of drug crystals after dissolution of the polymer. Formulation of solid dispersions did not further improve the dissolution rate compared with physical mixtures. X-ray spectra show that both drugs are in a highly crystalline state in the solid
dispersions, while no significant changes in the lattice spacings of PEG6000 indicate the absence of solid solution formation. IR spectra show the absence of a hydrogen bonding interaction between the benzodiazepines and PEG6000. Furthermore, it was concluded that the reduction of the mean drug particle size by preparing solid dispersions with PEG6000 is limited and that the influence of the polymorphic behavior of PEG6000 (as observed by DSC) on the dissolution was negligible.


The aim of the current study was to design oral fast-release polymeric tablets of prednisone and to optimize the drug dissolution profile by modifying the carrier concentration. Solid dispersions were prepared by the solvent evaporation method at different drug:polymer ratios (wt/wt). The physical state and drug:carrier interactions were analyzed by X-ray diffraction, infrared spectroscopy, and scanning electron microscopy. The dissolution rate of prednisone from solid dispersions was markedly enhanced by increasing the polymer concentration. The tablets were prepared from solid dispersion systems using polyethylene glycol (PEG) 6000 as a carrier at low and high concentration. The results showed that PEG 6000-based tablets exhibited a significantly higher prednisone dissolution (80% within 30 minutes) than did conventional tablets prepared without PEG 6000 (<25% within 30 minutes). In addition, the good disintegration and very good dissolution performance of the developed tablets without the addition of superdisintegrant highlighted the suitability of these formulated dosage forms. The stability studies performed in normal and accelerated conditions during 12 months showed that prednisone exhibited high stability in PEG 6000 solid dispersion powders and tablets. The X-ray diffraction showed that the degree of crystallinity of prednisone in solid dispersions decreased when the ratio of the polymer increased, suggesting that the drug is present inside the samples in different physical states. The Fourier transform infrared spectroscopic studies showed the stability of prednisone and the absence of well-defined drug:polymer interactions. Scanning electron microscopy images showed a novel morphology of the dispersed systems in comparison with the pure components.