PREPARATION AND CHARACTERIZATION OF SOLID DISPERSIONS FOR SOLUBILITY ENHANCEMENT OF BCS CLASS II DRUG

Dr. Monica R.P. Rao* and Pranoti A. Chandanshive

Department of Pharmaceutics, AISSMS College of Pharmacy, Pune-411001, India.

ABSTRACT
Budesonide is BCS class II drug (solubility 0.0457 mg/ml) with oral bioavailability of 10-20%. Solid dispersions of budesonide was prepared by solvent evaporation technique using Soluplus® in different ratios. These were characterized by infrared spectroscopy, differential scanning calorimeter, scanning electron microscopy and powder x-ray diffraction studies. FTIR studies confirmed the lack of interaction between drug and Soluplus®. Saturation solubility studies in different media such as water, 0.1 N HCl and phosphate buffer pH 7.4 were performed. A 9 fold increase in solubility in phosphate buffer was observed. Invitro dissolution studies revealed 90 % release whereas plain drug showed 38.75% release in 90 min. Polyethylene glycol (PEG) rectal suppositories were prepared using the solid dispersion bymoulding technique and compared with plain drug suppositories. The suppositories were examined for various properties. The dissolution time at 37°C was found to be 12 min and softening time was 10-12 min. The breaking test revealed that the suppositories had sufficient mechanical strength. The suppositories with solid dispersion exhibited 92 % release in 90 min in phosphate buffer pH 7.4 while plain drug suppositories displayed 68 % release. Thus we may conclude that improved saturation solubility and invitro dissolution of budesonide in presence of Soluplus® will result in its improved bioavailability.

KEYWORDS: Budesonide, Soluplus®, Solid dispersion, Rectal suppositories.
INTRODUCTION
The most challenging aspect in formulation development is to enhance the solubility and oral bioavailability of drugs that have low solubility. Nowadays with the help of combinatorial chemistry, it has become easy to enhance the solubility and bioavailability of solid solutions which shows improving solubility of the same. BCS class II drugs have low solubility and high permeability which has an effect on oral bioavailability. Solid dispersion technique involves at least two different components i.e. hydrophilic matrix and a hydrophobic drug which are combined together by different methods like fusion, solvent evaporation, lyophilization technique, extruding method, spray drying and gel entrapment method. Solid dispersion of telmisartan was prepared by using PEG 4000 and mannitol which improved the solubility and dissolution rate. Similar results were observed with solid dispersion of cefpodoxime proxetil prepared using PEG 4000 and PEG 6000 and of fluconazole using PEG 6000, mannitol, PVP K30 and beta-cyclodextrin as a carrier.

In the ancient era, drugs inducing unconsciousness, haemorrhoidal, vermicide and purgative actions were inserted through rectal route in the form of suppository. In modern days most of the remedial medicines are prepared for rectal delivery to gain therapeutic blood concentration of the medicine and thereby enhancing the bioavailability. By inserting the drug through rectal route the pre-systemic effect in the hepatic region and in GIT can be prohibited. Anal drug delivery systems, used as controlled release dosage form for treating ailments like arthritis, high blood pressure, asthma, AIDS, and diabetes. Moreover, there is a rising interest that the suppositories can be used in the treatment of post-operative pain and pain related to malignancy. Rectal drug delivery is the area of enthusiasm for many researchers to evaluate consumption of drug from the rectal region for a drug which is currently inserted through parental route. viz. antibiotic and polypeptides.

Rectal drug delivery has advantages such as reduced hepatic first pass metabolism, less gastric irritation associated with certain drugs and when the patient is unconscious. Rectal route is used for such purposes like those people having difficulty in swallowing oral medicine. It gives local and therapeutic action when administered in form of suppositories. Suppositories can be made by using lipophilic bases or hydrophilic bases. They melt or dissolve in rectal fluid and release the drug. Rectal drug delivery is also suitable for treatment of conditions afflicting the rectum and colon.
Ulcerative colitis (UC) is a chronic disease that results in inflammation and ulcers of the colon and rectum. It is generally authenticated by mucosal inflammation which generally extends from the proximal region of the colon to rectum. In ulcerative colitis, with the influx of neutrophils in lamina propria, there is the localized collection of pus cells surrounded by inflamed tissue and depletion of mucin followed by production of inflammatory mediators like cytokines. Conversely, Crohn’s Disease (CD) does not restrict to a confined region and can occur in any part of GIT, where the accompanying inflammation is described as irregular/patchy, segmented, and transmural. There are various conventional and unconventional therapies used for the treatment of ulcerative colitis which includes aminosalicylates, glucocorticoids, immunomodulators, etc. These therapies need to be administered frequently to patients, which reduces patient compliance and can cause systemic side-effects.\(^\text{[7,8]}\)

Budesonide (BUD) is a corticosteroid that is available in form of inhaler, pill, nasal spray and rectal forms. The inhaled form is used in long-term therapy of asthma and chronic obstructive pulmonary disease (COPD). The nasal spray is used in allergic rhinitis and nasal polyps and rectal form are used in inflammatory bowel disease that includes Crohn’s disease, ulcerative colitis and microscopic colitis. BUD belongs to BCS class II having low solubility and high permeability i.e., 0.0457 mg/ml in water. It has 10-20 % bioavailability and t\(_{1/2}\) is 2-3 h.\(^\text{[9]}\) In present study, Soluplus®(Polyvinyl caprolactam-polyvinyl acetate-polyethylene glycol graft copolymer)\(^\text{[10]}\) was used as acarrier for preparing the solid dispersions of BUD as it is reported to improve the solubility, dissolution, and bioavailability of poorly water-soluble drugs. Soluplus®was used as acarrier for atorvastatin calcium\(^\text{[11]}\) in which solid dispersions were prepared by hot melt extrusion process using various drug-polymer ratios and showed enhanced solubility of the drug. Etravirine\(^\text{[12]}\) solid dispersion was prepared by hot melt extrusion process and spray drying using Soluplus® as one of the carriers which showed improved solubility and dissolution rate. Gliclazide\(^\text{[13]}\) solid dispersion with Soluplus® as a carrier showed improved solubility and dissolution.

In the present study, solid dispersions of BUD with Soluplus® were prepared in different ratios to improve its solubility and dissolution rate. The solid dispersions were characterized by FTIR, DSC, PXRD and SEM. The solid dispersion was incorporated into polyethylene glycol suppositories and evaluated for various properties.
MATERIALS AND METHODS

Materials
Budesonide was gifted by Wockhardt Research Centre, Aurangabad. Soluplus® was obtained from BASF Chemical, Mumbai. Others chemicals and reagents used were of AR grade and procured locally.

Methods
1. Preparation of solid dispersions
Solid dispersions (SD) of BUD were prepared with Soluplus® with various drug-polymer ratios of (1:1, 1:2 and 1:3 as SD1, SD2 and SD3). Solvent evaporation method was used to prepare the solid dispersions. Acetone was used as the solvent as both drug and polymer are freely soluble in it. The process was done by taking the drug-polymer ratio of various concentrations as mentioned above. The solvent is evaporated using water bath (Electric water bath, Make- Meta lab scientific) at a temperature of 60°C to obtain a dry gel-like mass. The dry mass was pulverized and passed through 60 mesh sieve and stored in desiccator until further studies. Physical mixtures (PM) of the drug with Soluplus® in the ratio of 1:1, 1:2, 1:3 as PM1, PM2 and PM3 were also prepared by mixing in glass mortar for 5-10 min. All the samples were passed through sieve no 60 and stored in desiccators until further studies.[14]

2. Drug content
The percentage drug content in SD and PM was estimated by dissolving 40mg of SD and PM in pH 7.4 phosphate buffer and filtered. The filtrate was suitably diluted with pH 7.4 phosphate buffer and drug content was analyzed against blank by UV spectrophotometer (Make:Jasco V-730) at 247nm.[15]

3. Saturation solubility studies
Solubility determination was performed in triplicate. Excess drug/binary SDs/PMs were added to 20 ml of DW, 0.1 N HCl, phosphate buffer pH 7.4, fasting state simulated intestinal fluid (FaSSIF) and fed state simulated intestinal fluid (FeSSIF) separately and were equilibrated in an orbital shaker (CIS-24 Remi, India) at 37 ± 0.5°C for 24 h. The equilibrated suspensions were filtered through Whatman filter paper (0.45 µm) and assayed for drug content by UV-spectrophotometer (Make Jasco V-730) at 247nm.[16]
4. **In-vitro dissolution studies**  
The *in vitro* drug release studies was performed in triplicate for SD1, SD2, SD3 and PM1, PM2, PM3 of same ratio using USP type 2 dissolution apparatus (Lab India DS8000) using phosphate buffer pH 7.4 (900 ml) and the temperature was maintained at 37°C and the stirring speed was 50 rpm. The sample aliquots were withdrawn at time intervals of 15, 30, 45, 60,75 and 90 min and the same quantity was replaced by fresh medium to maintain the sink conditions. The samples were analyzed by using UV/Visible spectrophotometer (Make Lab UV 3000) at 247 nm. The cumulative percentage drug release was calculated.\[17\]

5. **Drug-excipient compatibility studies**  
Compatibility studies were carried out with potential formulation excipients to determine the possibility of any drug-excipient interaction by taking the mixture of drug and excipient of different ratios like (1:1, 1:2, 1:3) for 30 days at 37°C in oven (Make: Lab oven, Biomedica). FTIR spectra (Make- Jasco FTIR - 460 plus spectrophotometer) and drug content of the samples were recorded.\[18\]

6. **Fourier transform infrared (FTIR) Spectroscopy**  
Fourier transform infrared (Make- Jasco FTIR - 460 plus spectrophotometer) spectra of powdered samples of budesonide, Soluplus®, physical mixture and solid dispersions (SD) of different ratios (SD1, SD2, SD3) were obtained using a FTIR spectrophotometer by potassium bromide (KBr) mixture method (4 mg sample in 250 mg KBr). The scanning range was 400–4000 cm\(^{-1}\) and the resolution was 2.4 cm\(^{-1}\).\[19\]

7. **Differential Scanning Calorimetric Analysis (DSC)**  
The thermograms were recorded for BUD, physical mixture and SD using a METTLER TOLEDO DSC 823e differential scanning calorimeter. A heating rate 10°/min was employed in the 30-300°C temperature range. Standard aluminum sample pans were used. An empty pan was used as a reference standard. The analysis was performed on 5mg samples under nitrogen purge (40ml/min).\[20\]

8. **Powder X-ray diffraction study (PXRD)**  
The PXRD spectra of BUD, SD1, SD2 and SD3 were recorded using high power powder X-ray diffractometer (Ru-200B) with Cu as target filter having a voltage/current of 40 kV/40 mA at a scan speed of 40/min. The samples i.e., BUD, SD1, SD2 and SD3 binary complexes
were analyzed at 2θ angle range of 5°–50°. Step time was 0.5 s and time of acquisition was 1 h.[21]

9. Scanning Electron Microscopy (SEM)

The surface morphology of plain BUD and SDs were determined using field emission scanning electron microscope (Instrument: Oxford X-act, model: JEOL JSM-63 60 A). A field emission gun produces a beam with an extremely high electronic current density, by applying an intense electric field to a tungsten crystal with a needle-shaped tip. This needs an ultra-high vacuum (10⁻¹⁰Torr). The samples were sprinkled on a double adhesive tape stuck to an aluminum stub. The stubs were then coated with platinum to a thickness of about 10Å under an argon atmosphere using a gold sputter module in a high-vacuum. The stub containing the samples was placed in the SEM chamber.[22]

10. Stability studies

Stability study of physical mixtures and solid dispersions was carried out at 40°C +/- 2°C and 75 % RH +/- 5 %, as per ICH guidelines. (Stability chamber-Remi instrument). Molecular interactions (FTIR spectra) and drug content was determined at 0 and 90 days.[23]

11. Preparation of suppositories

Suppositories of polyethylene glycol were prepared using solid dispersion. The suppository base comprised of PEG 4000, PEG 6000 and water in ratio of 33:47:20.[24] The ingredients were heated in a porcelain dish till they melted; drug/solid dispersion was added and stirred till a homogenous mixture was obtained. The molten mass was poured into the suppository mould (lubricated with glycerin) and refrigerated at 4°C. The suppository mould is calibrated by preparing the blank suppository of the base PEG 4000 and 6000. Displacement value of plain drug and solid dispersion was determined as follows:

Weight of 6 PEG suppositories (W_B) and weight of 6 drug/solid dispersion suppositories (W_S) was determined. Amount of drug (W_I) was calculated using above and of suppository base (B_R = W_B – W_I) in the medicated suppository was calculated. The amount of PEG displaced by drug is given by W_F = W_B + B_R from which the displacement value of drug was calculated using the formula W_S = W_F / N.[5]
12. Evaluation of suppositories

1. **Breaking test:** An iron rod with a plastic disk on one side and pointed on the other end was used. A suppository is placed in between the pointed end of the iron rod and a metallic plate. Weights are placed on the disk in increasing order till the suppository collapses. The point at which it collapses is measured as a breaking point.\[25\]

2. **Dissolution test:** Dissolution test was performed on the whole suppository. The suppository of the formulation was placed in a beaker with phosphate buffer pH 7.4 maintained at constant temperature 37± 0.5°C. The time required by the whole suppository to melt or disperse in the media was noted.\[26\]

3. **Softening time:** Softening time was measured using a 10 ml graduated pipette fixed using a stand in phosphate buffer pH 7.4 maintained at 37°C. The suppository was pushed inside from the broad end side to reach the narrow end. A thin glass rod was placed on the top of the suppository and the time at which the rod just penetrates into the suppository is recorded as softening time.\[27\]

4. **Drug content:** Drug content was determined spectrophotometrically. Suppositories were melted and subsequently dissolved in phosphate buffer pH 7.4. After necessary dilutions, the solutions were subjected to UV spectroscopy (Make Lab UV 3000) at 247 nm wavelength.\[28\]

5. **Weight variation:** All the suppositories were weighed and average weight was calculated. Then all the suppositories were individually weighed and the variation from the average was calculated. No suppositories should deviate from average weight by more than 5%.\[29\]

6. **In vitro release studies:** These studies were performed using USP rotating basket type II dissolution apparatus (Make- Lab India DS8000). The dissolution media used was phosphate buffer pH 7.4 and the temperature was maintained at 37°C and the stirring speed was 50 rpm. Aliquots were withdrawn at time intervals of and the same quantity was replaced by fresh medium to maintain the sink condition. The aliquots were analyzed spectrophotometrically (Make Lab UV 3000) at 247 nm. All studies were run in triplicate (n=3).\[30\]

7. **Stability studies:** Short term stability studies were performed at a room temperature and refrigeration temperature (4°C) was kept for 15 days. The suppositories were individually wrapped in aluminum foil. Sample are taken after 15 days for drug content estimation and dissolution test also performed to determine the drug release profile.\[31\]
RESULTS AND DISCUSSION

1. Preparation of Solid Dispersions

Various methods are used to prepare solid dispersions depending on the nature of drug and polymer. These include solvent evaporation, melt method, hot melt extrusion and gel entrapment method. Melt method and melt extrusion method involve heating to melt the carriers and this may cause unwanted changes in the physicochemical profile of the drug such as degradation, crystallographic changes, etc. Hence in present study solvent evaporation method was used to prepare solid dispersions of BUD with Soluplus® with acetone as the solvent. In this method the drug is also in molecular form resulting in an intimate mixture between drug and polymer. Various ratios of drug and carrier such as 1:1, 1:2 and 1:3 were used. All the solid dispersions were found to be fine free flowing powders. The solid dispersions were compared with physical mixtures of the drug and polymer in similar ratios.

2. Drug content

The percentage drug content was determined by UV/Visible spectrophotometer (Make Lab UV 3000) at 247nm. SD was compared to PM that was prepared of various ratios like 1:1, 1:2 and 1:3. The drug content in all SDs was found to be between 95%-102% indicating no or negligible loss of drug during the process.

3. Saturation solubility studies

Saturated solubility studies were performed for BUD, PMs and SDs in different media “Fig.1”. The SD1(1:1) showed an almost 7 fold increase in solubility in water, 8 fold increase in 0.1 N HCl, 9 fold increase in phosphate buffer pH 7.4 as compared to plain BUD. SD2 and SD3 also displayed higher solubility than SD1 however the increase was not very significant. In bio relevant media, a 7 fold increase in FaSSIF and 9 fold increase in FeSSIF state was observed. This indicates that the higher solubilization effect is replicated in vivo. Soluplus® is a polymeric solubilizer with an amphiphilic chemical structure, which was particularly developed for solid solutions. Due to its bi-functional nature, it acts as a matrix polymer for solid solutions and also it is capable of solubilizing poorly soluble drugs in aqueous media. Soluplus® can increase the bioavailability of poorly soluble drugs. The physical mixtures of BUD and Soluplus® did not produce a remarkable increase in solubility as compared to SDs which was expected as the drug may not have been homogenously mixed with the polymer. However the PMs did show increase in solubility as compared to plain drug to the extent of 2-4 folds.\[32,33\]
4. **In-vitro** dissolution of solid dispersions

The *in-vitro* dissolution revealed that dissolution rate of solid dispersions was higher as compared to that of physical mixtures and drug alone “Fig.2”. From the study, it was found that SD1 showed nearly 90% release and PM1 showed 72% release in 90 min. SD2 and SD3 exhibited 62 and 60% release at 90 min respectively. The slower release in presence of higher polymer concentration could be attributed to the ability of Soluplus® to form matrix-type solid dispersions which results in slower drug diffusion through the tortuous channels formed in the matrix. The improvement in the dissolution of the drug may be due to its entrapment within the molten carrier during the melting (fusion technique) process, or due to the molecularly dispersed state of the drug in the solid dispersion. Also the drug is converted into amorphous state and its wetting property is improved. Thus the cumulative effect is improvement in dissolution rate.[34]

![Fig. 1: Saturation solubility in different media.](image1)

![Fig. 2: Drug release profile.](image2)
5. Drug-excipient compatibility studies
The drug-excipient compatibility studies “Fig 3”, revealed no significant difference in the IR spectra of the physical mixtures of BUD with Soluplus®. Minor peak modifications could be attributed to the dilution effect of the mixtures. Thus we may infer that the drug and excipient are compatible with each other.

![Fig. 3: FTIR of PMs, BUD, Soluplus®](image)

6. FTIR studies of solid dispersions
The prominent peaks of Budesonide was observed “Fig. 4”, in the region of 1722.43 cm\(^{-1}\) due to the C=O Aliphatic stretching, a peak at 1664.57 cm\(^{-1}\) due to C=C stretching and a peak at 2915 cm\(^{-1}\) due to aliphatic C-H stretching, a sharp peak at 3542 cm\(^{-1}\) due to alcoholic and phenolic –OH stretching was observed. Soluplus® shows a prominent peak at 3410.26 cm\(^{-1}\) which is due to polymeric OH stretching, a peak at 2922cm\(^{-1}\) due to aliphatic CH\(_3\) stretching. The disappearance of some peaks, overlapping of O-H and N-H group and broadening of the peak in the spectra of SD1 indicates that BUD is molecularly dispersed in the polymer matrix. However other peaks related to C-O-C, C-H stretching remains unchanged. This indicates that overall symmetry of the molecule might not be significantly changed.\(^{[35]}\)
7. Differential scanning calorimetry
The DSC thermograms of budesonide showed in “Fig. 5”, shows a sharp endothermic peak at melting point 251.56°C, indicating that the drug is highly crystalline. The absence of drug peak in SD1 indicates that the drug is in amorphous form and is molecularly dispersed in the polymer matrix which supports the FTIR results. Kappala Ramesh et al.\textsuperscript{[12]} reported the absence of drug peak in the solid dispersion formulation ESD4 (Etravirine: Soluplus®: MCC (1:2:0.5)) indicating the drug was in amorphous form.
8. Powder X-Ray diffraction patterns

The PXRD of Budesonide consist of sharp multiple peaks at 2θ angles of 15°, 17°, 19°, 24° and 27° indicating crystalline nature of the drug. The diffractogram of SD1 exhibited a halo pattern with reduced peak intensities. This may be due to partial amorphization of BUD in the solid dispersion. The diffractogram of Soluplus® was characterized by complete absence of any diffraction peak. Sambath L.et al.[13] reported similar findings for gliclazide solid dispersions in Soluplus®.

![Fig. 6: Powder X-ray diffraction patterns of A) SD1 and B) plain drug.](image)

9. Scanning electron microscopy (SEM)

SEM images “Fig.7”, of BUD revealed equant shaped crystals of BUD whereas that of solid dispersion showed matrix form of the polymer with no evidence of drug crystals. The images thus indicate the entrapment of molecular form of drug in the polymer.

![Fig. 7: SEM micrographs of A) BUD and B) SD 1.](image)
10. Preparation of suppositories
Since Soluplus® was not being dispersed uniformly in cocoa butter base; PEG base suppositories were prepared using plain drug and the solid dispersions by moulding method. Suppositories of plain drug were coded as F1 and those with SD were coded as F2. SD1 was used to prepare the suppositories as it was observed from results of saturation solubility that higher concentration of Soluplus® did not have a significant effect on solubility of BUD. The displacement value of BUD was found to be 0.99 and that of solid dispersion (SD1) was found to be 1.2. This was used to calculate the quantities of various ingredients including plain drug and SD1 in each suppository. The drug content was calculated to be 97-100 % in both suppositories. The weight variation studies of all suppositories were found to be within the acceptable range i.e. <5%.

11. Evaluation of suppositories for various parameters
The suppositories were evaluated for various parameters (Table 1). Breaking strength is a measure of mechanical strength indicating the fragility or brittleness or elasticity of suppositories which assess the ability of suppositories to withstand mechanical shocks during transportation and handling. Both the suppositories had adequate breaking strength which indicated that the drug or Soluplus® did not exert any adverse effect on the mechanical properties of the suppositories. PEGs are hydrophilic in nature and are miscible with aqueous fluids including physiological fluids. The suppositories were found to dissolve completely in 12-16 min in phosphate buffer pH 7.4 at 37°C. However this may not impede the release of the drug as the suppositories begin to soften at 8 to 10 min as indicated by the softening point. The softening point indicates the time taken by the formulation to soften under similar pressures found in the rectum. This will facilitate diffusion of the drug. The complete dissolution of the polymer in physiological medium will lead to formation of a viscous gel-like matrix from which the drug will be released. It will also prevent any leakage of the dissolved suppositories from the rectal cavity leading to longer residence time of the suppositories.[36]

Table 1: Evaluation of suppositories for various parameters.

<table>
<thead>
<tr>
<th>Formulation code</th>
<th>Breaking test (g)</th>
<th>Dissolution test (min)</th>
<th>Softening time (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1</td>
<td>65.23±1.56</td>
<td>16±2</td>
<td>10-12 min</td>
</tr>
<tr>
<td>F2</td>
<td>58.61±2.65</td>
<td>12±1</td>
<td>8-10 min</td>
</tr>
</tbody>
</table>

(n=3)
12. In vitro dissolution studies

In vitro dissolution studies in USP type II paddle apparatus in phosphate buffer pH 7.4 revealed the plain drug suppositories released 68% BUD in 90 min whereas the suppositories of SD1 released 92% BUD in a same time span. The data obtained clearly shows the amount of drug release from water-soluble bases is greater. This enhancement of the dissolution was due to enhanced solubility of budesonide. This is due to the effect of PEG bases having good hydrophilic property and solubilizing effect. Majri MA. et al,\(^{37}\) discussed that the dissolution rate of suppositories showed enhanced solubility in PEG base which therefore gave greater release of piroxicam suppositories. Baviskar P.\(^{38}\) et al, described the use of various bases used for the preparation of suppositories and discussed about their effectiveness for improved solubility for lornoxicam drug.

![Fig. 8: In vitro dissolution studies.](image)

13. Stability studies

The stability studies for SD 1 formulation was done by storing at 40°C +/- 2°C and 75% RH +/- 5% as per ICH guidelines. The drug content and FTIR studies assayed after 3 months did not show any significant change. The stability studies showed that there was no significant change in drug content and in vitro dissolution profile of suppositories after storing them for 15 days at refrigeration and room temperature. Thus it indicates that the suppositories were stable and can be used satisfactorily.\(^{39,40}\)

CONCLUSION

From the above studies, it can be concluded that solubility enhancement is a major aspect in drug development. The solubility and dissolution rate of budesonide was enhanced by solid dispersion prepared by solvent evaporation method using Soluplus ® as carrier. SD1 (1:1 drug carrier ratio) showed improved solubility and dissolution rate. Further rectal suppositories
were prepared using polyethylene glycols of different molecular weights as base and evaluated for various parameters. The suppositories were found to have desirable physical properties such as breaking point and softening time. In vitro release studies showed better dissolution profile for suppositories prepared with solid dispersions compared to plain drug suppositories. DSC, FTIR and PXRD studies confirmed amorphization of the drug. Results of FTIR concluded that there was no interaction between budesonide and Soluplus®. DSC .We may hence conclude that solid dispersions of budesonide using Soluplus® showed improved aqueous solubility and dissolution rate. Hence, suppositories can be effective in the treatment of ulcerative colitis.

ACKNOWLEDGEMENTS
I am thankful to Wockhardt Research Centre, Aurangabad, and BASF, The Chemical Company for providing gift samples of Budesonide and Soluplus® respectively. I am also thankful to Dr. Ashwini R Madgulkar, Principal, AISSMS College of Pharmacy for her constant support and guidance.

REFERENCES


