The need for effective management of diseases. Site-specific release systems provide many distinctive advantages over classical methods of drug delivery such as localized delivery of drug to a particular part of the body, reduce need for follow-up care, assurance of treatment continuity in the nocturnal phase and optimised drug absorption. Sustained drug delivery systems provide an alternative approach to regulate the bioavailability of therapeutic agents. In such systems an active therapeutic is embedded into a polymeric network structure in such a way that the drug is released from the material in a predefined manner. Depending on the drug delivery formulation and the purpose, the drug release time may be anywhere from a few hours to a month to several years. A variety of synthetic and natural polymers have been studied as drug carriers. Sustained release drug delivery technology offer copious advantages compared to conventional dosage forms which includes enhanced efficiency, sustained blood levels, reduced toxicity, attenuation of adverse effects and improved patient compliance and convenience. To generate slow release of drug to the gastrointestinal tract various mechanisms have been used such as encapsulation dissolution control, matrix dissolution control, reservoir device, osmotically controlled release, 

**INTRODUCTION**

High patient compliance and flexibility in designing dosage forms have made the oral drug delivery systems to be the most convenient mode of drug administration when compared to other dosage forms. To date, oral delivery is still the preferred route of drug administration, especially for chronic therapies where repetitive administration is required. Oral administration assures patients less pain, higher likelihood of compliance, greater convenience and reduced risk of cross-infection and needle stick injuries. Thus, formulations of oral drug delivery continue to take over more than half of the drug delivery market share. Drugs that are easily absorbed from gastrointestinal tract (GIT) and have short half-lives are eliminated quickly from the systemic circulation. Frequent dosing of these drugs is required to achieve suitable therapeutic activity. To avoid this limitation, the development of oral sustained-controlled release formulations is an attempt to release the drug slowly into the gastrointestinal tract (GIT) and maintain an effective drug concentration in the systemic circulation for a long time.

The concept of sustained drug release has emerged from the need for effective management of diseases. Site-specific release systems provides many distinctive advantages over classical methods of drug delivery such as localized delivery of drug to a particular part of the body, reduce need for follow-up care, assurance of treatment continuity in the nocturnal phase and optimised drug absorption. Sustained drug delivery systems provide an alternative approach to regulate the bioavailability of therapeutic agents. In such systems an active therapeutic is embedded into a polymeric network structure in such a way that the drug is released from the material in a predefined manner. Depending on the drug delivery formulation and the purpose, the drug release time may be anywhere from a few hours to a month to several years. A variety of synthetic and natural polymers have been studied as drug carriers.

**ABSTRACT**

The present study has been undertaken to develop a sustained-release tablet dosage form for metoprolol succinate using kondagugu gum as the rate-controlling polymer. The prepared tablets were coated with shellac as an enteric coat polymer and evaluated for tablet properties. In vitro release studies of prepared tablets were carried out for 2 hrs in pH 1.2 HCl buffer and 22 hrs in pH 6.8 phosphate buffer. In addition, swelling, kinetics of drug release from the matrices and stability of the tablet formulations were also investigated. Mathematical analysis of the release kinetics showed that the nature of drug release from the matrix tablets has followed super case II transport. FTIR and DSC studies have shown that no chemical interaction occurred between the drug and polymers used. The optimized formulation (F4) showed negligible difference in release mechanism as well as release kinetics when stability study was done for three months at 40±2°C and 75±5% RH.

**KEY WORDS:** Kondagugu gum, metoprolol succinate, matrix tablets, sustained release.

**AUTHOR FOR CORRESPONDENCE**

N. Srujana, Department of pharmaceutics, JSS College of Pharmacy, J.S.S University, Mysore, Karnataka, India
E-mail: sruji_chinni@yahoo.com
pH independent release formulations, time dependent release formulations, ion exchange controlled release, altered density formulations. Improved drug release systems can be developed by selecting an appropriate carrier capable of controlling the drug delivery. Suitable matrix systems which swell in water can be developed by compression of a hydrophilic polymer with the drug. New formulations which make use of different delivery devices from synthetic and natural polymers, which are either hydrophilic or hydrophobic, have been tested for these purposes. The challenge is to design oral drug delivery vehicles, which effectively works as sustained release dosage forms and the released drug gets absorbed at an efficient rate in the GI tract in order to be therapeutically effective. Several carbohydrate polymers are able to satisfy these requirements to some extent, having demonstrated their potential as starting materials for the construction of oral drug delivery vehicles.

Success of matrix systems can be linked to carbohydrate polymers as they respond to the presence of water or biological fluids and change their structure to form a gel layer which enables the drug to be release slowly from the matrix throughout the gastrointestinal tract (GIT) at the desired rate and time. Biodegradable polymers form an excellent platform for sustained drug delivery applications due to their hydrolytic instability, ease of fabrication, non-toxic degradation and matrix permeability. Therefore, in contrast to purely diffusion-controlled drug delivery systems, swelling and polymer erosion must also be considered.

Carbohydrate and biodegradable polymers have been extensively used to develop the sustained release (SR) formulations to decrease the release rates of drugs having short plasma life. Responsive polymers, in particular hydrophilic natural carbohydrate polymers, are some of the promising new resourceful carriers for the preparation of oral sustained release (SR) systems. A large number of polysaccharides like amylose, guar gum, chitosan, inulin, pectin, cycloexetrins, dextran, dextrin, chondroitin sulphate, and locust bean gum have been investigated for their use in sustained drug delivery systems. Very unique features of these polymers are optimal proportional of the hydrophobic and hydrophilic parts respectively and the number of free hydroxy groups in the polymeric molecule. One such responsive polymer is Kondagugu gum.

Kondagugu gum [KG] is the dried exudates obtained from tree Cochlospermum gossypium which belongs to the family Bixaceae. KG is a high molecular weight complex acetylated polysaccharide consisting mainly of D-galacturonic acid, D-galactose and L-rhamnose. KG has aroused lot of interest in the preparation of hydrophilic matrix tablets because of its high water swellability, nontoxicity, and low cost. Unlike other water soluble gums, it does not dissolve in water but absorbs it to form a viscous colloidal solution. Powdered KG swells in cold water to an extent that a 3% to 4% sol will produce a gel of uniform smoothness and texture.

Metoprolol (MTL), which is a β1-selective adrenergic blocking agent is prescribed widely in diverse cardiovascular diseases such as hypertension, angina pectoris, arrhythmias, and congestive heart failures was selected as model drug. Administration of conventional tablets of MTL has exhibited fluctuations in the plasma drug levels finally resulting either in the manifestation of side effects or reduction in drug concentration at the receptor site. MTL undergoes extensive first-pass metabolism in the liver, which leads to the low oral bioavailability, which is about 40 - 50% in humans and has a short biological half-life of 4 hrs. In order to avoid these disadvantages, several formulations like tablet, buccal sprays and capsules have been developed. CR dosage forms of osmotic pumps and CR solid dispersions dosage forms have been developed. The objective of the present study is to develop a sustained-release formulation of metoprolol and to study the dissolution of metoprolol succinate from kondagugu gum based sustained-release formulations.

**MATERIALS AND METHODS**

Metoprolol succinate was obtained as gift sample from Dr. Reddy’s laboratories, Hyderabad; Kondagugu gum was procured from Girijan Co-operative Society, Hyderabad; Directly compressible lactose (DCL) was obtained as gift sample from Strides Arcolab Ltd., Bangalore; All other chemicals used were of analytical grade and purchased from Loba Chemie, Mumbai.

**Collection and purification of Kondagugu gum**

Kondagugu gum was procured from Girijan Co-operative Society. First the foreign extraneous matter like bark etc was separated. Then the gum was powdered by using mortar and pestle. Further fine powder of gum was obtained using mixer grinder. The powdered gum was passed through sieve # 65 and then through sieve # 80. The powdered gum is dispersed in distilled water to get a 1% solution. The solution was kept in sonicator for 10 min until it was clear. After that, ethanol was added in the ratio of (2:1 v/v) to give precipitation of gum. Precipitated polymer is kept in an oven for drying and then powdered.

**Preparation of tablets**

Accurately weighed quantities of drug, polymer (kondagugu gum) and binder (PVP K-30, 4% w/w) were physically mixed with a mortar and pestle. Required
quantity of the solvent (ethanol) was added and the same was mixed thoroughly to form a mass suitable for preparation of granules. The dough mass was passed through sieve #22 to form granules which were dried in an oven at 50°C. The granules were mixed with required quantities of diluent (DCL), lubricant (talc, 3% w/w) and were compressed to form tablets in a 10 station rotary tablet machine (Rimek, Ahmedabad, India) at 100 rpm and using 9 mm round concave punches at an optimum pressure. Five formulations were prepared by varying the amount of KG viz, 30, 40, 50, 60 and 70% w/w of the tablet and coded as F1, F2, F3, F4 and F5 respectively.

The composition of various formulations is shown in Table 1.

**Water uptake study**

The water uptake by of the polymers can be measured by their ability to absorb water and swell. The water uptake study of the tablet was done by placing the tablet in Electrolab TDL-08L dissolution tester (USP) basket type, 900 ml of distilled water at 100 rpm. The medium was maintained at 37 ± 0.5°C throughout the study. At regular time intervals, the tablets were withdrawn, blotted to remove excess water and weighed. Swelling characteristics of the tablets were expressed in terms of water uptake (WU) as:

\[
WU(\%) = \frac{\text{weight of the swollen tablet} - \text{Initial weight of the tablet}}{\text{Initial weight of the tablet}} \times 100
\]

**Coating of the prepared tablets**

For the purpose of enteric coating, a solution of shellac (10% w/v) in ethanol was used along with PEG 6000 (4% w/w of shellac) as plasticizer. The coating solution was passed through a 0.3 mm sieve prior to coating. The prepared matrix tablets were coated with shellac solution till a weight gain of 2.5% w/w over the tablets was obtained. Coating of the tablets was carried out in a conventional coating pan (Ram Scientific Suppliers, Bangalore, India) at an inlet temperature of 55°C, pan rotation speed of 15 rpm, spray pressure of 4 kg/cm² and a spray rate of 1 ml/min. A omega type spray gun (Type 79) fitted with a 1 mm atomizing nozzle was used to spray the solution. The coated tablets were evaluated for hardness and drug content.

**Evaluation of prepared tablets**

The prepared tablets were evaluated for weight variation, friability (Electrolab EF-2 friabilator, Mumbai, India), thickness (Mitotoya screw guage), and hardness (Inweka hardness tester IHT 100 Evaluation data for the prepared formulations were shown in the Table 2.

**Content uniformity**

Twenty tablets of metoprolol succinate were weighed and powdered. Crushed powder of tablets equivalent to 0.15 gm was weighed and dissolved in pH 6.8 Phosphate buffer. The solution was filtered and diluted and drug content was analyzed spectrophotometrically at about 222 nm.

**In vitro drug release study**

To understand the release kinetics of tablets, release studies were carried out using USP XXII dissolution apparatus, basket type at 100 rpm and 37 ± 0.5°C. The release studies were carried out for the shellac coated tablets in triplicates in simulated gastric condition (0.1 N HCl) for initial 2 h and at later hours in simulated intestinal condition (7.4 pH phosphate buffer) The tablets were tested for drug release for 2 hrs in 1.2 pH HCl buffer (900 ml), as the average gastric emptying time in stomach is about 2 hrs. The dissolution media was replaced at the end of 2 hrs with 900ml of pH 6.8 phosphate buffer and drug release study was continued for another 22 hr. A 10-ml aliquot of the dissolution solution was withdrawn at regular interval of time and analyzed for drug released using a UV–visible spectrophotometer at λ_max of 222 nm. A 10-ml of the same solution maintained at 37.5°C was replaced back to the dissolution vessel so as to maintain the sink conditions.

**Mechanism of drug release**

The different mathematical models may be applied for describing the kinetics of the drug release process from tablets; the most suited model is selected depending upon the experimental results. The kinetics of metoprolol succinate release from tablets formulations were determined by finding the best fit of the release data to Korsmeyer-Peppas plots. Korsmeyer-Peppas model is one of the mathematical expression to evaluate the mechanism of drug delivery. The Korsmeyer-Peppas equation is as follows:

\[
\frac{M_t}{M_v} = 1 - A \left( \exp \left( -kt \right) \right)
\]

(1)

\[
\log (1 - \frac{M_t}{M_v}) = \log A - kt/2.303
\]

(2)

where, \( M_t/M_v \) is the fractional amount of drug released and \( t \) is the time in hrs. In this study, the release constant, \( k \) and constant, \( A \) were calculated from the slopes and intercepts of the plot of \( \ln (1 - \frac{M_t}{M_v}) \) versus time \( t \) respectively where, \( M_t \) is the amount of drug release at time \( t \); \( M_v \) is the amount of drug release after infinite time; \( k \) is a release rate constant incorporating structural
and geometric characteristics of the tablet; and A is the
diffusional exponent indicative of the mechanism of drug
release. To find out the release exponent, the log value of
percentage drug dissolved was plotted against log time
for each batch according to the above equation. If A is
equivalent to 0.5 indicates Fickian (case I) release;
greater than 0.5 but less than 1 for non-Fickian
(anomalous) release and A is greater than 1 indicates
super case II type of release. Case II generally refers to
the erosion of the polymeric chain, and anomalous
transport (Non-Fickian) refers to a combination of both
diffusion and erosion controlled drug release. The
interpretation of diffusional release mechanisms can be
obtained by the data given in Table 3 and the
corresponding results were tabulated in Table 4.

**Differential scanning calorimetry (DSC)**
DSC thermograms were recorded for pure metoprolol
succinate drug and the optimized formulation using a
differential scanning calorimeter. Accurately weighed
samples were placed on aluminum plates, sealed with
aluminum lids, and heated at a constant rate of 5 °C/min
over a temperature range of 0–400 °C. All dynamic DSC
studies were carried out using DuPont thermal analyzer
with 2010 DSC module. The instrument was calibrated
using high purity indium metal as standard.

**Fourier transform infrared spectroscopy (FTIR)**
FTIR spectra of the pure metoprolol succinate and the
optimized formulation were recorded using a Fourier
transform infrared spectrophotometer (FTIR 8400
Shimadzu, Japan). Samples were prepared as KBr disks
using a hydraulic pellet press and scanned from 4000 to
400 cm⁻¹.

**Stability studies**
Stability studies of the optimized formulations of
metoprolol succinate tablets was carried out to determine
the effect of formulation additives on the stability of the
drug and also to determine the physical stability of the
formulation. The stability studies were carried out at 40
°C/75% RH for 3 months (Thermolab, Mumbai, India).
Formulation was analyzed every 15 days for its hardness
and % drug content. The obtained results are shown in
the Table 5.

**RESULTS AND DISCUSSION**
The prepared tablets were having an average diameter of
9 mm. Percentage weight variation, percent friability and
content of active ingredient for all the formulations were
found to be well within United States Pharmacopoeia
(USP) limits. From the Table 2 it is clear that the
hardness of the core tablets increased as the amount of
copolymer concentration in the tablet increased.
Formulations containing 70% w/w of polymer showed
maximum hardness among the various ratios selected
(30%, 40%, 50%, 60%, and 70%). The percentage of drug
content lies in the range 98.9-100.4%.

The swelling behavior of the polymers used in a tablet
could be determined by water uptake by the tablet. The
percent swelling of the tablet was determined at different
time intervals. The complete swelling was achieved by
the end of 8 hr, hence percent swelling was determined at
the end of 10 hrs for all the developed formulations. The
maximum percentage of swelling was found in
Formulation F5 which was higher when compared to
other formulations, and least percentage of swelling was
found in F1, as is shown in Figure 1. There was rapid
increase in percentage swelling of F1, and F2 at the end
of 1st hr. F4 showed a gradual increase in percentage
swelling till the study period of 8 hrs. The increase in the
concentration of kondagugu gum may retard the water
uptake during 1 hr. As described by Seimann and Peppas
diffusion of drug significantly depends on the water
content of the tablet. This may be because the mobility of
the polymer chains strongly depends on the water
content of the system. At high water content, polymer
chain relaxation takes place with volume expansion
giving rise to high swelling of the system. Consequently,
faster and higher swelling of the tablet led to increase in
dimensions of the tablet, leading to increasing the
diffusion pathways and thus increasing the drug release.
So the drug release was found to be high initially and
then gradually decreased, this was true in F4. The Figure
2 showed swelling behavior of tablet at 0 min to 8 h. All
the tablets showed better radial and axial swelling, but
maximum swelling was seen in F5.

The enteric coated tablets were subjected to dissolution
test. Results showed that there were no signs of cracking,
peeling or disintegration in 0.1 N HCl i.e. the tablets
remained intact in 0.1 N HCl.

Further, drug release studies were carried out in
phosphate buffer pH 7.4. In vitro studies revealed that
the formulations containing 30 and 40% w/w of polymer
did not show sustained release whereas, the formulations
containing 60% showed sustained drug release from the
coated tablets over a period of time. Formulations
containing 30% and 40% w/w of polymer, released
almost entire drug within 10 and 12 hrs of dissolution
respectively. Formulation containing 30% w/w showed
almost 60% of the drug release within 4 hours whereas
the formulation containing 70% w/w showed 25 % of the
drug release in the same time. On the other hand tablets
containing 60% and 70% w/w of kondagugu gum
showed only about 81.89 and 73.87% of drug release at
the end of 12 hrs of dissolution. Hence the order of drug
delivery from the coated tablets with reference to
polymer concentration is; 30 >40 > 50 >60> 70%.

(Figure 2)
The data obtained from in vitro drug release studies was fit into Peppas model. From the plot of log M/M∞ versus t, the parameters such as release constant (k), constant (A) and the regression coefficient (R²) were calculated and are given in Table 3. In all the cases, the values of ‘A’ were found to be more than 1. This result indicates that the release of drug from the polymer matrix formulations was found to be super case-II transport, i.e., drug release by more than one mechanism. Super case II transport generally refers to erosion of polymeric chain and anamolous transport.

The IR spectra taken of metoprolol succinate drug and the optimized formulation (F4) were found to be identical (Figure 3). The characteristic IR absorption peaks of Metoprolol Succinate at 3600-2300 (NH2, OH Aliphatic and aromatic OH), 1580 (Carboxylic acid salt), 1580, 1515 (Aromatic ring), 1250, 1015 (Aromatic Ether), 1180 (Isopropyl Group) and 1100 cm⁻¹ (Aliphatic Ether, Secondary Alcohol) 820 1.4 (disubstituted Benzene) were obtained. The FTIR spectra of the pure drug as well as coated formulation indicated that no chemical interaction occurred between the metoprolol succinate and the polymers used. But, a slight shift in absorption peaks position was noticed. This result revealed that physical interaction occurred between drug and the polymer.

Stability studies of the drug formulations are performed to ascertain whether the drug undergoes any degradation during its shelf life. In the present study, the optimized formulation F4 was selected for stability studies. The obtained results of the stability studies are given in Table 3. From the stability study data, it was concluded that the drug was stable in the optimized formulation for the study period.

DSC thermograms of pure drug and the optimized formulation are presented in Figures 4 and 5 respectively. An endothermic peak corresponding to the melting point of pure drug was prominent. There was no significant shift in the peak temperature, even though there were some additional peaks in the formulation which clearly suggests that the drug was present in an unchanged form.

CONCLUSION
The results obtained indicate that kondagugu gum could be useful as matrix system for sustained drug delivery and various polymers could be used to modulate the drug release from the matrix tablet. The 24 hrs drug release study indicated that the prepared formulation is ideal for sustained release. Enteric coating and the rate of swelling favored sustained release of the drug from the formulation. The final product is expected to have the advantage of being biodegradable and pH dependant. Hence it can be stated that sustained release drug formulation can be prepared using kondagugu gum, a naturally available, environmental friendly, non-toxic and biodegradable gum as carrier.

ACKNOWLEDGEMENT
The authors wish to thank Dr.H.G.Shivakumar, Principal, JSS College of Pharmacy, JSS University Mysore, for their valuable support to carry out this research work.

REFERENCES

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Table 1: Composition of different Kondagugu gum matrix tablets of Metoprolol succinate

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Weight in mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metoprolol succinate</td>
<td>50</td>
</tr>
<tr>
<td>Kondagugu gum</td>
<td>90</td>
</tr>
<tr>
<td>PVP K-30</td>
<td>12</td>
</tr>
<tr>
<td>Talc</td>
<td>9</td>
</tr>
<tr>
<td>Lactose</td>
<td>139</td>
</tr>
<tr>
<td>Total weight</td>
<td>300</td>
</tr>
</tbody>
</table>

Table 2: Evaluation data for the prepared tablets

<table>
<thead>
<tr>
<th>Formulation code</th>
<th>Avg. weight(mg)</th>
<th>% weight variation*</th>
<th>Thickness (mm)</th>
<th>Hardness (Kg/ cm²)</th>
<th>Friability (%)</th>
<th>% Drug content*</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1</td>
<td>302.4</td>
<td>-2.0 to +2.2</td>
<td>5.0±0.12</td>
<td>5.8±0.48</td>
<td>0.84±0.71</td>
<td>99.1±0.83</td>
</tr>
<tr>
<td>F2</td>
<td>301.5</td>
<td>-2.4 to +3.9</td>
<td>5.0±0.15</td>
<td>6.1±0.71</td>
<td>0.88±0.92</td>
<td>98.9±0.41</td>
</tr>
<tr>
<td>F3</td>
<td>299.8</td>
<td>-3.5 to +2.2</td>
<td>5.0±0.11</td>
<td>6.3±0.63</td>
<td>0.71±0.51</td>
<td>100.1±0.77</td>
</tr>
<tr>
<td>F4</td>
<td>300.7</td>
<td>-2.6 to +3.2</td>
<td>4.97±0.13</td>
<td>6.4±0.93</td>
<td>0.78±0.67</td>
<td>100.4±0.11</td>
</tr>
<tr>
<td>F5</td>
<td>300.6</td>
<td>-2.8 to +3.2</td>
<td>5.01±0.12</td>
<td>6.5±0.96</td>
<td>0.81±0.49</td>
<td>100.2±0.14</td>
</tr>
</tbody>
</table>

*Average of 3 determinations

Table 3: Interpretation of diffusional release mechanisms

<table>
<thead>
<tr>
<th>Value of constant, A</th>
<th>Drug transport mechanism</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;0.5</td>
<td>Fickian diffusion</td>
</tr>
<tr>
<td>&gt;0.5&lt;1.0</td>
<td>Non-fickian diffusion</td>
</tr>
<tr>
<td>Higher than 1.0</td>
<td>Super case II transport</td>
</tr>
</tbody>
</table>

Table 4: Data obtained from Peppas model fitting for the formulations

<table>
<thead>
<tr>
<th>Formulation code</th>
<th>Slope(m)</th>
<th>Intercept(A)</th>
<th>Regression coefficient (R²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1</td>
<td>-0.0008</td>
<td>1.1071</td>
<td>0.996845</td>
</tr>
<tr>
<td>F2</td>
<td>-0.0007</td>
<td>1.1091</td>
<td>0.997716</td>
</tr>
<tr>
<td>F3</td>
<td>0.0006</td>
<td>1.0876</td>
<td>0.991717</td>
</tr>
<tr>
<td>F4</td>
<td>0.0006</td>
<td>1.3846</td>
<td>0.999024</td>
</tr>
<tr>
<td>F5</td>
<td>0.0004</td>
<td>1.7484</td>
<td>0.997164</td>
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</table>

Table 5: Stability studies of F4 formulation

<table>
<thead>
<tr>
<th>Sampling Interval</th>
<th>Hardness*</th>
<th>%Drug content</th>
</tr>
</thead>
<tbody>
<tr>
<td>0days</td>
<td>6.5±0.56</td>
<td>98.9±0.36</td>
</tr>
<tr>
<td>15days</td>
<td>6.4±0.39</td>
<td>98.1±0.78</td>
</tr>
<tr>
<td>30days</td>
<td>6.4±0.45</td>
<td>97.6±0.84</td>
</tr>
<tr>
<td>45days</td>
<td>6.4±0.87</td>
<td>97.4±0.92</td>
</tr>
<tr>
<td>60days</td>
<td>6.4±0.67</td>
<td>96.9±0.60</td>
</tr>
<tr>
<td>75 days</td>
<td>6.4±0.45</td>
<td>96.5±0.82</td>
</tr>
<tr>
<td>90days</td>
<td>6.3±0.12</td>
<td>96.5±0.32</td>
</tr>
</tbody>
</table>

* average of 3 determinations
Figure 3: FTIR spectra of pure drug and optimized formulation F4

Figure 4: DSC thermograms of pure drug

Figure 5: DSC thermograms of optimized formulation

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