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Preformulation Assessment of Transdermal Patches of Meloxicam

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Abstract
Transdermal administration has been popular because it reduces dose frequency and gastrointestinal irritation, and improving patient compliance. The therapy can be stopped at any moment by removing the patch from the target location, avoiding overdosing and underdosing [1-3]. However, due to the complicated structure of skin, transporting chemicals across skin is a significant problem. Consequently, during the course of the treatment, the drug must release at an intended rate through proper polymer matrix. In this study Infra-Red spectroscopy were used to conduct pre-formulation tests on drug and polymer compatibility. Transdermal patch preparation methods are discussed here, various methods are utilized such as casting solution preparation and transdermal patch preparation.
Keywords: Diffusion, Infra-Red spectroscopy, pre-formulation.

I. Introduction

A transdermal patch is a technology wherein the medication is first incorporated in a polymermatrices, then dispersed out and permeated through the skin's various layers. Transdermal delivery has gained popularity in recent years because that just bypasses hepatic first-pass metabolic and keeps plasma levels during therapy, reducing dosage frequently and gastrointestinal discomfort, and improving patient satisfaction. The therapy can be stopped at any moment by removing the patch from the targeted area, avoiding overdosing and underdosing. [11-13]

Transdermal administration has been popular because it reduces dose frequency and gastrointestinal irritation, and improving patient compliance. The therapy can be stopped at any moment by removing the patch from the target location,avoiding overdosing and underdosing [1-3]. However, due to the complicated structure of skin, transporting chemicals across skin is a significant problem. Consequently, during the course of the treatment, the drug must release at an intended rate through proper polymer matrix.

It is also believed that antihypertensive medicines delivered via a transdermal drug delivery method will give better treatment with fewer adverse effects, such as GI discomfort, GIT or liver breakdown, more frequent dosing, significant first-pass metabolism, and variable bioavailability. The main goal of designing an epidermal medication delivery system is to remove the characteristic of skin barrier, which prevents molecules from passing through it. So that a stable therapeutic level may be maintained for a longer period of time and better therapeutic efficacy can be achieved in the treatment of hypertension.

Methodology Preformulation Studies

A drug substance's molecular and physical properties must be determined before it can be formulated into a dosage shape. Medicaments substances definition as well as foundation for medicament's mixture with excipients during dosage form manufacturing are both provided by pre- formulation studies.

In this study Infra-Red spectroscopy was used to conduct pre-formulation tests on drug and polymer compatibility.[3]

Preformulation Study of Meloxicam [8 – 9]

Identification of Drug

Demeanor, color and nature of drug were evaluated.

Melting Point measurement

Medication's melting point was determined using the capillaries technique, and the frequency at which the melting of the drug was recorded. That is **256** degree Celsius.

Method for Estimation of Meloxicam by preparing standard curve [01-10]

1. Preparation of pH 7.4 Phosphate Buffer

Meloxicam curve of calibration in 7.4 pH phosphate buffer. A strong peak has been observed in the spectrum at 363 nm. Meloxicam's calibration curve was plotted at 363 nm in the concentration range of 1–7 µg/mL. The link has been observed to be linear. The percentage of drug release in the dissolving research will be determined using this equation.

2.. Calibration Curve of Meloxicam in pH-7.4 Phosphate Buffer

The peak intensity utilising Meloxicam's UV max in phosphate buffer pH 7.4 was determinedto be 363 nm in the above stock solution analysis. Aforementioned stock solution (100 g/ml) was mixed further to achieve a level of 10-50 g/ml. The standard curve was created for the whole concentration range, and the tests were done in triplicate. The graph and standard calibration curve represent in, respectively.

TABLE 1.1 Calibration curve of meloxicam in pH 7.4

S.no	Concentration (µg/ml)	Absorbance ± SD
1.	10	0.210 ± 0.0058
2.	15	0.349 ± 0.001
3.	20	0.450 ± 0.002
4.	25	0.527 ± 0.0102
5.	30	0.618 ± 0.0020
6.	35	0.757 ± 0.00757
7.	40	0.848 ± 0.0068
8.	45	0.958 ± 0.0104

(Where n = 3, Mean ± SD)

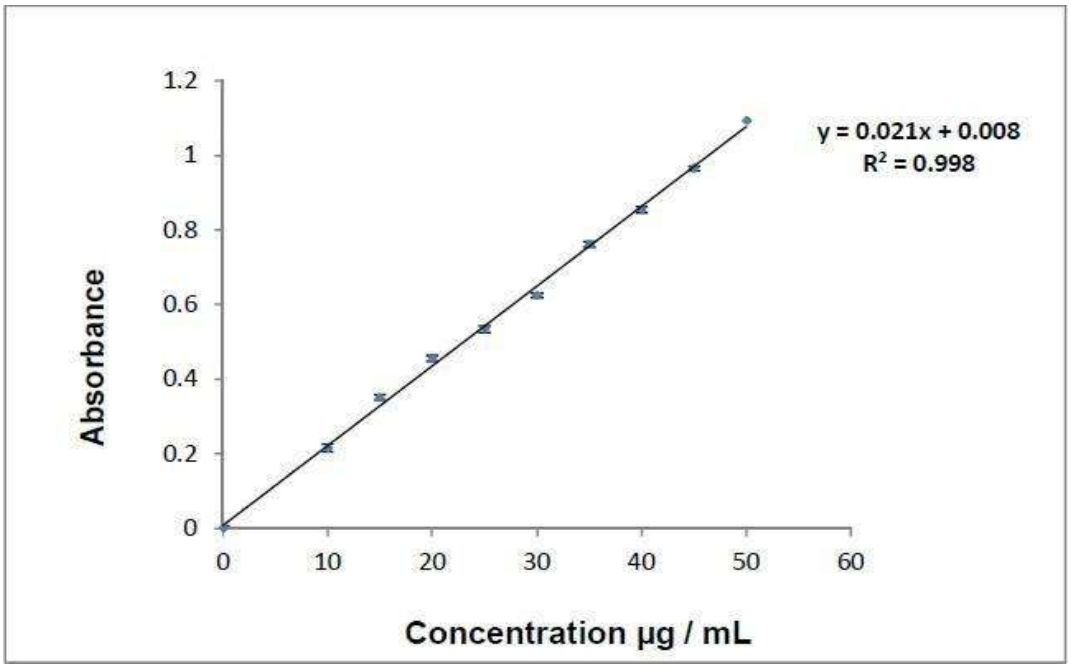

Figure 1: Standard Calibration Curve of Meloxicam in Phosphate Buffer pH 7.4

(R2) = 0.997 and Y = 0.021x + 0.008 The drug's regression coefficient (R2) in phosphate buffer 7.4 was discovered to be in the linearity range, near to one, showing a linear bond between absorbance and concentration.

Solubility:

Method of saturation solubility has been used to conduct the investigation, where a saturated mixture of the medication was produced and placed into glass vial. The medication was dissolved in 10mL of the solvent until it was completely dissolved. Sonication was done for 15 minutes of after which the solution was purified and diluted as needed. A UV spectrophotometer set at 363 nm was used to determine the quantity of medicine dissolved. Meloxicam is freely soluble in ethanol and soluble both in methanol and chloroform.

Fourier Transform Infrared and Spectroscopy for compatibility study:

The compacted powder technique and a KBr press were used for the FTIR studies. The pharmacological powder sample was combined with dried KBr crystals and crushed into pellet using a KBr press. The manufactured pellets were kept in the sample container and stored in the instrument to capture the IR peaks.

Photo Stability Study of Meloxicam [7, 8]

Meloxicam is a light sensitive drug; therefore, all the study performed in dark area using umber color glass apparatus to protect the drug from the degradation. A photo stability test was conducted under both dark and light conditions for a duration of 24 hours in order to assess the impact of light on Meloxicam degradation. For this photostability study drug solution of 1 mg / mL prepare in ethanol and transfer in two volumetric flasks among these ones kept in dark and other kept in light condition under the exposure of light at room temperature, up to 24 hrs. At a fixed time intervals of six hrs, 2mL sample withdrawn and analyzed at 363nm using U.V. Spectrophotometer.

Differential scanning calorimetric analysis [9, 10]

By the help of a differential scanning calorimeter, DSC peaks for the drug and excipients were measured in order to determine affinity of drug with the excipients and to identify the drug itself. Meloxicam DSC peak and the final formulation's DSC curve. The medication alone and powder mixture DSC peak elucidations.

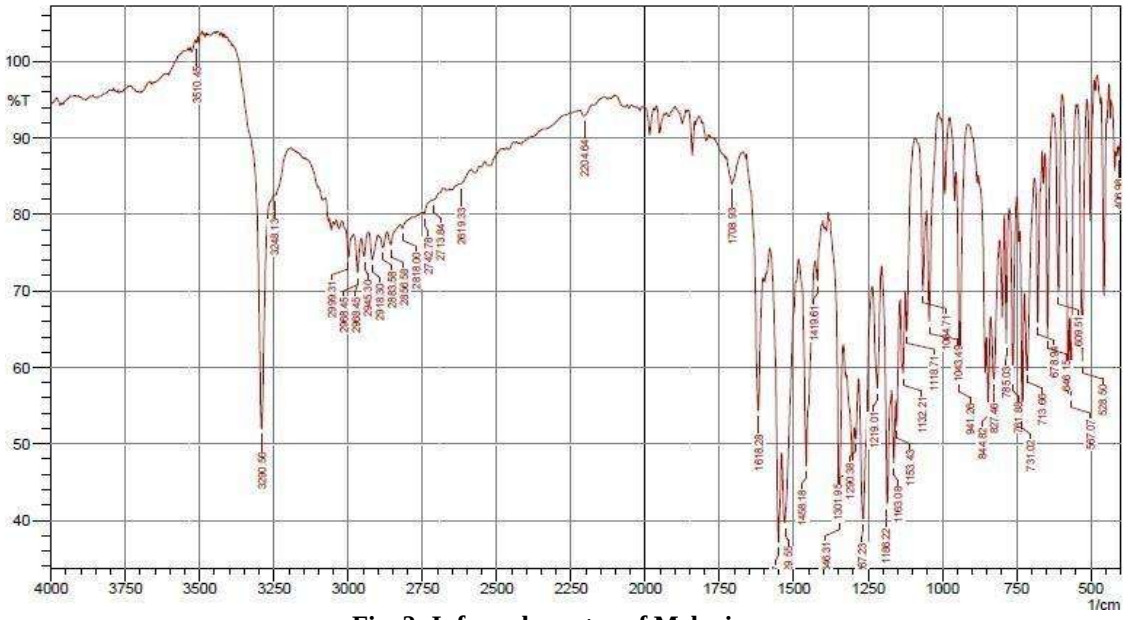

Fig. 2: Infrared spectra of Meloxicam

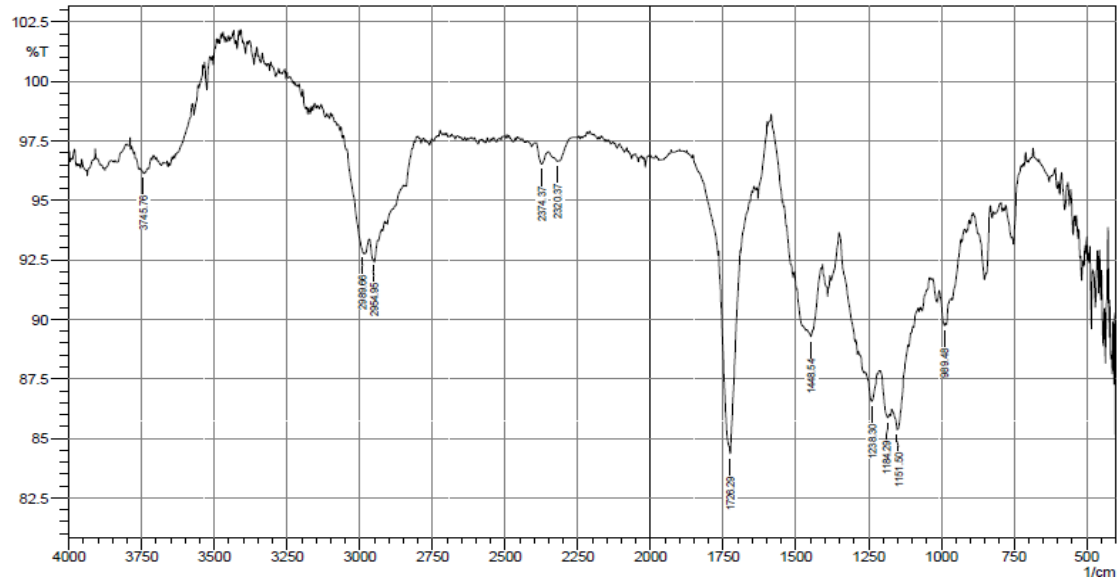

Fig. 3: Infrared spectra of Eudragit RS 100

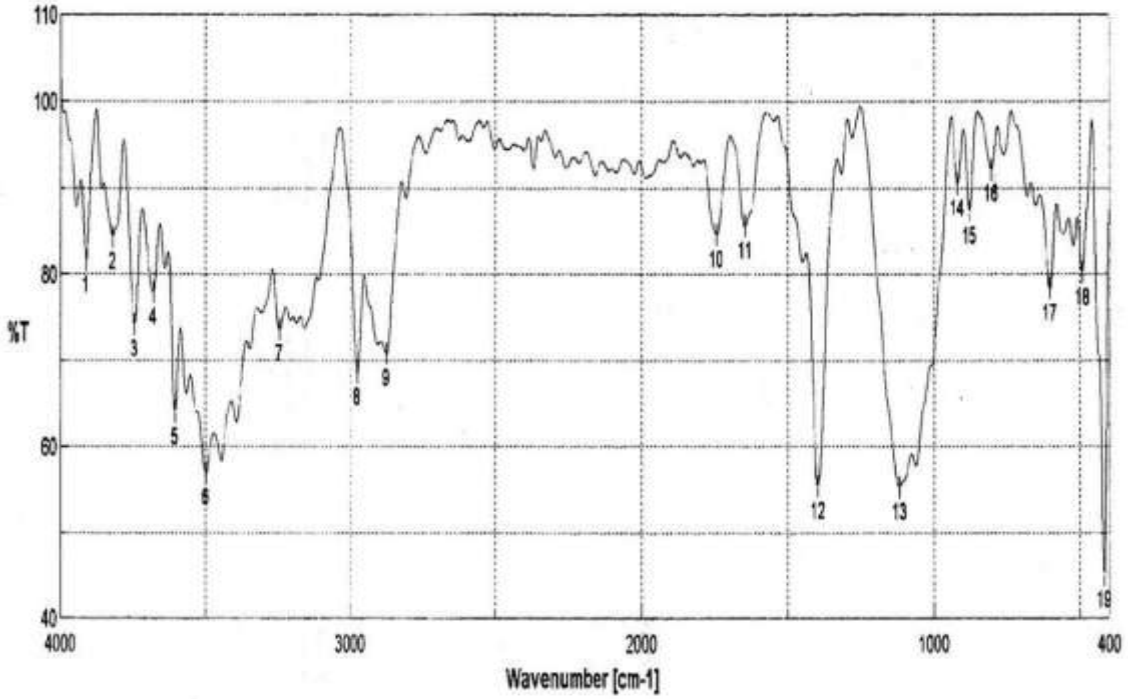

Fig. 4: Infrared spectra of Eudragit RL 100

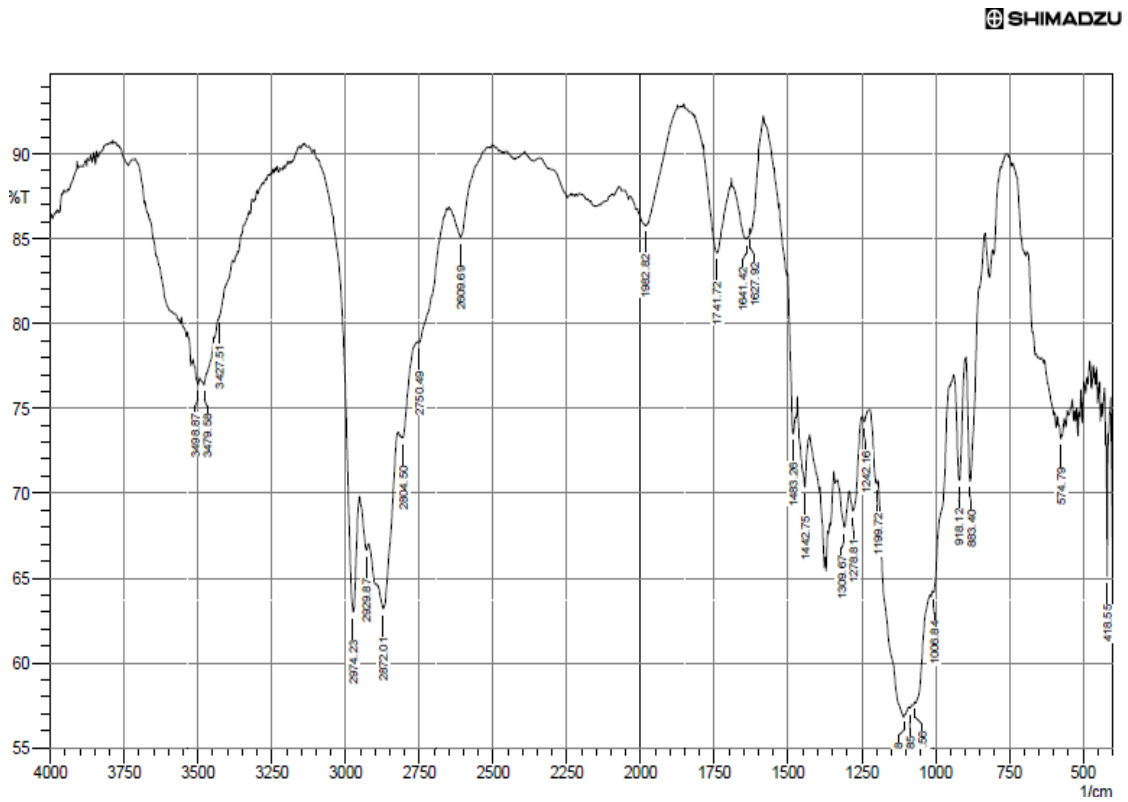

Fig. 5: Infrared spectra of Ethyl Cellulose

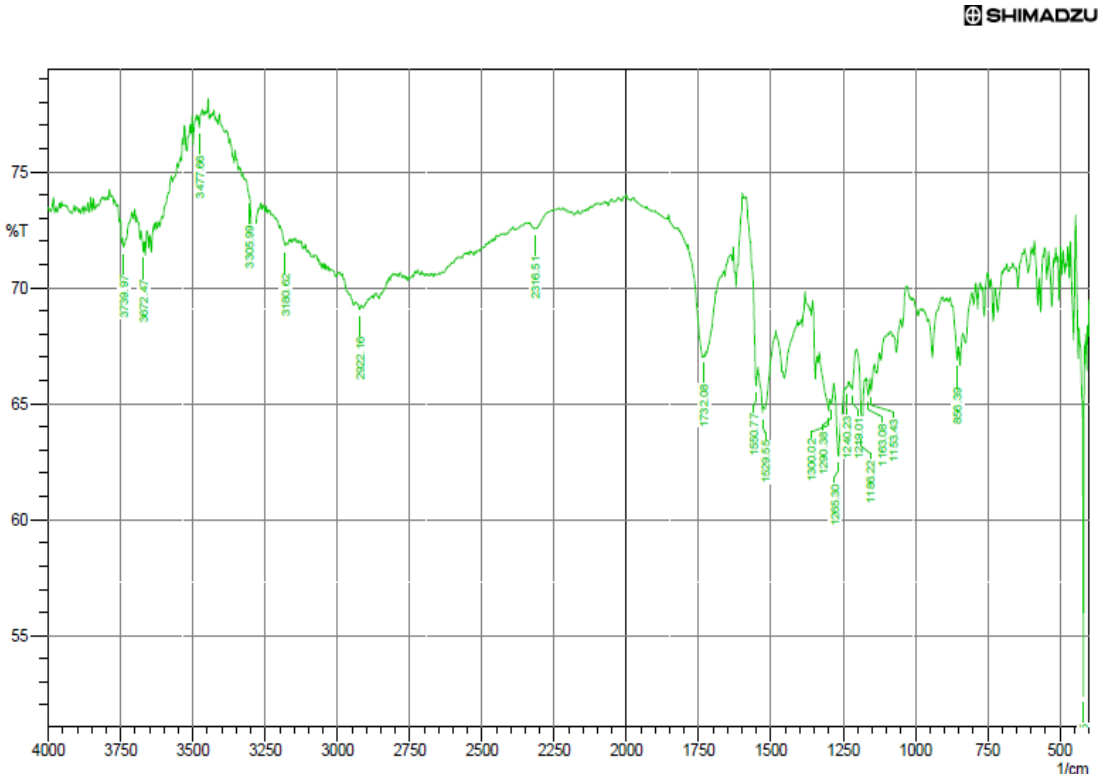

Fig. 6: Infrared spectra of PVA

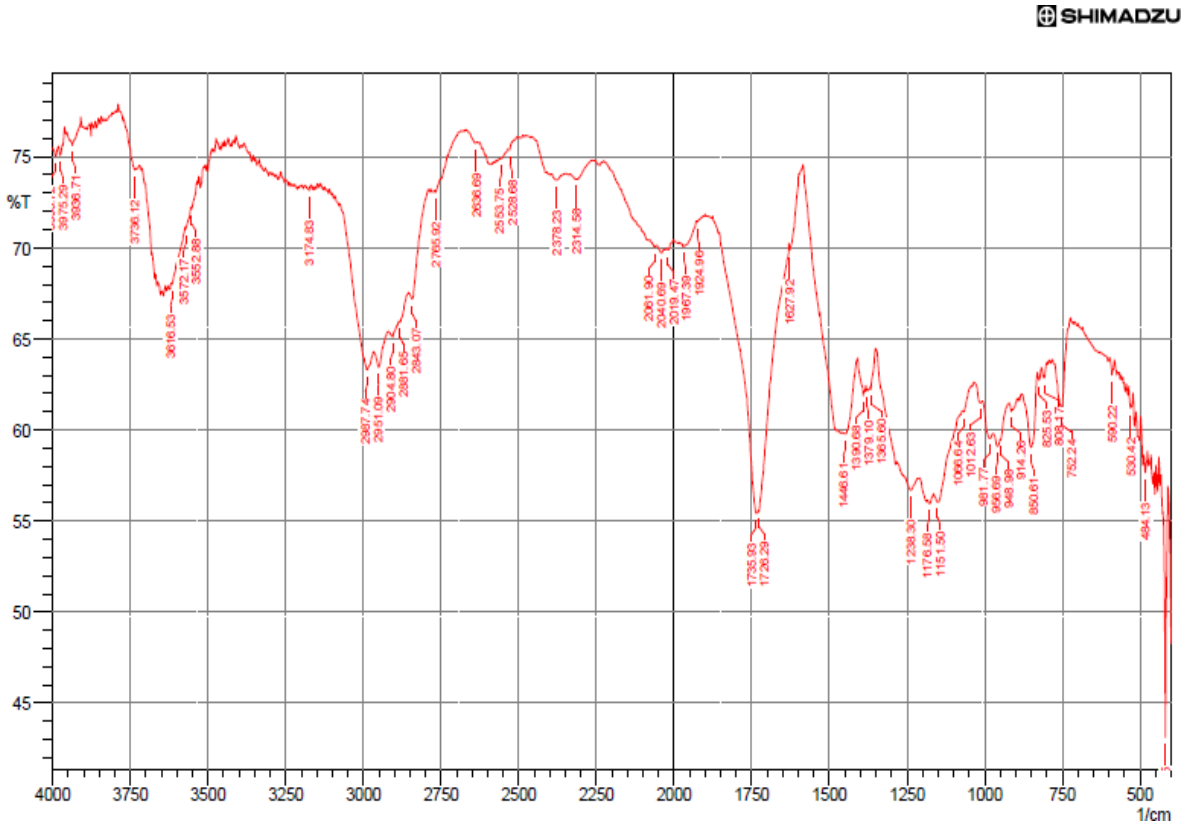

Figure 7: Infrared spectra of PVP

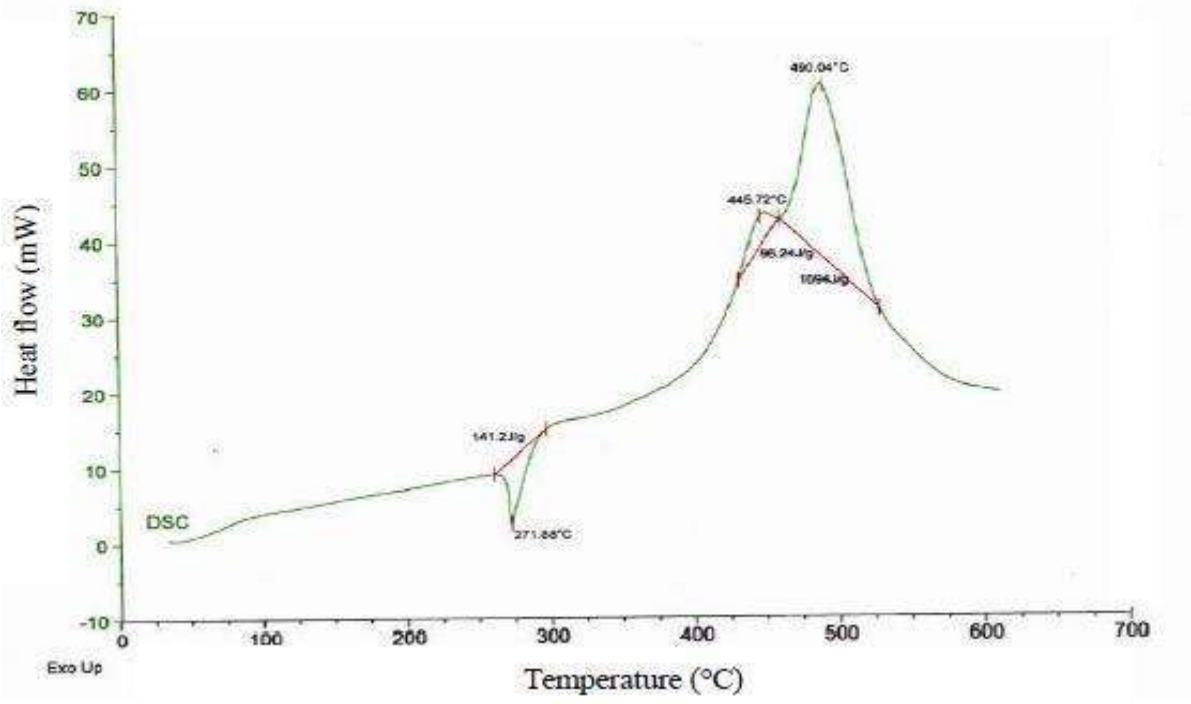

Fig. 8: DSC Spectra of Meloxicam Pure Drug

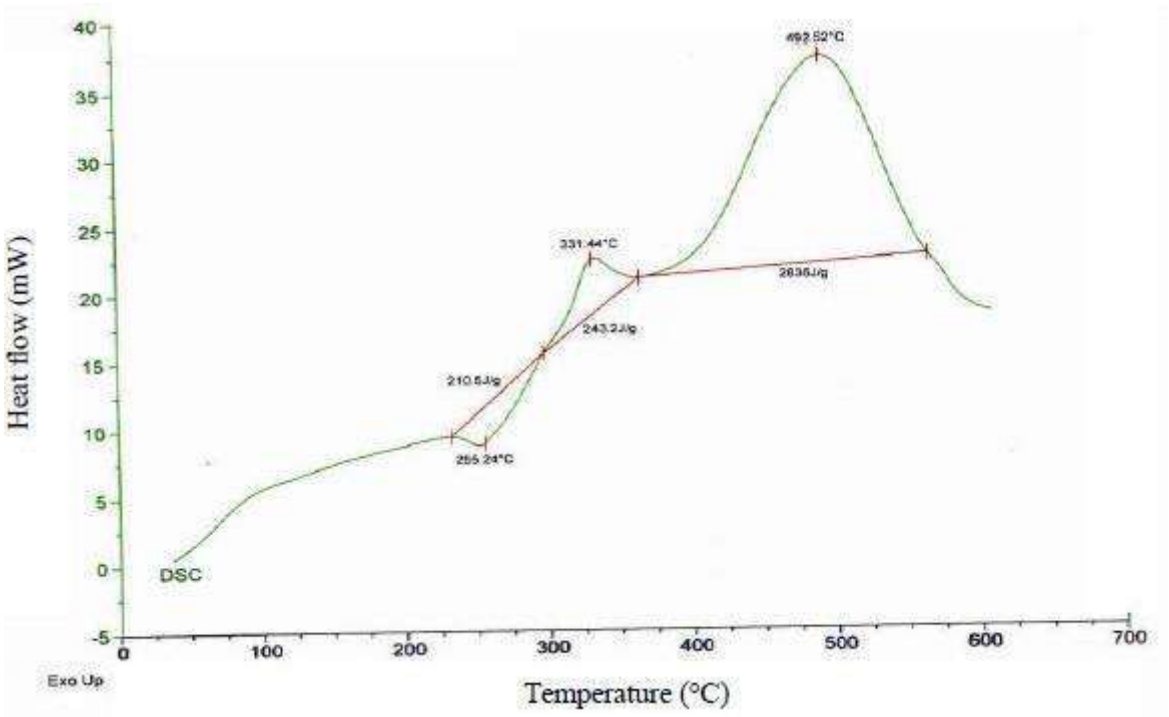

Fig. 9: DSC Curve of Meloxicam with polymer

II. Conclusion

Preformulation evaluation of the transdermal patches of meloxicam was done. In the present researchInfra-Red spectroscopy was used to conduct on drugand polymer compatibility with the drug was also checked and the results was withinlimit. There was no sign of incompatibility. Casting solution preparation and transdermal patch preparation was employed for the preparation of transdermal patches. It was concluded that the polymer was compatible with the drug and these can be utilized for the preparation of the transdermal patches.

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