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EVALUATION OF COMPATIBILITY OF FORMULATION EXCIPIENTS WITH PREGABALIN USING DSC

Velavan. P* and Venkatesan. P
Department of Pharmacy, Faculty of Engineering and Technology, Annamalai University, Annamalainagar, TN 608 002, INDIA.

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ABSTRACT

The compatibility between pregabalin with commonly used excipients in the formulation of nanoparticles was assessed by studying drug excipient study with a Differential scanning colorimeter (DSC). Results showed that there were no interactions between pregabalin and formulation excipients were observed by Differential scanning colorimeter. Drug excipient compatibility of pregabalin loaded nanoparticles was carried out. A modifies release nanoparticles of pregabalin were prepared by using PLGA as coating material. So before selection of excipients, the Preformulation study of drug pregabalin is completed for successful formulation of modified release nanoparticles. The result of this study we concluded that pregabalin with PLGA can be used to formulate pregabalin nanoparticles for modified release.

Key words: *Nanoparticles, Pregabalin, Differential scanning colorimeter.*

INTRODUCTION

In general, Drug interaction studies are based on the accelerated stability studies. It requires exposing the sample to moisture and maintaining it at different temperature like 4˚C, 37˚C (room temperature) and 60˚C maintained for a period of 45 days or more. And followed by assay of the sample and it may involve the instrumental methods like UV spectroscopy, HPLC methods etc. to evaluate the amount of drug remaining at the specified days. This involves lot of studies leading to more requirements of sample, solvent and time.

Now-a-days the drug interaction studies are more effectively done by the thermal methods which comprises differential scanning calorimeter, Thermal gravimetric analysis etc. Among this, differential scanning calorimetric is assigned the mostly reliable and best method. It requires only hours to study a sample by using the temperature programming method [1-4].

Thermal analysis refers to a group of techniques in which "Differential Scanning Colorimetry" is one. In this technique specific physical properties of a material are measured as a function of temperature. Thus thermal analysis is defined as, A Group of technique in which a physical property of a substance or its reaction products are measured as a function of temperature, whilst the substance is subjected to a controlled temperature program'.

These methods find the widespread application in both quality control and research field. Current area of application includes environmental measurement, composition analysis, product reliability, Stability, Chemical reactions, and dynamic properties [5-8].

Thermal analysis has been used to determine the physical and chemical properties of polymers, (like HPMC K4, HPMC K4 100M, Prinogeletc), pharmaceuticals i.e., drugs etc. An combined modern thermal analysis instrument can be used to the measure transition temperature, weight losses, energies of transition, dimensional changes, modules changes and viscoelastic properties. Purity of materials can be determined by using the temperature of phase changes and reaction as well as heats of reaction.

Pregabalin S-(3)-amino methyl hexanoic acid, is a structural analogues of -amino butyric acid (GABA). They constitute an important group of compounds that are used in the treatment of epilepsy and neuropathic pain. It is a white and crystalline solid. It is soluble in water and both acidic and basic aqueous solutions. Pregabalin has been studied for use in variety of disorders, including monotherapy in refractory partial seizures, diabetic neuropathy, surgical dental pain and other pain syndromes, post therapeutic neuralgia and social anxiety disorders. Pregabalins innovator is Pfizer-global and appears worldwide under the brand name lyrica. The half-life of pregabalin is 5-6.5 hrs.[1] Preformulation commences when a newly synthesized drug shows sufficient pharmacologic promise in animal models to warrants evaluation in man. These studies should focus on those physicochemical properties of the new compound that could affect drug performance and development of an efficacious dosage form. A thorough understanding of these properties may ultimately provide a rational for formulation design, or support the need for molecular modification. The aim of this study was to determine some of the drug excipient compatibility by using DSCfor the preparation of nanoparticles [9-13].

***Corresponding author:**
Velavan. P
Department of Pharmacy,
Faculty of Engineering and Technology,
Annamalai University, Annamalainagar, TN 608 002, INDIA.
Tel.: +91 4144 239738; Fax: +91 4144 238145.
**E-Mail: venkatesan1978@gmail.com*

MATERIALS AND METHODS

Pregabalin (99.79%) donated by M/S Shasun pharmaceuticals, Puducherry and PLGA was procured from Sigma Aldrich. All chemicals used in the study were of analytical grade and used without further purification.

Experimental Studies:

Pregabalin sample preparation:

Weigh exactly 2mg of pregabalin and transfer it in to standard aluminium pan cover with aluminium lid and crimp the pan using crimper. PLGA with Pregabalin sample prepared by weigh exactly 2mg of mixture of PLGA and pregabalin, transfer it in to standard aluminium pan cover with aluminium lid and crimp the pan using crimper. Formulation excipients with pregabalin sample prepared by excipients mixtures with pregabalin, transfer it in to standard aluminium pan cover with aluminium lid and crimp the pan using crimper. Then subject to programmed temperature changes using differential scanning calorimetery.

RESULTS AND DISCUSSION

DSC measures the heat loss or gain resulting from physical or chemical changes within a sample as a function of temperature. A sharp symmetric melting endotherm can indicate relative purity, where broad, asymmetric curve suggests impurities or more than one thermal process. The loss of water present in the compound is usually indicated by the endothermic peaks produced in DSC below 120°C. DSC analysis were performed to find out the physical nature of the Pregabalin and also to confirm absence of

drug-polymer interaction. Individual thermograms of pure drug, polymer and physical mixture were performed and the thermograms of DSC are shown from ***Fig 1*** - ***Fig 4***.The thermo grams showed the characteristic exothermic peeks of the drug at the melting point 186°C. This confirmed there was no interaction between the drug and polymer.

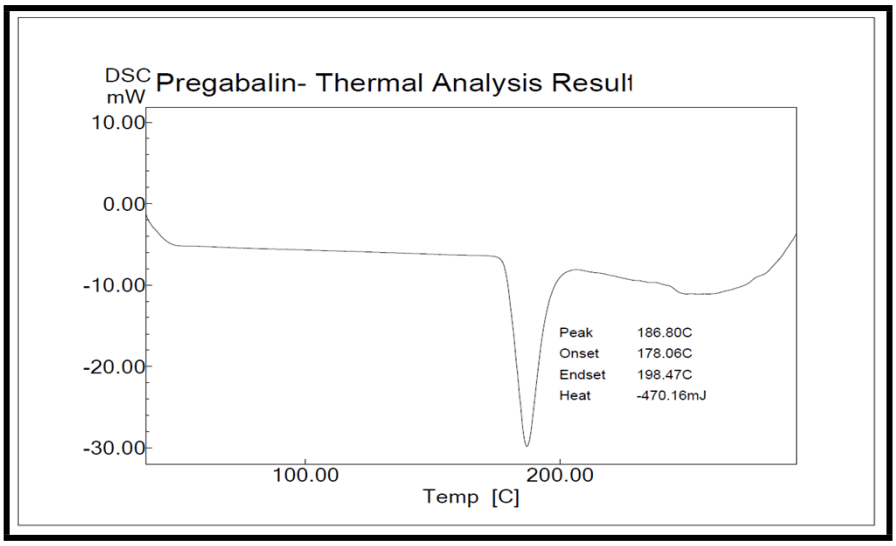

Fig. 1: DSC thermogram of Pregabalin

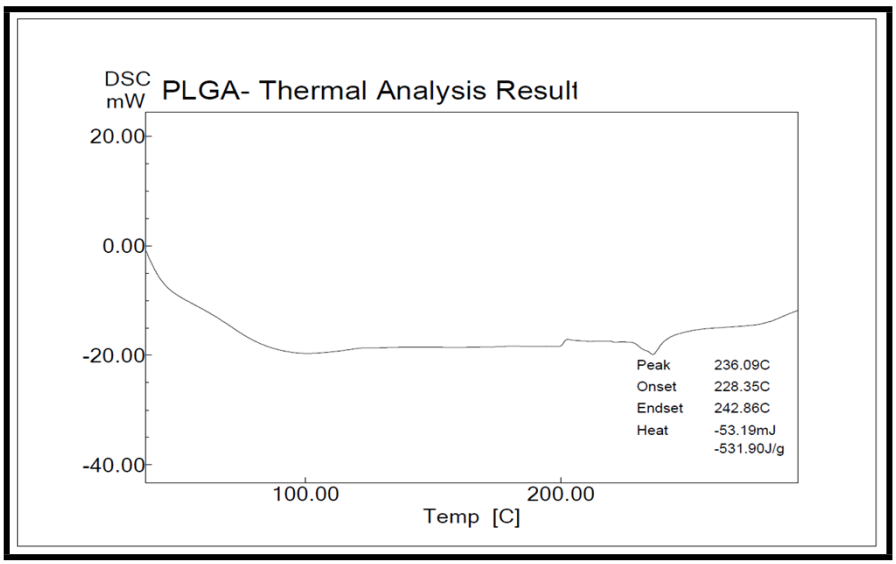

Fig. 2: DSC thermogram of PLGA

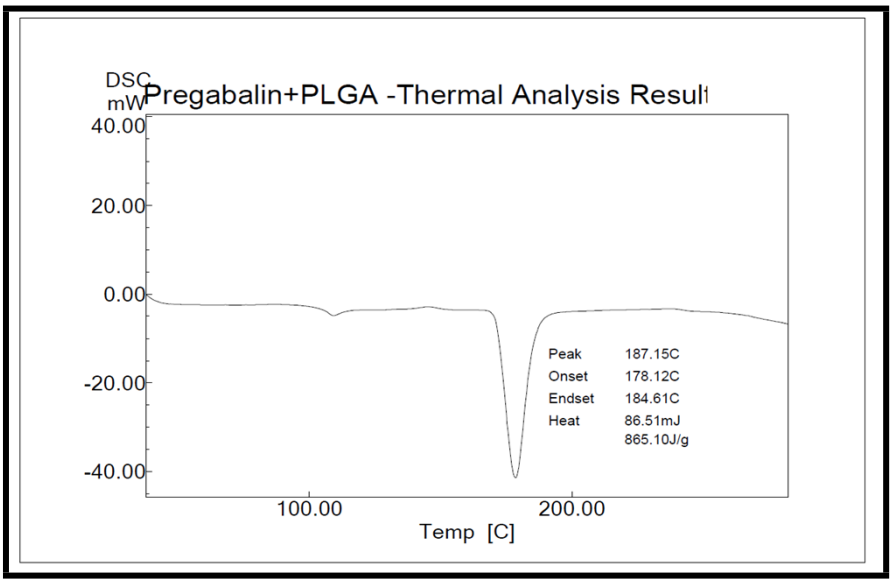

Fig. 3: DSC thermogram of physical mixture

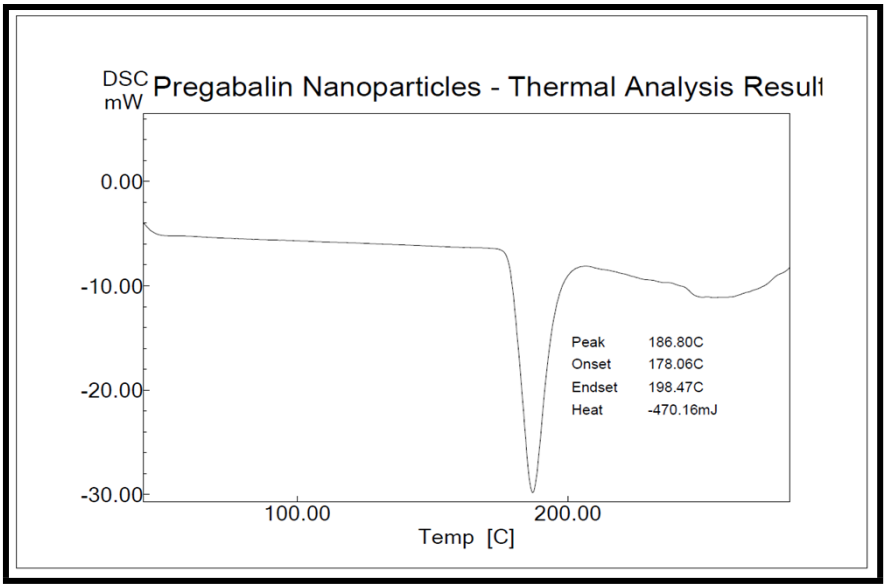

Fig. 4: DSC thermogram of nanoparticles

CONCLUSION

In this study the drug-excipient compatibility studies employing DSC has been carried out to confirm the inertness of Pharmaceutical excipients. In this study we have chosen the polymer for the preparation of polymeric nanoparticle is PLGA. Hence before going to the preparation of formulation we need to confirm the compatibility. DSC studies confirm the chemical inertness of the PLGA polymer with the drug pregabalin. From the results obtained we can conclude that PLGApolymer is compatible with the drug pregabalin to formulate modified release formulation.

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