ICPPS 2014

Proceeding

The 1st International Conference on Pharmaceutics & Pharmaceutical Sciences

Drug Delivery Systems:
From Drug-Discovery, Pre-formulation, Formulation and Technological Approaches for Poorly Soluble Drugs and Protein

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PREFACE From Chairman

It is our pleasure to present you the proceedings of The 1st International Conference on Pharmaceutics and Pharmaceutical Sciences (ICPPS) organized by The Faculty of Pharmacy Universitas Airlangga Surabaya Indonesia.

The proceeding was produced based on papers and posters presented at The 1st International Conference on Pharmaceutics and Pharmaceutical Sciences (ICPPS), held in Surabaya, Indonesia, 14-15 November 2014.

The proceeding clearly reflects broad interest, from the participants that coming from all around the world.

The papers presented were pharmaceutics and biopharmaceutics; requirements on how to evaluate molecules in discovery and their appropriateness for selection as potential candidate; their development in context of challenges and benefits, together with associated time and cost implications and also requirements to progress through pre-clinical and clinical.

In this an opportunity, I would like to express my appreciation to the editorial team of the proceeding who have been working hard to review manuscripts, and making the first edition of this proceeding be possible.

I would like also to thanks to all invited speakers and presenters who participated in The 1st International Conference on Pharmaceutics and Pharmaceutical Sciences (ICPPS) and your contribution to this proceeding.

Finally, I hope this proceeding will give contribution to the Pharmaceutics and Pharmaceutical Sciences research.

Chairman,

Dra. Esti Hendradi, MSI., Ph.D., Apt

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VALIDATION OF SPECTROPHOTOMETRIC METHOD FOR ESTIMATION OF EPERISONE HYDROCHLORIDE IN TABLET DOSAGE FORM

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INTRODUCTION

Eperisone (EPE) is chemically 4'-ethyl-3-methyl-3-piperidinopropiophenone (Figure 1), is antispasmodic drug (Paresh, et al., 2012). It is used in the treatment of different pathological conditions like acute and chronic muscle spasm, electroconvulsive therapy, neurological conditions, orthopedic manipulation, myelopathy, encephalomyelitis, spondylosis, spondylarthrosis, cervical and lumbar syndrome, arthrosis of the large joints obliterating arthrosclerosis of the extremity vessels, diabetical angthromboangitis obliterans and Reynaud's syndrome (Maske and Nagras, 2013). Literature survey revealed that EPE is estimated by HPLC (Din, et al., 2004) and AUC method of UV spectrophotometry (Maske and Nagras, 2013) in single component formulation. In this presentation we report a simple and rapid assay for the quantitation of EPE using UV spectrophotometry method.

A

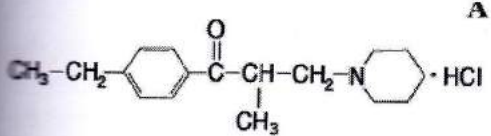

Figure 1 Chemical stuctures of eperisone

MATERIAL AND REAGENT

Working standard of pharmaceutical grade Eperisone Hydrochloride from PT Eisai Indonesia, (Wuhan Grand Pharmaceutical Group Co., Ltd.), methanol, commercial tablets contain EPE.

EXPERIMENTAL

Preparation of Standard Solutions and Pharmaceutical Samples

Stock standard solution was always freshly prepared by dissolving 25 mg of Eperisone Hydrochloride in 100 ml methanol (stock standard solution I) and 30 mg of Eperisone Hydrochloride in 50 ml methanol (stock standard solution II). Working standard solutions were prepared by dilution of stock solution with methanol to get solutions in concentration range of 1-18 µg/ml. For sample preparation, twenty tablets was weighed; average weight was determined and finely powdered. An accurately weighed quantity of tablet powder equivalent to 10 mg of Eperisone Hydrochloride was transfered to 100 ml volumetric flask and dissolved by sonication with methanol, volume was made up to mark. The solution was then filtered through filter membrane 0.45 µm. A 1.0 ml of the filtrate was further diluted with methanol in a 10 mlvolumetric flask up to mark (10 µg/ml) on label claim basis.

Determination of λ max

A 10 µg/ml solution of Eperisone Hydrochloride was prepared and scanned in UV range of 200-400 nm and spectrum was obtained. The spectrum of Eperisone Hydrochloride as shown in figure 2.

Method Validation

The developed method was validated with the following parameters.

Specificity

The Specificity of this method was determined by analyzing standard and sample. Specificity was showed by scanning at 200nm – 400 nm and analyzed the spectrum of standard and sample.

Linearity

The evaluation of the calibration curve's lin

earity was done based on the absorbance of the standard solutions that were prepared in methanol at the concentrations 1-18 µg/ml. The calibration curve was plotted as concentration versus absorbance.

Limit of Detection and Quantification

Limit of detection (LOD) and Limit of Quantification (LOQ) were determined by preparing the standard solutions in methanol at the concentrations 1-18 µg/ml.

Precision

The precision of this method was performed by repeatability and intermediate precision studies. Repeatability studies was performed by analyzing one concentration of the drug for six times on the same day. The intermediate precision was checked by repeating studies on three different days.

Accuracy

The accuracy of this method was evaluated through recovery experiments by adding three different amounts of Eperisone Hydrochloride standards i.e. 30, 45 and 60% of the concentration samples. Each concentration were replicated (n=3)

Analysis of Marketed formulations

The Samples that is contain of Eperisone Hydrochloride (brand A and brand B) were prepared as sample preparation method. Each of samples were replicated (n=3). The analysis was done in the same way as described earlier.

RESULTS AND DISCUSSION

A validated, simple and accurate UV-Spectrophotometric methods has been developed for determination of Eperisone Hydrochloride in tablet dosage forms. Eperisone hydrochloride showed maximum absorbance at 255.5 nm. From UV-spectrophotometric, showed that the absorbance of analyte in sample were same as standard (figure 2).

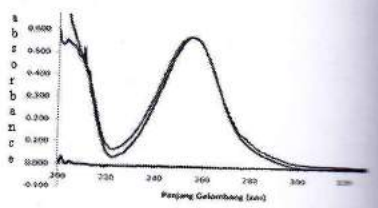

Figure 2 Spectra of : Wavelength (nm) and sample

Linierity was observed in concentration range 1-18 µg/ml and gave the equation Y = 0,05493X - 0,00315 with correlation coefficient value 0.9999 (figure 3).

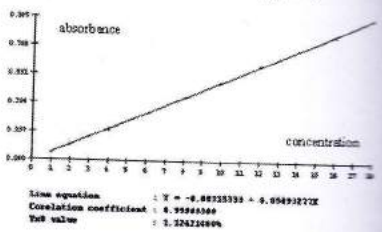

Figure 3 calibration curve of Eperisone in methanol

The LOD and LOQ were found to be 0.485 µg/ml and 1.373 µg/ml. The values of relative standard deviation (RSD) were found to be 1.13%; 0.16% and 0.74% in the different day. The three measurement were perfomed within one laboratory by same analyst in different days. The accuracy of the proposed method were 100.94% ± 0.81.

Analysis of Marketed formulations

The proposed method has been applied to the determination of Eperisone Hydrocloride in commercial tablet formulations and the recovery of label claim were 98.84% ± 0.32 µg/ml for brand A and 99.74% ± 0.47 µg/ml for brand B. The result of the analysis of marketed formulations indicate that the concentrations of Eperisone hydrochloride in tablet is within the requirements (USP) 95-105% .

CONCLUSION

A new UV-spectrophotometry method has been developed for the quantification of Eperisone hydrochloride in tablet dosage forms. The method was found to be simple, rapid, specific, precise and accurate for esti-

mation and can be employed for the routine quality control analysis Eperisone hydrochloride in tablet.

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