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Development and Validation of UV spectrophotometric method for Estimation of Gabapentin in Pharmaceutical dosage form

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ABSTRACT

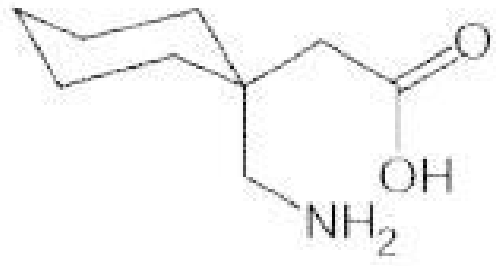
A simple, accurate, economical and reproducible UV Spectrophotometric method for estimation of Gabapentin in tablet dosage form has been developed. The method shows maximum absorbance of Gabapentin at 265nm used for the estimation. Gabapentin was found to be linear in the range for 2-10ug/ml. Percentage of Gabapentin present in pharmaceutical dosage form was found to be in the range of 99.11-99.91% respectively. The developed method validated according to ICH guidelines.

Key words: Gabapentin, UV-VIS spectrophotometer, Method development and Validation.

1. INTRODUCTION

Gabapentin (GBP) is chemically, 2-[1-(aminomethyl)cyclohexyl]acetic acid[1] and is used as an antiepileptic drug. GBP is also used in the treatment of neuropathic pain [2]. Figure 1 shows structure of Gabapentin.

Figure-1: Structure of gabapentin



GBP is official in USP. USP[3] describes liquid chromatography method for its estimation. Literature survey reveals LC/MS [4-7], GC/MS [8-9], HPTLC [10], HPLC [11-19], GLC [20], capillary electrophoresis [21-22], spectrofluorimetry [23-24] and colorimetry [25] methods for determination of GBP in pharmaceutical dosage forms as well as in biological fluids. Present communication describes simple, sensitive, rapid, accurate and economical spectrophotometric methods for estimation of GBP in pharmaceutical dosage forms.

2. Materials and Methods

2.1. Reagents and Materials

Gabapentin in the form gift sample supplied by Micro labs Ltd, Banglore, Ethanol obtained from Quligens pvt.ltd, Hyderabad. Double distilled water was used. Ethanol : Water (1:1) as used as solvent.

2.2. Instrument

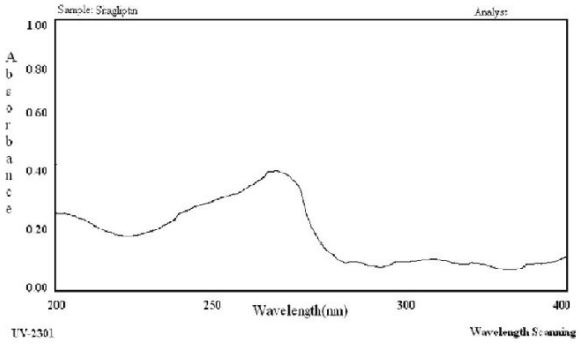
A shimadzu UV/Visible double beam spectrophotometer (model 1700) with 1cm matched quartz cells was used in present study for multi component analysis.

2.3. Methodology

2.3.1. Preparation of Standard Drug Solution

The standard stock solution of Gabapentin was prepared by dissolving 100mg of drug in 100 ml of volumetric flask containing 30ml of ethanol, distilled water (1:1). Finally the solvent make up to 100ml. The standard stock solution was further diluted to get the concentration of 4µg/ml and the solution was scanned between the range 200 - 400 nm in 1 cm cell against blank and the spectrum was recorded and show in figure 2.

Fig-2: UV spectrum of Gabapentin standard solution

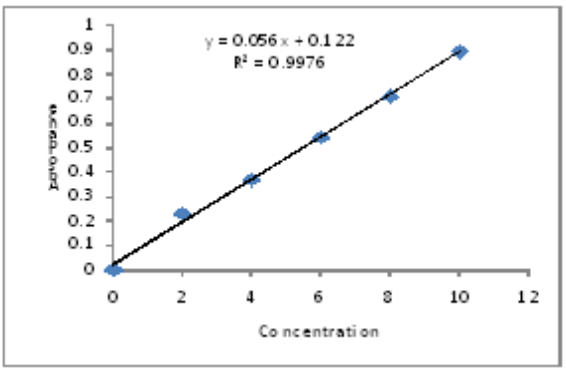


3. RESULTS

3.1. Construction of calibration curve

From the prepared stock (1mg/ml) solution, dilutions were made so as to obtain 2, 4, 6, 8, 10µg/ml with water. Absorbance of each dilution were measured at 265nm.A graph is plotted by taking absorbance on y-axis and concentration on x-axis shows in figure 1.

Fig-2: Calibration graph of Gabapentin standard solution



3.2. Validation of Method

Developed analytical method was validated in accordance with ICH guidelines (Q2A). Recovery studies were carried out by addition of pure drug to previously analyzed tablet sample at three different concentration levels (50%, 100% and 150%). The results of recovery studies are reported in Table-1. While precision of the method was determined by repeatability and intermediate precision (inter-day, intra-day) and expressed as % relative standard deviation (RSD). Intra-day precision was evaluated by analyzing concentration of GBP (6µg/ml) of sample solution at six different time intervals under the same experimental conditions on the same day. Intermediate precision (inter-day precision) was determined by analyzing above mentioned concentrations of solutions on six consecutive days. (Table 2).

Table-1: Results of recovery studies in Gabapentin in pharmaceutical dosage form

Amount of drug added	Amount of drug found	%RSD	% Recovery
50%	8.98± 0.002	0.78	99.77
100%	11.90± 0.004	0.95	99.16
150%	14.99± 0.003	0.86	99.86

Table-2: Results of Precision studies in Gabapentin in pharmaceutical dosage form

Analyate	Con of sample solution	Intra-day precision %RSD (n=6)	Inter-day Precision %RSD (n=6)
Gabapentin	6 µg/ml	1.009	1.231

3.3. LOD and LOQ

The LOD & LOQ were separately determined based on the standard deviation of Y-intercept of the calibration curve. The standard deviation of the Y-intercept and the slope of the calibration curves were used to calculate the LOD and LOQ by using the equations 3.3*standard deviation/slope for LOD, 10*standard deviation/slope for LOQ. The results are reported in table3.

Table-3 LOD &LOQ

Parameters	Gabapentin
LOD	1.20 µg/ml
LOQ	3.96 µg/ml

3.4. Analysis of Commercial Formulation

Twenty tablets were accurately weighed and crushed to fine powder. The tablet powder equivalent to 100mg of GBP was accurately weighed, transferred to 100ml volumetric flask, dissolved in small quantity of ethanol and water the (1:1) and finally made up to mark with ethanol and water (1:1) .This solution was filtered through whatmann filter paper No. 41. The filtrate was further diluted with ethanol and water (1:1) to get concentration of 6 µg/ml of GBP. The absorbance of the sample solution was measured at265nm.The content of Gabapentin in sample solution of tablet was calculated. This procedure repeated for six times. The results of assay are reported in table-4.

Table-4: Assay of marketed formulation-Gabacent

Lable claim per tablet (mg)	Mean amount found in each tablet (mg) (n=6)	Mean amount found (%) (n=6)	% RSD(n=6)
100	99.45	99.45%	0.98

4. DISCUSSION

The development of a simple, economic, rapid, sensitive, and accurate analytical method for the routine quantitative determination of samples will reduce unnecessary tedious sample

preparations and the cost of materials and labor. The proposed method is based upon direct estimation of Gabapentin tablets at 265 nm.

The developed method was validated as per ICH guidelines for Linearity, precision and recovery studies. The accuracy of the method was proved by performing recovery studies in the commercially available formulation and values were reported in Table 1. The precision of the method was checked in terms of Inter-day and Intra-day, where methods were repeated on six different days and also repeated on six different time periods in same day. The results were given in Table 2 and shows % RSD of less than 2 .The LOD & LOQ were reported in table 3. Based on the analysis of commercial tablets of Gabapentin, the Quantity is less when compared to that of labeled claim. The assay result was reported Table 4. UV Spectrophotometric method was used to quantitative analysis of Gabapentin which has shown accurate, reliable and precise results and so can be considered as alternative method for percentage purity determination and quantitative analysis of Gabapentin. The excipents having no influence the estimation of Gabapentin in the proposed method.

5. CONCLUSION

The developed method for estimation of Gabapentin in tablet dosage form is simple, economical, accurate and reproducible and can be conveniently adopted for the routine quality control analysis from its pharmaceutical formulations and bulk drug.

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