



Analysis of Different Brands of Pregabalin (75mg) Capsules Using high Performance Liquid Chromatographic (HPLC) Method

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ABSTRACT

The study involves quantitative analysis of 3 different brands (samples) of Pregabalin (75mg) Capsules used in Vadodara (India), using and High-Performance liquid Chromatographic method, The mobile phase was prepared by mixing Phosphate Buffer pH 3.0 adjusted with OPA: Methanol: Acetonitrile (30:35:35, v/v/v). The prepared mobile phase was sonicated and filtered through 0.45µm membrane filter. There is official method available so as per IP criteria this method is validated as well as performed. Instrument- SHIMADZU HPLC - LC-2030, Software-Lab Solutions used for performing the analysis at flow rate of 1mL/min and detection wavelength of 215nm. In the analysis for sample- 1 RT found 2.758 for 2nd sample RT time found- 2.757, 3rd RT on 2.758 found all three samples found suitable for market as well as complies the %label claim.

Key words-Pregabalin, Method Validation, Api, Capsules, marketed Study, Hplc.

Introduction

The purpose of Analysis is to identify substances, purify them, separate them, quantify them, determine the molecular structures of chemical compounds that make up pharmaceuticals, and determine how these compounds are combined to make up a pharmaceutical product. It's Mainly done by Chemical analysis of drug molecules or agents and their metabolites.

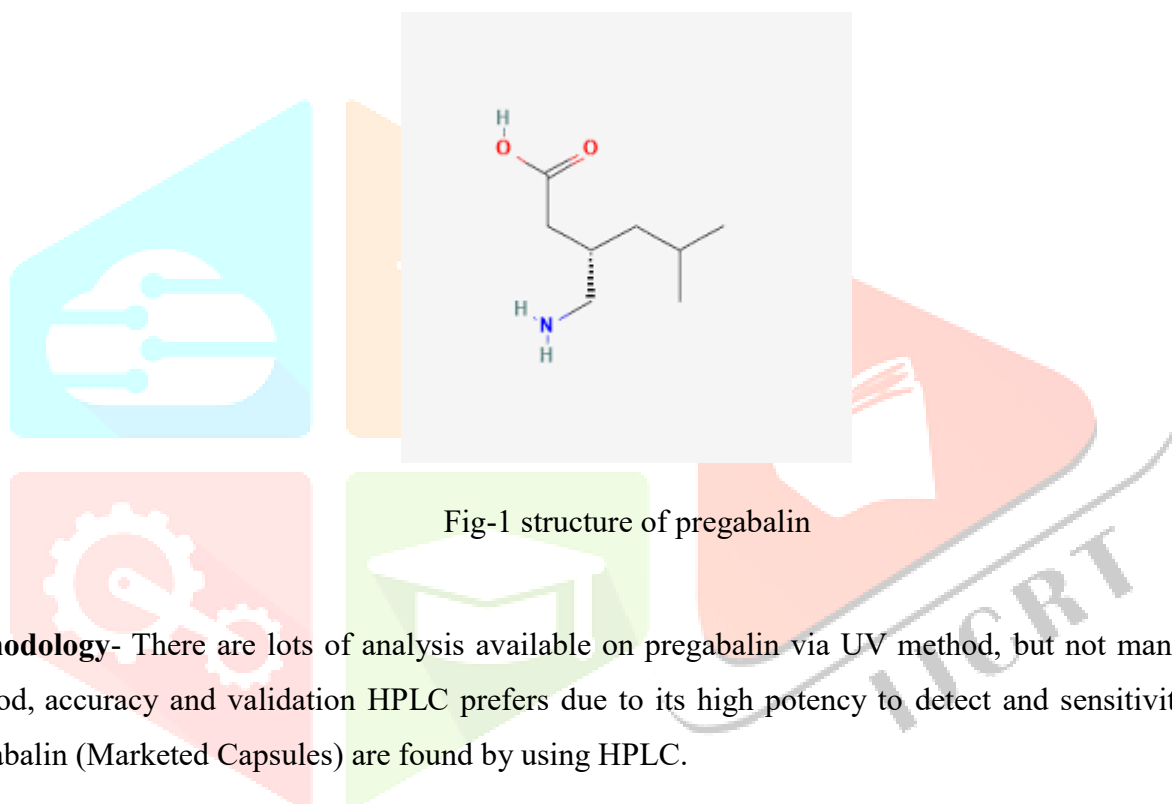
Pregabalin is a medication primarily used to treat neuropathic pain, fibromyalgia, generalized anxiety disorder (GAD), and certain types of seizures. It belongs to the class of medications known as anticonvulsants or antiepileptic drugs. Pregabalin was approved for use in India by the Central Drugs Standard Control Organization (CDSCO) on March 18, 2005.

Pregabalin's mechanism of action involves binding to the alpha2-delta subunit of voltage-gated calcium channels in the central nervous system.

Calcium Channel Modulation: Pregabalin binds to the alpha2-delta subunit of voltage-gated calcium channels in the central nervous system. These channels are involved in the transmission of pain signals and excitatory neurotransmitters.

Reduction in Neurotransmitter Release: By binding to the alpha2-delta subunit, pregabalin reduces the release of neurotransmitters such as glutamate, noradrenaline, and substance. These neurotransmitters are involved in pain signaling, anxiety, and other neurological processes.

Attenuation of Excitatory Signaling: The reduction in neurotransmitter release leads to a decrease in excitatory signaling within the central nervous system. This modulation of neurotransmitter release contributes to pregabalin's therapeutic effects in conditions such as neuropathic pain, fibromyalgia, and generalized anxiety disorder.



Methodology- There are lots of analysis available on pregabalin via UV method, but not many on HPLC method, accuracy and validation HPLC prefers due to its high potency to detect and sensitivity. Assay of Pregabalin (Marketed Capsules) are found by using HPLC.

Sample Collection-Here, Three Different Sample of Pregabalin Taken from Pharmaceutical shop both contain 75 mg of Pregabalin. For authenticity of tablets bill was taken. (VADODARA).

- Avg Weight of different samples are given below.

Table 1: The Average equivalent Weight of Capsules from Different Brands

Sr No	Samples	Weight
1	Sample (A)	76.1
2	Sample (B)	75.55
3	Sample (C)	75.98

Analysis of study:

High Performance Liquid Chromatography Instrument- SHIMADZU HPLC -LC-2030, Software-Lab Solutions.

Procurement: API Sample of Pregabalin Procured from Aura life Sci Pvt, Vadodara.

Preparation of mobile phase: The mobile phase was prepared by mixing Phosphate Buffer pH 3.0 adjusted with OPA: Methanol: Acetonitrile (30:35:35, v/v/v). The prepared mobile phase was sonicated and filtered through 0.45µm membrane filter.

Preparation of stock Solution- Accurately weighed and transferred about 75 mg of Pregabalin (PRE) in to 100 ml of volumetric flask, 50 ml of methanol was added and sonicated to dissolve. Volume was making up to the mark with diluent. Concentration of Pregabalin (PRE) is 7500 µg/ml, further diluted 1 ml of above solution to 10 ml volumetric flask and volume was make up to the mark with diluent. Concentration of Pregabalin (PRE) is 750 µg/ml, further diluted 1 ml of above solution to 10 ml volumetric flask and volume was make up to the mark with diluent. Concentration of Pregabalin (PRE) is 75 µg/ml. The optimum wavelength was selected for the estimation where both drugs give maximum absorbance, which was obtained by scanning solution in the range of 200-400 nm in UV spectrophotometer.

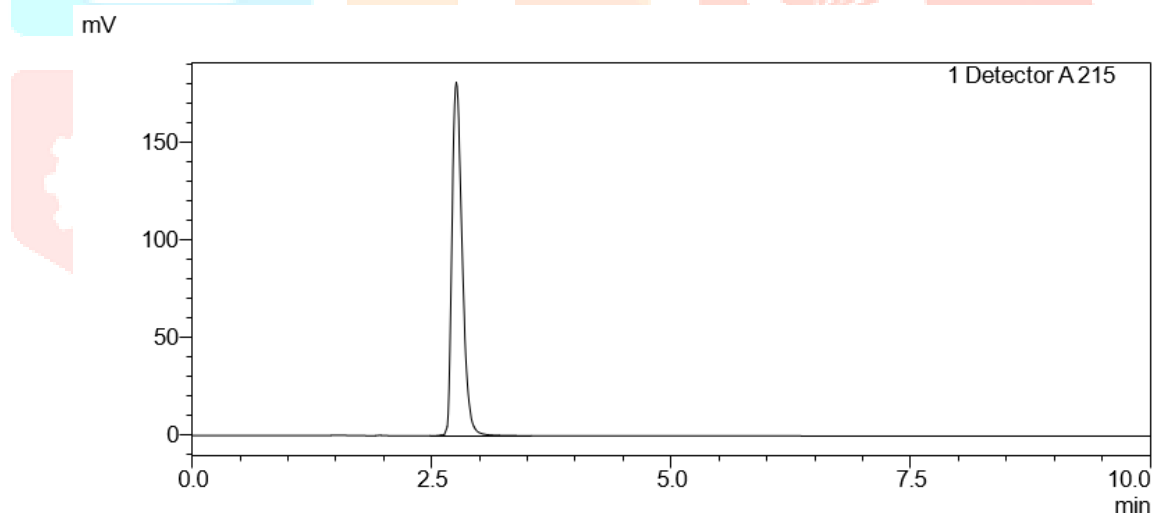
Chromatogram of API sample-75 µg/ml Pregabalin (PRE)

Fig-2 Chromatogram of API sample-75 µg/ml Pregabalin (PRE)

Table- 2 Peak area of chromatogram

Peak#	Ret. Time	Area	Height	Conc.	Unit
1	2.759	1342222	180693	0.000	mg/L
Total		1342222	180693		

Chromatogram of sample (A)-75 µg/ml Pregabalin (PRE)

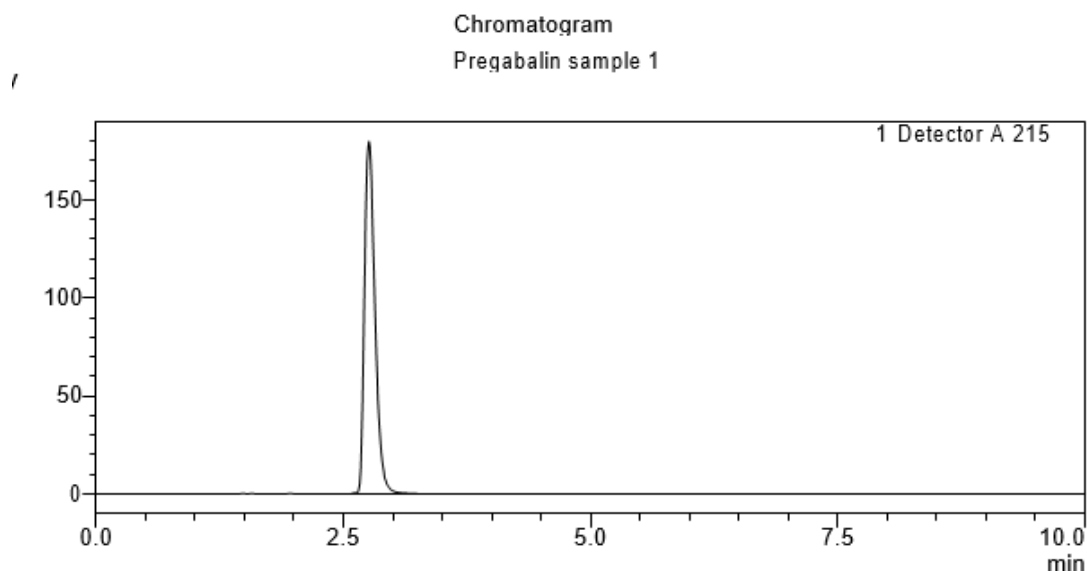


Fig-3

Chromatogram of sample (A)-75 µg/ml Pregabalin (PRE)

Table- 3 Peak area of chromatogram

Peak#	Ret. Time	Area	Height	Conc.	Unit
1	2.758	1337838	179808	0.000	mg/L
Total		1337838	179808		

Chromatogram of sample (B)-75 µg/ml Pregabalin (PRE)

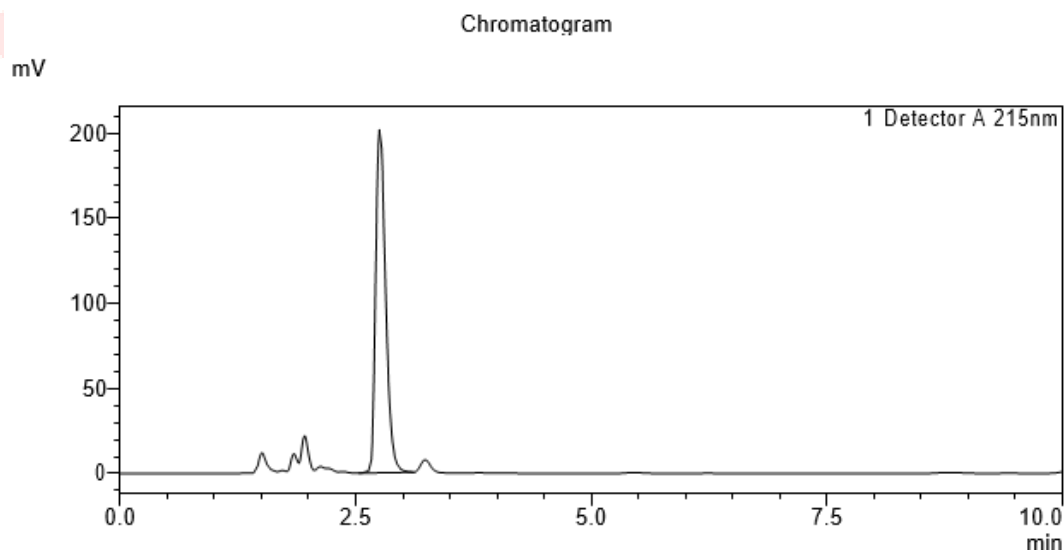


Fig-4 Chromatogram of sample (B)-75 µg/ml Pregabalin (PRE)

Table- 4 Peak area of chromatogram

Peak#	Ret. Time	Area	Height	Conc.	Unit
1	2.757	1512982	203743	0.000	mg/L
Total		1512982	203743		

Chromatogram of sample (C)-75 µg/ml Pregabalin (PRE)

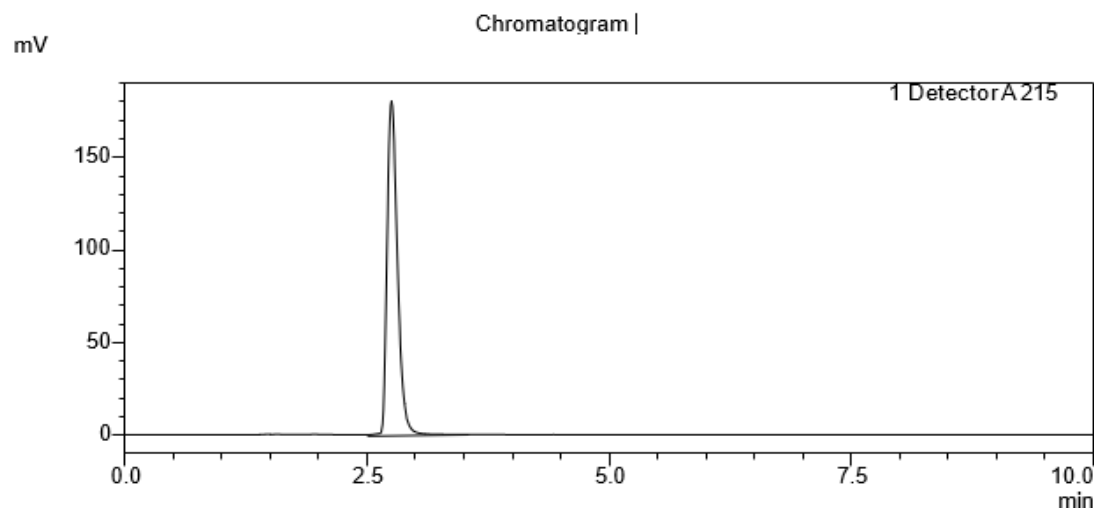


Fig-5 Chromatogram of sample (C)-75 µg/ml Pregabalin (PRE)

Table- 5 Peak area of chromatogram

Peak#	Ret. Time	Area	Height	Conc.	Unit
1	2.758	1339147	179977	0.000	mg/L
Total		1339147	179977		

Result and discussion

Table 6: Showing the Results Obtained Using HPLC Method

Sample Solution	Concentration (mg/ml)	Peak area	% Contain	Content(mg)
A	0.076	1337838	101.46%	76.11mg
B	0.075	1512982	100.73%	75mg
C	0.075	1339147	100.1%	74.87mg

- Pregabalin was found to be highly soluble in Phosphate Buffer pH 3.0 adjusted with OPA: Methanol: Acetonitrile (30:35:35, v/v/v). Using these solvents working standard solutions were prepared of desired concentration for RP-HPLC estimation of Pregabalin. The mean percentage amounts of Pregabalin estimated from tablet formulation using RP-HPLC method was found to be 96%. %label claim is within the limit of the range provided by the EU guideline.

Conclusion-

It can thus conclude that all the brands A, B, C, are within limit as laid down by EU and HPLC method. That the HPLC method is slightly more suitable for assay of Pregabalin Capsules than UV method because its procedure required less dilution. All brands of Pregabalin successfully comply limit of EU. And suitable for market Usage.

REFERENCES.

- 1) B.M et al, "Analysis of Different Brands of Dapagliflozin (10mg) Tablets Using high Performance Liquid Chromatographic (HPLC) Method." *ijpra*.**2023**,*8*(3),969-972.
- 2) "Drug Profile of Pregabalin"
<https://go.drugbank.com/drugs/DB00230>
- 3) Usman S, et al, "Modification and Validation of HPLC Analytical Method for the Estimation of Pregabalin in Capsule Dosage Form." *Int. J. Pharm. Sci. Rev. Res.* **2022**,*75*, (1),133-138.

