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ESTIMATION OF PRIMIDONE IN COMMERCIAL DOSAGE FORMS USING A SIMPLE AND CONVENIENT HPLC METHOD

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ABSTRACT

A simple fast and precise reverse phase high performance liquid chromatographic method has been developed for the determination of Primidone Tablets. A symmetry (5µ, 150 x 4 .6mm column) in isocratic mode with methanol: Water (50:50) as mobile phase. The Flow rate is1.0ml/min and effluent is monitored at 210nm.

Keywords: Primidone, HPLC method, assay

INTRODUCTION

Primidone is an anticonvulsant drug. Chemically Primidone is known as 5-ethyl-2,3-dihydro-5-phenyl-4,6(1H,5H)-Pyrimidinedione. It is not reported in any of the pharmacopoeias. A survey of literature reveals that HPLC methods[1,2,3] are reported for the simultaneous determination of Primidone and its active metabolites in rat plasma by high-performance liquid chromatography using a solid-phase extraction technique, simultaneous determination of primidone and its three major metabolites in rat urine by high-performance liquid chromatography using solid-phase extraction, Lack of In Vivo / In Vitro Correlations for 50mg and 250mg Primidone Tablets. However there is no HPLC method reported so far its estimation in commercial dosage form. Hence reverse phase HPLC method, for the determination of Primidone in pharmaceutical solid Dosage forms is described.
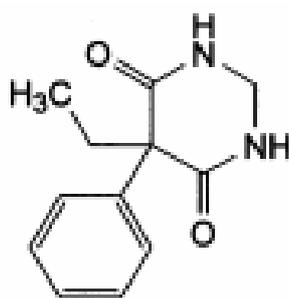
Primidone

EXPERIMENTAL

Instrument : High performance liquid chromatography shimadzu HPLC VP series, LC 10 detector ATVP SPD 10AVP pumps, Rheodyne injector with 20µl loop, and Winchrome computer based data station.

Chemicals and Reagents:
Reference standard Primidone is procured from M/S.Cure craft Ltd., Chennai, Methanol HPLC grade, Water HPLC grade were used.

Stationary Phase: Symmetry column (5µ, 150 x 4.6mm)

Preparation of Mobile Phase

Methanol and Water (1:1) are mixed, filtered through membrane filters of 0.45µ diameter and degassed.

Standard Stock Solution:

Weigh accurately 25mg primidone in 100ml volumetric flask dissolved in minimum amount of methanol, warmed and diluted upto the volume with methanol, to obtain 250 µg/ml concentration.

Sample solution:

Weigh and powder 20 tablets. A powder equivalent to 25mg of primidone is weighed and transferred to a 100 ml volumetric flask. Add methanol and sonicate for 5 minutes, make up to mark with methanol. The solution filtered through membrane filter (0.45µ).

The results are tabulated as follows:

Table-1

Formulation	Label claim mg/tab (mg/tab).	Amount estimated (mg/tab).	Percentage label claim (%).	Percentage deviation	Standard deviation	Related standard deviation
T A B L E T	250mg	249.76 249.23 249.15 249.00	99.90% 99.69% 99.66% 99.6%	(-)0.1 (-)0.31 (-)0.34 (-)0.4	0.3307	0.1326

Calibration

20 µl of the above working standard solutions an injected at a time interval of 15minutes. Evalution is performed with UV detector at 210nm.The retention time is found to be around 3.55 minutes. Peak areas are recorded and the calibration graph is obtained by plotting peak areas versus concentration.

Assay

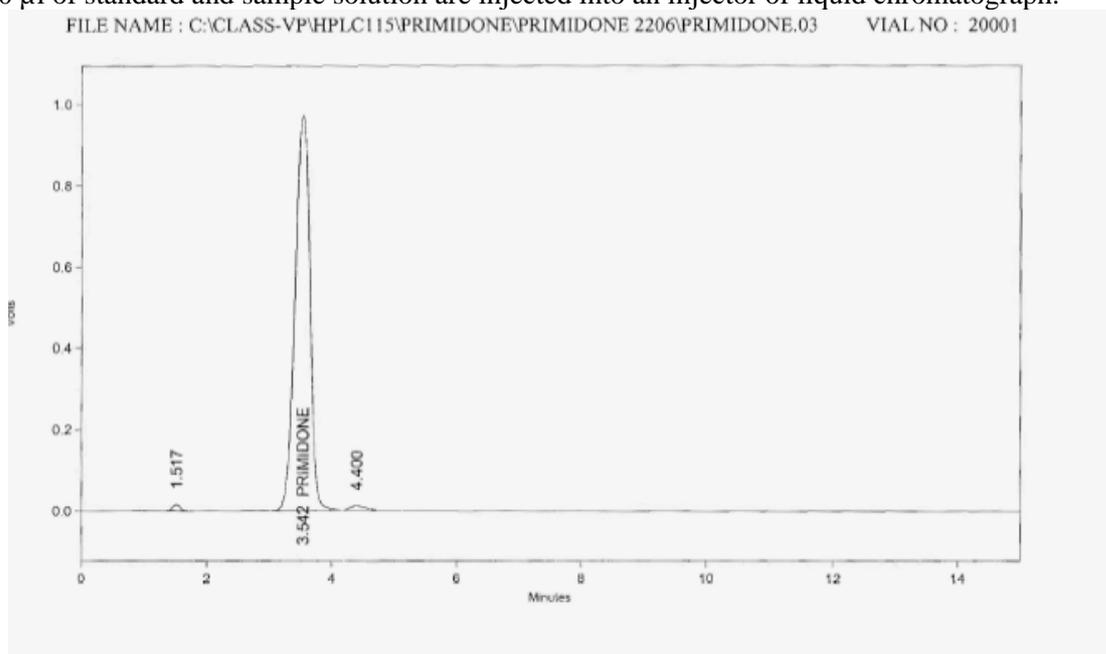20 µl of standard and sample solution are injected into an injector of liquid chromatograph.

Fig.-1: Chromatogram of sample

Formulation containing primidone the amount of primidone present per tablet is calculated by company the peak area with that of the standard (Fig.1).

Recovery Studies
To study the linearity, accuracy and precision of proposed method, recovery experiments were carried out. Known quantities of standard at two different levels were added to the pre analyzed sample, the recovery was estimated to be more than 99.0%.

RESULTS AND DISCUSSION
System suitability test is applied to a representative chromatogram to check various parameters such as efficiency, resolution and asymmetry. The results obtained are shown in Table II that is in concurrence with the USP requirements[4].

Linearity
The linearity of primidone is established by plotting graph of standard solutions versus concentration. The linearity is found to be between 100-500μg/ml.
Chromatography
The mobile phase of methanol and water in the ratio of 1:1 is found to be ideal for analysis of Primidone.

Table-2

S.NO	Parameter	Primidone
1	Theoretical plates	1106.45
2	Capacity factor	34.50
3	Resolution	6.18
4	Asymmetry	0.91
5	RSD of 5 Injections	0.336

Concentrate of primidone in oral dosage form is found to be with in limits and the RSD values are reasonably low. The precision of the method is studied by making 5 injections of standard and very low RSD values indicate good precision. The reproducibility and reliability of the method has been tested by performs recovery studies which showed good results.

CONCLUSION
The prepared method is very simple, rapid and now here involves use of complicated sample preparation. High percentage of recovery shows that the method is free from interferences of the excipients used in the formulation. There fore the method can be useful in routine QC analysis.

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