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***NOTE***

# UV Spectrophotometric Estimation of Phenytoin Sodium in Pure and Pharmaceutical Formulations

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A simple, sensitive, spectrophotometric method in UV region has been developed for the determination of phenytoin sodium in bulk and tablet dosage form. Solution of phenytoin sodium in ethanol shows a maximum at 205 nm. Beer's law was obeyed in the concentration range of 2-14 µg/mL with 0.999 as the correlation coefficient value. The slope and y-intercept obtained for the curve was 0.061 and 0.014, respectively. Results of the analysis were validated statistically and by recovery studies (101.88 ± 1.33) Result of percentage recovery and placebo interference shows that the method was not affected by the presence of excipients, which proves suitability of the developed method for the routine estimation of phenytoin sodium in bulk and solid dosage form.

**Key Words: Phenytoin sodium, UV spectrophotometry.**

Phenytoin sodium, chemically sodium 5,5-diphenyl-2,4-imidazolidine dione[1,2] (Fig. 1), is best known as an antiepileptic which is widely used therapy to the patients suffering from epilepsy. The empirical formula is $C_{15}H_{11}N_2NaO_2$ and its molecular weight is 274.25. An exhaustive and critical literature survey on analytical methods for the determination of phenytoin sodium using various techniques like spectrophotometry, titrimetry[1], nephelometric[3] chromatography, *etc*. was made. It is evident from the literature survey that most of the methods employed by different researchers suffer from various limitations like extractions with organic solvents[4,5], heating steps[6], higher or lower pH of the mobile phase[7], relatively difficult sample preparations[8,9], *etc.* some others. The present study is to develop an accurate and reliable UV method for determination of phenytoin sodium in bulk and its solid dosage forms.

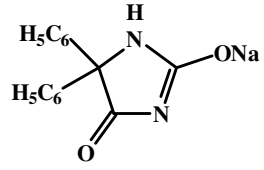


Fig. 1. Structure of phenytoin sodium

A Perkin-Elmer UV/Visible double beam spectrophotometer model Lambda12 with 1 cm matched quartz cells were used. Pure Phenytoin Sodium form (M/s. Briocia Pharma Pvt. Ltd., Pune) and tablet formulations were procured from the local pharmacy.

**Standard stock solution:** Phenytoin sodium (100 mg) was accurately weighed and dissolved in 100 mL of ethanol to give a stock (1 mg/mL).

**Method development:** Phenytoin is soluble in ethanol[1,2]. Aliquots of stock solution were transferred into series of 100 mL flasks and volume was adjusted with ethanol to give the concentration of 2, 4, 6, 8, 10, 12 and 14 μg/mL. The individual samples were scanned from 200-250 nm, the maximum absorbance was observed at 205 nm against the solvent blank ethanol.

**Beer's law standard plot:** Beer's law standard plot was constructed by plotting concentration vs. absorbance which is found to be linear in the concentration range of 2-14 μg/mL and the optical characteristics are given in Table-1.

TABLE-1
OPTICAL CHARACTERISTICS

| Parameters | | Values |
|---|---|---|
| $\lambda_{max}$ (nm) | | 205 |
| Beer's law limit (μg $mL^{-1}$) | | 2-14 |
| Sandell's sensitivity (μg $cm^{-2}$/0.001 absorbance unit) | | 0.03155 |
| Regression equation (Y = a + bc) | Slope (b) | 0.061 |
| | Intercept (a) | 0.014 |
| Correlation coefficient (r) | | 0.999 |

**Estimation of phenytoin sodium in tablet dosage forms:** A quantity of mixed contents of 20 tablets equivalent to 100 mg of phenytoin sodium was dissolved in 100 mL of ethanol. This solution is filtered using Whatman filter paper No. 1 and further diluted with ethanol to 10 μg/mL concentration and the absorbance measured at 205 nm against ethanol as a blank.

The repeatability of the method was studied by recording the UV-spectrum and measuring the absorbance at $\lambda_{max}$ 205 nm of standard solution of phenytoin sodium for six times. The results are summarized in Table-2.

The inter-day precision was done by analyzing formulation by same analyst and informant and the % RSD of inter-day values are shown in Table-2.

The intra-day precision was done by analyzing formulation in same day for six times of individual preparation and observation. The % RSD and datas are shown in Table-2.

**Recovery study:** Recovery studies were carried out by adding a known quantity of pure drug to the placebo/tablet base and the proposed method was followed. From the amount of drug found, percentage recovery was calculated. The results of analysis and recovery studies are given in Table-3.

TABLE-2
RESULTS OF ASSAY AND PRECISION STUDIES

| Sample | Label claim (mg/tab) | Amount found (mg/tab) | Precision** | | |
|---|---|---|---|---|---|
| | | | Repeatability | Inter-day | Intra-day |
| Phenytoin sodium tablets | 100 | 101.88 ± 1.33 | 0.635 | 0.00431 | 0.0040 |

*Mean of six determinations; **SD of five determinations.

TABLE-3
RECOVERY STUDY

| Drug | Label claim (mg/tab) | Estimated amount (mg/tab) | Spike level (%) | Amount of drug added (µg) | Amount of drug recovered (µg) | Percentage Recovery ± SD* |
|---|---|---|---|---|---|---|
| Phenytoin sodium tablets | 100.00 | 100.42 | 60 | 6.03 | 6.02 | 99.83 ± 0.254 |
| | | | 80 | 8.04 | 8.06 | 100.24 ± 0.457 |
| | | | 100 | 10.05 | 9.93 | 98.80 ± 0.746 |
| | | | 120 | 12.06 | 11.99 | 99.42 ± 0.708 |
| | | | 140 | 14.07 | 14.09 | 100.14 ± 0.532 |

*Mean of six determinations.

The optical characteristics like $\lambda_{max}$, Beers law range, regression and Sandell's sensitivity were given in Table-1. The regression analysis showed that the method was linear in the lowest concentration range of 2-14 µg/mL. The percentage recovery values indicated that there is no interference from the excipient(s) present in the formulation. The related standard deviation determined for the method also proved that it is precise.

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