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QUANTITATIVE SPECTROPHOTOMETRIC DETERMINATION OF ORNIDAZOLE TABLET FORMULATIONS USING IBUPROFEN SODIUM AS HYDROTROPIC SOLUBILIZING AGENT

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Various techniques are employed to enhance the aqueous solubility of poorly water-soluble drugs and hydrotropic solubilization is one of them. In the present investigation, hydrotropic solution of ibuprofen sodium (0.5M) was employed as solubilizing agent to solubilize the poorly water-soluble drug, ornidazole from fine power of its tablets for spectrophotometric determination. Ornidazole shows its maximum absorbance at 320 nm and Beer's law was obeyed in concentration range of 5-25 mcg/ml. Results of analysis were validated statistically and by recovery studies. The proposed method is new, simple, safe, environmentally friendly, accurate and cost-effective and can be successfully employed in routine to analyze ornidazole tablets. Hydrotropic agent and commonly used tablet additives did not interfere in the analysis.

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Keywords: Spectrophotometry, Hydrotropy, Ornidazole, Ibuprofen sodium.

1. Introduction

It is well documented that concentrated aqueous solutions of a large number of hydrotropic agents viz. sodium gluconate, niacinamide, urea, sodium benzoate, sodium salicylate, sodium ascorbate and sodium glycinate have been employed to enhance the aqueous solubilities of poorly water-soluble drugs[1-18] .The primary objective of the present investigation was to employ a hydrotropic solution to extract the drug from the fine powder of ornidazole tablets, precluding the use of costlier organic solvents for spectrophotometric analysis. Costlier organic solvents are more often employed to solubilize the poorly water-soluble drugs for spectrophotometric analysis. Volatility and pollution are drawbacks of such solvents. Various techniques are employed to enhance the aqueous solubility of poorly water-soluble drugs. Hydrotropic solubilization is one of them. In the present investigation, hydrotropic solubilizing agent, 0.5 M ibuprofen sodium was employed to solubilize ornidazole from the fine powder of its tablets to carryout spectrophotometric analysis.

2. Experimental

2.1 Materials and Methods

Shimadzu – uv/visible recording spectrophotometer (model UV - 160 A) with 1 cm matched silica cells was used for spectrophotometric analysis. Ornidazole bulk drug sample was obtained as gift sample from Anusandhan Laboratories, Indore. Ibuprofen bulk drug sample was obtained as gift sample from Alkem Laboratories Limited, Mumbai. Commercial tablets of

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ornidazole were purchased from the local market. All other chemicals and solvents used were of analytical grade.

2.2 Method of preparation of 0.5 M ibuprofen sodium solution

Ibuprofen (25.75 g) was suspended in 150 ml distilled water in a 500 ml beaker. Sodium hydroxide 5 g was dissolved in 50 ml distilled water, separately. Sodium hydroxide solution was added in ibuprofen slurry in successive portions and was stirred after each addition. When a clear solution was obtained due to conversion of ibuprofen in ibuprofen sodium, the pH of the solution was adjusted to 7.5 to 8.0 with sodium hydroxide solution and volume was made up to 250 ml with distilled water.

2.3 Calibration curve

Ornidazole (100 mg) was accurately weighed and transferred in a 25 ml volumetric flask and 20 ml of 0.5 M ibuprofen sodium was added and the drug was solubilized by shaking the flask. The volume was made up to the mark with distilled water. The stock solution was further diluted with distilled water to obtain various dilutions. Standard solutions of 10, 20, 30, 40, 50 and 60 mcg/ml of drug were used to plot the calibration curve by taking the absorbance at 320 nm against corresponding reagent blanks.

2.4 Preliminary solubility studies

More than 8 fold enhancement in aqueous solubility of ornidazole was found in 0.5 M ibuprofen sodium solution (as compared to water solubility).

2.5 Analysis of ornidazole tablets using 0.5 M ibuprofen sodium solution

Twenty tablets of ornidazole were weighed and finely powdered. Powder equivalent of 100 mg ornidazole was accurately weighed and transferred to a 25 ml volumetric flask. To it, 20 ml of 0.5 M ibuprofen sodium solution was added. The flask was shaken briskly for 10 minutes and then volume was made up to the mark with distilled water. After filtration through Whatmann filter paper, the filtrate was appropriately diluted with distilled water and absorbance was noted at 320 nm against reagent blank. The drug content was determined using the calibration curve (Table-1).

Table: Results of Analysis of Ornidazole Tablet Formulations with Statistical Evaluation (N=3).

Tablet Formulation	Label Claim per Tablet (mg)	% Label Claim Estimated (mean ± S.D.)	% Coefficient of Variation	Standard Error
I	500	99.36 ± 0.820	0.825	0.473
II	500	98.24 ± 1.763	1.794	1.018

2.6 Recovery Studies

For recovery studies, 30 and 60 mg ornidazole bulk drug sample was added to the pre-analyzed tablet powder equivalent to 100 mg of drug and estimation was done using the same procedure. Percent recoveries were calculated (Table-2). Each type of analysis was performed three times.

Table 2: Results of Recovery Studies with Statistical Evaluation (n=3).

Tablet Formulation	Amount of Drug in pre-analyzed Tablet Powder (mg)	Ornidazole Bulk Drug Added (mg)	% Recovery Estimated (mean ± S.D.)	% Coefficient Variation	Standard Error
I	100	30	98.77 ± 0.660	0.668	0.381
I	100	60	100.39 ± 0.994	0.990	0.574
II	100	30	99.06 ±1.449	1.496	0.837
II	100	60	100.71 ± 0.801	0.795	0.462

3. Results and discussion

More than 8 fold enhancement in aqueous solubility of ornidazole was found in 0.5 M ibuprofen sodium solution (as compared to water solubility). The mean percent label claims obtained in the case of proposed analytical technique, 99.36 (Formulation I) and 98.24 (Formulation II) are very close to 100 indicating the accuracy of the proposed method. The mean percent recoveries (using the proposed method of analysis) ranged from 98.77 to 100.71 which are very close to 100, indicating the accuracy of the proposed method. The low values of various statistical parameters viz. standard deviation, percent coefficient of variation and standard error (Table 1 and Table 2) further validated the proposed analytical method.

4. Conclusions

It is, thus, concluded that the proposed method of analysis is novel, simple, cost-effective, environment friendly, safe, accurate and reproducible. This method can be routinely employed in the analysis of ornidazole in tablet formulations precluding the use of organic solvent. Other poorly water-soluble drugs having λ_{max} above 300 nm may also be tried for solubility enhancement effect using 0.5 M ibuprofen sodium solution. If the solubility is enhanced appreciably, then, this hydrotropic solution can also be employed to analyze such drugs in their solid dosage forms precluding the use of organic solvents.

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