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Spectrophotometric analysis of tablets of nalidixic acid using melted niacinamide as solvent

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ABSTRACT

In the current attempt of research, novel method for spectrophotometric estimation of nalidixic acid in tablets using melted niacinamide as solvent was developed. The main objective behind research is to show "SOLIDS ALSO POSSESS SOLUBILIZING POWER". The current study deals with novel spectrophotometric analytical technique for quantitative estimation of nalidixic acid in tablets using melted niacinamide as solvent. According to the theory proposed by Maheshwari, each & every substance possesses solubilising power; substance may be a gas, solid or liquid. Niacinamide imbibes large solubilizing power to nalidixic acid and having approximate solubility more than 80 mg per gm of melted niacinamide (135˚C) whereas aqueous solubility of nalidixic acid is 0.21mg/ml at room temperature. Calibration curve of nalidixic acid was plotted by recording the absorbances of standard solutions of drug. The absorbances were observed at 330 nm against respective reagent blanks. The percentage label claims were found very close to 100 (100.93± 1.303 and 99.08±1.764) indicating accuracy of the proposed method. Percentage recoveries estimated by the proposed method are close to 100 (99.91±1.303 and 101.74±1.663) with significant low values of percentage deviation and standard error. Thus, it may be concluded that proposed method is simple, safe and precise and excludes use of toxic organic solvents.

Keywords: Mixed Solvency, Solubilizing Power, Spectrophotometric Analysis, Niacinamide, Nalidixic Acid.

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INTRODUCTION

The mixed solvency concept can serve as a milestone for solubility enhancement and therefore deserves an urgent attention of the scientific community to assess its efficiency and applicability. According to Maheshwari, each and every substance present on earth possesses solubilizing power be it a solid, liquid or gas. Some substances are good solvent for some and at the same time bad solvent for others[1-10].

Commonly used organic solvents for spectrophotometric analysis of water insoluble drugs include methanol, ethanol, chloroform, benzene, dichloromethane, dimethyl formamide, actonitrile, ethyl acetate, toluene, carbon tetrachloride, acetone, hexane etc. The main drawbacks of organic solvents include high cost, toxicity and pollution. Organic solvents have innumerous adverse effects caused by single exposure like dermatitis, headache, drowsiness, nausea, eye irritation and long term exposure causes serious effects such as neurological disorders, chronic renal failure, liver damage, necrosis, mutagenesis disorder. They should be replaced by other eco-friendly alternative sources. The present investigation is an attempt to show that solids can also be wisely used to act as solvent precluding the use of organic solvents. In a separate study, author has attempted soxhelation using phenol as solvent. The vapours of boiling phenol got condensed in extraction chamber to effect the extraction of active constituents from powder of crude drugs. The main objective of the present study is to demonstrate the solvent action of solids. Solid excipients can nicely be employed as solubilizers in the development of pharmaceutical dosage forms in solution form of poorly soluble drugs (mixed solvency concept) [11-20].

In the present research, melted Niacinamide (at 135°C) was employed for dissolution of nalidixic acid without using any organic solvents (therefore eco-friendly method).

MATERIALS AND METHOD

Nalidixic acid API was generous gift from M/S Alkem Laboratories Ltd., Mumbai. Nalidixic acid tablets were procured from the local market. All other chemicals were of analytical grade. The instrument used was Shimadzu UV-Visible spectrophotometer (model UV-160A) with 1 cm matched silica cells.

Experimental Methods

Solubility Studies

The solubility of nalidixic acid at room temperature was found to be 0.21mg/ml. Using approximate method of solubility determination, it was found that more than 80 mg nalidixic acid was dissolved by one gram of melted niacinamide (at 135°C).

Calibration Curve

10 gm niacinamide was taken in a 500ml volumetric flask and it was heated carefully on heating mantle. As soon as niacinamide was melted, 50 mg of standard sample of nalidixic acid was added and the flask was shaken to dissolve the drug. Intermittent heating and shaking was done for complete dissolution of drug. Then, the volume was made up to 500ml with distilled water. This was the stock solution of drug (100 µg/ml). By appropriate dilution of this stock solution with distilled water, standard solutions of the drug (10, 20, 30, 40, 50 µg/ml) were prepared and their absorbances were noted at 330 nm against the respective reagent blanks and using these values, the calibration curve was obtained.

Proposed Method

20 tablets of nalidixic acid, formulation I were weighed and crushed to get a fine powder. Ten gms of niacinamide was kept in a 500ml volumetric flask and the flask was carefully heated on heating mantle to melt the niacinamide. After complete melting of niacinamide, tablet powder equivalent to 50mg of drug was transferred to the flask and the flask was shaken for 10 minutes with intermittent heating and shaking. Then, 400ml of hot (90°C) distilled water was carefully (little at a time) added to the flask and the flask was shaken for about 5 minutes. Then, the flask was allowed to cool to attain room temperature and the volume was made up to mark with distilled water. After filtration through Whatman filter paper no.41, 5ml filtrate was diluted to 50ml with distilled water and the absorbance was noted at 330 nm against reagent blank. Using calibration curve the drug content was computed. Similar treatment was done for formulation II. All analyses were performed thrice.

Recovery Studies

Recovery studies taking 15 mg and 30 mg of pure drug as spiked drug together with pre-analysed tablet powder (equivalent to 50 mg) were performed using the same proposed method.

RESULTS AND DISCUSSION

The aqueous solubility of nalidixic acid at room temperature was 0.21mg/ml whereas the solubility of nalidixic acid in melted niacinamide was found to be more than 80 mg per gram of melted niacinamide at 135°C. It is evident from Table 1 that the percent drug estimated in formulation I and II were 100.93± 1.303 and 99.08 ± 1.764, respectively. The values are very close to 100, indicating accuracy and precision of the proposed method. Further, Table 2 shows that the range of percent recoveries varied from 99.91 ± 1.142 to 101.74 ± 1.663 which are again very close to 100.0, indicating the accuracy of the proposed method. Proposed analytical technique is supported significantly by small values of statistical parameters viz. standard deviation, percent coefficient of variation and standard error (Table 2).

Table 1: Analysis of Commercial Tablets of Nalidixic acid with Statistical Evaluation (n=3)

Tablet Formulation	Label Claim Per Tablet (mg)	% Label Claim Estimated (mean±sd)	% Coefficient of Variation	Standard Error
I	500	100.93 ± 1.303	1.291	0.752
II	500	99.08± 1.764	1.780	1.018

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

Tablet formulation	Drug present in preanalyzed tablet powder taken (mg)	Pure drug added (spiked)(mg)	% Recovery estimated (mean ± sd)	% Coefficient of variation	Standard error
I	50	15	99.91 ± 1.142	1.143	0.659
I	50	30	100.67 ± 1.064	1.057	0.614
II	50	15	101.74 ± 1.663	1.635	0.906
II	50	30	99.92 ± 1.605	1.606	0.927

CONCLUSION

The mixed solvency concept can be successfully employed in analytical estimation of various drugs. A large number of poorly water-soluble drugs having absorption maxima above 300 nm can be tried for estimation by this method. Such solvents (niacinamide) can be tried in place of costlier and toxic organic solvents.

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