

Original Article

TITRIMETRIC ANALYSIS OF IBUPROFEN BULK DRUG SAMPLE BY USING UREA AS A HYDROTROPIC SOLUBILIZING AGENT

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ABSTRACT

Objective: The objective of this study was to employ hydrotropic solubilization technique to facilitate the titrimetric analysis of poorly water soluble drug, ibuprofen precluding the use organic solvent.

Methods: In the present investigation, poorly water-soluble anti-inflammatory drug, ibuprofen has been solubilized using 8M of urea as hydrotropic agent for its titrimetric analysis instead of using organic solvent.

Results: There was an enhancement in solubility of ibuprofen in 8M urea solution as compared to solubility in distilled water. The mean percent estimation of ibuprofen estimated in bulk sample by Indian Pharmacopoeial Method is 98.56% while by the proposed method (using 8M urea) is 98.67%. The results of analysis by the proposed method are very close to the results of the standard method.

Conclusion: Proposed method is simple, economic, accurate, eco-friendly and can be successfully employed in the routine quantitative analysis of drug in bulk drug and dosage form in industries.

Keywords: Ibuprofen, Hydrotrophy, Urea, Titrimetry.

INTRODUCTION

Several techniques are used to enhance the aqueous solubility of poorly water soluble drugs. Hydrotropic solubilization is one of them. Hydrotrophy is a solubilization process whereby addition of large amount of second solute results in an increase in the aqueous solubility of another solute [1, 2]. Concentrated aqueous hydrotropic solutions of sodium benzoate, ibuprofen, urea, nicotinamide, sodium citrate and sodium acetate have been employed to enhance the aqueous solubilities of many poorly water-soluble drugs [3, 12]. Various poorly water soluble drugs like tinidazole [3], frusemide [4], piroxicam [5], ketoprofen [6], and cefixime [7] have been analysed by using hydrotropic solubilization phenomenon.

Various organic solvents used to solubilize the poorly water-soluble drugs to facilitate the acid-base titrations include methanol, ethanol, chloroform, dimethyl formamide and acetone. But organic solvents have some drawbacks including higher cost, toxicity and volatility. The Indian Pharmacopoeial method of titrimetric analysis of ibuprofen (a poorly water soluble drug) uses an organic solvent, ethanol for the solubilization of the drug.

The primary objective of this study was to preclude the use organic solvent & to employ hydrotropic solubilizing agent i.e. urea (8M) for the purpose of solubilization to facilitate the titrimetric analysis of poorly water soluble drug, ibuprofen.

MATERIALS AND METHODS

All chemicals & solvents used were of analytical grade. Ibuprofen was procured as a free gift sample from Cipla Ltd. Mumbai. A

Shimadzu UV/VIS Spectrophotometer with 1 cm matched silica cells was employed for spectrophotometric analysis.

Preliminary solubility study of Ibuprofen

Solubility of selected bulk drug ibuprofen was determined in distilled water and in 8M urea solution at $28 \pm 1^\circ$. An excess amount of the drug was added to screw capped 30 ml glass vials containing distilled water and 8M urea solution. The vials were shaken mechanically for 12 hr at $28 \pm 1^\circ$, in an orbital shaker. These solutions were allowed to equilibrate for next 24hr and then centrifuged for 5 min at 2000 rpm. Supernatant of each vial was filtered through Whatman filter paper No.41. and filtrates were diluted suitably and analyzed spectrophotometrically against the solvent blank.

Analysis of bulk sample of Ibuprofen by proposed method

For analysis of ibuprofen by proposed method (PM), accurately weighed quantity of ibuprofen sample (0.2 gm) was solubilized in 50 ml of 8M urea solution. The resultant solution was titrated with 0.1M sodium hydroxide solution using 0.1 ml phenolphthalein as an indicator. Necessary correction was made by conducting blank determination and the amount of ibuprofen drug was calculated.

Analysis of ibuprofen by Indian pharmacopoeial method [13]

For analysis of ibuprofen by Indian Pharmacopoeial method (IPM), accurately weighed quantity of ibuprofen sample (0.2 gm) was solubilized in 50 ml of ethanol (95%). The resultant solution was titrated with 0.1M sodium hydroxide solution using 0.1 ml phenolphthalein as an indicator. Necessary correction was made by conducting blank determination and the amount of ibuprofen drug was calculated.

Table 1: Results of titrimetric analysis of ibuprofen bulk drug sample (n=3)

| Method | Percent drug estimated (mean \pm SD) | % coefficient Variation | Standard error |
|--------|--|-------------------------|----------------|
| IPM | 98.56 \pm 0.495 | 0.502 | 0.285 |
| PM | 98.67 \pm 0.640 | 0.648 | 0.369 |

RESULTS AND DISCUSSION

From solubility study, it was found that there was more than 10 fold enhancement in solubility of ibuprofen in 8M urea solution as compared to solubility in distilled water.

As evident from table no.1, the mean percent estimated in the bulk drug sample of ibuprofen by I. P. and proposed method was 98.56% and 98.67% respectively. The results of analysis by the proposed method were very close to the results of analysis by

standard Indian Pharmacopoeial method. This confirms the accuracy of the proposed method.

The accuracy of the proposed method was validated statistically by low values of standard deviation, % coefficient of variation and standard error.

CONCLUSION

Thus, it may be concluded that the proposed method of analysis is new, rapid, simple, cost-effective, environmentally friendly, safe, accurate and reproducible. This method can be successfully employed in the routine analysis of ibuprofen in bulk drug sample. There is good scope for other poorly water soluble drug which may be tried to get solubilized by suitable hydrotropic agent to carry out their titrimetric analysis excluding the use of costlier, unsafe, volatile, pollution causing organic solvents.

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CONFLICT OF INTERESTS

Declared None

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