

Research Article



Trisodium Citrate Driven Hydrotropic Analysis: A Novel Approach for Ibuprofen Determination

Gaurav B. Kale*, Dr. Avinash M. Bhagwat, Manish M. Pujari, Resham N. Ingawale

YSPM, YTC, Faculty of Pharmacy, Satara-415011, India.

*Corresponding author's E-mail: gauravkale066@gmail.com

Received: 06-01-2025; Revised: 23-04-2025; Accepted: 10-05-2025; Published online: 15-05-2025.

ABSTRACT

The term "hydrotropy" refers to the enhancement of the solubility of a drug or various substances. Various organic solvents are commonly used to enhance the solubility of drugs, but these solvents can be hazardous in nature. To replace organic solvents, various hydrotropic agents, such as Trisodium citrate, sodium benzoate, urea, Nicotinamide, sodium salicylate, sodium glycinate, and sodium Ascorbate, have been observed to increase the solubility of many poorly water-soluble drugs. The present work focuses on the application of hydrotropy, specifically the enhancement of the solubility of the drug ibuprofen in 1.25 M Trisodium citrate (a hydrotropic agent). This study demonstrates the enhancement of the solubility of the practically water-insoluble drug ibuprofen, allowing for titrimetric assay analysis without the use of organic solvents.

Keywords: Ibuprofen, Hydrotropy, Tri- sodium citrate, Solubility enhancement.

INTRODUCTION

The hydrotropes is the category which is the chemical compound that cause a several fold enhancing the solubility for the poor water soluble solute substance / solute at normal condition. This concept of the hydrotropy is determined as a part of Green chemistry. It is unique & unprecedented solubilization technique. The different hydrotropic agent such as a Tri sodium citrate, Ibuprofen sodium, Urea, Sodium acetate are used to enhance the aqueous solubility of the large number of poorly water-soluble drug. The various harmful drawback of the organic solvent include higher cost, toxicity, pollution and error in the analysis due to volatility. The primary objective of this study was to minimize the use of organic solvents in the enhancing the solubility of the poorly water soluble drug.^{1,2}

MATERIAL AND METHODS

Analysis of Ibuprofen bulk drug by IP method:

About 500 mg of Ibuprofen bulk drug was accurately weighed and dissolved in 25 ml of ethanol (99.9%) previously neutralized to phenolphthalein solution, 25 ml of water was added and titrated with 0.1 M sodium hydroxide using phenolphthalein solution as indicator. Each ml of 0.1 M sodium hydroxide is equivalent to 0.0206g of Ibuprofen. Drug content was determined (n=3) and presented in Table A.²³

Analysis of Ibuprofen bulk drug by the proposed method:

About 500 mg of Ibuprofen bulk drug weighed and transferred to 250 ml conical flask. 25 ml of a solution of 1.25 M Tri sodium citrate was added and the flask was shaken for about 10 min to dissolve the drug. Titration was performed with 0.1 M sodium hydroxide using phenolphthalein as indicator. Blank titration was performed for necessary correction. Each ml of 0.1 M sodium hydroxide is equivalent to 0.0206 g of Ibuprofen. Drug content were determined (N=3) and presented in Table A.

RESULT AND DISCUSSION

Results of solubility studies of Ibuprofen revealed that enhancement in solubility in a hydrotropic solution containing 1.25 M Tri sodium citrate was more than 10 fold as compared to its solubility in distilled water. It is evident from the Table A. that the values of mean percent of Ibuprofen estimated in the drug sample was 100.528±0.3363 and 100.253±0.7237 by the Indian Pharmacopoeia and proposed titrimetric method respectively. The amounts of drug estimated by Indian Pharmacopoeia and proposed titrimetric method (Table A) are very close to each other and very near to 100.0mg, indicating the accuracy of the proposed method of analysis. Low values of deviation, percent coefficient of variation and standard error (table A) further validated the proposed titrimetric method.

Table A: Analysis data of bulk drug sample with statistical evaluation (n=3)

Amount of bulk drug taken (mg)	Method of analysis	Percent drug estimated (mean ± SD)	Coefficient of variation (%)	Standard error
500	IPM	100.528 ± 0.3363	0.3346	0.1942
500	PTM	100.253 ± 0.7237	0.7220	0.4170

(IPM- Indian Pharmacopoeia Method, PTM- Proposed Titrimetric Method)



CONCLUSION

In this, concluded that the proposed method is new, simple, environmentally friendly, accurate and reproducible. Decided advantage is that the organic solvent is precluded but not at the expense of accuracy. The proposed method can be successfully employed in the routine analysis of Ibuprofen in drug sample. Hydrotropic analysis is a valuable technique for enhancing the solubility of poorly water-soluble drugs without the need for organic solvents or complex formulations. This method improves drug dissolution, bioavailability, and analytical precision, making it a cost-effective and eco-friendly approach in pharmaceutical research. The use of hydrotropic agents allows for the development of reliable and reproducible analytical methods for drug estimation, ensuring accuracy in quality control and formulation development. Overall, hydrotropic analysis contributes significantly to modern pharmaceutical sciences by simplifying drug analysis and improving therapeutic efficacy. Hydrotropy may find wide use in development of aqueous formulations of poorly water soluble drugs in the future.

ACKNOWLEDGEMENT:

We are thankful to the staff of the YSPM, YTC, Satara for their valuable time and support. We also thankful to my mentor Dr. A.M.Bhagwat, HOD. OF Pharmaceutical chemistry, YSPM, YTC, SATARA .Special thanks to Mr. Prasad patil sir (Assistant of Chemistry laboratory).We are also great thankful to the Professor. Rajesh Maheshwari sir for their valuable guidance and my all FRIENDS.

Source of Support: The author(s) received no financial support for the research, authorship, and/or publication of this article

Conflict of Interest: The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

REFERENCES

- Maheshwari RK, Chaturvedi SC, Jain NK, Novel application of hydrotropic solubilizing additives in the estimation of aspirin in bulk sample and tablets. *Int. J Pharm Excipients* 2005;4(4): 84-88. DOI: 10.4103/0250-474X.78539. PMID: 21695002
- Maheshwari RK, Application of hydrotropic solubilization phenomenon in spectrophotometric estimation of norfloxacin in tablets, *Indian J Pharm Edu. Res*, 2006;8(40): 237-240. DOI: 10.4103/0250-474X.25714
- Maheshwari RK, Kumar S, Bhavsar N, Ansari A. Tritemetric analysis of Ketoprofen in the bulk drug sample using sodium citrate as hydrotropic agent, *International journal of pharma and Bio science*, 2013;4(2):58-61.
- Neuberg C. Hydrotropy. *Biochemical Journal*. 1916;10(5):589-96. doi:10.1042/bj010 0589
- Dhapté V, Mehta P. Advances in hydrotropic solutions: An updated review. *St. Petersburg Polytechnical University Journal: Physics and Mathematics*. 2015;1(4):424-35. doi:10.1016/j.spjpm.2015.12.002
- Thorat YS, Gonjari ID, Hosmani AH. Solubility enhancement techniques: a review on conventional and novel approaches. *International journal of pharmaceutical sciences and research*. 2011;2(10):2501. doi:10.13040/IJPSR.0975-8232.2(10).2501-13
- Varma MVS, Kaushal AM. The Effect of Hydrotropic Agents on the Solubility and Thermal Properties of Mefenamic Acid. *AAPS PharmSciTech*. 2004;5(4):51-6.
- Maheshwari RK, Application of hydrotropic solubilization in the analysis of aceclofenac, *Asian J Chem*, 2006;(18):1572-1574, 2006.
- Maheshwari RK, Chavda V, Sahoo K, Varghese S, Novel application of hydrotropic solubilization in the spectrophotometric analysis of diclofenac sodium in solid dosage form, *Asian J Pharmaceutics*, 2006;8(1): 30-32.
- Maheshwari RK, Chaturvedi SC, Jain NK, Novel application of hydrotropic solubilization in the quantitative analysis of some NSAIDs and their solid dosage forms. *Indian J Pharm Sci*, 2007;69:101-105. DOI:10.4103/0250-474X.32117
- Maheshwari RK, Arif D, Mittal P, Manchandani P, Indurkha A, Jawade S, A novel method for quantitative determination of aceclofenac in bulk drug and tablets using ibuprofen sodium as a hydrotropic solubilizing agent. *J Applied Chem Res*, 2008;6(5):63-68.
- Maheshwari. k, Sita Prasad, P. Pandey, G.wanare. Novel spectrometric analysis of piroxicam tablet using Ibuprofen sodium as hydrotropic solubilizing agent. *International journal of pharmaceutical science and drug research*. 2010;4(3):210-121. 10.25004/IJPSDR.2018.100402
- Priyanka Ansari, Manoj Goyal, SUMAN Jain, Review article Hydrotropic solubilization, *International journal of pharmaceutical and phytochemical Research*. 2013;3(1):17-23.
- Ekta Sainani, D. B. Joshi, R.Bhadauria, M.L.Chaudhary. Hydrotropy- Novel concept of drug solubilization, *International journal of pharmaceutical and biological science archive*. 2022;10(6):20-27.
- Redasani VK, Patel PS, Chhajed CF, Surana SS. Quantitative Determination of Meloxicam in bulk and in tablet by UV-Spectrophotometry. *International Journal of Pharmaceutics and Drug Analysis*. 2014;2(3):50-54.
- Bhagwat AM, Khadke AP, Patil AM, Shelar NS. Essential Procedural Review On Cleaning Aspect Of Accessories Used In Industrial Laboratories. *European Journal Of Biomedical And Pharmaceutical Sciences*. 2017;1(4):179-187
- Ingawale ss, Bhagwat AM, Khadke AP, Khadke AA. Data Integrity :A Need Of Pharmaceutical Industry. *European Journal Of Biomedical And Pharmaceutical Sciences* 2017;8(4):199-211
- Indian Pharmacopoeia. 4th Edn, Vol I, Controller of Publications, Delhi: 764, (1996).

For any questions related to this article, please reach us at: globalresearchonline@rediffmail.com

New manuscripts for publication can be submitted at: submit@globalresearchonline.net and submit_ijpsrr@rediffmail.com

