ASIAN JOURNAL OF PHARMACEUTICAL AND CLINICAL RESEARCH

INNOVARE ACADEMIC SCIENCES
Knowledge to Innovation

Vol 9, Suppl. 1, 2016

Online - 2455-3891
Print - 0974-2441

Research Article

QUANTITATIVE ANALYSIS OF SALICYLIC ACID BULK SAMPLE USING HYDROTROPIC SOLUBILIZING AGENTS

SAMPATTI PATIL, PREETI MEHTA*, BHAGWAT CHAVAN

Department of Pharmaceutical Chemistry, JSPM's Jayawantrao Sawant College of Pharmacy & Research, Hadapsar, Pune - 411 028, Maharashtra, India. Email: preetigandhi2007@gmail.com

Received: 09 May 2016, Revised and Accepted: 19 May 2016

ABSTRACT

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

Methods: In the present investigation, poorly water-soluble keratolytic drug, salicylic acid, has been solubilized using nicotinamide (2 M) and sodium benzoate (2 M) as hydrotropic agents for its titrimetric analysis instead of using an organic solvent.

Results: There was an enhancement in solubility of salicylic acid in 2 M nicotinamide and sodium benzoate solutions as compared to solubility in distilled water. The mean percent estimation in the bulk drug sample of salicylic acid by Indian Pharmacopeial method is 98.89% while by use of proposed method, i.e., using 2 M nicotinamide and 2 M sodium benzoate solutions were 98.90% and 98.97%, respectively. Compared to sodium benzoate, salicylic acid was found to be more soluble in nicotinamide solution. The results of analysis by proposed method are very close to the results of the standard method.

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

Keywords: Salicylic acid, Hydrotropy, Sodium benzoate, Nicotinamide, Titrimetry.

INTRODUCTION

Several techniques are used to enhance the aqueous solubility of poorly water-soluble drugs. Hydrotropic solubilization is one of them. Hydrotropy is a solubilization process whereby addition of large amounts of a second solute results in an increase in the aqueous solubility of another solute. Concentrated aqueous solutions of a large number of hydrotropic agents, *viz*., sodium benzoate, sodium salicylate, niacinamide, urea, sodium citrate, and sodium acetate have been employed to enhance the aqueous solubilities of poorly water-soluble drugs [1-9]. Various poorly water-soluble drugs such as furosemide [1], ketoprofen [2], tinidazole [3], and cefixime [4] have been analyzed using hydrotropic solubilization phenomenon.

Various organic solvents such as methanol, chloroform, dimethylformamide, and ethanol have been employed for solubilization of poorly water-soluble drugs to conduct their titrimetric analyses. Drawbacks of organic solvents include their higher costs, toxicities, and pollution. Due to these drawbacks, it is necessary to preclude the use of organic solvents during quantitative estimations of drugs. The Indian Pharmacopieal method (IPM) of titrimetric analysis of salicylic acid (a poorly water-soluble drug) uses an organic solvent, ethanol for the solubilization of the drug. Sodium benzoate and nicotinamide solutions are cheaper, non-toxic than ethanol and thus can be better substituted for ethanol.

The primary objective of this study was to preclude the use of organic solvent and to employ hydrotropic solubilizing agents, i.e. nicotinamide (2 M) and sodium benzoate solution (2 M) for the purpose of solubilization to facilitate the titrimetric analysis of poorly water-soluble drug, salicylic acid.

METHODS

All chemicals and solvents used were of analytical grade. Salicylic acid (S.D. Fine Chemicals Ltd., Mumbai) were procured from market. A Schimadzu ultraviolet/visible Spectrophotometer with 1 cm matched silica cells was employed for spectrophotometric analysis.

Preliminary solubility study of salicylic acid

Solubility of selected bulk drug salicylic acid was determined in distilled water, 2 M nicotinamide and 2 M sodium benzoate solutions at 28±1°. In this, an excess amount of drug was added to screw capped 30 ml glass vials containing distilled water, 2 M nicotinamide, and 2 M sodium benzoate solutions. The vials were shaken mechanically for 12 hrs at 28±1° in orbital shaker. These solutions were allowed to equilibrate for next 24 hrs 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 solvent blank.

Analysis of salicylic acid bulk sample by the IPM

For the analysis of salicylic acid by IPM [10], accurately weighed quantity of salicylic acid bulk sample (0.3 g) was solubilized in 50 ml of ethanol. After adding 20 ml of distilled water, it was titrated with sodium hydroxide solution (0.1 M) using phenol red solution as indicator. Necessary correction was done by conducting blank determination and amount of salicylic acid was calculated.

Analysis of salicylic acid bulk sample by proposed method

For the analysis of salicylic acid by proposed method using nicotinamide solution, accurately weighed quantity of salicylic acid bulk sample (0.3 g) was solubilized in 50 ml of 2 M nicotinamide solution. After adding 20 ml of distilled water, it was titrated with sodium hydroxide solution (0.1 M) using phenol red solution as indicator. Necessary correction was done by conducting blank determination and amount of salicylic acid was calculated. The same procedure was applied for another hydrotropic agent, i.e., sodium benzoate (2 M).

RESULTS AND DISCUSSION

From solubility study, it was found that there was an enhancement in solubility of salicylic acid in nicotinamide (2 M) and sodium benzoate

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

Method	Percent drug estimated (mean±SD)	Percentage coefficient variation	SE
IPM	98.89±0.555	0.562	0.322
PMN	98.90±0.475	0.482	0.275
PMSB	98.97±0.375	0.379	0.217

IPM: Indian pharmacopeial method, PMN: Proposed method using nicotinamide solution, PMSB: Proposed method using sodium benzoate solution, SE: Standard error, SD: Standard deviation

(2 M) solutions as compared to solubility in distilled water. Salicylic acid was found to be more soluble in 2 M nicotinamide solution than in 2 M sodium benzoate.

As evident from Table 1, the mean percent estimated in the bulk drug sample of salicylic acid by IPM is 98.89%. In the proposed method of analysis, the mean percent estimated by use of 2 M nicotinamide and 2 M sodium benzoate solutions were 98.90% and 98.97%, respectively.

The results of analysis by proposed method are very close to the results of analysis by IPM. This confirms the accuracy of proposed method. Validation of proposed method is confirmed statistically by low values of standard deviation, percent coefficient of variation, and standard error.

CONCLUSION

It may be concluded that the proposed method of analysis can be successfully employed in the routine analysis of salicylic acid in bulk drug sample. This method is new, rapid, simple, cost-effective, environmentally friendly, safe, accurate, and reproducible. Thus, suitable hydrotropic agents can be used for other poorly water-soluble drugs to carry out their titrimetric analysis excluding the use of costlier, unsafe, volatile, pollution causing organic solvents.

ACKNOWLEDGMENTS

The authors are thankful to the Principal and management of JSPM's Jayawantrao Sawant College of Pharmacy and Research, Hadapsar, Pune, for providing necessary facilities to carry out present research work.

REFERENCES

1. Maheshwari RK. A novel application of hydrotropic solubilization in spectrometric estimation of Frusemide in tablets. Pharm Rev 2006;4:148.
2. Maheshwari RK, Pande S. A novel spectroscopic method for the estimation of Ketoprofen in tablet dosage form using hydrotropic solubilization phenomenon. Middle East J Sci Res 2010;6(3):209-12.
3. Maheshwari RK, Rajput MS, Sinha S. Ecofriendly spectrophotometric estimation of tinidazole in tablets using lignocaine hydrochloride as hydrotropic solubilizing agent. Asian J Pharm 2009;3(4):319-21.
4. Maheshwari RK. Spectrophotometric determination of cefixime in tablets by hydrotropic solubilization phenomenon. Indian Pharm 2005;4:63-8.
5. Maheshwari RK, Chaturvedi SC, Jain NK. Analysis of aceclofenac in tablets using hydrotropic solubilization technique. Indian Drugs 2006;43:516-8.
6. Maheshwari RK, Dewangan A, Soni PK, Kansagra PK, Jain SK. Novel application of hydrotropic solubilization in the spectrophotometric analysis of paracetamol tablet dosage form. Asian J Chem 2006;18:2879-82.
7. Poochikian GK, Cradock JC. Enhanced chartreusin solubility of hydroxyl benzoate hydrotropy. J Pharm Sci 1979;68(6):728-32.
8. 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 Exicip 2005;4:84-8.
9. Maheshwari RK, Chaturvedi SC, Jain NK. Novel spectrophotometric estimation of some poorly water soluble drugs using hydrotropic solubilizing agents. Indian J Pharm Sci 2006;68:195-8.
10. Ministry of Health and Family Welfare, Indian Pharmacopoeia Commission. Indian Pharmacopoeia. Vol. III. Delhi: Controller of Publication; 2007. p. 1693.