ABSTRACT

In the proposed research work a successful attempt was made to develop simple, accurate, novel, safe and precise methods for the estimation of poorly water-soluble drugs i.e. Amlodipine besylate, Olmesartan medoxamil, Hydrochlorothiazide, Torasemide, Pramipexole dihydrochloride, Furazolidone, Lomefloxacin HCl, Citalopram hydrobromide, Ziprasidone, Entacapone, Meloxicam, Lercanidipine, Ketoconazole in single drug containing dosage form. Some poorly water-soluble model drugs in combination i.e. Eprosartan mesylate and Hydrochlorothiazide, Olmesartan medoxamil and Hydrochlorothiazide, Levofloxacin and Ornidazole, Furazolidone & Metronidazole, Metronidazole and Ofloxacin, Metoprolol succinate and Olmesartan medoxamil, Metoprolol succinate and Telmisartan were quantitatively estimated in combined dosage form.

The method was developed by experimentation based on thorough literature survey and ascertained by statistical parameters of sampling. The entire work was performed on Shimadzu UV/VIS double beam-double detector spectrophotometer (Model- 1700 series).

It is evident from the literature survey that more is the concentration of hydrotropes; more is the aqueous solubility of poorly water-soluble drugs. Therefore, highly concentrated solutions of hydrotropic agents were used in the present investigation. Following concentrated aqueous solutions of hydrotropic agents were employed in the present investigation; 2 M sodium benzoate (2 M SB), 2 M niacinamide (2 M NM), 2 M sodium salicylate (2 M SS), 4 M sodium acetate (4 M SA), 8 M urea (8 M UR), 2M citric acid (2M CA), 8% phenol (8% P) and 2 M sodium citrate (2 M SC) solutions.

The selected hydrotropic agent did not interfere in spectrophotometric estimations. Similar interference studies were conducted to observe interference of additives in spectrophotometric estimation of poorly water-soluble model drugs. It was found that additives did not interfere in the spectrophotometric estimations of these drugs.

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Abstract

Equilibrium solubilities of drugs in distilled water and hydrotropic solutions were determined (at room temperature) by determining the drug contents of respective saturated solutions by spectroscopic method. The enhancement ratios (solubility in hydrotropic solution/solubility in distilled water) for the selected drugs were found to be more than 30 fold as compared to distilled water. There is good enhancement in aqueous solubility of selected poorly water-soluble drugs in presence of large amounts of hydrotropic agents. Therefore, it was thought worthwhile to make use of hydrotropic solubilization techniques in development of spectrophotometric methods for the analysis of poorly water-soluble drugs.

In order to perform spectrophotometric analysis linearity was determined at $\lambda_{\text{max}}$ of the drugs. Beer’s ranges and regression equations for the drugs used were found to linear and their correlation coefficients were found to be near to 1.

In combined dosage form two poorly water-soluble drug models were present. After observing the spectral characteristics and due to difference in absorbance maxima and having no interference with each other so both drugs can be simultaneously estimated by two methods, one was simultaneous equation method (Vierordt’s method) and absorbance ratio method (Q Analysis method).

The mean percent label claims of marketed formulations were found to be accepted limit i.e near to 100%. The standard deviation, coefficient of variance and standard error were obtained for poorly-water-soluble drug models were satisfactorily low.

The developed methods were validated according to ICH guidelines and values of linearity, range, accuracy, precision, LOD, LOQ, robustness and other statistical analysis were found to be in good accordance with the prescribed values. The percent RSD values during statistical analysis were found to less than 2.

Therefore, These spectrophotometric methods precluded the use of organic solvents and thus avoid the problem of residual toxicity, error due to volatility, pollution, cost etc.. By proper choice of hydrotropic agents, the use of organic solvents in analysis may be discouraged to a large extent so the proposed methods are worth adopting in pharmacopoeia. The proposed method shall prove equally
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effective to analyze all drugs in the corresponding drug sample and may prove to be of great importance in pharmaceutical analysis.
It was thus, concluded that following methods for poorly water soluble drug models were successfully developed

- Spectrophotometric Method Development and Validation for Quantitative Estimation of Amlodipine Besylate in Bulk Drug and their Dosage Forms by using Hydrotropic Agent,
- Application of Hydrotropic Solubilization Phenomenon for Quantitative Analysis of Olmesartan Medoxamil in Tablet,
- Novel Spectrophotometric Quantitative Estimation of Hydrochlorothiazide in Bulk Drug and their Dosage Forms by using Hydrotropic Agent,
- Novel Spectrophotometric Quantitative Estimation of Torasemide in Tablets using Mixed Hydrotropic Agent,
- Novel UV-Spectrophotometric Method for Quantitative Estimation of Furazolidone using Mixed Hydrotropic Agent,
- Eco Friendly Spectrophotometric Method for Quantitative Estimation of Lomefloxacin using Hydrotropic Approach,
- Ecofriendly Spectrophotometric Method Development and Their Validation for Quantitative Estimation of Pramipexole Dihydrochloride using Mixed Hydrotropic Agent,
- Economical Spectrophotometric Method for Quantitative Estimation of Citalopram Hydrobromide using Hydrotropic Solubalization Technique,
- Novel Spectrophotometric Method for Estimation of Ziprasidone Hydrochloride Monohydrate using Hydrotropic Solubalization Technique
- A Novel Approach Using Hydrotropic Solubalization Technique for Quantitative Estimation of Entacapone,
- Quantitative Estimation of Meloxicam: A Novel Approach using Hydrotropic Solubalization Technique,
- Quantitative Estimation of Lercanidipine Hydrochloride: A Novel Approach Using Hydrotropic Solubalization Technique,
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- Quantitative Estimation of Ketoconazole: A Novel Approach using Hydrotropic Solubalization Technique,
- Mixed Hydrotropy Solubilization Approach for Quantitative Estimation of Eprosartan Mesylate and Hydrochlorothiazide by UV Spectrophotometer,
- Economic Spectrophotometric Methods for Quantitative Estimation of Olmesartan Medoxamil and Hydrochlorothiazide using Mixed Hydrotropy,
- Quantitative Estimation of Levofloxacin and Ornidazole by UV Spectrophotometer: A Mixed Hydrotropy Solubilization Method,
- Novel UV Spectrophotometer Methods for Quantitative Estimation of Metronidazole and Furazolidone using Mixed Hydrotropy Solubalization,
- Novel Economic Method for Quantitation of Metronidazole and Ofloxacin Using UV Spectrophotometer,
- Ecofriendly UV Spectrophotometer Method for Quantitation of Olmesartan Medoxamil and Metoprolol Succinate using Hydrotropic Agent,
- Novel Economic Method for Quantitation of Metoprolol Succinate and Telmisartan using UV Spectrophotometer.