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NOTE

Analysis of Amoxicillin by Application of Hydrotropic Solubilization Phenomenon in Solid Dosage Form

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A novel, safe and sensitive method of spectrophotometric estimation in ultraviolet region has been developed using 5 M potassium acetate as hydrotropic solublizing agent for the quantitative determination of amoxicillin, a poorly water soluble antibiotic drug in tablet dosage form. Amoxicillin shows maximum absorbance at 274 nm. Beer's law was obeyed in the concentration range of 50-350 µg/mL.The hydrotropic agent and the additive used in formulation did not interfere in analysis. Proposed method is new, simple, accurate and reproducible. Statistical data proved the accuracy, reproducibility and the precision of the method.

Key Words: Spectrophotometer, Hydrotropy, Amoxicillin.

Increasing the aqueous solubility of insoluble and slightly soluble drugs is of major importance. In hydrotropic solubilization phenomenon, addition of large amount of a second solute results in an increase in the aqueous solubility of another solute. Concentrated aqueous hydrotropic solutions of urea, nicotinamide, sodium benzoate, sodium salicylate, sodium acetate and sodium citrate have been observed to enhance the aqueous solubility of many poorly water soluble drugs[1-14].

Maheshwari *et al.* has developed new analytical methods based on hydrotropic solubilization phenomenon for poorly water soluble drugs cefixime[1], frusemide,ketoprofen[2,3], salicylic acid[2], tinidazole[4], ofloxacin, metronidazol, norfloxacin, nalidixic acid, tinidazole and aceclofenac[5].

There was considerable increase in the solubility of amoxicillin in 5.0 M potassium acetate (a hydrotropic solution). Therefore, it was thought worthwhile to solubilize the drug present in its tablet powder with the help of 5.0 M potassium acetate to carry out its spectrophotometric analysis.

The instrument used was Shimadzu UV-Visible spectrophotometer (model UV-160A) with 1 cm matched silica cells. Amoxicillin trihydrate was generous gift by Alkem Labs Ltd., Bombay (India). Commercial tablets of amoxycillin were procured from the market. Other chemicals were of analytical grade.

Preparation of calibration curve: Accurately weighed 500 mg of amoxicillin drug sample was transferred to a 100 mL volumetric flask containing 5 M potassium acetate solution. Flask was shaken for 5 min to solubilize the drug and volume was made to mark with distilled water to get stock solution (500 mcg/mL). Stock solution was further diluted with distilled water to obtain various dilutions containing 50, 100, 150, 200, 250, 300 and 350 mcg/mL. The absorbances of these solutions were noted at 274 nm against respective reagent blanks to get calibration curve.

Preliminary solubility studies of drug: Solubility of amoxicillin was determined at 28 ± 1ºC in distilled water and 5 M potassium acetate solution. Enhancement in solubility of drug was more than 12 fold in 5 M potassium acetate solution as compared to distilled water. This enhancement in solubility is due to hydrotropic solubilization phenomenon.

Analysis of amoxicillin tablet formulations: 20 Tablets of amoxicillin were weighed and ground to a fine powder. An accurately weighed powder equivalent to 500 mg of drug was transferred to a 100 mL volumetric flask containing 5 M potassium acetate solution. Flask was shaken for 5 min to solubilize the drug and the volume was made to mark with distilled water. The solution was filtered through Whatmann filter paper no. 41. Fresh filtrates and filtrate was kept at room temperature for 48 h, both were analyzed after sufficient dilutions with distilled water by measuring the absorbances at 274 nm against reagent blanks. Drug content of tablets were computed using the calibration curve and values are reported in Table-1.

TABLE-1
ANALYSIS DATA OF AMOXICILLIN TABLET FORMULATIONS WITH STATISTICAL EVALUATION

Tablet formulation	Label claim/ tablet (mg)	% Label claim estimated* (mean ± SD)	Coefficient of variation (%)	Standard error
I	500	98.39 ± 1.224	1.244	0.707
II	250	100.74 ± 0.932	0.925	0.538

*Average of three determinants.

Recovery studies: To evaluate the validity and reproducibility of the proposed method, recovery experiments were carried out by adding a known amount of bulk drug sample to the preanalyzed tablet powder at two levels (50 and 100 mg) and analyzing them by the same proposed method. The total amount of drug was determined and the amount of added drug was found by the difference. The results of recovery studies are presented in Table-2.

TABLE-2
RESULTS OF RECOVERY STUDIES OF TABLET FORMULATIONS WITH STATISTICAL EVALUATION

Tablet formulation	Drug present in pre-analyzed tablet powder taken (mg)	Amount of pure drug added (mg)	% Recovery estimated* (mean ± SD)	CV (%)	SE
I	500	50	101.22 ± 2.304	2.276	1.330
	500	100	99.44 ± 1.409	1.417	0.813
II	500	50	98.67 ± 0.768	0.778	0.443
	500	100	98.91 ± 0.934	0.944	0.545

*Average of three determinants.
CV = Coefficient of variation; SE = Standard error.

Conclusion

Table-1 shows good agreement between the amounts estimated by the proposed method and the amount claimed by the manufacturers. Per cent label claims (98.67 ± 0.786 and 101.22 ± 2.304) are very close to 100 indicating accuracy of the proposed method. The low values of statistical parameters validated the method. Presence of potassium acetate and other tablet excipients did not interfere in the spectrophotometric estimation.

The recovery studies confirmed the accuracy and reproducibility of the method, while low values of statistical parameters validated the method. Estimated per cent recoveries ranged from 101.22 ± 2.304 and 99.44 ± 1.409 which are very close to 100 indicating the accuracy of the proposed method and also the low values of statistical parameters (Table-2) confirms the proposed method. It was, thus, concluded that the proposed method new, simple, cost-effective, accurate, safe free from pollution and precise and can be successfully employed in the routine analysis of amoxicillin in the tablet dosage forms.

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