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NOTE

Spectrophotometric Analysis of Amoxycillin in Tablets Using Hydrotropic Solubilization Technique

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In the present investigation, hydrotropic solution of urea (10.0 M) was employed to solubilize amoxycillin trihydrate (a poorly water-soluble drug), from fine powder of its tablets, to carry out spectrophotometric analysis. Beer's law was obeyed in the concentration range of 50–350 μg/mL at 274 nm. Recovery studies and statistical data proved the accuracy, reproducibility and the precision of the proposed method. Presence of urea and commonly used tablet excipients did not interfere in the spectrophotometric estimation.

Key Words: Spectrophotometry, Hydrotropy, Amoxycillin, Urea.

In hydrotropic solubilization phenomenon, addition of large amount of a second solute results in an increase in solubility of another solute. Concentrated aqueous solutions of a large number of hydrotropic agents have been employed to enhance the aqueous solubility of many poorly water-soluble drugs[1–10].

Amoxycillin is a widely used antibiotic. There was more than 11-fold enhancement in the solubility of amoxycillin trihydrate in 10.0 M urea solution (a hydrotropic solution) as compared to the solubility in distilled water. Therefore, it was thought worthwhile to extract the drug from the fine powder of amoxycillin tablets with 10.0 M urea solution to carry out spectrophotometric analysis.

The instrument used was Shimadzu UV/Vis recording spectrophotometer (model UV-160 A) with 1 cm matched silica cells. Amoxycillin trihydrate was obtained as a gift sample from Ranbaxy Laboratories Limited, Dewas. Commercial tablets of amoxycillin were purchased from the local market. Other chemicals were of analytical grade.

The standard solution of amoxycillin trihydrate was prepared in distilled water which contained 500 μg/mL of amoxycillin based on anhydrous basis. Dilutions containing 50, 100, 150, 200, 250, 300 and 350 μg/mL of amoxycillin were used to plot the calibration curve by noting the absorbances at 274 nm.

Solubility of amoxycillin trihydrate was determined in distilled water and 10.0 M urea solution at 28 ± 1°C. Enhancement in solubility of drug was more

than 11-fold in 10.0 M urea solution as compared to its solubility in distilled water. This tremendous enhancement in solubility is due to hydrotropic solubilization phenomenon.

Twenty tablets of amoxycillin 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 50 mL of 10.0 M urea solution. The flask was shaken for about 10 min to solubilize the drug and the volume was made up to the mark with distilled water. The solution was filtered through Whatmann filter paper No. 41. Fresh filtrate and filtrate kept at room temperature for 48 h, both were analyzed after sufficient dilutions with distilled water by measuring the absorbances at 274 nm against corresponding reagent blanks. Drug contents of tablets were computed using the calibration curve and values are reported in Table-1.

TABLE-1
ANALYSIS OF COMMERCIAL TABLETS OF AMOXYCILLIN TRIHYDRATE

Tablet formulation	mg/tablet	% Label claim estimated (Mean ± S.D.)	% Coefficient of variation	Standard error
I	500	98.75 ± 1.32	1.34	0.75
II	250	99.31 ± 0.98	0.99	0.56

*Average of three determinations

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
RECOVERY STUDY FOR SPIKED CONCENTRATION OF AMOXYCILLIN TRIHYDRATE ADDED TO PREANALYZED TABLET POWDER

Tablet formulation	Drug present in preanalyzed tablet powder (mg)	Pure drug added (spiked) (mg)	% Recovery estimated* (Mean ± S.D.)	% Coeff. of variation	Standard error
I	500	50	99.13 ± 1.22	1.23	0.70
	500	100	101.30 ± 0.87	0.86	0.50
II	500	50	100.78 ± 1.42	1.40	0.61
	500	100	99.33 ± 1.02	1.03	0.58

*Average of three determinations

Table-1 shows good agreement between the amounts estimated by the proposed method and the amounts claimed by the manufacturers. Per cent label

claims (98.75 ± 1.32 and 99.31 ± 0.98) are very close to 100 indicating the accuracy of the proposed method while the low values of statistical parameters validated the method. Presence of urea and other tablet excipients did not interfere in spectrophotometric estimation. The accuracy and reproducibility of the proposed method were further confirmed by recovery studies. Estimated per cent recoveries ranged from 99.13 ± 1.22 to 101.30 ± 0.87 which are very close to 100 indicating the accuracy of the proposed method. Again, low values of statistical parameters (Table-2) validated the proposed method.

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