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Spectrophotometric Estimation of Amoxicillin Trihydrate in Bulk and Pharmaceutical Dosage Form

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Abstract: New simple, sensitive, rapid, reproducible and economical spectrophotometric method have been developed for the determination of amoxicillin trihydrate in pharmaceutical bulk and tablet dosage form using citro phosphate buffer pH 7.2. The system obeys Lambert-Beer's law at 231 nm in the concentration range 2.5-50 µg/m. Molar absorptivity, correlation coefficient and Sandell's sensitivity values were found to be $1.0020 \times 10^4 \text{ mol}^{-1} \text{ cm}^{-1}$, 0.9996 and $0.03906 \text{ µg cm}^{-2}$ respectively. The proposed methods have been successfully applied to the analysis of the bulk drug and its tablet dosage form. The methods have been statistically evaluated and were found to be precise and accurate

Keywords: Spectrophotometric, Estimation, Amoxicillin trihydrate.

Introduction

Amoxicillin trihydrate is chemically (2S, 5R, 6R)-6-[(R)-(-)-2-amino-2-(p-hydroxy phenyl) acetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid trihydrate. It is one of the most widely used semisynthetic penicillins¹ in the treatment of acute bacterial sinusitis and community-acquired pneumonia^{2,3}. It is official in IP, BP, and USP. The official methods of the estimation are calorimetry⁴ and microbiological⁵. Other methods of its estimation including titrimetry⁶, polarography⁷, folrimetry⁸⁻¹¹, HPLC¹², calorimetry¹³⁻²⁰ and spectrophotometry²¹⁻²⁴. In the present investigation we have developed simple, sensitive and reproducible spectrophotometric method for the determination of amoxicillin trihydrate.

Experimental

Instrument

All the spectral and absorbance measurements were made on an ELICO SL-59, UV-VIS spectrophotometer by using 1 cm match quartz cells.

Materials

Amoxicillin trihydrate used in the present investigation is obtained from Tini Pharma Ltd, Renigunta, Tirupati. Disodium hydrogen phosphate and citric acid were purchased from local market.

Methods

An accurately weighed amount of amoxicillin trihydrate equivalent to 100 mg was transferred in to 100 mL volumetric flask. To this 50 mL of citro phosphate buffer pH 7.2 was added, sonicated for 10 minutes, shaken thoroughly for 15 minutes and then made the volume with citro phosphate buffer pH 7.4. Filter and further dilutions were made with citro phosphate buffer pH7.2. A series of standard solutions containing 2.5-50 µg/mL of amoxicillin trihydrate were prepared in citro phosphate buffer pH 7.2 and absorbences were measured at 231 nm against solvent blank. The samples were stored at room temperature and again absorbances were measured after 48 hrs that indicates amoxicillin trihydrate is stable in the citro phosphate buffer pH 7.2.

Estimation of amoxicillin trihydrate in pharmaceutical formulations (Tablets, capsules, suspension and syrup)

An accurately weighed amount of tablets, capsules, suspension and syrup are transferred in to a 50 mL volumetric flask and to this 25 mL of citro phosphate buffer pH 7.2 was added, sonicated for 10 minutes, shaken thoroughly for 15 minutes and then made the volume with citro phosphate buffer pH 7.2. Filter and further dilutions were made with citro phosphate buffer pH 7.2. The absorbances of these solutions were measured at 231 nm against solvent blank.

Results and discussion

Beer's law was obeyed in the concentration of 2.5-50 µg/mL in the proposed method. The optical characteristics are summarized in Table 1.

Table 1. Validation parameters

Parameters	Method
λ max	231 nm
Beer's law limits (µg/mL)	2.5-50 µg/mL
Stability	48 h
Sandell's sensitivity	0.03906
µg/cm ² /0.001 absorbance unit	
Molar extinction coefficient, L mole ⁻¹ cm ⁻¹	1.0020 × 10 ⁴
% Relative standard deviation	0.3360
% Range of error	
0.05 confidence limits	0.2809
0.01 confidence limits	0.4156
Correlation coefficient	0.9996
Regression equation (Y*)	0.0244
Slope (a)	
Intercept (b)	0.0012

$Y^* = b + a C$, where "C" is concentration in µg/mL and Y is absorbance unit.

The effect of different parameters was studied and optimum conditions were included. Sandell's sensitivity of 0.03906 µg/cm²/0.001 absorbance unit showed that the proposed method was quite sensitive. Linear regression of absorbance on concentration gave the equation $Y = 0.0012 + 0.0244 C$ where C is the concentration in µg/mL and Y is the absorbance

at 231 nm with a correlation co-efficient of $r = 0.9996$. This indicates a good linear relation ship. The values obtained for the determination of amoxicillin trihydrate in several pharmaceutical formulations (Tablets, capsules, suspension and syrup) by the proposed method are given in Table 2. To evaluate the validity and reproducibility of the method known amounts of pure drug was added to previously analyzed pharmaceutical preparations and the mixtures analyzed by proposed method and the percent recoveries are given in Table 2. The results showed that the proposed method has reasonable precision and accuracy.

Table 2. Estimation of amoxicillin trihydrate in marketed formulations

Sample	Labeled Amount, mg	Amount obtained, mg	%Recovery by proposed method
Tablet 1	250	249.6	99.84
Tablet 2	250	249.9	99.96
Capsule 1	250	249.1	99.64
Capsule 2	250	249.6	99.84
Suspension 1	125	126.7	101.36
Suspension 2	250	251.1	100.44

Conclusion

The developed method was found to be sensitive, accurate, precise and reproducible and could be used for the routine estimation of amoxicillin trihydrate in bulk and pharmaceutical formulations.

References

1. Canfe K, Atesoglu-Gocmez S, *Boll Chim Farm.*, 2002, **141(6)**, 423.
2. Sinus and Allergy Partner Health Partnership, Antimicrobial treatment guidelines for acute bacterial rhinosinusites, *Otolaryngol Head Neck Surg*, 2000, **123(suppl)**, S32
3. Barlett JG, Mundy LM Community-acquired pneumonia, *N Engl J Med.*, 1995, **333**, 1618.
4. British pharmacopoeia, 1980, Her Majesty's stationary Office London, pp 31-32.
5. The United States Pharmacopoeia, XX, Mark Printing Company, Easton, PA, pp 42-43.
6. Bird A E and Redup CE, *Proc Anal Div Chem Soc.*, 1977, **4(10)**, 285-8.
7. Nunez V, Luis J and Suella S A., *IRCS Med. Sci.*, Libr Compend, 1981, **9(7)**, 649.
8. Puigdelino E, Obiols G and Moreno D, *J Afinidad*, 1973, **30**, 749..
9. Davidson D F, *Clin Chim Acta*, 1976, **69**, 67.
10. Katsumi Miyazaki, Osamu Oginno, Hiroyki, Sato, Mashiro Nckano and Takaichi Arita, *Chemical and Pharmaceutical Bulletin*, 1977, **25**, 253.
11. Barabhaia R H, Turner P and Shaw Elizabeth, *Clin. Chim. Acta*, 1977, **77 (3)**, 373.
12. Brooks M A, Hackman M R and Mazzo D J, *J Chromatogr.*, 1981, **210(3)**, 531.
13. Patel A A, Gandhi T P, Patel P R, Patel M R and Patel V C, *Indian J Pharm Sci.*, 1979, **41(6)**, 229.
14. Rana N G, Dhyani H K, Patel M R and Shah B J, *Indian Drugs*, 1980, **17(5)**, 142.
15. Cisciba A and Orbar H, *Magy Kem Foly*, 1977, **83(11)**, 504.
16. Dubois P, Lacroix J, Lacroix R, Levillain D and Viel C, *J Pharm Belg.*, 1981, **36(3)**, 206.
17. Naik Pradeep N and Emmmanuel J E, *Indian Drugs*, 1983, **21(3)**, 121.
18. Bhatkar R G, Almeida and Lilian, *Indian Drugs*, 1983, **21(2)**, 70.
19. Emmmanuel J E, Shetty and Arun R, *Indian Drugs*, 1983, **2(2)**, 72.
20. Sane R T, Naik V G, Malkar V B, Sapre D S, Nadkarni A D, Pnadit U R and Doshi V J, *Indian Drugs*, 1983, **21(2)**, 76.
21. Mollo A R and Corrigan O I, *J Pharm Biomed Anal*, 2002, **28(6)**, 1205.
22. Salem H and Saleh G A, *J Pharm Biomed Anal.*, 2002, **29(5)**, 859.
23. Nagaralli B S, Seetharamappa J and Melwanki M B, *J Pharm Biomed Anal.*, 1999, **21(3)**, 473.
24. Qureshi S Z, Qayoom T and Helalet M I, *Arch Sci Med (Torino)*, 1982, **139(4)**, 407.