



## INFLUENCE OF STORAGE CONDITIONS ON THE POTENCY OF AMOXICILLIN DISPERSIBLE TABLETS STORED IN HOSPITAL AND COMMUNITY PHARMACIES IN DIFFERENT REGIONS OF KERALA

KIRON S S<sup>1</sup>, ARUN SHIRWAIKAR<sup>2</sup>, SARITHA M<sup>3</sup>

1-Academy of Pharmaceutical Sciences, Pariyaram Medical College, Kannur Kerala, India, 2-Dean College of Pharmacy, Gulf Medical University, Ajman, United Arab Emirates, 3-Crescent College of Pharmacy, Payyangadi, Kannur, Kerala  
Email: drarun@gmu.ac.ae; arunshirwaikar@gmail.com

### ABSTRACT

Stability is defined as the capacity of a drug substance or drug product to remain within established specifications to maintain its identity, strength, quality, and purity throughout the retest or expiration dating periods. Amoxicillin is an analog of ampicillin, derived from basic penicillin nucleus, 6-aminopenicillanic acids. Different brands of Amoxicillin tablets were selected for this study as amoxicillin molecule is highly sensitive to temperature and humidity. Adequate quantities of samples were procured from hospital and community pharmacies located in different regions of Kerala. Samples collected from different time intervals were suitably coded and analyzed for all the listed parameters. It was observed that, there were seasonal fluctuations in the Mean Kinetic Temperature and Mean Kinetic Humidity in the various regions of Kerala. The study data show that percentage strength of amoxicillin was least in samples collected from Cochin (coastal area) compared with those collected from Kozhikode and Kannur. Mean kinetic humidity was more in coastal area, which may have accelerated the degradation of amoxicillin in samples from Cochin. Microbiological data showed significant reduction in zone of inhibition for samples collected from Cochin in comparison with other regions. The study identifies the importance of storage conditions of antibiotics in pharmacies for better pharmaceutical care. Hence the regulatory authorities and pharmaceutical organizations should highlight the importance of maintaining good storage conditions in hospital and community pharmacies functioning in state of Kerala.

**Key words:** Potency, Temperature, Humidity, Various regions.

### INTRODUCTION

Improper storage of the pharmaceutical products is one of the fundamental concerns in patient care. This study emphasizes the importance of proper storage of pharmaceuticals in pharmacy premises till it reaches the consumer. The loss of potency during storage may influence the efficacy and safety of pharmaceuticals. The purpose of this study is to evaluate the influence of storage conditions on the potency of amoxicillin tablets collected from different regions of Kerala.

### MATERIALS AND METHODS

Different brands of Amoxicillin tablets were selected for this study as amoxicillin molecule is highly sensitive to temperature and humidity. Adequate quantities of samples were procured from hospital and community pharmacies located in different regions of Kerala. All the analytical evaluations were done in collaboration with Sterling Test House, Cochin. The analytical work was conducted according to Indian Pharmacopoeia using UV spectrophotometric method. The samples were collected at different time intervals i.e. within six months of the date of manufacturing, after 6 months from date of manufacturing and before 6 months of date of expiry, within 6 months of date of expiry. Samples collected from these intervals were suitably coded and analyzed for all the listed parameters. Dissolution studies of samples were performed using distilled water in USP type II apparatus. The temperature was maintained at  $37 \pm 0.5^\circ\text{C}$  and the rotation speed was 100 rpm. The samples were withdrawn at various time intervals and analyzed UV spectrophotometrically. Microbiological evaluation of test samples at  $10\mu\text{g/ml}$  concentration was performed using E. coli MTCC 443 in nutrient agar medium. The mean kinetic temperature and the mean kinetic humidity from different regions of Kerala were provided by meteorological department, Thiruvananthapuram.

### RESULTS AND DISCUSSION

Stability is the capacity of a drug substance or drug product to remain within established specifications to maintain its identity, strength, quality, and purity throughout the retest or expiration dating periods. Physical, chemical, and microbiological data were

generated as a function of time and storage conditions (e.g., temperature and relative humidity [RH]). Pharmaceutical manufacturers determine a drug's shelf life or expiration date, through stability testing.<sup>1</sup> This type of testing ensures that a drug's potency and integrity are intact over a specific period of time. Drugs can lose their potency long before the expiration date if exposed to oxygen, heat, light, or humidity. There are more than 40 penicillins in clinical practice today and almost all of them follow the same degradation behavior at the beta-lactam moiety. Amoxicillin is a semi-synthetic beta-lactam antibiotic belonging to the group of penicillins. The chemical structure of amoxicillin consists of d-4-hydroxyphenylglycine side chain attached to 6-aminopenicillanic acid moiety.<sup>2</sup> It was observed that, there were seasonal fluctuations in the Mean Kinetic Temperature and Mean Kinetic Humidity in the various regions of Kerala. The climate of Kerala is mainly tropical, with seasonally excessive rainfall and hot summer. As the State stretches from north to south with the Arabian Sea in the west, relative humidity in general is high. From January to March, humidity varies from 35% in the interior to 71 % in the coastal areas of Kerala. The relative humidity during the monsoon period rises to about 85%. March is the hottest month with a mean maximum temperature of about  $33^\circ\text{C}$ . Mean kinetic temperature is minimum in the month of July when the State receives plenty of rainfall with heavily clouded sky.

Stability data of amoxicillin tablets from different regions of Kerala are shown in Table no: 1. Data show that percentage strength of amoxicillin was least in samples collected from Cochin (coastal area) compared with those collected from Kozhikode and Kannur. Mean kinetic humidity was more in coastal area, which may have accelerated the degradation of amoxicillin in samples from Cochin. This influence of humidity was significantly less on samples collected from other centers. Similar issue was reported in a study conducted at chemist retail outlets functioning in Delhi where they highlighted the importance of maintaining facility in retail chemist outlets to control the environmental factors, especially in summer months<sup>3</sup>. Other performance test like disintegration time was within satisfactory limits, although a slight increase in disintegration time was observed in third sample timing. Microbiological data showed significant reduction in zone of inhibition for samples collected from Cochin in comparison with other centers.

**Table: 1 Stability data of AMOXICILLIN 250MG DT from various regions of Kerala**

Sample time	Sample Number	KANNUR [Amt (%)]	KOZHICODE [Amt (%)]	COCHIN [Amt (%)]
FIRST (I)	1	246.43(98.57)	250.37(101.15)	249.22(99.69)
	2	252.68(101.07)	242.89(97.16)	251.56(100.62)
	3	251.42(100.57)	248.63(99.45)	247.23(98.89)
SECOND (II)	1	240.12(96.04)	243.44(97.38)	239.87(95.95)
	2	247.23(98.89)	246.13(98.45)	242.63(97.05)
	3	238.72(95.48)	249.72(99.89)	221.69(88.67)
THIRD (III)	1	212.32(84.93)	186.43(74.57)	185.46(74.18)
	2	220.12(88.05)	195.61(78.24)	188.59(75.44)
	3	193.57(77.42)	219.18(87.67)	180.18(72.07)

1. Within six months of date of manufacturing,
2. After 6 months from date of manufacturing and before 6 months of date of expiry,
3. Within 6 months of date of expiry.

### CONCLUSION

Evaluation made during the study provides significant evidences that the quality of a drug substance or product under the influence of various environmental factors may change with time. Maintaining proper storage conditions at hospital and community pharmacies is essential to reduce such impact caused by environmental factors. The pharmaceutical products were found to retain their potency when stored in pharmacies having good storage facilities. Hence the regulatory authorities and pharmaceutical organizations should highlight the importance of maintaining good storage conditions in hospital and community pharmacies functioning in state of Kerala.

### ACKNOWLEDGEMENT

The authors express their sincere thanks to HOD and staff of Sterling lab, Ernakulum, Pharmacy in-charge of Pariyaram Medical College and Meteorological department, Thiruvananthapuram for providing all facilities and moral support to conduct work. Authors also thank

the Community and Hospital Pharmacies in Kozhikode, Kannur and Ernakulum for their help regarding samples collection

### REFERENCES

1. Ivanovic Ivanaa, Zivanovic Ljiljana and Zecevic Mira. A stability indicating assay method for cefuroxime axetil and its application to analysis of tablets exposed to accelerated stability test conditions. *Journal of Chromatography* 2006; 1119: 209-215.
1. Eric Verdon, Regine Fuselier, Dominique Hurtaud-Pessel, Pierrick Couedor, Nathalie Cadieu, Michel Laurentie. Stability of penicillin antibiotic residues in meat during storage Ampicillin. *Journal of Chromatography* 2000; 882: 135-143.
2. Praveen Khullar, Rajesh Khanna, Naresh Sharma and DB Anantha Narayana. Temperature and Humidity mapping and real time, short term, on site, quality monitoring studies of four pharmaceutical formulations stored in Chemist retail outlets in Delhi. *Pharma Times* July 2008; 40(7): 13-20.