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The HPLC-UV method in the assessment of fluconazole generic quality

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Statement of the Problem: The quality of generic drugs is a problem attracting increasing attention as both market growth and use in patients exceeds that of originals. There is an assumption that the therapeutic efficacy of generics and original drugs is equal. However, recent studies, as well as practicalities, have shown that the efficacy of generics differs drastically from the originals. It has become an issue not only for the health-related quality of life in patients, but also for microbial drug resistance. New methods are needed to ensure the quality, and to compare the efficacy of generics vs original drugs. These methods must be reliable and relatively cheap to keep generic advantages**.**

Purpose: The purpose of this study is to elaborate the HPLC method for elucidation of the quality of fluconazole drug products and to compare available generics of fluconazole.

Methodology & Theoretical Orientation: Ten generics of fluconazole derived from the Russian market were analyzed by HPLC with UV detector. The optimal conditions for HPLC-UV were developed followed by Assay method for fluconazole and standard deviation was calculated. The dispersion of the Assay data for 150 mg was: from 116.69 to 151.53 and for 50 mg: from 38.09 to 49.74 mg. The results demonstrated that only one out of ten generics appeared to be of pharmacopoeia quality.

Conclusion & Significance: The current study underlines the importance of using the HPLC-UV method to assess fluconazole, and will contribute to the knowledge base regarding assessment methods. Further research is needed to compare the efficacy of generics and original drugs on other criteria.

Recent Publications

1. Macquart de Terline D, Diol B I, Bernard M, Do B, Ikama MS (2017) substandard drugs among five common antihypertensive generic medications: an analysis from 10 African countries. Doi: 10.1097/HJH.0000000000001560.
2. Al Tabakha M M, Fahelelbom K M S, Obaid D E E, Sayed S (2017) Quality attributes and *in vitro* bioequivalence of different brands of amoxicillin trihydrate tablets. Pharmaceutics. 20:9(2). Doi: 10.3390/pharmaceutics9020018.
3. Manani R O, Ajuga K O, Chepkwony H K (2017) Pharmaceutical Equivalence of Clarithromycin Oral Dosage Forms Marketed in Nairobi County, Kenya. Sci Pharm. 26:85(2). Doi: 10.3390/scipharm85020020.
4. Bate R, Mathur A, Lever H M, Thakur D, Graedon J (2016) Generics substitution, bioequivalence standards, and international oversight: complex issues facing the FDA. Trends Pharmacol. Sci. 37(3):184-191. Doi: 10.1016/j.tips.2015.11.005.
5. Tattevin P, Crémieux A C, Rabaud C, Gauzit R (2014) Efficacy and quality of antibacterial generic products approved for human use: A systematic review. Clin Infect Dis. 58(4):458-469. Doi: 10.1093/cid/cit769.

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