International Conference on **Toxicology and Clinical Pharmacology** &

2nd International Conference on

CO-ORGANIZED EVENT

Generic Drugs and Biosimilars

December 14-16, 2017 Rome, Italy

In-vitro determination of antimycotic activity of the fluconazole generics on Russian pharmaceutical market

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Statement of the Problem: The quality of drugs is regulated by the health authorities of the marketed countries and theoretically all the drugs on the market must meet the criteria of efficacy and safety. However, an issue of the quality of registered generics has arisen as generics imply deviations in parameters of bioequivalence by its definition. Fluconazole was selected as a target for elucidation of the generic quality on the Russian market for several reasons: The originator, Diflucan (by Pfizer), is an old product for RU market and is available in different forms and dosages with either Rx or OTC status. Thus, plenty of generics of foreign and domestic manufacturers exist and another reason is that it possesses antimicrobial activity that can be utilized along with the HPLC-UV Assay methods. The task of this study is to measure in-vitro antimicrobial activity of the Fluconazole generics derived from RU market and to check the consistency of the data with HPLC-UV Assay results.

Methodology & Theoretical Orientation: In this comparison study, the activity of 10 generics of fluconazole against C. albicans were measured. Overnight culture of C. albicans strain 927 from Mechnicov institute was cultivated on synthetic media (1) with adjusted pH, followed by the method of microdilutions. The plates were incubated at 30°C for 22 hours and the activity of fluconazole generics were measured by MIC.

Conclusion & Significance: The current study underlines the importance of using complex methods for generic quality determination. In-vitro activity of 10 fluconazole generics was measured and the results are confirmed by the HPLC-UV Assay method. Minimal dosing error by HPLC-UV corresponds to the maximal in-vitro antimycotic activity.

Recent Publications

- Macquart de Terline D, Diop BI, Bernard M, Do B, Ikama MS, N'guetta R, Balde DM, Tchabi Y, Sidi Aly A, Ali Toure I, 1. Zabsonre P, Damorou JF, Takombe JL, Narayanan K, Fernandez C, Tafflet M, Plouin PF, Empana JP, Marijon E, Jouven X, Antignac M. Substandard drugs among five common antihypertensive generic medications: an analysis from 10 African countries.
- 2. Al-Tabakha MM, Fahelelbom KMS, Obaid DEE and Sayed S (2017) Quality Attributes and In Vitro Bioequivalence of Different Brands of Amoxicillin Trihydrate Tablets. Pharmaceutics. 9 (2).
- Manani R O, Abuga K O and Chepkwony H K (2017) Pharmaceutical Equivalence of Clarithromycin Oral Dosage 3. Forms Marketed in Nairobi County, Kenya. Sci Pharm. 85 (2).
- Bate R, Mathur A, Lever H M, Thakur D, Graedon J, Cooperman T, Mason P, Fox E R (2016) Generics Substitution, 4. Bioequivalence Standards, and International Oversight: Complex Issues Facing the FDA. Trends Pharmacol Sci. 37 (3): 184-91.
- Tattevin P, Crémieux A C, Rabaud C and Gauzit R (2014) Efficacy and quality of antibacterial generic products 5. approved for human use: a systematic review. Clin Infect Dis. Epub. doi: 10.1093/cid/cit769.

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