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Formulation Development of Immediate Release Tablets Containing Fluoroquinolone Antibiotic by use of Experimental Design

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The aim of this research is to prepare Moxifloxacin hydrochloride immediate release tablets by wet granulation using experimental design technique. Moxifloxacin is a fourth-generation fluoroguinolone that has been shown to be effective against Gram-positive, Gram-negative, and atypical strains, as well as multi-drug resistant Streptococcus pneumoniae. [1] Optimization has proven as an effective tool in product development. The purpose of carrying out optimization is to select the best possible formulation from pharmaceutical as well as consumer point of view. High dose drug that experience poor flow and poor compactibility was granulated to obtain suitable flow and cohesion for compaction. The selection of suitable filler and binder in the formulation of immediate release tablets and granulate residual moisture are very important because they affect physical parameters and in-vitro release profile. [2] The experimental design 2³⁻¹ was applied with following independent variables: filler type (X_1) , binder type (X_2) , granulate residual moisture (X_3) . Weight variation, thickness, hardness, friability, disintegration time and drug release after 15 minutes were examined as dependent variables. [2] Different fillers examined were Mannitol and Cellulose microcrystalline. Different binders examined were and Povidone. The tablets Maltodextrin prepared using Cellulose microcrystalline as a filler and Povidone as a binder in optimized formulation showed the best comparable results for physical parameters. In-vitro release profiles were tested in 900ml 0.1 M HCl, at 37 ± 0.5°C, in USP paddle apparatus with stirring rate of 50 rpm. Percent of drug released was determined by UV/VIS spectrophotometric method. Taking into consideration the fact that more than 85 % of the drug is released from product and optimized formulation within 15 minutes, in-vitro release profiles are considered similar without further mathematical evaluation. Analysis of the obtained results showed that the binder type (X_2) and granulate residual moisture (X_3) have significant influence on response parameters. The other independent variable, filler type (X_1) does not have significant influence.

- [1] Miravitlles M, Anzueto A. Moxifloxacin: a respiratory fluoroquinolone. Expert Opin Pharmacother. 2008; 10:1755–1772. doi:10.1517/14656566.9.10.1755
- [2] Blaisdell P, Frank M, Busse W D, Chien N C, Dogramatzis D, Raeder M, Rodman L E, Dahl T, Pemberton M, Scannon P J, Bristol D R, Burton S, James R, Sidebittom C, Twenty-First Century Pharmaceutical Development, 1st edition. Englewood, Interpharm Press, 2001.