



Development of Clozapine Tablets by Direct Compression - Analysis of Pharmaceutical Equivalence by Dissolution Profiles

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SUMMARY. The aim of this work was to develop clozapine tablets that can be classified as a pharmaceutical equivalent to a reference brand product. Tablets were produced by direct compression and dissolution tests were realized in order to evaluate the dissolution profiles. The results show that the tablets can be classified as immediate release dosage forms due to clozapine fast release, and such release was dependent on the amount of sodium croscarmellose in the formulation. Analysis of f1 and f2 factors was frustrated due to the fast drug release; the tablets were analyzed by the dissolution efficiency and the dissolution curve shape. The dissolution efficiency was higher than 98 % and the analysis of the dissolution shape curve showed that the tablets from one batch of the developed formulations were similar to the reference brand product. The clozapine tablets obtained in this study can be considered as pharmaceutically equivalent to the reference brand product.

KEY WORDS: Clozapine, Dissolution profiles, Pharmaceutical equivalence.

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