CLUSTER ANALYSIS TECHNIQUES FOR TESTING "SIMILARITY" OF DRUG DISSOLUTION PROFILES

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A new approach for testing "similarity" through comparison of drug dissolution profiles, based on multivariate data analysis is presented. The dissolution curve corresponding to three brands of Oxicame tablets were prepared by dissolution measurements at multiple pre-specified time points. Reference and test data were simultaneously subjected to cluster analysis and comparisons between the dissolution characteristics of different lots were carried out. All the results were compared with information provided by the difference (f_1) and similarity (f_2) factor tests. Unlike the f_2 criterion, the proposed methods reflect variability within the individual dissolution curves, being also highly sensitive to profile variations.

Keywords: multivariate data analysis, drug dissolution profiles, Oxicame.

1. Introduction

In vitro dissolution test has been recognized as an important parameter of tablets' quality and, because its correlation with drug bioavailability, under strictly defined conditions, as a surrogate of *in vivo* studies for the assessment of product bioequivalence. Because it is essential to investigate the drug release characteristics of pharmaceutical preparation, dissolution has become highly significant and one of the primary pharmacopoeial tests that is performed to ensure that tablets, capsule and other drug products comply with the pre-established quality standards.

In response to the need of assessing "similarity", numerous strategies have been proposed for comparing dissolution profiles (see, for example, O'Hara *et al.*, 2008, for a review of them). FDA Guidance for Industry and the European regulatory bodies recommend the difference (f_1) and similarity (f_2)

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