Saudi Pharmaceutical Journal (2014) **22**, 391–402

King Saud University

Saudi Pharmaceutical Journal

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REVIEW

Study on requirements of bioequivalence for registration of pharmaceutical products in USA, Europe and Canada

Upendra C. Galgatte *, Vijay R. Jamdade, Pravin P. Aute, Pravin D. Chaudhari

PES Modern College of Pharmacy, Sector No. 21, Yamunanagar, Nigdi, Pune-411044, Maharashtra, India

Received 14 April 2013; accepted 17 May 2013
Available online 31 May 2013

KEYWORDS

Bioavailability;
Bioequivalence;
Pharmacokinetics

Abstract The present study was aimed to study the requirements of bioequivalence for the registration of pharmaceutical products in the USA, Europe and Canada. Before going into bioequivalence studies it is essential for the pharmaceutical industry to study the guidelines of bioequivalence for the respective country where the industry wants to market its products and thus enter into generic market. This study reviews the requirements of bioequivalence with study parameters such as study design, fasting or fed state studies, volunteers recruitment, study dose, sampling points, analytical method validation parameters, moieties to be measured in plasma, pharmacokinetic parameters, criteria for bioequivalence, GCP requirements etc, which are needed for the pharmaceutical industry to carry out bioequivalence studies and to file ANDA. Test products and reference products are needed for this study. Test products are usually manufactured by a sponsor and reference products are provided by the government laboratories of the respective countries. Sampling points also vary with respect to the regulatory guidelines of these countries. All these countries follow ICH GCP guidelines. The criterion of bioequivalence for these countries is 90% CI 80–125% for C_{max}, AUC_t, $AUC_{0-\infty}$.

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Contents

* Corresponding author. Tel.: +91 (20) 27661315/14, mobile: +91 9890755938; fax: +91 (20) 27661314.
E-mail address: ucgpharm@rediffmail.com (U.C. Galgatte).

Peer review under responsibility of King Saud University.

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http://dx.doi.org/10.1016/j.jsps.2013.05.001

1. Introduction

The concepts of bioavailability (BA) and bioequivalence (BE) have gained considerable importance during the last three decades because of their application to new brand-name drugs, as well as to generic drugs. During this period, regulatory authorities also started developing and formulating the regulatory requirements for the approval of generic drug products. Consequently, tremendous advances have been made in the application of assessment approaches to these scientific concepts. BA and BE have become the cornerstones for the approval of brand-name and generic drugs globally and have been utilized for brand-name drugs to reduce the cost of development. It is encouraging to know that there are continuing efforts by regulatory authorities and the scientific community, both nationally and internationally, to understand and develop more efficient and scientifically valid approaches to the assessment of BE of various dosage forms including some of the tough complex special dosage forms. Because of the importance of generic drugs in healthcare, it is imperative that the pharmaceutical quality and *in vivo* performance of generic drugs be reliably assessed (Midha and McKay, 2009). Because generic drugs would be interchanged with innovator products in the market place, it must be demonstrated that the safety

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