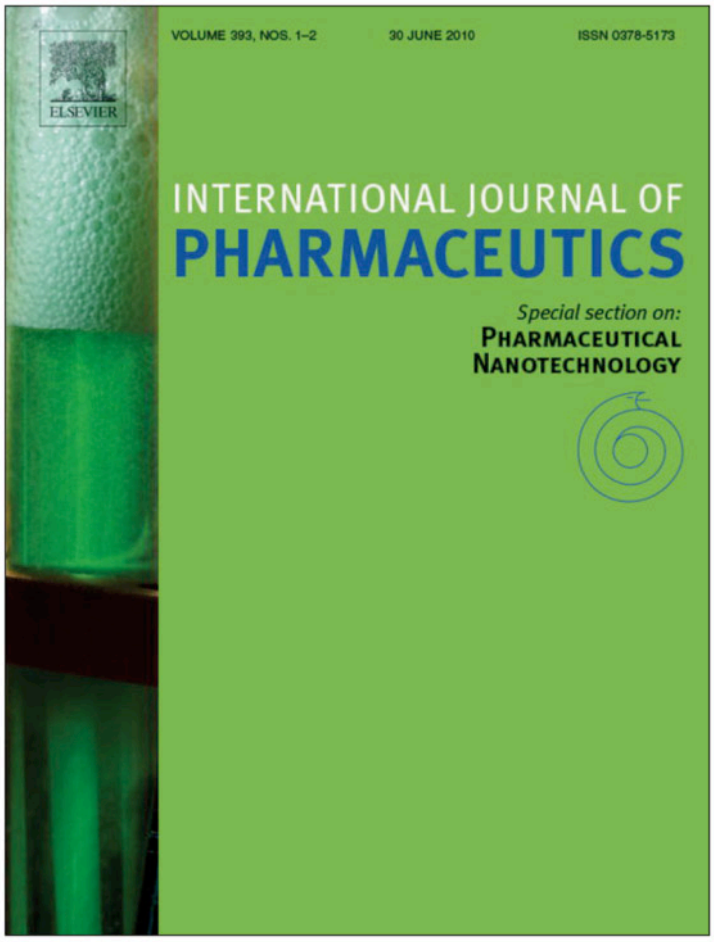
Provided for non-commercial research and education use.
Not for reproduction, distribution or commercial use.



This article appeared in a journal published by Elsevier. The attached copy is furnished to the author for internal non-commercial research and education use, including for instruction at the authors institution and sharing with colleagues.

Other uses, including reproduction and distribution, or selling or licensing copies, or posting to personal, institutional or third party websites are prohibited.

In most cases authors are permitted to post their version of the article (e.g. in Word or Tex form) to their personal website or institutional repository. Authors requiring further information regarding Elsevier's archiving and manuscript policies are encouraged to visit:

http://www.elsevier.com/copyright

Author's personal copy

International Journal of Pharmaceutics 393 (2010) 55–60

Contents lists available at ScienceDirect

International Journal of Pharmaceutics

journal homepage: www.elsevier.com/locate/ijpharm

Rapidfilm®: An innovative pharmaceutical form designed to improve patient compliance

Valentina Reiner[a], Nadia Giarratana[a,*], Nunzia Ceppi Monti[a], Armin Breitenbach[b], Peter Klaffenbach[b]

[a] APR Applied Pharma Research SA, via Corti 5, CH-6828 Balerna, Switzerland
[b] Labtec GmbH, A tesa Company, Raiffeisenstrasse 4, D-40764 Langenfeld, Germany

ARTICLE INFO

Article history:
Received 13 January 2010
Received in revised form 22 March 2010
Accepted 27 March 2010
Available online 2 April 2010

Keywords:
Ondansetron
Orally disintegrating tablet (ODT)
Orodispersible tablet
Bioequivalence
Orodispersible film
Delivery system

ABSTRACT

The aim of the research was to assess the bioequivalence between Rapidfilm®, a new patented delivery system, versus the traditional orodispersible tablet (ODT).

A randomized, two-way, single dose, crossover, bioequivalence study was conducted in 24 fasting, healthy volunteers with two formulations of ondansetron (Ondansetron Rapidfilm® vs. Zofran® Zydis® Lingual ODT by GlaxoSmithKline GmbH & Co. KG).

Plasma samples were analysed by a validated LC–MS/MS method during a collection period of 24 h post-dosing. The analysis of variance (ANOVA) on the targeted pharmacokinetic parameters did not show any significant difference between the two formulations and 90% confidence intervals (CIs) fell within the common acceptance range of 80–125%, satisfying the bioequivalence criteria. These results allow Rapidfilm® to claim the same panel of indications of the conventional immediate release oral solid dosage forms, but offering several advantages also over the ODT: it can result in higher patient convenience for several applications.

© 2010 Elsevier B.V. All rights reserved.

The full article is available on request.