Abstract

The objectives of this study were to develop the formulation of valsartan to improve dissolution profile using central composite design. Valsartan is a anti-hypertensive oral dosage form used for treatment hypertension and myocardial infarction. It is a poorly soluble drug with low dissolution rate. In this study 20 different formulations of valsartan were prepared by varied amount of PEG-600, PG, and PEG-400, with other excipients as per the central composite design protocol. Central composite design was used to choose the optimize condition with improved dissolution profile. The optimum formulation was F-5 which was containing PEG-400, PG and PEG-600 in a ratio of 25:25:60. The physical properties of different formulations like uniformity, the angle of repose, Carr’s Index, weight variation, appearance and drug release were in the acceptable range.

The rate of release valsartan from formulation F-5 was more than 72% after 2 hours, while the formulation F-7 showed only 35% of drug release. Formulation F-5 was further improved by the addition of KHCO₃ (2.5 w/w %), which release 86% valsartan in comparison to marketed formulation Diovan (96%). Fourier transforms infrared spectroscopy (FT-IR) and HPLC indicate that there was no interaction between the valsartan and the excipients used. No adduct formation or degraded products were observed using HPLC. The stability studies were carried out as per the ICH guidelines. The formulations were stable during the study period and having shelf life more than 3.5 years. Finally it can be concluded that developed formulation of valsartan is stable and can be further improved for routine purpose on the basis of current data.

Formulation and Development of Valsartan as an Oral Dosage Form (Capsule)

By
Obaida Amer Imran
Supervisor
Dr. Ashok K. Shakya

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Deanship of Postgraduate Studies and Scientific Research
Al-Ahliyya Amman University
Jordan
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Author(s): Imran Obaida, Amer (Aut) Shakya Ashokk (Supervisor)
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