Amlodipine Besylate-Excipients Interaction in Solid Dosage Form. Abdoh, A.; Al-Omari, M. M.; Badwan, A. A.; Jaber, A. M. Y.. The Jordanian Pharmaceutical Manufacturing Co., Naor, Jordan. Pharmaceutical Development and Technology (2004), 9(1), 15-24. Publisher: Marcel Dekker, Inc., CODEN: PDTEFS ISSN: 1083-7450. Journal written in English. CAN 141:248467 AN 2004:114612 CAPLUS (Copyright (C) 2008 ACS on SciFinder (R))

Abstract

This article studies the compatibility of amlodipine besylate in its solid formulations with various drug excipients. The various factors affecting amlodipine besylate stability were studied using high-performance liq. chromatog. (HPLC). It has been found that binary 1:1 mixts. of amlodipine besylate and an excipient are stable at 65° and 40°/75% RH. Further investigations were conducted to study the stability of amlodipine besylate in multicomponent mixts., including mixts. with actual formulations. The study reveals that mixts. of lactose, magnesium stearate, and water induce some instability on amlodipine besylate. The major degrdn. product confirmed by HPLC-mass spectrometry is amlodipine besylate glycosyl. This is in conformity with the well-known Maillard reaction between primary amines and lactose. Thus, lactose-free amlodipine formulations are recommended from the safety, quality, efficacy, and process cost points of view.