

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. Journal code: 9610932. ISSN:1083-7450. Journal; Article; (JOURNAL ARTICLE); (RESEARCH SUPPORT, NON-U.S. GOV'T) written in English. PubMed ID 15000463 AN 2004110264 MEDLINE (Copyright (C) 2008 U.S. National Library of Medicine 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 liquid chromatography (HPLC). It has been found that binary 1:1 mixtures of amlodipine besylate and an excipient are stable at 65 degrees C and 40 degrees C/75% RH. Further investigations were conducted to study the stability of amlodipine besylate in multicomponent mixtures, including mixtures with actual formulations. The study reveals that mixtures of lactose, magnesium stearate, and water induce some instability on amlodipine besylate. The major degradation 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.