Use of Forced Degradation Studies on S-(−)-Amlodipine Besylate to Generate Information on the Degradation Products

Š. Hadžidedić ¹, A. Uzunović ¹, S. Pilipović ¹, S. Kocova El-Arino ²

¹ Agency for Medicinal Products and Medical Devices of B&H, 71000 Sarajevo, Bosnia and Herzegovina
² National Research Centre, Tahrir Street, Cairo, Egypt

E-mail: s.hadzidedic@alims.gov.ba (Š. Hadžidedić)

Amlodipine is a long-acting calcium channel blocker used in the treatment of hypertension and angina pectoris. S-(−)-amlodipine besylate is a safer and longer-acting alternative to the existing racemate [1]. Although several products based on the active enantiomer have reached the market, information on its chemical, physical and thermal stability during storage is lacking [2, 3]. The objective of the present study was to evaluate the critical properties of the S-enantiomer and to obtain information on the degradation pathways during storage of the bulk drug. The degradation products formed upon subjecting S-(−)-amlodipine besylate to different conditions (hydrolysis, oxidation, high and low pH, dry heat and photolysis) were resolved on a Lichrospher RP-18 column using 237 nm as detection wavelength [4, 5]. A good understanding of the chemical and physical stability of the drug was gained based on the results of the forced degradation study.

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