Conference abstract PPAT10

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

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Sci Pharm. 2010; 78: 699

doi:10.3797/scipharm.cespt.8.PPAT10

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.

Acknowledgements: This work was supported by ALIMS B&H.

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