

Title: MS/MS AND HPLC CHARACTERIZATION OF FORCED DEGRADATION PRODUCTS OF CLOPIDOGREL AND PANTOPRAZOLE SODIUM

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Abstract:

A new simple and sensitive reverse phase high performance liquid chromatographic method was developed for simultaneous estimation of Clopidogrel and Pantoprazole Sodium following forced degradation studies as per ICH guidelines. The degradation products were observed in acid and alkaline hydrolysis for Clopidogrel; whereas Pantoprazole Sodium showed degradation on exposure to light. All the degradants were separated by preparative thin layer chromatography and subjected to structural elucidation by mass spectrometry using electron spray ionization technique. The base peak of CLP with m/z of 532.7 was formed in positive ESI mode. The daughter ion of CLP was observed at m/z of 451.4. Two degradants with m/z of 536.1 and m/z of 597.0 were formed by acid hydrolysis to give a carboxylic acid derivative and another by dehydrogenation respectively. Degradation product with m/z of 583.1 was di-sodium adduct of CLP and was formed only in alkaline hydrolytic condition. The base peak of photo degradant of PAN with m/z of 493.1 was formed in positive ESI mode showed same m/z value of the base peak of PAN. This indicated that under photolytic degradation only structural modification occurred in PAN molecule. The mechanisms for the formation of degradation products for CLP and PAN are presented in the paper. A linear gradient mode of elution was used for separation of CLP, PAN and their degradants on a Hi Q Sil C18HS column using a UV detector. The developed method was validated and used for the analysis of marketed tablets of CLP and PAN in combination.

Biography:

Dr. Jinesh Bahubali Nagavi has completed his PhD in Analytical Chemistry at JSS University. He has worked as an Instructor and Lecturer at RAK Medical and Health Sciences University, UAE. He has published more than 11 papers in reputed journals, presented his research work in more than 10 International & national conferences. He has been serving as an Assistant Professor of Pharmaceutical Chemistry at Sarada Vilas College of Pharmacy, RGUHS, Karnataka, India. Dr. Jinesh has special interest in bioanalytical method development and validation, pre-clinical trials and clinical research.

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