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Enantiomeric Separation and Determination of Stereospecific Drug Release from Marketed Racemic Omeprazole Products by Chiral HPLC

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SUMMARY. The objective of carrying out this research work was to investigate the effect of chirality on stereospecific dissolution of omeprazole enantiomers from various marketed racemic omeprazole products. Omeprazole is used for the treatment of gastro-duodenal ulcers and symptomatic gastro-oesophageal reflux. Dissolution of various marketed products was performed using USP type I apparatus in 0.1 N HCl for 2 h and in pH 6.8 phosphate buffer for 1 h at 100 rpm. The separation of enantiomers was done using a chiral HPLC method on CHIRAL AGP column (100 x 4.6 mm i.d.). The wavelength for UV detection was set at 210 nm. The mobile phase was 10 mM phosphate buffer with 5 % acetonitrile adjusted to pH 6.5 at a flow rate of 0.9 ml min-1 with an injector valve fitted to a 50 μ L volume sample loop. The retention times for R and S enantiomers of omeprazole were 5 and 7.5 min, respectively. The dissolution of S enantiomer of Ocid-20 and Omee was found to be significantly more compared to their R enantiomer at 5 and 10 min dissolution time points after which there was no stereospecific discrimination in the dissolution. From the S/R ratios of different racemic omeprazole marketed products it was concluded that at 5 and 10 min dissolution time points there was a stereospecific drug release between the S and R enantiomers with the brands Ocid-20 and Omee (p < 0.05) but no stereospecificity was observed with Omez-20 (p > 0.05).

KEY WORDS: Chirality, Chiral separation, Enantiomers, Omeprazole, Stereospecificity.

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