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Study of Forced Degradation Behaviour of Eprosartan Mesylate and Development of Validated Stability Indicating Assay Method by UPLC

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SUMMARY*. The present research work describes comprehensive stress testing of eprosartan mesylate (EM) according to ICH guideline Q1A (R2), and development of a stability-indicating reversed phase ultra performance liquid chromatographic (UPLC) assay. The drug was subjected to acid (0.5N HCl), neutral and alkaline (0.5 N NaOH) hydrolytic conditions at 80 °C, and to oxidative decomposition at room temperature. Photolysis was carried out by exposing the drug during the day time to sunlight (60,000–70,000 lux) for two days and oxidative study was performed with 0.5 mg/ml in 30 % hydrogen peroxide (H_2O_2) at room temperature for 25 hr. The solid drug was also subjected to 50 °C for 30 days in a hot air oven. Degradation of the drug was found to occur under alkaline, acidic and neutral hydrolytic conditions. Separation of the drug and the degradation products was successfully achieved on a BEH (bridged ethylene hybrid) C18 column (1.7 μm, 2.1 mm × 150 mm) with gradient elution of water–acetonitrile as mobile phase. The flow rate and detection wavelength were 0.1 ml/min and 232 nm, respectively. The method was validated and the response was found to be linear in the drug concentration range 5–25 μg/ml ($r^2 = 0.999$). The %RSD in intra-day and inter-day precision studies was < 0.8 %. Recovery of the drug from a mixture of degradation products was between 98.3 and 99.8 %. The LOD and LOQ of developed method were obtained at 0.15 μg/ml and 0.45 μg/ml respectively. The method was specific to the drug, selective to degradation products, and robust. PDA purity test also confirmed the specificity of the method.

KEY WORDS: Eprosartan mesylate, Stress testing, Stability indicating assay, Validation, UPLC.

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