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Bindaiya S, Argal A. Stability indicating assay of orlistat and its degradation products by HPLC. *Bull. Pharm. Res.* 2013;3(2):44-50.

Abstract: A simple, selective, rapid, precise and economical RP-HPLC stability-indicating method has been developed and validated for the quantitative estimation of orlistat (API) and their degradation products. Chromatographic separation was accomplished using C18 column with mobile phase consisting of acetonitrile:0.1% formic acid (85:15, *v/v*), flow rate was 1.0 ml/min and the detection wavelength was 215 nm. The method was validated for linearity, accuracy, precision, specificity and robustness. The API was subjected to stress condition of acid decomposition (0.1 N HCl refluxed for 8 h at 80°C), alkali decomposition (0.1 N NaOH refluxed for 8 h at 80°C), neutral hydrolysis (Distilled water refluxed for 12 h at 80°C), oxidative decomposition (3% H_2O_2 for 24 h at RT), thermal decomposition (Drug at 100°C for 24 h), photolytic decomposition (70,000-80,000 lux at 7 days). Percentage assay of degraded products were acid (13.37), alkali (9.23), neutral hydrolysis (1.44), oxidative decomposition (5.04) respectively and there is no degradation in thermal and photolytic decomposition was found in degradation studies. Forced degradation study showed that orlistat is a labile in acid, alkali, neutral and oxidative conditions. It is stable to light and dry heat. No interference of degradation products was found at the RT of principle peak. The assay recommended for analysis of the API and degradation products in stability samples. It may be applied to a routine analysis in industries.

Key words: Antiurolithiatic activity, Polyherbal formulation, ABP, Glycolic acid.

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