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RESEARCH ARTICLE

STABILITY INDICATING ASSAY OF ORLISTAT AND ITS DEGRADATION PRODUCTS BY HPLC

Shailendra Bindaiya[1]* and Ameeta Argal[2]

[1]*Research Scholar, Institute of Pharmaceutical Science and Research Center, Bhagwant University, Sikar Road, Ajmer-305 004, Rajasthan, India*
[2]*Department of Pharmaceutical Chemistry, Rajeev Gandhi College of Pharmacy, Kolar Road, Bhopal-462 042, Madhya Pradesh, India*

**E-mails*: sb_pharmatech@yahoo.co.in, ameetaargal@yahoo.com
Tel.: +91 9301112620, +91 9926905557.

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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 of degraded products were 13.37, 9.23, 1.44 and 5.04 for acid, alkali, neutral hydrolysis and oxidative decomposition respectively. No degradation was observed in thermal and photolytic conditions. Forced degradation study showed that orlistat is 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 retention time of principal peak. The assay can be recommended for analysis of the API and degradation products in stability samples. It may be applied to a routine analysis in industries.

Key words: Orlistat, RP-HPLC, Stability indicating assay, Degradation, Method validation.

INTRODUCTION

The ICH guideline Q1A on stability testing of new drug substances and products (ICH, 1993) emphasizes that the testing of those features which are susceptible to change during storage and are likely to influence quality, safety and/or efficacy must be done by validated stability-indicating testing methods. The ICH guideline Q3B entitled 'Impurities in new drug products' emphasizes on providing documented evidence that analytical procedures are validated and suitable for the detection and quantitation of degradation products (ICH, 1996). The ICH guideline Q6A, which provides note for guidance on specifications (ICH, 1999), also mentions the requirement of stability-indicating assays under universal tests/criteria for both drug substances and drug products. The same is also a requirement in the guideline Q5C on stability testing of biotechnological/biological products (ICH, 1995) since there is no single assay or parameter that profiles the stability characteristics of such products. The standard conditions for photo stability testing are described in ICH Q1A (ICH, 2003). The objective of the analytical procedure should be clearly understood since this will govern the validation characteristics, which need to be evaluated.