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A validated stability indicating high performance liquid chromatographic method for Olanzapine (Article)

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Abstract

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The present study describes the development and validation of isocratic stability indicating reversed phase high performance liquid chromatographic (HPLC) method for olanzapine (OLZ). An Alltima Cyano (250.0 × 4.6 mm, 5 µm) column and acetate buffer (pH 4.5) and acetonitrile (40:60 v/v) as a mobile phase were used. The detection was carried out at the wavelength of 254 nm. OLZ was subjected to various stress conditions. Degradation was observed for OLZ in acid, base, oxidative, heat conditions and stable in other stress conditions. The proposed method could able to separate OLZ from the known impurity and degradation products. The developed method was validated as per ICH guideline Q2(R1). The specificity of the method proved from forced degradation studies as the stability indicating power of the method. The developed HPLC method can be used in quality control and stability sample analysis of OLZ.

SciVal Topic Prominence

Topic: Clozapine | Antipsychotic Agents | therapeutic drug

Prominence percentile: 81.905

Reaxys Database Information

View Compounds

Author keywords

Forced degradation | Liquid chromatography | Olanzapine | Stability indicating

Indexed keywords

EMTREE drug terms: olanzapine

EMTREE medical terms: analytical parameters | Article | drug selectivity | drug solubility | drug specificity | drug stability | forced degradation study | high performance liquid chromatography | human | limit of detection | limit of quantitation | linearity | measurement accuracy | measurement precision | mental disease | quality control | schizophrenia | validation process

Chemicals and CAS Registry Numbers:

olanzapine, 132539-06-1

Drug tradename:

zyprax

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Q1A (R2)

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Q1B

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