Impurity Profiling and Characterization of Degradation product of Drug Favipiravir by Hyphenated Techniques

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Abstract

Background: Impurity profiling and characterization of degradation products are critical components of pharmaceutical development to ensure the quality, safety, efficacy, and stability of drug substances. Regulatory guidelines such as ICH Q1A(R2) and Q3A/Q3B emphasize the identification and characterization of degradation products formed during manufacturing and storage.

Objective: The present study aimed to develop a stability-indicating RP-HPLC method for Favipiravir and to isolate and characterize its major degradation product using hyphenated analytical techniques.

Methods: A validated RP-HPLC method was developed using a C18 column with 15 mM ammonium acetate and acetonitrile (80:20, v/v) as the mobile phase. Forced degradation studies were performed under acidic, alkaline, oxidative, photolytic, and thermal stress conditions according to ICH guidelines. The major degradation product formed under acidic conditions was isolated by preparative HPLC and characterized using UV–Visible spectroscopy, FTIR, LC–MS, LC–MS/MS, and ˆ1H-NMR spectroscopy.

Results: Favipiravir exhibited significant degradation under acidic conditions, producing one major degradation product. Spectral characterization revealed a molecular ion peak at m/z 137 ([M+H]ˆ+), along with characteristic FTIR, UV, and NMR signals consistent with **p-toluic acid**. The combined analytical data confirmed the identity of the isolated degradation product.

Conclusion: The developed RP-HPLC method proved to be accurate, precise, and stability indicating for Favipiravir. Integration of preparative HPLC with hyphenated analytical Techniques enable successful isolation and structural characterization of major degradation product as **p-toluic acid**. The findings contribute valuable information to impurity profiling, stability assessment, regulatory compliance, and pharmaceutical quality control while expanding the impurity database for Favipiravir.

Keywords

Impurity Profiling, Degradation product, Favipiravir, Hyphenated techniques.