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(57) Abstract :
A Quality by Design (QbD)-aided stability-indicating method was developed for quantifying Sonidegib and its process-related impurities in the bulk drug substance using Ultra Performance Liquid Chromatography (UPLC). The method employed AutoChrom and Design Expert software for predicting physicochemical properties, generating ionization graphs, and establishing the Analytical Target Profile (ATP). Sonidegib was subjected to forced degradation under various conditions, including oxidative, hydrolytic, thermal, and photolytic stress. All degradation products and impurities were effectively separated using an Acquity Ethylene Bridged Hybrid C18 column with gradient elution and a mobile phase containing ammonium acetate buffer and a mixture of acetonitrile and methanol. The developed method demonstrated high reliability for quantifying Sonidegib and related impurities, ensuring compliance with regulatory guidelines.

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