Drug Physicochemical Properties

Determination of Chemical Stability

Determination of physicochemical properties is one of the first stages in non-clinical drug discovery and development. In these sense, it is important to test drug stability under physiological conditions, such as stomach and intestine pH, which may affect drug`s pharmacokinetic and pharmacodynamic.

Test System: Aqueous solution in pH 2.2 and 6.8

Reference Item: Upon request

Experimental number: Triplicate

Main read-outs: Test item quantification by UHPLC-MS

PS: Prior to the evaluation of chemical stability, the development and validation of the analytical method for the test item are indispensable prerequisites.

Validation Data

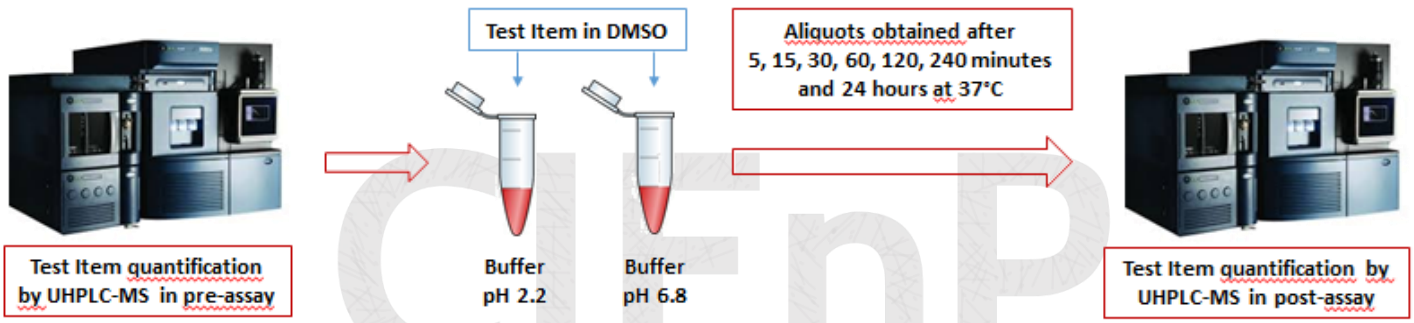

Figure 1. Experimental protocol for chemical stability determination. Firstly, the Test Item is prepared in DMSO and quantified by UHPLC-MS in pre test. After the Test Item is prepared in DMSO and after is diluted in buffer pH 2.2 and 6.8. The Test Item is incubated at 37°C and aliquots are obtained after 0.083, 0.25, 0.5, 1, 2, 4 and 24 hours for quantification by UHPLC-MS in post test. Analysis is performed in triplicate.

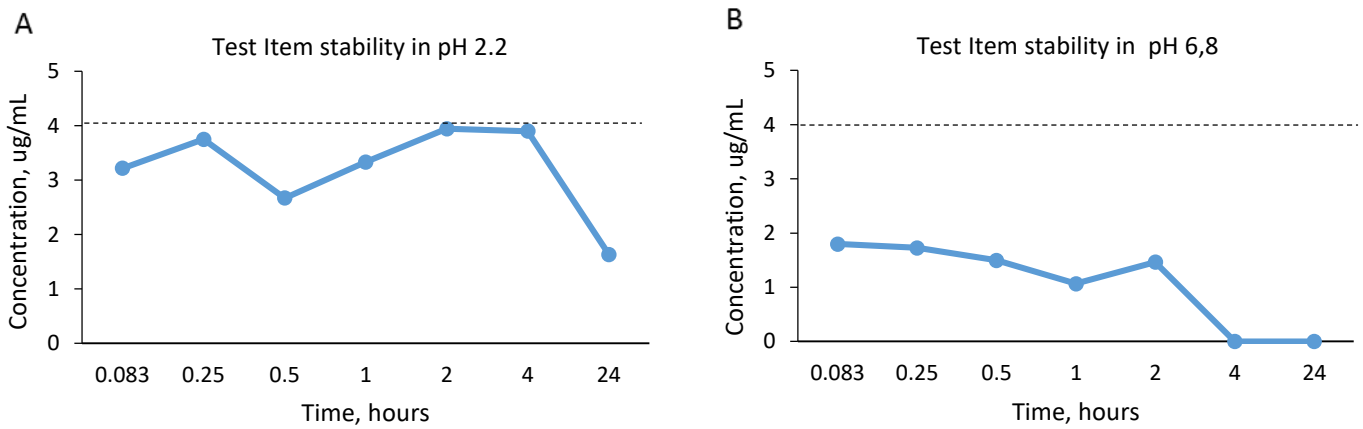

Figure 2. Test Item quantification after 0.083, 0.25, 0.5, 1, 2, 4 and 24 hours at 37°C in pH 2.2 (A) and Ph 6.8 (B). Dotted lines represents Test Item quantification in pre test.

References:
[1] Kerns, E. H., Di, L. Drug Like Proprieties: Concept, Structure Design and Methods from Toxicity Optimization Press: Elsevier, London, UK, 2016.
[2] OECD 105. OECD GUIDELINE FOR THE TESTING OF CHEMICALS Water Solubility.

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