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Analytical Quality by Design (AQbD) approach to the development of in vitro release test for topical hydrogel

Réka Szoleczky, Mária Budai-Szűcs, Anita Kovács

University of Szeged, Faculty of Pharmacy, Institute of Pharmaceutical Technology and Regulatory Affairs, Szeged, Hungary

The aim of our study was to adapt the Analytical Quality by Design (AQbD) approach to design an effective in vitro release test method development using USP Apparatus IV with semi-solid adapter (SSA) for diclofenac sodium hydrogel.

The analytical target profile (ATP) of the in vitro release test and, in addition, ultra high-performance liquid chromatography were defined and the critical method attributes (CMAs) (min. 70% of the drug should be released during the test, 6 time points should be obtained in the linear portion of the drug release profile and the relative standard deviation of the released drug should be not over 10 %) were selected. An initial risk assessment was carried out, in which the CMAs (ionic strength, pH of the media, membrane type, rate of flow, volume of the semi-solid adapter (sample amount), individual flow rate of cells, drug concentration %, and the composition of the product) were identified.

Based on the results, it was possible to determine the high-risk parameters of the in vitro drug release studies performed with USP Apparatus IV with SSA, which were the pH of the medium and the sample weight of the product. Focusing on these parameters, we developed a test protocol for our hydrogel system.