

Publication

An Impedance-Based Method to Determine Reconstitution Time for Freeze-Dried Pharmaceuticals

JournalArticle (Originalarbeit in einer wissenschaftlichen Zeitschrift)**ID** 3386790**Author(s)** Werk, Tobias; Huwyler, Joerg; Hafner, Mathias; Luemkemann, Joerg; Mahler, Hanns-Christian**Author(s) at UniBasel** [Huwyler, Jörg](#) ; [Werk, Tobias](#) ;**Year** 2015**Title** An Impedance-Based Method to Determine Reconstitution Time for Freeze-Dried Pharmaceuticals**Journal** Journal of pharmaceutical sciences**Volume** 104**Number** 9**Pages / Article-Number** 2948-2955

The reconstitution of freeze-dried products is usually determined by visual inspection with the naked eye. This can inevitably lead to significant variability in the ability to detect complete reconstitution of the dried solid. It was thus the goal of our study to assess an automated method to monitor reconstitution of a freeze-dried protein drug product in its primary packaging. A newly developed measuring device was used to measure impedance. This was achieved by detecting minor changes in impedance of the reconstitution medium, which occurred because of solid material dissolving during the dissolution process. This measurement system was capable of consistently detecting the dissolution of the last visible residues of freeze-dried lyophilisates. The endpoint of reconstitution was defined at an impedance change of less than 1 Ω for at least 7 s. Finally, we compared reconstitution times determined by the automated impedance method with results obtained by a visual method. In contrast to human operators, the new method delivered both accurate and precise results. Besides detection of the reconstitution endpoint, the impedance method and apparatus can monitor reconstitution endpoints as well as reconstitution kinetics. This standardized method can therefore advantageously be used for the determination of the reconstitution endpoint.

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