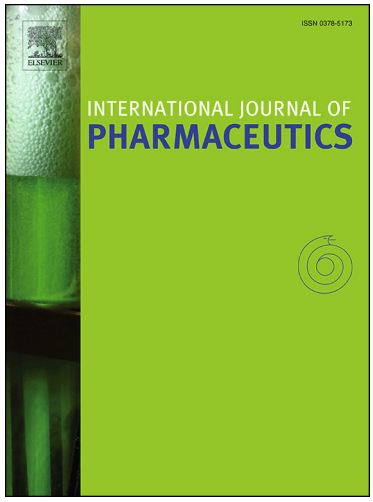
Accepted Manuscript



Model-based NIR spectroscopy implementation for in-line assay monitoring during a pharmaceutical suspension manufacturing process

Maxim Verstraeten, Daan Van Hauwermeiren, Mario Hellings, Eline Hermans, Jeroen Geens, Chris Vervaet, Ingmar Nopens, Thomas De Beer

PII: S0378-5173(18)30352-1
DOI: https://doi.org/10.1016/j.ijpharm.2018.05.043
Reference: IJP 17514

To appear in: *International Journal of Pharmaceutics*

Please cite this article as: M. Verstraeten, D. Van Hauwermeiren, M. Hellings, E. Hermans, J. Geens, C. Vervaet, I. Nopens, T. De Beer, Model-based NIR spectroscopy implementation for in-line assay monitoring during a pharmaceutical suspension manufacturing process, *International Journal of Pharmaceutics* (2018), doi: https://doi.org/10.1016/j.ijpharm.2018.05.043

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

ACCEPTED MANUSCRIPT

Model-based NIR spectroscopy implementation for in-line assay monitoring during a pharmaceutical suspension manufacturing process

Maxim Verstraeten[a,1], Daan Van Hauwermeiren[c], Mario Hellings[d], Eline Hermans[d], Jeroen Geens[d], Chris Vervaet[b], Ingmar Nopens[c], Thomas De Beer[a]

[a] *Laboratory of Pharmaceutical Process Analytical Technology, Department of Pharmaceutical Analysis, Faculty of Pharmaceutical Sciences, Ghent University, Ottergemsesteenweg 460, 9000 Ghent, Belgium*
[b] *Laboratory of Pharmaceutical Technology, Department of Pharmaceutics, Faculty of Pharmaceutical Sciences, Ghent University, Ottergemsesteenweg 460, 9000 Ghent, Belgium*
[c] *BIOMATH, Department of Mathematical Modelling, Statistics and Bioinformatics, Faculty of Bioscience Engineering, Ghent University, Coupure Links 653, 9000 Ghent, Belgium*
[d] *Pharmaceutical Development & Manufacturing Sciences, Janssen, Pharmaceutical Companies of Johnson & Johnson, Beerse, Belgium*

Abstract

The implementation of Process Analytical Technology (PAT) instruments is generally achieved stochastically. Sub-optimal PAT locations could introduce variation in the measurements which is not related to the analyte of interest. For this reason, rational approaches should be considered to establish an optimal sensor placement where relevant measurements are possible and the impact of disturbances is minimized. The aim of this paper is to demonstrate how mechanistic modelling can support appropriate sensor implementation by means of a case study. A PAT method was developed for a bottle filling process of a pharmaceutical formulation with the goal of increasing the yield of the process by gaining process understanding and redefining the endpoint of the process. To ensure proper measurements, an advanced measuring interfacing was assembled. The design of this device was rationalized with the help of a model-based approach using three-dimensional Computational Fluid Dynamics modeling. This allows to maximize the performance of the PAT method and exploit its full benefits.

Keywords: Process Analytical Technology, Computational Fluid Dynamics, Near Infrared Spectroscopy, Model-based optimization

1. Introduction

PAT is a system for designing, analyzing and controlling manufacturing through timely measurements (i.e. during processing) of critical quality and performance attributes of raw and in-process materials and processes, with the goal of ensuring final product quality [1]. The goal of PAT is to understand, monitor and control the manufacturing processes, hence guaranteeing final product quality. This enables the design and development of well-understood processes, which can consistently deliver quality products at the end of the manufacturing process. PAT has been a unique opportunity to revolutionize pharmaceutical manufacturing in the last decade, largely driven by the growing need for improving manufacturing efficiency and productivity while ensuring higher quality standards and guaranteeing patient safety [2]. In the pharmaceutical industry, there is an increased awareness that these demands cannot be fulfilled by relying on conventional manufacturing using batch processes with tedious and time-intensive offline sampling and final

*Corresponding author
Email addresses: Maxim.Verstraeten@ugent.be (Maxim Verstraeten), Thomas.DeBeer@ugent.be (Thomas De Beer)
URL: http://www.ugent.be/fw/en/research/pharmaceutical-analysis/pat (Maxim Verstraeten)
[1]Phone number: +32(0)9 264 83 55

Download English Version:

https://daneshyari.com/en/article/8519699

Download Persian Version:

https://daneshyari.com/article/8519699

Daneshyari.com