

Accepted Manuscript

Multivariate evaluation of the effect of the particle size distribution of an active pharmaceutical ingredient on the performance of a pharmaceutical drug product: A real-case study

D. Copelli, A. Cavecchi, C. Merusi, R. Leardi

PII: S0169-7439(17)30647-0

DOI: [10.1016/j.chemolab.2018.04.013](https://doi.org/10.1016/j.chemolab.2018.04.013)

Reference: CHEMOM 3623

To appear in: *Chemometrics and Intelligent Laboratory Systems*

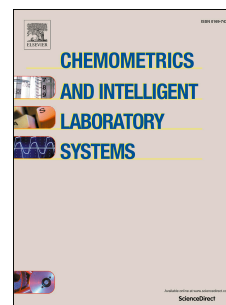
Received Date: 6 October 2017

Revised Date: 14 December 2017

Accepted Date: 16 April 2018

Please cite this article as: D. Copelli, A. Cavecchi, C. Merusi, R. Leardi, Multivariate evaluation of the effect of the particle size distribution of an active pharmaceutical ingredient on the performance of a pharmaceutical drug product: A real-case study, *Chemometrics and Intelligent Laboratory Systems* (2018), doi: 10.1016/j.chemolab.2018.04.013.

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.



MULTIVARIATE EVALUATION OF THE EFFECT OF THE PARTICLE SIZE DISTRIBUTION OF AN ACTIVE PHARMACEUTICAL INGREDIENT ON THE PERFORMANCE OF A PHARMACEUTICAL DRUG PRODUCT: A REAL-CASE STUDY

D. Copelli^{a,b}, A. Cavecchi^a, C. Merusi^a, R. Leardi^c

^aChiesi Farmaceutici, Largo Belloli 11/A – 43122, Parma, ITALY

^bDepartment of Chemical and Geological Sciences, University of Modena and Reggio Emilia, 41100 Modena, ITALY

^cDepartment of Pharmacy, University of Genova, viale Cembrano 4, I-16148 Genova, ITALY

d.copelli@chiesi.com

Abstract

In the pharmaceutical field, and in particular for inhalation drug products based on Dry Powder Inhaler, the Active Pharmaceutical Ingredient particle size distribution is one of the key parameters to drive the final drug product performance. In this paper the impact of the Active Pharmaceutical Ingredient particle size on the Aerodynamic Particle Size Distribution of the final drug product was evaluated by applying different multivariate approaches. By using both the commonly employed particle size distribution descriptors (D10, D50, D90 and SPAN) and the whole particle size distribution curves it has been demonstrated that the latter gives an information which is easier to understand and interpret. Finally, models estimating the effects of the Active Pharmaceutical Ingredient particle size distribution, device life and drug product dosage on the Aerodynamic Particle Size Distribution of the final drug product were also established.

Keywords

Particle size distribution, Active Pharmaceutical Ingredient, Multivariate Analysis, Principal Properties, Multiple Linear Regression

Download English Version:

<https://daneshyari.com/en/article/7561852>

Download Persian Version:

<https://daneshyari.com/article/7561852>

[Daneshyari.com](https://daneshyari.com)