Accepted Manuscript

Research paper

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PII: S0939-6411(17)31430-3
DOI: https://doi.org/10.1016/j.ejpb.2018.02.036
Reference: EJPB 12716

To appear in: *European Journal of Pharmaceutics and Biopharmaceutics*

Received Date: 14 December 2017
Revised Date: 23 February 2018
Accepted Date: 27 February 2018

Please cite this article as: A. Ganguly, J. Stewart, A. Rhoden, M. Volny, N. Saad, Mass Spectrometry in Freeze-Drying: Motivations for Using a Bespoke PAT for Laboratory and Production Environment, *European Journal of Pharmaceutics and Biopharmaceutics* (2018), doi: https://doi.org/10.1016/j.ejpb.2018.02.036

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Mass Spectrometry in Freeze-Drying: Motivations for Using a Bespoke PAT for Laboratory and Production Environment

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ABSTRACT

Mass Spectrometry has commonly been used in the semi-conductor industry where maintaining a clean environment with minimum contaminants under high vacuum is crucial for successful manufacturing. Since the technology's early usage for pharmaceutical manufacturing in the early '80s, particularly in the freeze-drying environment, much has changed. The focus of the current work is aimed at asking some key questions regarding the maturity of the technology, its challenges and importance of having an application-specific instrument for quantitative process analyses applied to freeze-drying. Furthermore, we compare the use of mass spectrometers in early installations from the 80's with recent experiences of the technology in the production and laboratory environments comparing data from different MS technologies. In addition, the manuscript covers broad application of the technology towards detection of and sensitivity for analytes including silicone oil, Helium and also explores the option of using MS in detecting water vapor and nitrogen concentration not just in primary drying, but also in secondary drying. The technology, when purpose built, has the potential for use as a robust, multi-purpose PAT tool in the freeze-drying laboratory and production environments.

Abbreviations:

CM: Capacitance manometer
FBRM: Focused Beam Reflectance Measurement
Fluorescence: Fluorescence Spectroscopy
GC-MS: Gas Chromatography Mass Spectrometry
ICP-MS: Inductively Coupled Plasma Mass Spectrometry
Laser Headspace: NIR laser measurements tuned typically for oxygen or carbon dioxide
LC-MS: Liquid Chromatography Mass Spectrometry
MIR: Mid Infrared Spectroscopy
MS: Mass Spectrometry
MTM: Manometric temperature measurement
NIR: Near Infrared Spectroscopy
RGA: Residual Gas Analyzer
RTD: Resistance temperature detector
TDLAS: Tunable diode laser absorption spectroscopy
SIMS: Secondary Ion Mass Spectrometry

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