Accepted Manuscript

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Nuwan Kothalawala, Thilak K. Mudalige, Patrick Sisco, Sean W. Linder

PII:	S1570-0232(18)30358-1
DOI:	doi:10.1016/j.jchromb.2018.05.028
Reference:	CHROMB 21192
To appear in:	
Received date:	1 March 2018

Received date:	1 March 2018
Revised date:	10 May 2018
Accepted date:	18 May 2018

Please cite this article as: Nuwan Kothalawala, Thilak K. Mudalige, Patrick Sisco, Sean W. Linder , Novel analytical methods to assess the chemical and physical properties of liposomes. The address for the corresponding author was captured as affiliation for all authors. Please check if appropriate. Chromb(2017), doi:10.1016/j.jchromb.2018.05.028

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Novel analytical methods to assess the chemical and physical properties of liposomes

Authors

Nuwan Kothalawala, Thilak K. Mudalige, Patrick Sisco* and Sean W. Linder*

Office of Regulatory Affairs, Arkansas Laboratory, U.S. Food and Drug Administration, 3900 NCTR Road, Jefferson, AR 72079, United States

Abstract

Liposomes are used in commercial pharmaceutical formulations (PFs) and dietary supplements (DSs) as a carrier vehicle to protect the active ingredient from degradation and to increase the half-life of the injectable. Even as the commercialization of liposomal products has rapidly increased, characterization methodologies to evaluate physical and chemical properties of the liposomal products have not been wellestablished. Herein we develop rapid methodologies to evaluate chemical and selected physical properties of liposomal formulations. Chemical properties of liposomes are determined by their lipid composition. The lipid composition is evaluated by first screening of the lipids present in the sample using HPLC-ELSD followed by HPLC-MSMS analysis with high mass accuracy (<5 ppm), fragmentation pattern and lipid structure databases searching. Physical properties such as particle size and size distribution were investigated using Tunable Resistive Pulse Sensing (TRPS). The developed methods were used to analyze commercially available PFs and DSs. As results, PFs contain distinct number of lipids as indicated by the manufacture, but DSs were more complicated containing a large number of lipids belonging to different sub-classes. Commercially available liposomes have particles with wide size distribution based on size measurements performed by TRPS. The high mass accuracy as well as identification lipids using multiple fragment ions aided to accurately identify the lipids and differentiate them from other lipophilic molecules. The developed analytical methodologies were successfully adapted to measure the physiochemical properties of commercial liposomes.

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