Accepted Manuscript

Title: Characterization of polydisperse macrogols and macrogol-based excipients via HPLC and charged aerosol detection

Authors: Christiane Theiss, Ulrike Holzgrabe

PII: S0731-7085(18)31151-8
DOI: https://doi.org/10.1016/j.jpba.2018.07.043
Reference: PBA 12114

To appear in: *Journal of Pharmaceutical and Biomedical Analysis*

Received date: 15-5-2018
Revised date: 20-7-2018
Accepted date: 21-7-2018

Please cite this article as: Theiss C, Holzgrabe U, Characterization of polydisperse macrogols and macrogol-based excipients via HPLC and charged aerosol detection, *Journal of Pharmaceutical and Biomedical Analysis* (2018), https://doi.org/10.1016/j.jpba.2018.07.043

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

Characterization of polydisperse macrogols and macrogol-based excipients via HPLC and charged aerosol detection

Christiane Theiss, Ulrike Holzgrabe*

Institute for Pharmacy and Food Chemistry, University of Wuerzburg, Am Hubland, 97074 Wuerzburg, Germany

***To whom correspondence should be addressed:**

Prof. Dr. Ulrike Holzgrabe, Institute for Pharmacy and Food Chemistry, University of Wuerzburg, Am Hubland, DE-97074 Wuerzburg, Germany; Tel. +499313185461, Email: ulrike.holzgrabe@uni-wuerzburg.de

Highlights

- A generic HPLC-CAD method to characterize macrogol-based emulsifiers was developed.
- 13 emulsifiers were separated for qualitative analysis of the oligomer distribution
- The excipients and their precursors can be separated simultaneously.
- The method is suitable to separate polymer macrogols from PEG 300 to PEG 3000.
- Fatty acids with more than 12 carbon atoms can be detected by CAD.

Abstract

Macrogol-based emulsifiers and their respective precursor substances, i.e. macrogols (PEG), fatty acids (FA), and fatty alcohols (FAA), are widely used excipients which are usually characterized by a series of tests described within the European Pharmacopoeia (Ph. Eur.). Examples are bulk parameters such as the hydroxyl value, the peroxide value, and the determination of fatty acids composition by gas chromatography. The choice of tests depends on the emulsifier considered and its possible precursors. Though all methods are well established, most of them are time consuming and, in some cases, prone to errors and exhibit a low reproducibility. Here, an alternative and supplemental method was developed, using a HPLC-system coupled to a charged aerosol detector (CAD). Seven PEG samples, five saturated as well as two nonsaturated FA samples, and two FAA samples were analyzed. Together with these precursors, 13 macrogol-based emulsifiers of 3 different groups, i.e. macrogol ethers with FAA, macrogol esters with FA, and polysorbates, were successfully analyzed for oligomeric distribution and free precursor molecules in one run.

Download English Version:

https://daneshyari.com/en/article/7625648

Download Persian Version:

https://daneshyari.com/article/7625648

Daneshyari.com