

Accepted Manuscript

Title: Analytical procedures for the quality control of pharmaceuticals in terms of residual solvents content – challenges and recent developments

Author: Maciej Tankiewicz, Jacek Namieśnik, Wiesław Sawicki

PII: S0165-9936(15)30059-5

DOI: <http://dx.doi.org/doi: 10.1016/j.trac.2015.09.008>

Reference: TRAC 14566

To appear in: *Trends in Analytical Chemistry*



Please cite this article as: Maciej Tankiewicz, Jacek Namieśnik, Wiesław Sawicki, Analytical procedures for the quality control of pharmaceuticals in terms of residual solvents content – challenges and recent developments, *Trends in Analytical Chemistry* (2015), <http://dx.doi.org/doi: 10.1016/j.trac.2015.09.008>.

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.

1 **Analytical procedures for the quality control of pharmaceuticals in terms of residual**
2 **solvents content – challenges and recent developments**

3
4 **Maciej Tankiewicz*¹, Jacek Namieśnik², Wiesław Sawicki¹**

5
6 **1) Chair & Department of Physical Chemistry, Faculty of Pharmacy with Subfaculty of**
7 **Laboratory Medicine, Medical University of Gdansk, Al. Gen. J. Hallera 107, 80-416**
8 **Gdańsk, Poland**

9 **2) Department of Analytical Chemistry, Faculty of Chemistry, Gdansk University of**
10 **Technology, G. Narutowicza Str. 11/12, 80-233 Gdańsk, Poland**

11 * Corresponding author: Maciej Tankiewicz, Ph.D. Eng., e-mail: tankiewicz@gumed.edu.pl,
12 tel./fax: 0048 58 349 16 52

13
14 **Highlights**

- 15 • residual solvents in pharmaceuticals – problems and challenges
- 16 • overview of regulatory and general methods
- 17 • sample preparation techniques for analysis
- 18 • final determination methods
- 19 • recent developments in the determination of residual solvents

20
21 **Abstract**

22
23 Residual solvents play an important role in the synthesis of drug substances and in product
24 formulations. At the same time they pose a problem and must be removed, because many of
25 them have toxic or environmentally hazardous properties. Therefore, constant monitoring of
26 quality control is needed. In this paper, we present an overview of regulatory and general
27 methods described by various Pharmacopoeias. Next, the most commonly used
28 methodologies for the determination of residual solvents in different pharmaceutical samples
29 are reviewed to demonstrate their limitations, which form the basis for discussion about new
30 methods. Several interesting new alternatives for sample preparation and gas chromatography
31 (GC) separation are presented using examples from recent literature. The techniques
32 described are direct injection, headspace analysis with different modifications and variations,
33 liquid extraction, single-drop microextraction, solid-phase microextraction. Various GC

Download English Version:

<https://daneshyari.com/en/article/7688941>

Download Persian Version:

<https://daneshyari.com/article/7688941>

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