

Literature list Pharmaceutical and biomedical analysis

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(Photo copies of the articles marked with * are printed to you in advance)

Sampling

“Labile Metabolites” D. Dell Chromatographia 2004, 59, S139–S148 DOI: 10.1365/s10337-003-0169-5

Solubility, buffer preparation

On the preparation of buffer solutions-Thomson, Bruce M.; Kessick, Michael A. J Chem Edu (1981), 58(9), 743-6. DOI: 10.1021/ed058p743

The Preparation of Buffers and Other Solutions A Chemist’s Perspective- Edward A. Pfannkoch
ur Molecular Biology Problem Solver: A Laboratory Guide. Edited by Alan S. Gerstein ISBNs: 0-471-37972-7 (Paper); 0-471-22390-5 (Electronic) The AAPS Journal 2007; 9 (1) Article 4
DOI:10.1002/0471223905.ch3

Sample preparation

Advances in sample preparation in electromigration, chromatographic and mass spectrometric separation methods Martin Gilar, Edouard S.P. Bouvier, Bruce J. Compton J Chromatogr A, 909, Iss 2, 2001, 111-135 DOI: 10.1016/S0021-9673(00)01108-0

Critical overview of selected contemporary sample preparation techniques Lourdes Ramos J Chromatogr A, 1221, 2012, 84-98 DOI: 10.1016/j.chroma.2011.11.011

Separation and method development

Capillary electrophoresis

<http://www.sepscience.com/Techniques/CE/642-/CE-Solutions-2-Method-Development-in-CE-Selecting-your-Background-Electrolyte>

<http://www.sepscience.com/Techniques/CE/643-/CE-Solutions-3-The-CE-Capillary>

<http://www.sepscience.com/Techniques/CE/644-/CE-Solutions-4-Capillary-Conditioning--The-Foundation-of-Precision-in-CE>

Liquid Chromatography

[How to start analytical method development- Dr. Krishnasarma Pathy](#)

* HPLC method development and validation in pharmaceutical analysis (Ghulam Shabir) 2013, page 59-66, 71-85

Detection- Mass spectrometry

*K. Mastovska: *State of the art Mass Spectrometric and Chromatographic Techniques for Drug Analysis* ACS Symposium Series, Vol. 992 (2008) Chapter 15, pp 283–298 DOI: 10.1021/bk-2008-0992.ch015

Validation and quality assurance

Bioanalytical methods

Guideline on bioanalytical method validation Committee for Medicinal Products for Human Use (CHMP)
21 July 2011 EMEA/CHMP/EWP/192217/2009

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2011/08/WC500109686.pdf

Workshop/Conference Report — Quantitative Bioanalytical Methods Validation and Implementation: Best Practices for Chromatographic and Ligand Binding Assays C. T. Viswanathan et al., *The AAPS Journal* 2007; 9 (1) Article 4. DOI: 10.1208/aapsj0901004

Key Elements of Bioanalytical Method Validation for Small Molecules, Surendra Bansal and Anthony DeStefano, *The AAPS Journal* 2007; 9 (1) Article 11 . DOI: 10.1208/aapsj0901011

OECD series on principles of good laboratory practice and compliance monitoring Number 1: OECD Principles on Good Laboratory Practice (as revised in 1997)
[http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/mc/chem\(98\)17&doclanguage=en](http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/mc/chem(98)17&doclanguage=en)

C. A. James and H. M. Hill, “Procedural Elements Involved in Maintaining Bioanalytical Data Integrity for Good Laboratory Practices Studies and Regulated Clinical Studies”, *The AAPS Journal* 2007; 9 (2) Article 14 DOI: 10.1208/aapsj0902014

Pharmacopeia, ICH guidelines, Regulatory aspects of drug analysis

Technical Guide for the elaboration of monographs, European Pharmacopeia 6th edition 2011
<http://www.edqm.eu/en/technical-guides-589.html> Chapters included: 1.1 (p. 6), 1.2 (p. 6), 1.4 (p. 7), 2 (p. 10-11), 2.1 (p. 11-13), 2.3.1 (p. 17-18) 2.4.1 (p. 22), 2.4.8 (p. 28-39) 2.5 (p. 44), 2.8 (p.47)

ICH guideline, Q2 (R1), Validation of analytical procedures: Text and methodology.
<http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html>

Global organisations for regulatory issues

<http://www.oecd.org/chemicalsafety/testing/goodlaboratorypracticeglp.htm>

<http://www.ich.org/about/history.html>

<http://www.ema.europa.eu/ema/>

<http://www.edqm.eu/en/edqm-homepage-628.html>

<http://www.usp.org/>

<http://www.pmda.go.jp/english/pharmacopoeia/index.html>

<http://www.lakemedelsverket.se/>

<http://www.fda.gov/>

<http://www.iso.org/iso/home.html>

Research documentation

Research documentation at Karolinska Institute – a handbook v. 1, 2010

http://internwebben.ki.se/sites/default/files/handbook_v1.1.pdf

Risk assessment

*"To perform a risk assessment of your laboratory work" Analytical Pharmaceutical Chemistry, Uppsala University 2010-09-20 (appendix IV in the laboratory instruction)

Literature search

Literature search tips from the Uppsala University library : <http://www.ub.uu.se/>

We recommend the use of Scifinder Scholar. Register an account here: <https://origin-scifinder.cas.org/registration/index.html?corpKey=E4F899BF-86F3-F00A-11AC-F2AE40C76356>

Reference management

This freeware can be used as an aid for reference management in a scientific report: Zotero
<http://www.ub.uu.se/sv/Service/Bibliotekets-kurser-/Referenshantering/Zotero/> . More information regarding reference management can be found here: <http://www.ub.uu.se/en/Service/Reference-management/>

Information how to access UU's e-resources outside the UU-network
<http://www.ub.uu.se/en/Service/Support/Access-to-e-resources-from-home/>

Italic= further reading and tips/tricks