

Instructions for Authors

November 2011

Information provided in this document is intended solely as a guide for authors wishing to submit articles for publication in Pharmeuropa online and Pharmeuropa Bio & Scientific Notes online.

1. PHARMEUROPA ONLINE AND PHARMEUROPA BIO & SCIENTIFIC NOTES ONLINE: AIMS AND SCOPE

Pharmeuropa online and Pharmeuropa Bio & Scientific Notes online (Bio & SN) are aimed at providing information on the work of the European Pharmacopoeia Commission and of the Biological Standardisation Programme. They provide feedback from the users of the European Pharmacopoeia, hence they publish papers by individual contributors on any aspect of pharmaceutical quality control. Articles submitted for publication in Pharmeuropa online and Pharmeuropa Bio & SN must have a clear, direct link with the work of the pharmacopoeias, especially the European Pharmacopoeia.

2. SUBMITTING ARTICLES TO PHARMEUROPA ONLINE/PHARMEUROPA BIO & SN

It is assumed that the copyright of material submitted is that of the contributor or that the necessary clearances have been obtained and that material submitted has not been offered simultaneously to another publication. Authors are required to state clearly if material has been submitted to another publication. In submitting an article for publication, it is assumed that all authors of the article have given their consent to publication.

2.1. Where to send articles

Articles should be sent (for the attention of the Editors of Pharmeuropa online/Pharmeuropa Bio & SN) preferably by e-mail to publishing@edqm.eu or by post to the following address:

European Directorate for the Quality of Medicines & HealthCare
Publications & Multimedia Department
7 allée Kastner
CS 30026
F-67081 Strasbourg
France

If submitting an article by post, please send 2 complete hard copies accompanied by an electronic version. An acknowledgement of receipt is sent by e-mail to the author to whom correspondence is to be addressed within 5 working days of receipt of the article.

2.2. Requirements

2.2.1. General requirements

Articles are typewritten (Arial font, font size 12) on 1 side only of A4 size paper, double spaced and with at least a 2.5 cm margin all around. Electronic versions of texts are preferably in Word or RTF format (PDF format is

unacceptable). Authors are encouraged, wherever possible, to avoid footnotes and to include the information in the main body of the text.

2.2.2. Requirements for tables and figures

Authors are asked to submit tables and figures of an appropriate quality and size for publication and to include all original files. Numerical data and tables are acceptable in Word or Excel format. All figures are to be saved in individual files, in EPS format (best choice), or in PSD or TIFF format (with a minimum resolution of 300 ppi). Vectorial images embedded in PDF or Microsoft Word documents can sometimes be exploited, subject to prior testing. Bitmap images embedded in Microsoft Word and PDF files are generally of very poor quality and will not be accepted. Formats intended for the internet are also unacceptable (i.e. GIF, JPEG, PNG, etc.).

Text in figures must be in Arial font (font size 8). If text is to be added to a figure (e.g. key to symbols) it should be supplied on a separate page or included as part of the figure legend. In no case should there be handwriting on the original figure. If black and white figures are submitted, grey scale is only acceptable at an intensity of 25 %. Authors are asked to avoid reverse type where possible (i.e. white lettering on a dark background) and a shaded background (especially if a suitable electronic version cannot be supplied).

3. PRESENTATION OF ARTICLES

Two types of manuscript will be considered for publication:

- **Articles in Pharmeuropa Bio & SN:** articles describing one or more methods of analysis applicable to pharmaceutical quality control in the broadest sense or the results of analysis of pharmaceutical products;
- **Readers' Tribune:** discussion articles and letters commenting on the policy or decisions of the European Pharmacopoeia Commission or on previously published papers.

Further instructions pertaining to these 2 types of manuscript are given below.

3.1. Articles in Pharmeuropa Bio & SN

Articles are accepted in either English or French, however if the text is written in French it must be accompanied by a comprehensive summary in English. Articles written in French will not be translated. As a general rule, articles should not exceed 3500 words and should contain a reasonable number of figures and tables. Articles are written in a clear, concise and coherent manner and are well structured. Poorly written articles will not be considered for publication and will be returned to the author.

Articles are structured as follows:

- Title
- Sub-title (if necessary)
- Authors (including correspondence details)
- Abstract
- Keywords
- 1. Introduction
- 2. Participants (where applicable)
- 3. Materials and methods
- 4. Results and discussion (may be split into 2 sections if necessary)
- 5. Conclusion
- 6. Acknowledgements (if necessary)
- 7. Participants (listed by country in alphabetical order) (where applicable)
- 8. Abbreviations (if necessary)
- 9. References
- Appendices (if necessary)

Sub-sections are numbered accordingly, e.g. 1.1, 1.1.1, 1.1.2 etc., and should not exceed 5 hierarchical levels. Indented paragraphs are preferably listed using bullet points or dashes. If necessary, e.g. if reference is made to the paragraph elsewhere in the text, indented paragraphs are listed using a), b) etc.

Title. The title should be as clear and concise as possible, contain important keywords and not exceed 80 characters (including spaces). A sub-title may be included if necessary.

Authors. Authors' names and initials are given with their current addresses and, if different, their addresses at the time the article was drafted. The author to whom all correspondence is to be addressed is indicated (corresponding author). Please supply a full postal address and an e-mail address for the corresponding author and ensure that these addresses are correct and sufficiently clear.

Abstract. A concise, self-contained summary of the problem and the principal results, without experimental details, and which does not contain references.

Keywords. General words are to be avoided. Not more than 6 keywords or phrases will usually be necessary.

Introduction. A concise statement of the background of the topic, including relevant earlier work, and the aim. The introduction should indicate why this topic is considered important and outline its relevance to the European Pharmacopoeia.

Participants. A general overview of the participants involved in the work (only for articles concerning the Biological Standardisation Programme).

Materials and methods. Reasonably detailed accounts of experimental procedures, sufficient to allow readers to repeat the work.

Results. A clear presentation of the important results, clarified by tables and figures (see below for further requirements). When a new analytical procedure is being described this section may include experimental details.

Discussion. The principal conclusions to be drawn from the results and their implications. This section may include comparisons with other relevant studies.

Acknowledgements. If necessary, acknowledgements may be included.

Participants (listed by country in alphabetical order). A list of the individual participants involved in the work, in order of country (only for articles concerning the Biological Standardisation Programme).

Abbreviations and units. Abbreviations are either defined on first use in the text or, if they are numerous, are compiled in a list containing all abbreviations used in the text. The International System of Units (SI) is used.

References. These are cited in the text according to the EDQM's guide for citing references (see Appendix 2).

Appendices. Authors are encouraged, wherever possible, to avoid appendices and to include the information in the main body of the text. However, if the text contains, for example, numerous tables that have to be grouped together, authors should present this information in the form of an appendix.

Figures and tables. Figures and tables are kept to a minimum and are as clear and simple as possible. Before including a figure or table, consider if it is really necessary (for example, avoid including a figure and a table that represent the same information). Axes are labelled using SI units. Wherever possible, the use of figures rather than tables to represent numerical data is encouraged.

Photographs. Only well-contrasted photographs will be accepted.

3.2. Readers' Tribune

There is no fixed format, but as a rule articles should not exceed 800 words in length. The requirements for figures and tables described in Section 3.1 apply.

4. EVALUATION PROCEDURE

Articles are evaluated by the editorial boards of Pharmeuropa online and Pharmeuropa Bio & SN, and are subject to editorial modifications before publication. If the article is considered suitable for publication, any comments received from the editorial board may be sent to the corresponding author and a revised version of the article may be requested. The revised version is checked by the Editors to ensure that the comments have been taken into account. Proofs of the article with the finalised page layout are sent to the corresponding author along with a release form. Authors may comment on the page layout, although the Editors of Pharmeuropa online and Pharmeuropa Bio & SN reserve the right to make the final decision regarding matters of style (e.g. location of figures/tables).

5. RETURN OF MATERIAL

The original manuscript and illustrations will not be returned to the author.

APPENDIX 1

CHECKLIST FOR AUTHORS OF SCIENTIFIC NOTES

1. For articles submitted by post, are the hard copies and electronic copies identical?
2. For articles written in French, is a summary in English included?
3. Is the corresponding author's postal address and e-mail address correct and clearly indicated?
4. Is the title concise (fewer than 80 characters, including spaces) and does it contain important keywords?
5. Is a list of keywords included?
6. Does the text include an abstract?
7. Do all figures and tables have a legend with figure axes correctly labelled using SI units?
8. Are all figures and tables referenced in the text?
9. Are all references cited in the text listed in the references section using the EDQM's guide for citing references?
10. Is the text correctly structured using numbered sections and sub-sections?

APPENDIX 2

UNIFORM REQUIREMENTS FOR REFERENCE CITING IN PHARMEUROPA ONLINE AND PHARMEUROPA BIO & SN

INTRODUCTION

1. CITATION OF MATERIAL IN JOURNALS

- 1.1 Monograph in Pharmeuropa online
- 1.2 Monograph in Pharmeuropa
- 1.3 Scientific note in Pharmeuropa
- 1.4 Scientific note in Pharmeuropa SN
- 1.5 Scientific article in Pharmeuropa Bio
- 1.6 Scientific article in Pharmeuropa Bio & SN
- 1.7 Standard journal article
- 1.8 Article with more than 3 authors
- 1.9 Article with no author given
- 1.10 Material accepted for publication but not yet published
- 1.11 Volume with a supplement
- 1.12 Issue with a supplement
- 1.13 Volume with a part
- 1.14 Issue with a part
- 1.15 Issue with no volume
- 1.16 No issue or volume
- 1.17 Type of article/source indicated as required (I)
- 1.18 Type of article/source indicated as required (II)

2. CITATION OF BOOKS AND MONOGRAPHS

- 2.1 Monograph in the European Pharmacopoeia (I)
- 2.2 Monograph in the European Pharmacopoeia (II)
- 2.3 General chapter in the European Pharmacopoeia
- 2.4 Monograph in the USP

- 2.5 General chapter in the USP
- 2.6 Standard book with personal author(s)
- 2.7 Editor(s)/Compiler(s) as author
- 2.8 Organisation as author and publisher
- 2.9 Book with series title and individual volume
- 2.10 Chapter in a book
- 2.11 Chapter as part of an edited/translated work

3. CITATION OF MISCELLANEOUS SOURCES

- 3.1 Conference proceedings
- 3.2 Conference paper
- 3.3 Poster
- 3.4 Dissertation
- 3.5 EMA guideline
- 3.6 ICH guideline
- 3.7 WHO guideline
- 3.8 WHO report
- 3.9 WHO technical report series
- 3.10 International standards
- 3.11 ISO standards

4. CITATION OF MATERIAL AVAILABLE ONLY IN ELECTRONIC FORMAT

- 4.1 Electronic journal
- 4.2 CD-ROM
- 4.3 Website
- 4.4 No author identified, no date

INTRODUCTION

The following real and fictitious examples are given as a guide to the citation style to be used in Pharmeuropa online and Pharmeuropa Bio & SN. The style has been adapted from the 'Vancouver' citation style to meet the requirements of the EDQM. References are indicated in the text using square brackets, and are numbered in the order of citation. References are listed in the reference list at the end of the article. Punctuation forms an integral part of the reference; the style used in the examples below must be carefully copied.

1. CITATION OF MATERIAL IN JOURNALS

Cite the names and initials of all authors unless there are more than 3, when only the first 3 should be given followed by 'et al'. The authors' names are followed by the title of the article, the title of the journal abbreviated according to the style of Index Medicus, the year of publication, the volume number, and the first and last page numbers.

1.1 Monograph in Pharmeuropa online

- [1] Valine, monograph 0796. *Pharmeuropa online* 2012;**24**(1).

1.2 Monograph in Pharmeuropa

- [2] Methyl dopa, monograph 0045. *Pharmeuropa* 2002;**14**(3):54-62.

1.3 Scientific note in Pharmeuropa

- [3] Purewel TS. Test methods for dry powder inhalers to check performance under normal use and unintentional misuse conditions. *Pharmeuropa* 2002;**14**(3):14-18.

1.4 Scientific note in Pharmeuropa SN

- [4] Weber C, Matingen S, Holzgrabe U. Batch variability of bacitratrin: HPLC versus MEKC. *Pharmeur Sci Notes* 2005(1):47-51.

1.5 Scientific article in Pharmeuropa Bio

- [5] Frommer I, Klaus R, Dias A *et al.* Feasibility study to evaluate the correlation between results of *in vitro* assays and established *in vivo* assays for potency determination of various disease vaccines. *Pharmeur Bio* 2001(1):52-66.

1.6 Scientific article in Pharmeuropa Bio & SN

- [6] Ekman L, Fransson D, Claeson P *et al.* Development of an alternative method for determination of terpene lactones in ginkgo dry extract. *Pharmeur Bio Sci Notes* 2009(1):67-71.

1.7 Standard journal article

- [7] Turner AK, Smith S. Liver transplantation is associated with a decreased risk for pancreatobiliary disease. *Ann Intern Med* 1996;**124**(11):980-3.

1.8 Article with more than 3 authors

- [8] Ozben T, Nacitarhan S, Tuncer N *et al.* Plasma and glycosylated haemoglobin in non-insulin dependent diabetes mellitus. *Ann Clin Biochem* 1985;**38**(3):303-6.

1.9 Article with no author given

- [9] Immunologic status of the leukaemia patient and the effects of blood transfusion on antitumor responses. *Curr Opin Gen Surg* 1983;**7**:325-65.

1.10 Material accepted for publication but not yet published

- [10] Browell DA, Orwell QR. Physiological status of the cancer patient and the effects weight gain on staging of solid tumours. *Curr Opin Gen Surg* [in press].

1.11 Volume with a supplement

- [11] Brenner M, Rogerson J. SSRIs in the treatment of bipolar depression. *Environ Health Perspect* 2004;**102**(Suppl 8):375-82.

1.12 Issue with a supplement

- [12] Moithier DK, Sanchez K, Massie MJ. Women's reactions to ovarian cancer. *Semin Oncol* 1994;**31**(19 Suppl 2):89-97.

1.13 Volume with a part

- [13] Knaup T, Naciturn S, Hendreson PR. Potency testing of diphtheria toxoid vaccines. *Ann Clin Biochem* 1995;**32** (Pt 4):203-6.

1.14 Issue with a part

- [14] Sesardic GH, Millson SM. Two hundred consecutive cases of leg ulceration in ageing patients. *Pharm J* 1994;**107**(986 Pt 3):367-8.

1.15 Issue with no volume

- [15] Clawson I, Dobby T, Fillener-Tsai L. Hepatitis B (rDNA) vaccine BRP. *Clin Orthop* 1997;(428):129-34.

1.16 No issue or volume

- [16] Brunwell DA, Lennard TW. Collaborative study for the establishment of a help-line for patients suffering from cancer. *Curr Opin Gen Surg* 1993:325-33.

1.17 Type of article/source indicated as required (I)

- [17] Schuzberger W, Fischer PA. Perindopril in Parkinson's disease. *Lancet* 1986;**327**:1337 [letter].

1.18 Type of article/source indicated as required (II)

- [18] Clements R, Jefferies R. Haematological complications of nephropathy HVN. *Kidney Int* 1992;**38**:1285 [abstract].

2. CITATION OF BOOKS AND MONOGRAPHS

Cite author's name and initials, full title, edition, place of publication, publisher, year of publication, and page numbers if necessary. Do not repeat digits unnecessarily. Page numbers are not cited for the European Pharmacopoeia because it exists in both English and French versions, with different pagination. Furthermore, the monograph title and number are sufficient to lead the reader to the specified monograph/chapter.

2.1 Monograph in the European Pharmacopoeia (I)

- [19] Salbutamol sulfate, monograph 0687. Ph. Eur. Suppl. 7.2. Strasbourg, France: Council of Europe; 2010.

2.2 Monograph in the European Pharmacopoeia (II)

- [20] Arnica flower, monograph 1391. Ph. Eur. 7th Edition. Strasbourg, France: Council of Europe; 2010(vol 1).

2.3 General chapter in the European Pharmacopoeia

- [21] Bacterial endotoxins, general chapter 2.6.14. Ph. Eur. 7th Edition. Strasbourg, France: Council of Europe; 2010(vol 1).

2.4 Monograph in the USP

- [22] Calcium gluceptate. USP 25, NF 20. Rockville, USA: United States Pharmacopoeial Convention, Inc; 2002.

2.5 General chapter in the USP

- [23] Electrophoresis, general chapter <726>. USP 25, NF 20. Rockville, USA: United States Pharmacopoeial Convention, Inc; 2002.

2.6 Standard book with personal author(s)

- [24] Ringsven MK, Bond D. Medicines management skills for pharmacists. 2nd Edition. Albany, USA: Delmar Publishers; 1996:134-48.

2.7 Editor(s), compiler(s) as author

- [25] Norman IJ, Croft SJ, editors. Mental health care for retired people. Dundee, Scotland: Churchill Livingstone; 1996.

2.8 Organisation as author and publisher

- [26] Royal Cheshire Hospital, University of Cheshire, Department of Clinical Pharmacy. Compendium of pharmacy research and practice development, 1999-2000. Cheshire, UK: Cheshire University; 2001.

2.9 Book with series title and individual volume

- [27] Bennett GL, Hammlet R. Chemokines; iodination of and use in receptor binding analysis. Methods in Enzymology. Brighton, UK: Academic Press; 2002(vol 288):134-48.

2.10 Chapter in a book

- [28] Porter RJ, Meldrum BS. Antiepileptic drugs. In: Basic and clinical pharmacology. 6th Edition. Paris, France: Appleton and Lange; 1995:361-80.

2.11 Chapter as part of an edited/or translated work

- [29] Phillips SJ, Summers JP. Hypertension is dangerous: stroke and myocardial infarction events in the over 50 age group. In: Laragh JH, Brenner BM, editors. Hypertension, the pathophysiology, diagnosis, and management. 2nd Edition. London, UK: Raven Press; 1995:465-78.

3. CITATION OF MISCELLANEOUS SOURCES**3.1 Conference proceedings**

- [30] Nicouma J, Sissons H, editors. Recent advances in clinical cardiology. Proceedings of 11th international congress of EMG and clinical cardiology: Cape Town, South Africa; 1995 Oct 15-19. Brighton, UK: Dingthton publishers Int; 1996.

3.2 Conference paper

- [31] Walker AR, McKellar RB. Preliminary observations on the density of mitochondria of human kidney cells. In: Irvin AD, Cunningham MP, Dustoff AS, editors. Advances in the control of theileriosis. Proceedings of the 5th international conference for research on animal diseases; 1981 Feb 9-13. Oxford, UK: Delaware Publishers; 1981:125-6.

3.3 Poster

- [32] Gerard M, Moussard N, Whitehew LW. Comparative study of reversed phase and hydrophobic interaction chromatography for the analysis of human growth hormone formulations. Poster 32. The 8th European meeting of chromatography and molecular biology: La Grande Motte, France; 2001 June.

3.4 Dissertation

- [33] Kappin SJ. Post-hospital home health care in the elderly population: up-take and use. St. Louis, MO: Washington Univ; 1995 [dissertation].

3.5 EMA guideline

- [34] Note for guidance on dry powder inhaler (DPI) for use in chronic asthma: chemistry, manufacturing, and

in-house controls: chemistry, manufacturing, and controls documentation. Ref: CPMP/QWP/2845/00. EMEA; 2000 Nov [guideline].

3.6 ICH guideline

- [35] Stability testing: photostability testing of drug substances for use in animals. Ref: Q1B. ICH; 1998 Nov 6 [guideline].

3.7 WHO guideline

- [36] Horowitz B, Minor P, Morgenthaler JJ. Guidelines on viral activation and addition procedures intended to assure the viral safety of animal blood plasma products. WHO Expert Committee on Biological Standardization; 2003 Dec 26-30.

3.8 WHO report

- [37] Swahele S, Lilley N, Yu MW *et al.* An international collaborative study to establish a WHO international standard for B20 rDNA assays. Ref: BS/00.1928. WHO Expert Committee on Biological Standardization; 2000.

3.9 WHO technical report series

- [38] Technical Report Series 96, 47th report. WHO Expert Committee on Biological Standardization; 2004 Jul.

3.10 International standards

- [39] European Committee for Standardization (CEN). Respiratory therapy equipment – Part 1: Nebulizing systems and their components. Ref: EN 13544:2001.

3.11 ISO standards

- [40] International Organization for Standardization. Particle size analysis -laser diffraction methods – Part 1: General principles. Ref: ISO 13320-1:1999.

4. CITATION OF MATERIAL AVAILABLE ONLY IN ELECTRONIC FORMAT

The basic format for electronic sources follows the same principles as for printed references. If deemed necessary, the source of the material (CD-ROM, computer file, etc.) should be identified. The URL address and the date the information was accessed are included at the end of the reference.

4.1 Electronic journal

- [41] VandenBos G, Knapp C, Dowler S. Role of reference elements in the selection of resources by pharmacology students. *J of Bibliographic Research* 1992;5:118-23 [available at: <http://jbr.org/articles.html>, accessed 2001 Oct 13].

4.2 CD-ROM

- [42] Ley J-T, McBairn H. *Clinical cardiology, illustrated* 2nd Edition. San Fransisco: CDEA Multimedia Group; 1995 [CD-ROM].

4.3 Website

- [43] Medicines and Healthcare products Regulatory Agency [website] [available at: <http://www.mhra.gov.uk/index.htm>, accessed 2011 Mar 14].

4.4 No author identified, no date

- [44] GVU's 9th WWW survey. [available at: <http://www.dc.gatech.edu/gvu/usersurveys/>, accessed 2000 Aug 8].