Instructions for authors

Pharmeuropa online and Pharmeuropa Bio & Scientific Notes online

February 2013

Before submitting an article for publication in Pharmeuropa online (Readers' tribune) and Pharmeuropa Bio & Scientific Notes, authors are requested to comply with the instructions in the following document.

Aims and scope

Pharmeuropa online and Pharmeuropa Bio & Scientific Notes (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.

Contributions

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. Authors alone are responsible for the views expressed in signed contributions. If personal communications are cited in the text, authors must obtain written permission for use of such information from those cited.

Mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the European Pharmacopoeia Commission or by the Council of Europe in preference to others of a similar nature that are not mentioned.

Two types of manuscript will be considered for publication:

- 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.

Submitting articles

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

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 include an electronic version with the hard copy. Please note that any original material sent by post will not be returned to the author.

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.

Preparing the manuscript

| Item | Requirements |
|-------------------|--|
| Electronic format | Word or RTF |
| Document format | 2.5 cm margins all around |
| | Numbered pages |
| | A4 |
| Text | Arial (Greek letters in symbol font) |
| | Font size 10 |
| | Double spacing |
| Footnotes | To be avoided; include information in text |
| Tables | Word or Excel |
| Figures | Format: vector EPS (preferred), PSD, TIFF or PDF (except for PDFs generated from scans or screenshots) |
| | Resolution: minimum 300 dpi |
| | Saved in individual files and not embedded in the manuscript file |
| | White background; no background grids |
| | Colour figures: CMYK mode (jpeg, gif and png acceptable for photographs) |
| | Black and white figures: greyscale only |
| | Chemical structures are preferably produced using ChemDraw |
| Figure legends | Arial |
| | Font size 8 |
| | Avoid reverse type (i.e. white lettering on a dark background) |
| | Avoid shaded background |

Technical requirements

General requirements

Pharmeuropa Bio & SN

Articles are accepted in English (using UK English spelling) 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. Articles must be well structured, written in a clear, concise and coherent manner and only contain a reasonable number of tables and figures. Poorly written articles will not be considered for publication and will be returned to the author. Authors who are not native speakers of the language they have used for their article are encouraged to have their manuscript checked carefully by a native speaker before submitting the article for publication.

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 | It clearly indicates the subject of the article, is as concise as possible, contains important keywords and does not exceed 100 characters (including spaces). A sub-title may be included if necessary. |
|--------------------------|---|
| Authors | Authors' surnames and initials are given with their current postal addresses and, if different, their addresses at the time the article was drafted. The author to whom all correspondence is to be addressed (corresponding author) is indicated. Please supply a full postal address and an e-mail address for the corresponding author and ensure that these addresses are correct. |
| Abstract | A concise, self-contained summary (around 250 words) of the problem and the principal results, without experimental details, and which does not contain references. The abstract will be available in the PubMed database of the National Library of Medicine. |
| Keywords | Authors are required to include not more than 6 keywords and to avoid general words. The keywords used will be available in the PubMed database of the National Library of Medicine. |
| 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 | Where applicable, a general overview of the participants involved in the work. |
| 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, contributions from individuals that do not warrant authorship may be acknowledged (for example, technical assistance). Authors are required to obtain written permission from any individuals cited. |
| Participants | Where applicable, individual participants involved in the work may be listed in this section and are listed by country in alphabetical order. |
| 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 | Authors are responsible for the accuracy of references and are required to check them before submitting the article. References are numbered consecutively in the order of citation in the text, using numbers in square brackets, and the list is compiled according to the EDQM's requirements for citing references. All citations in the text appear in the list of references. Reference to personal communications in the text is to be avoided, unless absolutely necessary. If included, authors must obtain written permission from the person(s) cited. |
| Figures and tables | They are kept to a minimum and are as clear and simple as possible. Figures and tables are numbered consecutively, each has a title and they do not represent the same information. Wherever possible, the use of figures rather than tables to represent numerical data is encouraged. Axes are labelled using SI units and all symbols and abbreviations are defined. The formatting of tables and figures is consistent throughout the manuscript. Figures containing chemical structures are preferably produced using ChemDraw. |
| | Colour figures may be included but the colours used should nevertheless allow the figure to remain comprehensible if printed in black and white. Authors should avoid using bright colours and relying on distinctions between colours that colour-blind readers are unable to make. |
| | Authors are responsible for obtaining the necessary permission for reproducing any material that is protected by copyright (this includes any images downloaded from the internet.) |
| Photographs | Only well-contrasted photographs will be accepted, in sufficiently high resolution to allow for good printed reproduction at the size required (a minimum of 200 dpi is required). |

| 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. |

Readers' tribune

There is no fixed format, but articles should be clear and concise. The technical requirements above and the general requirements for figures and tables apply. Articles are accepted in English (using UK English spelling) or French, but will not systematically be translated into the other language. Articles written in French must be accompanied by a comprehensive summary in English.

Review 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 accepted 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 (if necessary, the authors provide appropriate justification if comments have not 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 or tables). Significant changes to the text are unacceptable at this stage.

Publication

Pharmeuropa Bio & SN

Articles are first published online in individual PDF format at the earliest possible date and then assigned for publication in the next cumulative issue of Pharmeuropa Bio & SN (a cumulative issue is published once a year at the end of each year). A PDF of the article, with the pagination that will be used in the cumulative issue, is sent to the corresponding author when the article is first published online. The publication date given for each article is that of its first publication online. Articles published in a cumulative issue of Pharmeuropa Bio & SN are indexed (abstract and keywords) in the PubMed database of the National Library of Medicine.

Readers' tribune

Articles are published online in individual PDF format at the earliest possible date and a PDF of the article is sent to the corresponding author as soon as the article is published.

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. Are the corresponding author's full postal address and e-mail address correct and clearly indicated?
- 4. Is the title concise (fewer than 100 characters, including spaces) and does it contain important keywords?
- 5. Does the text include an abstract?
- 6. Is a list of keywords included?
- 7. Is the text correctly structured using numbered sections and subsections?
- 8. Do all figures and tables have a legend with figure axes correctly labelled using SI units?
- 9. Are all figures and tables referenced in the text?
- 10. Are all graphics supplied in an acceptable format?
- 11. Have the necessary clearances been obtained for publication of any material protected by copyright?
- 12. Are all references cited in the text listed in the references section according to the EDQM's requirements for citing references?
- 13. Has permission been obtained for use of personal communications and from individuals cited under Acknowledgements?

Uniform requirements for reference citing

Introduction

The following real and fictitious examples are given as a guide to the citation style to be used in Pharmeuropa online (Readers' tribune) 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.

Print documents

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.

Scientific note in Pharmeuropa

Purewel TS. Test methods for dry powder inhalers to check performance under normal use and unintentional misuse conditions. *Pharmeuropa* 2002;**14**(3):14-20.

Article in Pharmeuropa Scientific Notes

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

Article in Pharmeuropa Bio

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.

Article in Pharmeuropa Bio & Scientific Notes (identifier from database may be added)

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. PubMed PMID: 20144453.

Journal article with a Digital Object Identifier (DOI)

Sitkowski J, Bednarek E, Bocian W *et al.* Assessment of oversulfated chondroitin sulfate in low molecular weight and unfractioned heparins diffusion ordered nuclear magnetic resonance spectroscopy method. *J Med Chem* 2008;**51**(24):7663-5. DOI: 10.1021/jm801198b. PubMed PMID: 19055319.

Standard journal article

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

Article with more than 3 authors

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.

Article with no author given

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

Material accepted for publication but not yet published

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].

Volume with a supplement

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

Issue with a supplement

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

Volume with a part

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

Issue with a part

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

Issue with no volume

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

No issue or volume

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.

Type of article/source indicated as required

Schutzberger W, Fischer PA. Perindopril in Parkinson's disease [letter]. *Lancet* 1986;**327**:1337. Clements R, Jefferies R. Haematological complications of nephropathy HVN [abstract]. *Kidney Int* 1992;**38**:1285.

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.

Monograph in Pharmeuropa

Methyldopa, monograph 0045. Pharmeuropa 2002;14(3).

Monograph in the European Pharmacopoeia

Salbutamol sulfate, monograph 0687. Ph. Eur. Suppl. 7.2. Strasbourg, France: Council of Europe; 2010. Arnica flower, monograph 1391. Ph. Eur. 7th Edition. Strasbourg, France: Council of Europe; 2010.

General chapter in the European Pharmacopoeia

Bacterial endotoxins, general chapter 2.6.14. Ph. Eur. 7th Edition. Strasbourg, France: Council of Europe; 2010.

Monograph in the USP

Calcium gluceptate. USP 25, NF 20. Rockville, USA: United States Pharmacopeial Convention, Inc; 2002.

General chapter in the USP

Electrophoresis, general chapter <726>. USP 25, NF 20. Rockville, USA: United States Pharmacopeial Convention, Inc; 2002.

Monograph in the JP

Acetazolamide, official monographs. JP XVI. Tokyo, Japan: Ministry of Health, Labour and Welfare; 2011.

General chapter in the JP

Bacterial endotoxins test, general test 4.01. JP XVI. Tokyo, Japan: Ministry of Health, Labour and Welfare; 2011.

Standard book with personal author(s)

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

Editor(s), compiler(s) as author

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

Organisation as author and publisher

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

Book with series title and individual volume

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.

Chapter in a book

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

Chapter as part of an edited/or translated work

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.

Book title in a language other than English/French

Weidenbörner M. Lexikon der Lebensmittelmykologie. Hamburg, Germany: B. Behr's Verlag, 1998. German.

Electronic documents

The basic format for electronic sources follows the same principles as for printed references. The URL address and the date the information was accessed are included at the end of the reference.

Journal article

Rautmann G, Daas A, Buchheit KH. Collaborative study for the establishment of the 3rd international standard for dihydrostreptomycin. *Pharmeur Bio Sci Notes* [Internet] 2012:16-38. PubMed PMID: 23327890 [available from: http://pharmeuropa.edgm.eu/PharmeuropaBioSN, accessed 2013 Jan 13].

Monograph in Pharmeuropa online

Valine, monograph 0796. *Pharmeuropa online* [Internet]. 2012;**24**(1) [available from: http://pharmeuropa.edqm.eu, accessed 2012 January 13].

Monograph in Pharmacopeial forum online

Tamsulosin Hydrochloride Capsules. *Pharmacopeial forum* [Internet]. 2013;**39**(1)[available from: http://www.usppf. com, accessed 2013 January 21].

CD-ROM/DVD

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

Website

MHRA publishes medicines reclassification guidance [Internet]. Medicines and Healthcare products Regulatory Agency. [available from: www.mhra.gov.uk/NewsCentre/Pressreleases/CON213182, accessed 2013 Jan 14].

Citation of miscellaneous sources

Conference proceedings

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.

Conference paper

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.

Poster

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.

Dissertation

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

EMA Guideline

Note for guidance on dry powder inhaler (DPI) for use in chronic asthma: chemistry, manufacturing, and in-house controls: chemistry, manufacturing, and controls documentation [guideline]. Ref: CPMP/QWP/2845/00. EMEA; 2000 Nov.

ICH guideline

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

WHO guideline

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.

WHO report

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.

WHO technical report series

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

EU law documents

Commission Decision 2008/753/EC of 18 September 2008 concerning the non-inclusion of methyl bromide in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance. *Official Journal of the European Union* L 258; 2008 Sept 26: 68-9.

Commission Regulation 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs. *Official Journal of the European Union* L 364; 2006 Dec 20: 5-24.

International standard

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

ISO standards

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