

1. Qualification of Contributors

As a rule, the principal author of a paper shall be a member of the Japanese Society of Generic and Biosimilar Medicines. However, this does not apply if someone outside Japan submits a paper or if a paper is submitted on request.

2. Copyrights

The copyrights of papers, abstracts, articles and the like that are published in the journal are vested in the Japanese Society of Generic and Biosimilar Medicines.

3. Details of Papers

Papers to be submitted shall discuss the formulation, quality, equivalence, added value and other scientific reporting on generic medicines (including biosimilars; GE); surveillance and research relating to the provision of information and dependable supply; and research, surveillance, interpretation and reporting on pharmacology and medical economics of GE. The papers shall never have been published or submitted to any scientific journal or other publisher.

Any research into humans or human tissues shall comply with the ethical principles of the World Medical Association Declaration of Helsinki. Such research must have the approval of the ethics committee of the institution or equivalent body, depending on the subject area. Any animal testing shall follow the animal test guidelines prescribed by the institution.

3-1 Examples of Subject Areas

Formulation design/stability testing of GE
 Bioequivalence testing of GE Efficacy/safety of GE
 Added value of GE Industrialization of GE
 Manufacture/quality control of GE
 Assessment of GE at medical institutions
 Reporting on discussions by manufacturers based on assessments by medical institutions
 Requests for GE from medical institutions
 Various issues associated with the introduction of GE into hospitals
 Current status of the use of GE at hospitals and associated problems
 Supply/distribution of GE and provision of information
 The relationship between domestic and international pharmaceutical regulations/guidelines, and the development/manufacture of GE
 GE and medical economics Etc.

3-2 Type

Japanese Journal of Generic Medicines mainly accepts general papers, short reports, research results and review articles as a rule.

- General papers: as a rule, they need to include new findings on GE obtained from original research activities.
- Short reports: they shall include new findings, valuable data, case reporting and others as a rule, even if it is fragmentary research.
- Research results: they shall include valuable data, although it is not necessary to include new findings.
- Review articles:
 Comprehensive papers: these should be based on the author's research performance and include an overview and comments on studies associated with the author's field.

Invited papers: these are written at the request of the editorial board of the journal.

- Lecture reports: these are written at the request of the editorial board of the journal by the presenters of lectures (symposiums, etc.) at the meeting of the Japanese Society of Generic and Biosimilar Medicines. However, submissions based on short presentations are handled as general papers.

3-3 Languages

Japanese or English

3-4 Length

The length of manuscripts, according to the type of the manuscript, should be as follows. Character count does not include the title, the name(s) of the author(s), the institution(s) of the author(s), as stated in 3-5, and the summary in English (with its Japanese translation) and keywords, and include the main text, figures and tables, references and footnotes.

- General papers: the printed paper shall not exceed 7 pages (1,900 Japanese characters by 6 = 11,400 Japanese characters).
- Short reports: the printed paper shall not exceed 5 pages (1,900 Japanese characters by 4 = 7,600 Japanese characters).
- Research results: the printed paper shall not exceed 7 pages (1,900 Japanese characters by 6 = 11,400 Japanese characters).
- Review articles:
 Comprehensive papers: the printed paper shall not exceed 10 pages (1,900 Japanese characters by 9 = 17,100 Japanese characters).
 Invited papers: the printed paper shall not exceed 13 pages (1,900 Japanese characters by 12 = 22,800 Japanese characters).
- Lecture reports:
 Lectures of up to 30 minutes: the printed paper shall not exceed 5 pages (1,900 Japanese characters by 4 = 7600 Japanese characters).
 Lectures of up to 60 minutes: the printed paper shall not exceed 10 pages (1,900 Japanese characters by 9 = 17100 Japanese characters).
- Each page should be A4 size, with 40 characters by 40 horizontal lines.
- A figure or a table corresponds to 300-600 Japanese characters depending on its size.

3-5 Format

- The first page of the manuscript shall state the title, the names of each author (if the paper is in Japanese, the names in Roman alphabet are to be given as well), the name and address of each institution (the address is only required for the principle author), contact e-mail address, the contact for requesting copies and the contact address for proofreading.
- The second page shall contain an English summary of up to 250 words (with its Japanese translation) and up to 5 keywords (with their Japanese translations).
- The main text should start from the third page.
- Figures, tables and photographs shall be labeled as Fig., Table, and Photo respectively. Serial numbers are to be given if there is more than one. They should carry their

own titles and be supplied separately from the main text. In principle, the original figures, tables, and photographs prepared by the author should be provided. Citation of figures, tables and photographs shall be indicated in the text or in the margin.

- Units: International System of Units (SI) should be used based on the Japanese Pharmacopoeia, 16th edition (2011).
- References: References are numbered in the order in which they are cited, and the number of each reference is given followed by a closing parenthesis as a superscript to the relevant part, along with a closing parenthesis. All references are summarized in the references section at the end of the paper.

– Description of references

For journals, give the details in the following order: 1) name of the author (names of a maximum of 3 authors should be given; other names have to be omitted), 2) title of the paper, 3) name of the journal, 4) year of publication, 5) volume number and 6) page numbers. The name of the journal with its title in the Roman alphabet is typed in italics.

For published books, give the details in the following order: 1) name of the author, 2) title of the book (and the section title), 3) edition and volume number, 4) name of the editor, 5) place of publication, 6) name of the publisher, 7) year of publication and 8) page number. The accessed date should also be given for web pages.

Example

Journal articles:

- 1) Haskins LS, Tomaszewski KJ, Crawford P. Patient and physician reactions to generic antiepileptic substitution in the treatment of epilepsy. *Epilepsy Behav.*, 2005; 7: 98–105.
- 2) Grant R, O’Leary K, Weilburg J, et al. Impact of concurrent medication use on statin adherence and refill persistence. *Arch Intern Med.*, 2004; 164: 2343–8.

Books:

- 3) Meltzer PS, Kallioniemi A, Trent JM. Chromosome alterations in human solid tumors. In: Vogelstein B, Kinzler KW, editors. *The genetic basis of human cancer*. New York: McGraw-Hill; 2002. p. 93–113.

– Footnotes

A footnote shall be provided on the same page as the one in which the footnote symbol or number is placed. The footnote symbol or number shall be clearly indicated in the text.

– Disclosure of Conflict of Interests (COI)

In accordance with this Society’s Rules on Managing Conflict of Interests, all papers submitted shall carry a declaration at the end of the main text, stating whether or not any of the coauthors has a conflict of interests. If there is a conflict of interests, the name of the company or organization in question shall be stated. If any financial assistance, whether direct or indirect, was received from a specific company in the process of conducting the research or preparing the manuscript, this fact shall be stated in the paper.

Example: No conflict of interests.

Conflict of interests. This study was funded by ○○ Co., Ltd.

4. Contribution Procedure

A contributor shall send the contribution data to the

following address by E-mail. Microsoft Office software shall be used for preparing the documents:

- Address: Editorial Office of the Japanese Journal of Generic Medicines
c/o International Academic Publishing Co., Ltd.
Publishing Center, 332-6, Yamabuki-cho, Shinjuku-ku, Tokyo, 162-0801, Japan
TEL: +81-3-6824-9363 FAX: +81-3-5206-5332
E-mail: jjgm-edit@je.bunken.co.jp
Changed to the above E-mail address in January 2025.
Contact: Editorial Office of the Japanese Journal of Generic Medicines
- The acceptance procedure shall be deemed complete when the contributor receives an e-mail response from the contact. If no such e-mail arrives within one or two business days, the contributor shall make an inquiry to the contact as to whether to re-send the contribution data as there could be cases where contribution data fail to be properly received.

5. Evaluation of the Papers and Results

Papers submitted are subject to an assessment for acceptance by two examiners. If a paper is returned after assessment with a request to be resubmitted, it shall be sent back within two months of the day the paper is returned. If the paper is resubmitted after this time, it shall be handled as a new contribution. The journal may request partial corrections to a manuscript for publication. The order in which papers are published shall in principle be the order in which they are received, although it is subject to change for the convenience of assessment and editing.

However, review articles (invited papers) and lecture reports defined in 3-2 are not subject to the assessment mentioned above, but shall be accepted for publication or rejected based on the judgment of the chair of the editorial board; however, the journal may request partial corrections of a manuscript for publication.

6. Publication Fees

Contributors (except the author of an invited paper or a lecture report) shall pay upon request the following publication fees (consumption tax not included) after the paper has been accepted.

- 2,000 yen per printed page
- 3,000 yen per page exceeding the length provided in 3-4
- Figures and tables preparation fee if they are prepared separately: 2,000 yen per 50 cm²

7. Separate Off-Prints

The journal provides PDF file of relevant page to the author at the time of publication.

If the author wishes to obtain printed separate off-prints, the number of copies to be needed can be ordered at the time of proofreading, which is available for a fee.

8. Others

- The author may proofread a paper only once. As a rule, no additions or corrections shall be accepted thereafter, except for typographical errors.
- These rules shall apply from the papers published in the journal, volume 18, number 2. Contributors should refer to the current rules for contributions (available on the web site of the Japanese Society of Generic and Biosimilar Medicines).

Appended table: Instruction by submission type

Type	Length	Evaluation	Publication fee	Notes
General papers	The printed paper shall not exceed 7 pages	Subject to assessment	2,000yen × number of pages	
Short reports	The printed paper shall not exceed 5 pages	Subject to assessment	2,000yen × number of pages	
Research results	The printed paper shall not exceed 7 pages	Subject to assessment	2,000yen × number of pages	
Review articles: Comprehensive papers	The printed paper shall not exceed 10 pages	Subject to assessment	2,000yen × number of pages	
Review articles: Invited papers	The printed paper shall not exceed 13 pages	Not subject to assessment: partial corrections may be requested by the judgment of the chair of the editorial board.	Free	
Lecture reports	Lectures of up to 30 minutes: the printed paper shall not exceed 5 pages Lectures of up to 60 minutes: the printed paper shall not exceed 10 pages	Not subject to assessment: partial corrections may be requested by the judgment of the chair of the editorial board.	Free	Submissions based on short presentations are handled as general papers.

Recommendations concerning statistical analysis, etc.

The editorial board of the Japanese Journal of Generic Medicines

Samples

When study samples are drugs used for medical purposes, give the name of the manufacturer and the lot numbers if possible. If symbols such as “A,” “B,” etc. are used, provide the reason.

Statistics

For comparison between 2 or more groups, it is recommended to prepare the paper taking the following matters concerning data aggregation, statistical analysis, and discussion into consideration:

- 1) The parameter that shows the fluctuation of measured values should basically not be given in standard error, but in standard deviation. It is desirable to show the data distribution visually such as by a Box plot.
- 2) For comparison of the mean between groups,
 - 2-a) Discuss the uniformity of the arrangement of background factors (items) other than the evaluation item between the groups to be compared.
 - 2-b) Describe the authors’ opinion on how large a difference in the value of the subject indicator has to be considered as a meaningful difference (clinically

significant differences).

- 2-c) Describe the justification for the selection of the number of subjects and the number of cases in the study.
- 2-d) Use multiple comparison to compare 3 or more groups.
- 2-e) The p value should not be shown as $p < 0.05$ or $p < 0.01$, etc; the precise p value should be shown.
- 2-f) For the discussion of results based on statistical tests and statistical estimations, clinically significant differences, the number of data (number of subjects and number of cases), etc. should be considered in addition to the results such as statistical significance tests. Note that the statistical conclusion is not directly connected to clinical “equivalence” or “nonequivalence.” It may help to include and utilize a confidence interval so that a hasty discussion can be avoided.

Please take the recommendations listed above into consideration.