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1 PURPOSE

This Boehringer Ingelheim (BI) cross-divisional Associated Document (AD) details the minimum requirements needed to meet the mandatory technical and non-technical specifications globally, and are of a BI-approved, preferred, and consistent format and style.

This AD supplements BI-VQD-11905_65 -090 BI Style Guide for Submission Documents.

2 DEFINITIONS & ABBREVIATIONS

See [eGlossary](#) or type <http://glossary/> in your browser.

A term in *italics* indicates a definition is available in the glossary.

3 PROCEDURE / CONTENT

3.1 MANDATORY TECHNICAL AND NON-TECHNICAL SPECIFICATIONS

3.1.1 Document language

- All documents needed for international purpose must be available in English language. British English is preferred and should consistently be used throughout the document, as well as amongst documents belonging to the same project and / or submission.
- Documents needed for submission of a local product may be created in local language. For translations the BI “Language Management” has to be contacted.

3.1.2 Font type, size, and colour

- General font requirements
 - The use of a black font colour is **mandatory**. The only exception is hyperlink texts (see Section [3.1.6.2](#)).
 - Hand-written notes **must be avoided and not included in a document**.
- Font requirements for narrative text and Table of Contents (TOC)
 - The font for narrative text including headers and TOC is 12 point Times New Roman (TNR), unless otherwise described in this document.
 - Characters and fonts: Symbols are allowed in the body of the text but **must be avoided** in headings and captions. Frequently, symbols do not appear correctly in the bookmarks and published TOC.

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- Font requirements for non-narrative text
 - For non-narrative text (e.g. data tables), the fonts listed in [Table 1](#) may be used. **TNR is preferred**, however.
 - Use font sizes ranging from 9 to 12 point (or equivalent based on font type). When choosing a point size for tables, a balance should be made between providing sufficient information on a single page that may facilitate data comparisons while still achieving a point size that remains legible. Generally, point sizes 9-10 are recommended for tables; smaller point sizes **must be avoided**. Footnotes **should be** 9 point font and single spaced.

Table 1 Additional Fonts for Non-narrative Text and Special Characters

Font type	Font name
Sans Serif	Arial
	Arial Italic
	Arial Bold
	Arial Bold Italic
Non-proportional	Courier New
	Courier New Italic
	Courier New Bold
	Courier New Bold Italic
Serif	Times New Roman
	Times New Roman Italic
	Times New Roman Bold
	Times New Roman Bold Italic
Other	Symbol
	Zapf Dingbats

3.1.3 Page orientation

The page orientation can switch between portrait and landscape within the document, depending on the content of the page. This eliminates the need for the reviewer to rotate pages. See Sections [3.2.5.5](#) and [3.2.5.6](#) for additional information on header and footer orientation.

3.1.4 Page size and margins

- The text area **must fit onto** A4 and US letter size with upper, lower, left and right margins of **at least** 25.4 mm or 1 inch all round, i.e. the text area **must not be larger**

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than 22.86 x 15.92 (portrait) / 15.92 x 22.86 (landscape) cm (9.00 x 6.27 / 6.27 x 9.00 inches).

- A mixture of A4 and US letter format pages within a single document is allowed as long as the above margins are followed.
- Oversized documents and promotional materials submitted in Portable Document Format (PDF) should be created according to their actual page size.

3.1.5 Page numbering

- For ease of navigation, the initial page of a document **must be numbered** as page one, but it is not mandatory to add the number to the initial page.
- If a document is split because of its size, the second or subsequent file is numbered consecutively to that of the first or preceding file.
- Pagination may follow the format: Page x of y (i.e. Page 3 of 7).

3.1.6 Document navigation

3.1.6.1 Table of contents and bookmarks

- Documents that contain headings and are more than 5 pages **must contain** a hypertext linked TOC and bookmarks.
- For documents with a TOC, provide bookmarks and hypertext links for each item listed in the TOC including all tables, figures, publications, other references, and appendices that are essential for navigation through documents.
- Use invisible rectangles and blue text for hypertext links in the TOC
- Bookmarks (and subsequently the generated TOC) are **up to four levels deep** in the hierarchy. If a Heading Style 5 is necessary, it **must have the same optical layout** as a Heading Style 4 but use level Heading Style 5 in order to display correctly in the bookmarks and TOC. It is **not allowed** to display further heading styles in the bookmarks or TOC, as this makes it difficult to review the document.
- Set the magnification setting to “Inherit Zoom” so the destination page displays as the same magnification level used in the primary document.

3.1.6.2 Hypertext links

- Use hypertext links throughout the body of all documents to link to supporting annotations, related sections, references, appendices, tables or figures that are not located on the same page as the narrative text. If the reference appears more than one time on the same page, the hypertext link should only be set the first time the citation appears on the page.
- Hypertext links in text **must be distinguished** by use of blue (underlined) text.

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- Hypertext links within the submission package are only allowed to be set by publishing units. Hypertext links that open a file or document **should be set** to open the file or document in a new window.
- Set the magnification setting to “Inherit Zoom” so the destination page displays as the same magnification level used in the primary document.
- Hypertext links to *external* websites (internet, etc.) or email addresses **must be avoided**, as they often change their locations over time, and BI takes over responsibility for the content of a referenced internet link.
- Hyperlinks to *internal* websites (e.g. intranet, MyBI etc.) **must not be used** for documents intended to be submitted, as they cannot be accessed by external parties and may lead to refusals.

3.1.6.3 Headings / numbering

- Text headings are structured into levels. It is important that each level is consistently defined and used throughout the document.
- Multiple-line headings should be spaced like general text (see Section 3.2.1)
- Heading Levels:
 - **1st level:** Left-justified, bold print, 14 point, all in capital letters, preceded by two extra lines spacing (or start of a new page), and followed by one extra line spacing. Text returns to the left margin.
 - **2nd level:** Left-justified, bold print, 12 point, all in capital letters, preceded by one extra line spacing (or start of a new page), and followed by one extra line spacing. Text returns to the left margin.
 - **3rd level:** Left-justified, bold print, 12 point, capitalisation of the first letter of the first word only, preceded by one extra line spacing (or start of a new page), followed by one extra line spacing. Text returns to the left margin.
 - **4th level:** Left-justified, 12 point, capitalisation of the first letter of the first word only, preceded by one extra line spacing (or start of a new page), and followed by one extra line spacing. Text returns to the left margin.

Example:**1. EFFICACY PARAMETERS****1.1 PRIMARY EFFICACY PARAMETERS****1.1.1 Appropriateness of measurements**

1.1.1.1 Intent to treat analysis

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3.1.7 Tables and figures

- The title of a table or figure should always begin with the key word “Table” or “Figure” respectively, with capitalisation of the first letter only. In the title itself, the first letter of the first word should be capitalised.
- Table titles are located above the table. Figure titles can be located above or below the figure, but the approach used within a document must be consistent. Both table and figure titles should be single-spaced.
- Table and Figure titles should briefly summarise the contents of the respective object and **must not be** more than 255 characters in length. Additional descriptive information should be contained in column / row headers and / or footnotes as needed.
- Tables and figures should be numbered in a unique manner over the entire document.

3.1.7.1 Other considerations for tables and figures

- **Do not use** background shading in tables and figures.
- Photographs may be included in documents as figures. Black and white photographs are recommended, unless scientifically necessary and to meet specific regulatory expectations (e.g. coloured chromatograms of plant extracts).
- Tables **must use** only black font; bold, italics, or underlining may be used for emphasis where needed.
- Figures should be generated in black and white or greyscale whenever possible. The use of symbols, differential shading, or other methods of differentiating various types of data in figures is preferred; however, if necessary for clarity, colour may be used in figures. When colour is used, care should be taken to further differentiate data using symbols or other markers if possible, to avoid ambiguity for colour-blind reviewers or in the case the document is printed in greyscale.

3.1.7.2 Footnotes for tables and figures

- Footnotes **should be** 9 point font and single spaced.
- If there are multiple footnotes, the beginning of the footnote text should be aligned with the beginning of the text of all other footnotes.

Example:

Table 11: 1 Composite primary endpoint, intention-to-treat period, adjudicated data – RS

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	DE	SoC
Number of patients randomised, N (%)	177 (100.0)	90 (100.0)
Complete thrombus resolution	81 (45.8)	38 (42.2)
Freedom from recurrent VTE	170 (96.0)	83 (92.2)
Freedom from mortality related to VTE	177 (100.0)	89 (98.9)
Composite endpoint met	81 (45.8)	38 (42.2)
Difference in rate (90% CI) ¹	-0.038 (-0.141, 0.066)	
Difference in rate (95% CI) ¹	-0.038 (-0.161, 0.086)	
p-value for non-inferiority	<0.0001	
p-value for superiority	0.2739	

¹ Mantel-Haenszel weighted difference with age group as stratification factor

Source data: Table 15.2.1.1: 1

- In instances where superscripted numbers are not optimal, an asterisk (*) or other listing schemes may be used (a, b, c ...)
Note: if the table text font size is 9 or 10, superscripted schemes should not be used.
- Footnotes for a table that spans multiple pages should be placed at the end of the table.

3.1.8 File size

In the event the file or its PDF rendition exceeds 100 Megabytes (MB), the document **must** be split into two or more files. In this case, make the division at logical places within the document (e.g. 1st Level Headings).

3.1.9 Page numbers

- For general guidance on pagination see Section 3.1.5. Every page of a document as defined must be numbered consecutively (including appendices and attachments) starting at page one.
- Special cases and exceptions for page numbering:
 - Where a document is split because of its size (i.e. documents of more than 100 MB), the second or subsequent file should be numbered consecutively to that of the first or preceding file. The total number of pages in the header of each document is the sum of the pages of all files.
 - Where several small components with their own internal page numbering have been combined into a single document, it is not necessary to provide additional page numbering; instead the start of each component should be bookmarked (see Section 3.1.5).

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3.1.10 File formats

- The following file formats should be used:
 - PDF Version 1.4 is preferred. Consult regional guidance to submit other versions of PDF.
 - SAS XPORT transport files (XPT) for datasets, index files (IDX) for SAS
 - Extensible Markup Language (XML)
 - Style Sheets (XSL) including Cascading Style Sheets (CSS), Document Type Definition, Module (DTD, MOD) and XML scheme (XSD) for the XML document information files
 - ASCII text (e.g. SAS program files) using txt for the file extension
 - Graphic: Whenever possible, use PDF. When appropriate or when PDF is not possible, use:
 - Joint Photographic Experts Group (JPEG)
 - Portable Network Graphics (PNG)
 - Scalable Vector Graphics (SVG)
 - Graphics Interchange Format (GIF). Special formats for very high resolutions may be appropriate on a case-by-case basis.
 - Media Files (MPEG)
 - Microsoft Word (MS Word) for draft labelling
- The Rich Text Format (RTF) is **not appropriate** for electronic submissions.

3.1.11 Portable document format files

3.1.11.1 Source of electronic documents

- Text-based PDF files **must be** created whenever possible.
 - The main body of text and main tables must be text searchable.
 - For documents created within BI, text-based PDF files are to be generated as PDF renditions of Word files within the document management system using the appropriate templates or as SAS output in PDF format.
- Avoid the use of image-based PDF files.
 - If a document is created using an image-based PDF, such as legacy documents or documents that were generated independent from BI and might be available only as hard copies, it **should be** made text searchable where possible.
 - If optical character recognition software is used, verify that imaged text is converted completely and accurately **before** storage and archiving in the document management system.

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- Instructions for scanner settings
 - Avoid the use of greyscale or colour because of file size. If necessary, refer to [Table 2](#) for minimum resolution settings for scanning.
 - The optimal image resolution and bit depth depends to a large part on the actual need for viewing the image. **Do not** provide images at high resolution and depth without determining the need. High resolution and depth images result in large files, taking up valuable storage space.
 - When creating PDF files containing images, images **must not** be resampled. Resampling does not preserve all of the pixels in the original.

Table 2 Minimum resolution settings for scanning

Document type	Resolution
Paper documents	300 Dots per inch (dpi)
Plotter output graphics	300 dpi
High-Pressure Liquid Chromatography (HPLC) or similar images	300 dpi
Photographs – colour (24-bit RGB)	600 dpi
Photographs – black and white (8-bit greyscale)	600 dpi
Gels and karyotypes (8-bit greyscale)	600 dpi

3.1.11.2 PDF settings

- The document open options set the document view when the file is opened. Set the initial view of the PDF files to **Bookmarks Panel and Page** to help with the ease of review. If there are no bookmarks, the initial view is set as **Page only**. Magnification and Page Layout is to be set to **Default**.
- If the page (content) orientation is switching within a document, the PDF file should be adjusted accordingly so that a reviewer does not need to rotate pages (see Section [3.1.5](#)).

3.1.11.3 Security settings

- There **must be no** security settings or password protection on PDF files.
- Printing, changes to the document, selecting text and graphics, and adding or changing notes and form fields **must be** allowed.

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3.1.11.4 Embedded fonts

- There is no need to embed the standard fonts (see Section 3.1.1).
- Fully embed all non-standard fonts used in the PDF file, especially specific BI fonts and the BI logo.
- For two-byte fonts such as Japanese fonts, it is sufficient to embed a subset of the font (i.e. only characters used in the document will be embedded). Other customized fonts **should not be** used.

3.1.11.5 Image compression to reduce file size

- For lossless compression of colour and greyscale images, ZLIB / DEFLATE should be used (4.1), (4.2).
- For lossless compression of black and white images, the ITU Telecommunication Standardization Sector [former Consultative Committee for International Telegraph and Telephone (CCITT)] Group 4 (G4) Fax compression technique should be used. It is specified as ITU.T.6 recommendations [former: “CCITT recommendations T.6 (1988) - Facsimile coding schemes and coding control functions for Group 4 facsimile apparatus” – updated by: “Terminal characteristics for Group 4 facsimile apparatus,” Recommendation ITU-T T.563 (10 / 96), ITU-T, Telecommunication Standardization Sector of ITU. (1996)].
- Medical images such as X-ray, Computed Tomography (CT), sonography, Positron Emission Tomography (PET), and Single-Photon Emission Computed Tomography (SPECT) **should not** be compressed.
- If lossless compression is used, there should not be a change in the label size and format.
- A captured image should not be subjected to non-uniform scaling (i.e. sizing).

3.1.11.6 Optimise for fast web view

Create files from source documents using the “Optimise the PDF for fast web view” option to reduce file sizes and file opening times.

3.1.11.7 Use of thumbnails

PDF files **must not** contain embedded thumbnails.

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3.2 BI-PREFERRED FORMATTING REQUIREMENTS**3.2.1 Text general**

- Text should be left-justified with one (1) or one and a half (1.5) line spacing.
- One line break should be added between paragraphs.
- Paragraphs which span a page break should contain at least two lines of text on either side of the page break (a heading should not be separated from its subsequent paragraph). The “keep with next” or “keep lines together” options available in MS Word should be utilised to achieve proper page breaks, not hard returns.
- A decimal point rather than a comma should be used (e.g. 0.25 not 0,25). Use a leading zero if the absolute number is less than one (e.g. 0.25 not .25).
- A range of numbers should be indicated by a dash without blanks (e.g. 9-12).

3.2.2 Table formatting (font)

Example:

Table 10: 1 Format as 'corporate style (CS) table label' or 'CS table label continued' if needed

	Treatment A	Treatment B	Total ¹
Number of randomised patients ² , N (%)	xxx (xx.x)	xxx (xx.x)	xxxx (100.0)
Age ³ , mean (SD) [years]	xx (x.x)	xx (x.x)	xx (x.x)
BMI, mean (SD) [kg/m ²]	xx (x.x)	xx (x.x)	xx (x.x)

Additional explanatory text is to be added before the footnotes.

1 Use CS footnote reference or CS table footnote as format. Preferably, use numbers for footnoting.

2 Indent slightly to align the footnote text with the text in the table.

3 Use no blank line between table and reference to source/source data if the reference comes without other footnotes, but use 1 blank line between last footnote and reference to source/source data if the reference comes with footnotes.

Source data: Table x

3.2.3 Numbering of tables and figures

- Two approaches are acceptable, but the approach used within a document must be internally consistent:
 1. Tables and figures may be numbered consecutively throughout the document.

Example of numbering of a figure (table),

Figure 1 (Table 1).

Reference in the text to this figure (table):

In Figure 1 (Table 1) the following information is given ...

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2. Figures and tables may be numbered according to the numbering of the section, followed by a colon, space and a consecutive number according to where they appear in the text.

To avoid lengthy table captions, it is also possible to use only the first level number of a section together with a consecutive number per section:

Example of numbering of a figure (table), e.g. as first figure (table) in section 12, appearing in the sub-section **12.2.3.4**:

Figure 12: 1 (Table 12: 1).

Reference in the text to this figure (table):

In Figure 12: 1 (Table 12: 1) the following information is given ...

- Titles of tables and figures should be repeated for tables and figures that span more than one page, using the format “Table 1 (cont.):” or “Table 1 (cont’d):”
- Further details for the formatting of tables and figures may be regulated by individual document template, if necessary.

3.2.4 File name

- The file name is an identifying name given to an electronically stored computer file, conforming to limitations imposed by the operating system. The file name must conform to the following format:
 - All characters **must be** lower case.
 - Numbers (digits) may be part of the file name.
 - No special characters like commas, colon, underscore, and no spaces. The only special character allowed is dash (-) and a full stop/period (.) for the extension.
 - Maximum length for the file name is 64 characters, including the extension (e.g. “.pdf”); only one extension is permitted.
- Appropriate file names or naming conventions should be provided by individual document Standard Operating Procedures (SOPs) / Guidelines.

3.2.5 Document identification

3.2.5.1 Identifying number(s)

- A unique identifying number **must be placed** on every page of a submission-relevant document. To ensure consistency of BI submission documents, the Document Number + major version in the document management system is the preferred option for this purpose.
- For nonclinical and clinical documents, additional study-specific identifying numbers **may be added** as appropriate.

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For Chemistry, Manufacturing, and Control (CMC) documents, the “BI number” or study / internal number or analytical procedure number (if applicable) **may be added** as appropriate.

3.2.5.2 Company identification

- The BI logo should appear on the first page in the upper right corner of the page.
- The BI logo definition **must be used** in compliance with the Corp Design rules (4.3).
- For submission-relevant documents, the true type BI Logo font **must be embedded** into the PDF file as appropriate.
- The words **BI should appear** in bold font in the header of every page after the first page.
- Preference is to include the BI company information when possible.

3.2.5.3 Global master dossier core document title

For CMC and Nonclinical documents the global master dossier core document title as defined by “List of Submission-relevant BI Core Documents” (4.4) should appear on the title page (for documents in report format (4.5)) or first page (for documents in the non-report format (4.6)) and in the header of every subsequent page, unless otherwise agreed previously with the responsible function.

3.2.5.4 Proprietary confidential information and copyright statement

For submission-relevant documents a proprietary confidential information and copyright statement is **mandatory**. This statement **must be placed** at least on the title page or first page of the document. It is also recommended to place an abbreviated statement as part of the document header on each page of the document.

- The full statement should read as follows (original style and font size):

Proprietary confidential information

© 2020 Boehringer Ingelheim International GmbH or one or more of its affiliated companies. All rights reserved.

This document may not - in full or in part - be passed on, reproduced, published or otherwise used without prior written permission

- The abbreviated statement should read as follows (original style and font size):

Proprietary confidential information © 2015 Boehringer Ingelheim International GmbH or one or more of its affiliated companies

Note: This statement is addressing BI requirements on the external use of submission documents and does not necessarily reflect the definitions on document confidentiality according to “Information Protection” Policy (4.7).

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3.2.5.5 Document header

- The document header is part of the upper margin of the page and should be separated from the text.
- Landscape pages should have headers aligned to the landscape layout.
- Refer to Section 3.1.4 for further information on margins.

3.2.5.6 Document footer

- Document footers **must not be used** for submission-relevant documents.
- Landscape pages should have footers aligned to the landscape layout.
- Eight (8) point font is acceptable for the confidentiality statement printed in the footer of documents.

3.2.6 Style of chemical notation

- Chemical notation should be according to the International Union of Pure and Applied Chemistry (IUPAC) or Chemical Abstracts Service (CAS).
- Graphic and molecular formulae should be drawn up according to the IUPAC.

3.2.7 Citing references in the text

- In-text references may be made to other sections, figures, tables, references or appendices within the same document, and / or to other documents.
- In-text references within the same document may be written as “see xxxx”. Capitalise the first letter of the section, figure, table or appendix that is cited in the in-text reference, and include the text plus number in the reference.
- If an in-text reference goes to a large appendix, additional details may be given to clearly identify the source of the reference; e.g. section (or page number) of the appendix.

Examples: (Detailed information is provided in Section 2 of Appendix 5) or
(see Table 16) or
(see Appendix 5, Section 2) or
(see Appendix 16.1.13.1, Table 1.1)

- For clinical and nonclinical documents, in-text references to other documents should use either consecutive numbering or BI reference style for Clinical Trial Reports (CTRs).

Example (consecutive numbering):

“Other investigators (1, 2, 3) have used a similar design ...”

Example (CTR reference style):

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“Other investigators (U94-1234, U97-0987, c00012340-01) have used a similar study design ...”

- For CMC documents, the in-text reference to other documents may be general descriptive text (e.g. “the primary stability data”), or the identifying number of the document, or the document title with or without the identifying number. If the identifying number of the document is cited, it should be either the Document Number or the BI number. The in-text reference should generally cite the location of the information in the Common Technical Document (CTD) format (e.g. “batch analyses (3.2.P.5.4)”).
- The use of other references may be defined by specific document SOPs, guidelines or Corporate Procedures (CPs) if necessary.

3.2.8 Style of the reference list

- The requirement for a reference list of documents cited in the text is defined in specific document SOPs, Guidelines or other CPs. Not all submission-relevant documents require a reference list.
- The official BI reference style (Vancouver style) is an internationally accepted standard for referencing in scientific journals (4.8). This citation format is preferred for submission relevant documents.

3.2.8.1 General format

- Format for publications
Author(s) Last Name *space* **Initial(s)**. *space (max. 3 authors followed by et.al.)* **Full title.** *space* **Journal abbreviation** *space* **Publication year; Volume(Issue):pp-pp**(*first page-last page*).
- Format for unpublished documents / technical reports
Full title. *space* **Study / internal number** (if available). *space* **Version number** (if applicable). *space* **Document (Report) date**.
- The official BI Document Identifier (see Section 3.2.4) must be added to the general format.
- Depending on the reference style, the identifier may precede the reference (for CTRs) or can be added at the end of the citation (for Nonclinical and CMC documents, others). For CMC documents, the document (report) date may be omitted.
- For Drug Master Files (DMF) the DMF Number is used as the reference identifier.
- For references to BI internal documents, it is recommended to omit the name(s) of author(s).

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3.2.8.2 Examples for consecutive numbering, as they appear in the text

1. [14C]BIBR 277 SE: investigations on non-linearity and metabolism by means of the isolated perfused rat liver. B682. 11 Dec 1996. U97-2015-01.
2. Clemenz M, Frost N, Schupp M, et al. Liver specific peroxisome proliferator-activated receptor alpha target gene regulation by the angiotensin type 1 receptor blocker telmisartan. *Diabetes* 2008;57(5):1405-1413.
3. Inouye SK, Charpentier PA. Precipitating factors for delirium in hospitalized elderly persons: predictive model and interrelationship with baseline vulnerability. *JAMA* 1996;275(11):852-857. R08-2611.
4. DMF 17322, Respimat[®] Inhaler for the use with inhalation spray drug product.
5. Batch Analyses for Telmisartan Tablets 40 mg / tablet. A123456

3.2.8.3 Examples for BI reference style in alpha-numeric order

Published references:

- P08-06297 Clemenz M, Frost N, Schupp M, et al. Liver-specific peroxisome proliferator-activated receptor alpha target gene regulation by the angiotensin type 1 receptor blocker telmisartan. *Diabetes* 2008;57(5):1405-1413.
- R08-2611 Inouye SK, Charpentier PA. Precipitating factors for delirium in hospitalized elderly persons: predictive model and interrelationship with baseline vulnerability. *JAMA* 1996;275(11):852-857.

Unpublished references:

- c00012340-06 Investigator's Brochure. Idarucizumab (BI 655075). Version 6. 20 Feb 2006.
- U97-2015-01 [14C]BIBR 277 SE: investigations on non-linearity and metabolism by means of the isolated perfused rat liver. B682. 11 Dec 1996.

3.2.9 Style conventions**3.2.9.1 Acronyms and abbreviations**

- In both the text and list of acronyms and abbreviations, the expanded form is given in lowercase letters, unless the expansion contains a proper noun, is a formal name, or begins a sentence (capitalise the first word only) (4.9).
- If a document contains a list of acronyms and abbreviations, the list should be sorted alphabetically.
- Acronyms and abbreviations should be distinctive and used consistently throughout a document. If the document has an abbreviation list, the definition of the abbreviation / acronym should be provided in the abbreviation list and does not need to be spelled out the first time it is used. In documents without an abbreviation list, the abbreviation /

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acronym should be completely spelled out at first use with the abbreviation in parentheses following the complete word or phrase. Thereafter, only the acronym or abbreviations should be used.

Example:

AE	Adverse event
aPTT	Activated partial thromboplastin time
aVTEt	Acute VTE treatment
C _{max}	Maximum measured concentration

3.2.9.2 BI drug names and drug product names

- Different names and codes are used for BI drugs or Active Pharmaceutical Ingredients (APIs) during the process of development, e.g. BI substance code, International Nonproprietary Name (INN) and trade name. The format of salt or hydrate forms are provided by a corporate procedure (4.10).
- All BI compounds and trade names are referenced in the Corporate Product Database (CPD-x) and all CPD-x dependent electronic systems.
- The INN_Mod or INN should be used as preferred term, if no INN is available, the respective BI Substance code should be used.

Examples: nevirapine (Viramune®)
 nevirapine (BIRG 587 BS)
 WAL 1097 (impurity of epinastine hydrochloride [WAL 801 CL])
 nevirapine (Viramune®); epinastine hydrochloride (WAL 801 CL)

- In case of non-BI reference substances, the INN_Mod or INN should be used as described above.
- There are no recommendations for the specific use of trade names. Follow the corporate guidelines for appropriate use of BI trademarks.(4.11)
- Details for the use of specific naming conventions may be defined by other SOPs, CPs, guidelines or guidance, if necessary.
- If trade names are used, the ® or ™ symbols should be added only at the first mention within the document body, but may be omitted thereafter. These symbols should not be used in section headings or table / figure titles.

3.2.10 Format deviations

Submission-relevant documents not compliant regarding format requirements specified by this or other dedicated CPs / SOPs need an approval by Global Regulatory Affairs (GRA) and the respective Corporate Archive. A waiver form is available (4.12).

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4 LIST OF REFERENCES

No.	Document ID	Title
4.1		RFC 1950 ZLIB Compressed Data Format Specification version 3.3. P. Deutsch, J-L. Gailly. May 1996 [R06-2121]
4.2		RFC 1951 DEFLATE Compressed Data Format Specification version 1.3. P. Deutsch. May 1996 [R06-2122]
4.3		Guidance on Corporate Logo, current version; Corporate Design Webpage: CDweb / Basics / Corporate Logo
4.4	<i>001-MCS-65-710_RD-08</i>	List of Submission-relevant BI Core Documents
4.5	<i>029-DCP-001</i>	Nonclinical and Chemistry, Manufacturing and Controls Reports
4.6	<i>029-DCP-002</i>	Format for Non-Report Documents
4.7	<i>100-BIPOL-00211</i>	Global Information Protection Policy
4.8		International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals: Writing and editing for biomedical publication. J Pharmacol Pharmacother 2010;1(1):42–58. [R06-2233]
4.9		AMA Manual of Style, A Guide for Authors and Editors, Chapter “Abbreviations”, current version on the internet
4.10	<i>029-RCP-004</i>	Boehringer Ingelheim Code for Research and Development Compounds
4.11		Corporate Procedure on Tradenames of Human Pharmaceutical Preparations (SBU Ethical Pharmaceuticals), the Use of Trademarks and Generic Names”, current version; BI Intranet: MyBI / Our Functional Areas / CBD Finance / Global Legal / Corporate Legal Human Pharma / Information Portal / Internal Information Sources
4.12	<i>BI-VQD-11905_65-090_AD-02</i>	Planned Exceptions to BI Submission Document Processes and Format Requirements – Waiver Form

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5 DOCUMENT HISTORY

Version	Effective Date (dd mmm yyyy)	Description of Changes	GPO
1.0	08 Feb 2021	New Reference Document to the Cross-Divisional Regulation 001-MCP-090	Andrea Wagner
2.0	See document information in DMS for controlled documents	3.2.3 Numbering of Tables and Figures in 2. examples and text better aligned First sentence of 3.2.3 moved into 3.1.7 Tables and Figures Technical update to implement new Medicine naming convention Abbreviations moved to eGlossary.	Andrea Wagner

Document Approvals

Approved Date: 25 Apr 2022

Task: Initial Approval Verdict: Approve Purpose:	Andrea Wagner, (andrea_1.wagner@bi-docs.com) Author Approval 11-Apr-2022 12:00:58 GMT+0000
Task: Initial Approval Verdict: Approve Purpose:	Benita Glahn, Dr. (benita.von_glahn@bi-docs.com) Reviewer Approval 19-Apr-2022 09:31:44 GMT+0000
Task: Final Approval Verdict: Approve Purpose:	Joerg Schnitzler, Dr. (joerg.schnitzler@bi-docs.com) Quality/Compliance Approval 19-Apr-2022 12:15:18 GMT+0000
Task: Final Approval Verdict: Approve Purpose:	Lennart Jungersten, Dr. (lennart.jungersten@bi-docs.com) Management Approval 25-Apr-2022 07:42:17 GMT+0000