**ENGLISH QC FORMATTINGS**

1. **US Region:**
2. Ensure “Track Changes” option is turned “ON” before starting the QC.

Before starting any English QC Activity, make sure that the Track Change-Formatting functionality settings are checked.

Please see the screen shots below:

Click the Track Changes Option in “Review” Tab. Then Click on “Advanced Options”.

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Paper orientation in printing: 

1. Apply the markers (Paragraph attribute on).
2. Alignment of the text must be consistent i.e. left or Justification.
3. Font and font size must be consistent throughout the document except font size in the table. If there is a lot of content in the table, font size may be less than the font size in the paragraph.
4. Number and Measuring Unit should always be separated by a non-breaking space (replace normal/soft space with hard/non-breaking space – press ***shift + ctrl + space bar***.
5. Replacing soft hyphens with hard hyphens throughout the document as per US specification - press ***shift + ctrl + minus button***.
6. Check if the line number is getting displayed at the bottom bar, if not then right click on the bottom bar and select line number.
7. Removal of extra normal spaces between the texts.
8. Removal of extra line spaces between the paragraphs or before and after headings.
9. As per the FDA Stylesheet, casing of headings:

In USPI:

* 1st level headings - BOLD and UPPERCASE
* 2nd level headings - BOLD and Sentence case (1st letter of each word uppercase).
* 3rd level heading UNBOLD and UNDERLINE, Sentence case

In TOC:

* 1st level headings - BOLD and UPPERCASE
* 2nd level headings - Unbold and Sentence case (1st letter of each word uppercase).

1. Casing of product name and drug name must be consistent throughout the document.
2. Casing of unit litre ‘L’ must be uppercase.
3. Representation of units must be consistent “mcg” or “µg”.
4. Symbols must be insert from insert symbol menu.
5. End period or comma or semicolon must be present at the end of sentence for consistency.
6. Widow orphan control and keep with next to avoid breaking of heading and sentence.
7. When adding “Keep with Next” option for a particular heading, please remember do uncheck the “suppress line numbers”.
8. Word settings set to “Do not compress images in file” to ensure illustration micro-text resolution is maintained after adding a high-resolution image to the document. (How: File→Options→Advanced→Image Size and Quality→check Do not compress images in file’).
9. Representation of table and figure heading (table and figure with number, alignment and casing).
10. Using of comma as thousand separators or no thousand separators (e.g., 1,000 or 1000 and 10,000 or 10000).
11. Font of bullets and content should be the same as font of entire document.
12. Paragraph indentation and spacing must be consistent (Indentation - Left, Right, Special), (Spacing – Before, After, Line Spacing).
13. Insert repeat headers for tables (if the table is continuing in next page).
14. If there is an abbreviation in the table it must be checked for the expansion in the footnote, also whenever the abbreviation is updated/deleted the same must be checked in the footnote.
15. Keep with next must be applied to:

* Every heading/ subheading and its consecutive line space.

Bullet points:

* If there are 3 bullet points apply KWN to first 2 bullet points
* If there are 2 bullet points apply KWN to first bullet point
* If there is only one bullet point or more than 3 bullet points present under the heading, apply KWN only to heading and its consecutive line space.
* Applies to Excipients section and Address part.

1. Terms like *in vitro*, *in vivo, in utero, in situ, de novo, E.coli* and other Latin terms/scientific words must be italicized in the document.
2. Images also must be checked for correctness all the abbreviations in the graph must be expanded in the footnote.
3. Images must be checked for clarity and legibility, ILL number must be present on all the images
4. The ILL number must be checked for readability on the image and the same number must be entered in “ALT text” field if the “ALT text” field is blank.
5. Ensure hyperlinks of cross references, (including table of contents (TOC), “see Boxed Warning”, “see Medication guide”, “See IFU”) are active and correct.
6. Check if the cross-reference numbers are valid and all their respective sections/subsections are present in the document. Also, the first letter of casing of cross references must be uppercase and must match with be italicized in USPI e.g. [see Warnings and Precautions (5.2)].
7. Check for left vertical sideline bars (Recent Major Changes-RMC) wherever variation text is present and is applicable to the below safety sections content only.

***BOXED WARNINGS, INDICATIONS AND USAGE, DOSAGE AND ADMINISTRATION, WARNINGS AND PRECAUTIONS, & CONTRAINDICATIONS***

1. Representation of U.S.A. or U.S. in a USPI must have end periods after each word (including the last word).
2. Check for consistency of r-Ball (registered mark) or TM (trademark) symbols first and last instance.
3. Language should be selected as “English (United States)” in Set proofing language (doesn’t follows vowels a, e, i, o, u and letter ‘z’ used in words like authori**z**ation).

**II.** **Core Data Sheet EQC**

1. Ensure “Track Changes” option is turned “ON” before starting the QC.

Before starting any English QC Activity, make sure that the Track Change-Formatting functionality settings are checked.

Please see the screen shots below:

Click the Track Changes Option in “Review” Tab. Then Click on “Advanced Options”.

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Paper orientation in printing: 

1. Apply the markers (Paragraph attribute on).
2. Alignment of the text must be consistent i.e. left or Justification.
3. Font and font size must be consistent throughout the document except font size in the table. If there is a lot of content in the table, font size may be less than the font size in the paragraph.
4. Number and Measuring Unit should always be separated by a non-breaking space (replace normal/soft space with hard/non-breaking space – press ***shift + ctrl + space bar***.
5. Replacing soft hyphens with hard hyphens throughout the document as per US specification - press ***shift + ctrl + minus button***.
6. Check if the line number is getting displayed at the bottom bar, if not then right click on the bottom bar and select line number.
7. Removal of extra normal spaces between the texts.
8. Removal of extra line spaces between the paragraphs or before and after headings.
9. Casing of product name and drug name must be consistent throughout the document.
10. Casing of product name and drug name must be consistent throughout the document.
11. Casing of unit litre ‘L’ must be uppercase.
12. Representation of units must be consistent “mcg” or “µg”.
13. Symbols must be insert from insert symbol menu.
14. End period or comma or semicolon must be present at the end of sentence for consistency.
15. Widow orphan control and keep with next to avoid breaking of heading and sentence.
16. When adding “Keep with Next” option for a particular heading, please remember do uncheck the “suppress line numbers”.
17. Word settings set to “Do not compress images in file” to ensure illustration micro-text resolution is maintained after adding a high-resolution image to the document. (How: File→Options→Advanced→Image Size and Quality→check Do not compress images in file’).
18. Representation of table and figure heading (table and figure with number, alignment and casing).
19. Comma used as a thousand separators or no thousand separators (e.g., 1,000 and 10,000).
20. Font of bullets and content should be the same as font of entire document.
21. Paragraph indentation and spacing must be consistent (Indentation - Left, Right, Special), (Spacing – Before, After, Line Spacing).
22. Insert repeat headers for tables (if the table is continuing in next page).
23. If there is an abbreviation in the table it must be checked for the expansion in the footnote, also whenever the abbreviation is updated/deleted the same must be checked in the footnote.
24. Keep with next must be applied to:

* Every heading/ subheading and respective paragraph is breaking.
* Applies to Excipients section and Address part.

1. Terms like *in vitro*, *in vivo, in utero, in situ, de novo, E.coli* and other Latin terms/scientific words must be italicized in the document.
2. Images also must be checked for correctness all the abbreviations in the graph must be expanded in the footnote.
3. Images must be checked for clarity and legibility, ILL number must be present on all the images.
4. The ILL number must be checked for readability on the image and the same number must be entered in “ALT text” field if the “ALT text” field is blank.
5. CDS follows US Region spellings (doesn’t follows vowels a, e, i, o, u and letter ‘z’ used in words like authorization).

**CDS QC is also similar to a QC of USPI with few additional checks and exceptions.**

1. Document would have coloured text which must not be changed/deleted.
2. All the cross references/end notes must be checked for hyperlinking (double click end note), if they are active and correct in CDS along with the cross-reference’s representation
3. Check if End notes are consecutive, if any number is deleted the next number must be checked if the number is the next consecutive one.
4. Once English QC is completed - view the document in final view (Review>No markup) to ensure that all changes made to the document are at right place and correct format.

**III. EU Central Region:**

1. Ensure “Track Changes” option is turned “ON” before starting the QC.

Before starting any English QC Activity, make sure that the Track Change-Formatting functionality settings are checked.

Please see the screen shots below:

Click the Track Changes Option in “Review” Tab. Then Click on “Advanced Options”.

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Paper orientation in printing: 

1. Apply the markers (Paragraph attribute on).
2. Alignment of the text must be left.
3. Font and font size must be TimesNewRoman 11 pt and left alignment except font size in the table. If there is a lot of content in the table, font size may be less than the font size in the paragraph.
4. Number and Measuring Unit should always be separated by a non-breaking space (replace normal/soft space with hard/non-breaking space – press ***shift + ctrl + space bar***.
5. Replacing soft hyphens with hard hyphens throughout the document as per US specification - press ***shift + ctrl + minus button***.
6. Check if the line number is getting displayed at the bottom bar, if not then right click on the bottom bar and select line number.
7. Removal of extra normal spaces between the texts.
8. Removal of extra line spaces between the paragraphs or before and after headings.
9. As per the EU QRD template, casing of headings:

* 1st level headings - BOLD and UPPERCASE
* 2nd level headings - BOLD and Sentence case
* 3rd level heading UNBOLD and UNDERLINE or ITALICS, Sentence case

1. Casing of product name and drug name must be consistent throughout the document.
2. Casing of unit litre ‘L’ must be uppercase.
3. Representation of units must be consistent “mcg” or “µg”.
4. Symbols must be insert from insert symbol menu.
5. End period or comma or semicolon must be present at the end of sentence for consistency.
6. Widow orphan control and keep with next to avoid breaking of heading and sentence.
7. When adding “Keep with Next” option for a particular heading, please remember do uncheck the “suppress line numbers”.
8. Word settings set to “Do not compress images in file” to ensure illustration micro-text resolution is maintained after adding a high-resolution image to the document. (How: File→Options→Advanced→Image Size and Quality→check Do not compress images in file’).
9. Representation of table and figure heading (table and figure with number, alignment, and casing).
10. Comma used as a thousand separators (e.g., 1,000 and 10,000)
11. Font of bullets and content should be the same as font of entire document.
12. Paragraph indentation and spacing must be consistent

(Headings, Subheadings, bullets of Indentation – Left 0, Right 0, Special – Hanging 1 cm), (Spacing – Before 0, After 0, Line Spacing - Single).

(Paragraph of Indentation – Left 0, Right 0, Special – None), (Spacing – Before 0, After 0, Line Spacing - Single).

1. Page Margins –

* Top of page: 2.0 cm
* From bottom of page: 2.0 cm
* From left of page: 2.5 cm
* From right of page: 2.5 cm
* Gutter: 0 cm
* Header: 1.3
* Footer: 1.3 cm

1. Insert repeat headers for all the tables (if the table is continuing in next page).
2. If there is an abbreviation in the table it must be checked for the expansion in the footnote, also whenever the abbreviation is updated/deleted the same must be checked in the footnote.
3. Keep with next must be applied to:

* Every heading/subheading and respective paragraph breaking.
* Applies to Excipients section and Address part.

1. Terms like *in vitro*, *in vivo, in utero, in situ, de novo, E.coli* and other Latin terms/scientific words must be italicized in the document.
2. Images also must be checked for correctness all the abbreviations in the graph must be expanded in the footnote.
3. Images must be checked for clarity and legibility, ILL number must be present on all the images
4. The ILL number must be checked for readability on the image and the same number must be entered in “ALT text” field if the “ALT text” field is blank.

**EU CENTRAL SPECIFICATIONS**

1. Open the document, go to the Info tab:

* Check the Info tab for the following:
* Check that Title Field is Trade name<,>INN<->Active Ingredient Name
* Check that Tag Field is same as Title Field
* Check the Author. If the author is anything other than CHMP then remove that author name and add CHMP
* Click on Show all properties, Check that Subject is EPAR

1. There are two styles in the document which are similar– defined as

* Title A - Times New Roman 11 Bold
* Title B - Times New Roman 11 Bold

(and NOT Times New Roman (Bold) 11)

* Title A and Title B are added in word doc so when these files are converted to PDF - book marks are auto generated. They should not be “Times New Roman (Bold)” instead should be “Times New Roman”, “bold” and “font 11”

1. Language should be selected as “English (United Kingdom)” in Set proofing language (follows vowels a, e, i, o, u and letter ‘s’ used in words like authori**s**ation).

**IV. EU Non-Central Region**

1. Ensure “Track Changes” option is turned “ON” before starting the QC.

Before starting any English QC Activity, make sure that the Track Change-Formatting functionality settings are checked.

Please see the screen shots below:

Click the Track Changes Option in “Review” Tab. Then Click on “Advanced Options”.

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Paper orientation in printing: 

1. Apply the markers (Paragraph attribute on).
2. Alignment of the text must be consistent i.e. left or Justification.
3. Font and font size must be consistent throughout the document except font size in the table. If there is a lot of content in the table, font size may be less than the font size in the paragraph. Only Russian country follows fonts size - TimesNewRoman 12 pt.
4. Number and Measuring Unit should always be separated by a non-breaking space (replace normal/soft space with hard/non-breaking space – press ***shift + ctrl + space bar***.
5. Replacing soft hyphens with hard hyphens throughout the document as per US specification - press ***shift + ctrl + minus button***.
6. Check if the line number is getting displayed at the bottom bar, if not then right click on the bottom bar and select line number.
7. Removal of extra normal spaces between the texts.
8. Removal of extra line spaces between the paragraphs or before and after headings.
9. Casing of headings and subheadings must be consistent.
10. Casing of product name and drug name must be consistent throughout the document.
11. Casing of unit litre must be consistent ‘L’ or ‘l’.
12. Representation of units must be consistent “mcg” or “µg”.
13. Symbols must be insert from insert symbol menu.
14. End period or comma or semicolon must be present at the end of sentence for consistency.
15. Widow orphan control and keep with next to avoid breaking of heading and sentence.
16. When adding “Keep with Next” option for a particular heading, please remember do uncheck the “suppress line numbers”.
17. Word settings set to “Do not compress images in file” to ensure illustration micro-text resolution is maintained after adding a high-resolution image to the document. (How: File→Options→Advanced→Image Size and Quality→check Do not compress images in file’).
18. Representation of table and figure heading (table and figure with number, alignment and casing).
19. Using of comma as thousand separators or no thousand separators (e.g., 1,000 or 1000 and 10,000 or 10000).
20. Font of bullets and content should be the same as font of entire document.
21. Paragraph indentation and spacing must be consistent (Indentation - Left, Right, Special), (Spacing – Before, After, Line Spacing).
22. Page margins for only Russia - Please follow below requirements:

* Text has TNR #12 (except section names) style;
* line interval – 1.5
* head margin – 2 cm
* bottom margin – 2 cm
* left margin – 3 cm
* right margin – 1.5 cm

1. Insert repeat headers for tables (if the table is continuing in next page).
2. If there is an abbreviation in the table it must be checked for the expansion in the footnote, also whenever the abbreviation is updated/deleted the same must be checked in the footnote.
3. Keep with next must be applied to:

* Every heading/ subheading and its consecutive line space.

Bullet points:

* If there are 3 bullet points apply KWN to first 2 bullet points
* If there are 2 bullet points apply KWN to first bullet point
* If there is only one bullet point or more than 3 bullet points present under the heading, apply KWN only to heading and its consecutive line space.
* Applies to Excipients section and Address part.

1. Terms like *in vitro*, *in vivo, in utero, in situ, de novo, E.coli* and other Latin terms/scientific words must be italicized in the document.
2. Images also must be checked for correctness all the abbreviations in the graph must be expanded in the footnote.
3. Images must be checked for clarity and legibility, ILL number must be present on all the images
4. The ILL number must be checked for readability on the image and the same number must be entered in “ALT text” field if the “ALT text” field is blank.
5. Check if the cross-reference numbers are valid and all their respective sections/subsections are present in the document.
6. Check for consistency of r-Ball (registered mark) or TM (trademark) symbols first and last instance.
7. Only Israel follows the US region spellings (doesn’t follows vowels a, e, i, o, u and letter ‘z’ used in words like authori**z**ation) and other countries follow consistency of UK spellings.

**V. Middle East and Africa Region**

1. Ensure “Track Changes” option is turned “ON” before starting the QC.

Before starting any English QC Activity, make sure that the Track Change-Formatting functionality settings are checked.

Please see the screen shots below:

Click the Track Changes Option in “Review” Tab. Then Click on “Advanced Options”.

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Paper orientation in printing: 

1. Apply the markers (Paragraph attribute on).
2. Alignment of the text must be consistent i.e. left or Justification.
3. Font and font size must be consistent throughout the document except font size in the table. If there is a lot of content in the table, font size may be less than the font size in the paragraph.
4. Number and Measuring Unit should always be separated by a non-breaking space (replace normal/soft space with hard/non-breaking space – press ***shift + ctrl + space bar***.
5. Replacing soft hyphens with hard hyphens throughout the document as per US specification - press ***shift + ctrl + minus button***.
6. Check if the line number is getting displayed at the bottom bar, if not then right click on the bottom bar and select line number.
7. Removal of extra normal spaces between the texts.
8. Removal of extra line spaces between the paragraphs or before and after headings.
9. Casing of headings and subheadings must be consistent.
10. Casing of product name and drug name must be consistent throughout the document.
11. Casing of unit litre must be consistent ‘L’ or ‘l’.
12. Representation of units must be consistent “mcg” or “µg”.
13. Symbols must be insert from insert symbol menu.
14. End period or comma or semicolon must be present at the end of sentence for consistency.
15. Widow orphan control and keep with next to avoid breaking of heading and sentence.
16. When adding “Keep with Next” option for a particular heading, please remember do uncheck the “suppress line numbers”.
17. Word settings set to “Do not compress images in file” to ensure illustration micro-text resolution is maintained after adding a high-resolution image to the document. (How: File→Options→Advanced→Image Size and Quality→check Do not compress images in file’).
18. Representation of table and figure heading (table and figure with number, alignment and casing).
19. Using of comma as thousand separators or no thousand separators (e.g., 1,000 or 1000 and 10,000 or 10000).
20. Font of bullets and content should be the same as font of entire document.
21. Paragraph indentation and spacing must be consistent (Indentation - Left, Right, Special), (Spacing – Before, After, Line Spacing).
22. Insert repeat headers for tables (if the table is continuing in next page).
23. If there is an abbreviation in the table it must be checked for the expansion in the footnote, also whenever the abbreviation is updated/deleted the same must be checked in the footnote.
24. Keep with next must be applied to:

* Every heading/ subheading and its consecutive line space.

Bullet points:

* If there are 3 bullet points apply KWN to first 2 bullet points
* If there are 2 bullet points apply KWN to first bullet point
* If there is only one bullet point or more than 3 bullet points present under the heading, apply KWN only to heading and its consecutive line space.
* Applies to Excipients section and Address part.

1. Terms like *in vitro*, *in vivo, in utero, in situ, de novo, E.coli* and other Latin terms/scientific words must be italicized in the document.
2. Images also must be checked for correctness all the abbreviations in the graph must be expanded in the footnote.
3. Images must be checked for clarity and legibility, ILL number must be present on all the images
4. The ILL number must be checked for readability on the image and the same number must be entered in “ALT text” field if the “ALT text” field is blank.
5. Check if the cross-reference numbers are valid and all their respective sections/subsections are present in the document.
6. Check for consistency of r-Ball (registered mark) or TM (trademark) symbols first and last instance.
7. Spellings must be consistent within the document i.e. US vs UK spellings.

**VI. JAPAC Region**

1. Ensure “Track Changes” option is turned “ON” before starting the QC.

Before starting any English QC Activity, make sure that the Track Change-Formatting functionality settings are checked.

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Paper orientation in printing: 

1. Apply the markers (Paragraph attribute on).
2. Alignment of the text must be consistent i.e. left or Justification.
3. Font and font size must be consistent throughout the document except font size in the table. If there is a lot of content in the table, font size may be less than the font size in the paragraph.
4. Number and Measuring Unit should always be separated by a non-breaking space (replace normal/soft space with hard/non-breaking space – press ***shift + ctrl + space bar***.
5. Replacing soft hyphens with hard hyphens throughout the document as per US specification - press ***shift + ctrl + minus button***.
6. Check if the line number is getting displayed at the bottom bar, if not then right click on the bottom bar and select line number.
7. Removal of extra normal spaces between the texts.
8. Removal of extra line spaces between the paragraphs or before and after headings.
9. Casing of headings and subheadings must be consistent.
10. Casing of product name and drug name must be consistent throughout the document.
11. Casing of unit litre must be consistent ‘L’ or ‘l’.
12. Representation of units must be consistent “mcg” or “µg”.
13. Symbols must be insert from insert symbol menu.
14. End period or comma or semicolon must be present at the end of sentence for consistency.
15. Widow orphan control and keep with next to avoid breaking of heading and sentence.
16. When adding “Keep with Next” option for a particular heading, please remember do uncheck the “suppress line numbers”.
17. Word settings set to “Do not compress images in file” to ensure illustration micro-text resolution is maintained after adding a high-resolution image to the document. (How: File→Options→Advanced→Image Size and Quality→check Do not compress images in file’).
18. Representation of table and figure heading (table and figure with number, alignment and casing).
19. Using of comma as thousand separators or no thousand separators (e.g., 1,000 or 1000 and 10,000 or 10000).
20. Font of bullets and content should be the same as font of entire document.
21. Paragraph indentation and spacing must be consistent (Indentation - Left, Right, Special), (Spacing – Before, After, Line Spacing).
22. Insert repeat headers for tables (if the table is continuing in next page).
23. If there is an abbreviation in the table it must be checked for the expansion in the footnote, also whenever the abbreviation is updated/deleted the same must be checked in the footnote.
24. Keep with next must be applied to:

* Every heading/ subheading and its consecutive line space.

Bullet points:

* If there are 3 bullet points apply KWN to first 2 bullet points
* If there are 2 bullet points apply KWN to first bullet point
* If there is only one bullet point or more than 3 bullet points present under the heading, apply KWN only to heading and its consecutive line space.
* Applies to Excipients section and Address part.

1. Terms like *in vitro*, *in vivo, in utero, in situ, de novo, E.coli* and other Latin terms/scientific words must be italicized in the document.
2. Images also must be checked for correctness all the abbreviations in the graph must be expanded in the footnote.
3. Images must be checked for clarity and legibility, ILL number must be present on all the images
4. The ILL number must be checked for readability on the image and the same number must be entered in “ALT text” field if the “ALT text” field is blank.
5. Check if the cross-reference numbers are valid and all their respective sections/subsections are present in the document.
6. Check for consistency of r-Ball (registered mark) or TM (trademark) symbols first and last instance.
7. Spellings must be consistent within the document i.e. US vs UK spellings.

**VII. LATAM Region**

1. Ensure “Track Changes” option is turned “ON” before starting the QC.

Before starting any English QC Activity, make sure that the Track Change-Formatting functionality settings are checked.

Please see the screen shots below:

Click the Track Changes Option in “Review” Tab. Then Click on “Advanced Options”.

Machine generated alternative text:
Track Changes Options 
Show 
Comments 
@ Ink 
Highlight Updates 
Other Authors 
Insertions and Deletions 
Pictures ay Comments 
Formatting 
Balloons in All Markup view shcn,v: 
Revisions 
Reviewing Pane: 
Advanced Options.. 
Change User Name... 
Cancel  Machine generated alternative text:
Advanced Track Changes Options 
Color: 
Color: 
Color: 
Color: 
Merged cells: 
Split cells: 
Color: 
Measure in: 
Preserve 
author 
author 
Green 
Green 
Light Yellow 
Light Orange 
author 
Centimeters 
Cancel 
Markup 
Insertions: 
Deletions: 
Changed lines: 
Comments: 
Moves 
Track moves 
Moved from: 
Moved to: 
Strikethrough 
Outside border 
author 
Double strikethrough 
Double underline 
Table cell highlighting 
Inserted cells: 
Deleted cells: 
Formatting 
Track formatting 
Light Slue 
Pink 
Formatting: 
Balloons 
Preferred width: 
Margin: 
(nonel 
9.4 cm 
Right 
@ Show lines connecting to text 
Paper orientation in printing: 

1. Apply the markers (Paragraph attribute on).
2. Alignment of the text must be justified (ctrl + J).
3. Font and font size must be consistent throughout the document except font size in the table. If there is a lot of content in the table, font size may be less than the font size in the paragraph.
4. Number and Measuring Unit should always be separated by a non-breaking space (replace normal/soft space with hard/non-breaking space – press ***shift + ctrl + space bar***.
5. Replacing soft hyphens with hard hyphens throughout the document as per US specification - press ***shift + ctrl + minus button***.
6. Check if the line number is getting displayed at the bottom bar, if not then right click on the bottom bar and select line number.
7. Removal of extra normal spaces between the texts.
8. Removal of extra line spaces between the paragraphs or before and after headings.
9. Normal spaces must be present between number and symbols (<, >, ≥, ≤, =, +).
10. No spaces must be present between number and symbols (degree symbol (°), percentage symbol (%)).
11. Casing of headings and subheadings must be consistent.
12. Casing of product name and drug name must be consistent throughout the document.
13. Casing of unit litre must be consistent ‘L’ or ‘l’.
14. Representation of units must be consistent “mcg” or “µg”.
15. Symbols must be insert from insert symbol menu.
16. End period or comma or semicolon must be present at the end of sentence for consistency.
17. Widow orphan control and keep with next to avoid breaking of heading and sentence.
18. When adding “Keep with Next” option for a particular heading, please remember do uncheck the “suppress line numbers”.
19. Word settings set to “Do not compress images in file” to ensure illustration micro-text resolution is maintained after adding a high-resolution image to the document. (How: File→Options→Advanced→Image Size and Quality→check Do not compress images in file’).
20. Representation of table and figure heading (table and figure with number, alignment and casing).
21. Using of comma as thousand separators or no thousand separators (e.g., 1,000 or 1000 and 10,000 or 10000).
22. Font of bullets and content should be the same as font of entire document.
23. Paragraph indentation and spacing must be consistent (Indentation - Left, Right, Special), (Spacing – Before, After, Line Spacing).
24. Insert repeat headers for tables (if the table is continuing in next page).
25. If there is an abbreviation in the table it must be checked for the expansion in the footnote, also whenever the abbreviation is updated/deleted the same must be checked in the footnote.
26. Keep with next must be applied

* Heading and respective paragraph breaking
* Applies to Excipients section and Address part.

1. Terms like *in vitro*, *in vivo, in utero, in situ, de novo, E.coli* and other Latin terms/scientific words must be italicized in the document.
2. Images also must be checked for correctness all the abbreviations in the graph must be expanded in the footnote.
3. Images must be checked for clarity and legibility, ILL number must be present on all the images
4. The ILL number must be checked for readability on the image and the same number must be entered in “ALT text” field if the “ALT text” field is blank.
5. Check if the cross-reference numbers are valid and all their respective sections/subsections are present in the document.
6. Check for consistency of r-Ball (registered mark) or TM (trademark) symbols first and last instance.
7. Spellings must be consistent within the document i.e. US vs UK spellings or may be follows both.