الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Guidance for Graphic Design of Medication Packaging

Version 3.1

Date of issue	8 October 2015
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Saudi Food & Drug Authority

Drug Sector

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Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

Document Control

Version	Author	Date	Comments
1.0	Executive Directorate of Pharmacovigilance	8 October 2015	Draft
2.0	Executive Directorate of Pharmacovigilance	28 January 2019	This guidelines separated from the "Guidelines on Container Closure Systems"
3.0	Vigilance Executive Directorate	23 February 2020	Update (This version doesn't include any scientific update)
3.1	Vigilance Executive Directorate	10 November 2022	Update (Next page shows the updated details)

What is New in version no. 3.1?

The following table shows the update to the previous version:

Section	Description of change
VII. Medication Errors Reports And Corrective Actions	**ADD:** Method of reporting medication errors
VIII. Concentration Designation & Recommendations	**ADD:** New section to present all recommendations for concentration designation regardless of the dosage form also the Elimination of Ratio expression.
IV. Design Recommendations For Secondary Packaging	**ADD:** To differentiate between similar products names by using TALL Man Letters (bolded uppercase letters)
IX. A Guide To Labeling And Packaging Of Ophthalmic Preparation	**Delete:** of the Arabic term معقم/ـة from Packaging Of Ophthalmic Preparation
1.7 Warnings	**ADD:** Warning statement Warning : Paralyzing agent (Implementation Date 1-1-2023)

Table of Contents

I. INTRODUCTION

This guidance is complementary to the GCC Guidance for Presenting the SPC (Summary of Product Characteristics), PIL (Patient Information leaflet), and Labeling Information with more illustrations and details to minimize medication errors.

The design considerations and principles outlined can be applied to all products dosage forms. Preliminary version of this guidance was revised by Medical Error Recognition and Revision Strategies (Med-ERRS) a former for-profit subsidiary of Institute for Safe Medication Practices (ISMP)

II. SCOPE

This guidance is applicable to SFDA registered or under-registration medicinal products intended for human use in Saudi Arabia.

III. DESIGN RECOMMENDATIONS FOR PRIMARY PACKAGING (BLISTER PACKS)

1. BLISTER PACKS FOR ORAL MEDICATIONS

1.1 Product name and strength

The name and strength of the product should appear over each blister pocket. Batch number and expiry date should be applied on each blister pocket as well. If it is not possible, the batch number and expiry date should be added at the end of each blister strip, preferably at both ends.

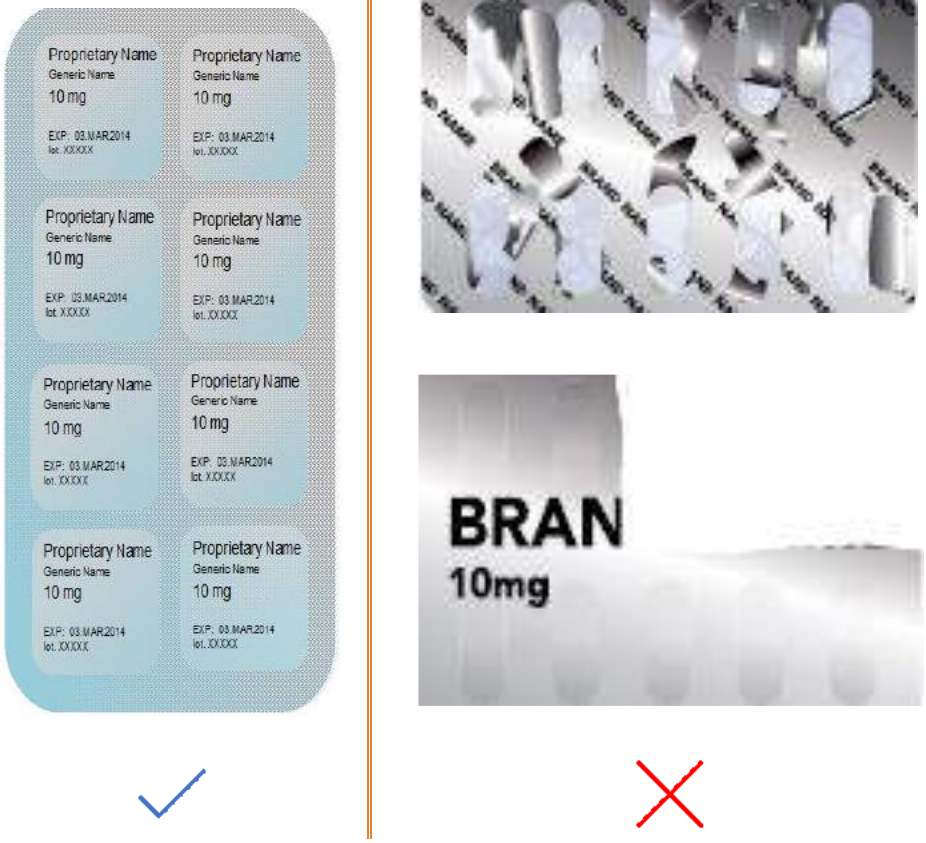


Figure 1

Optional: If the medication is given every day, print the days of the week on the reverse side of the blister or capsule.

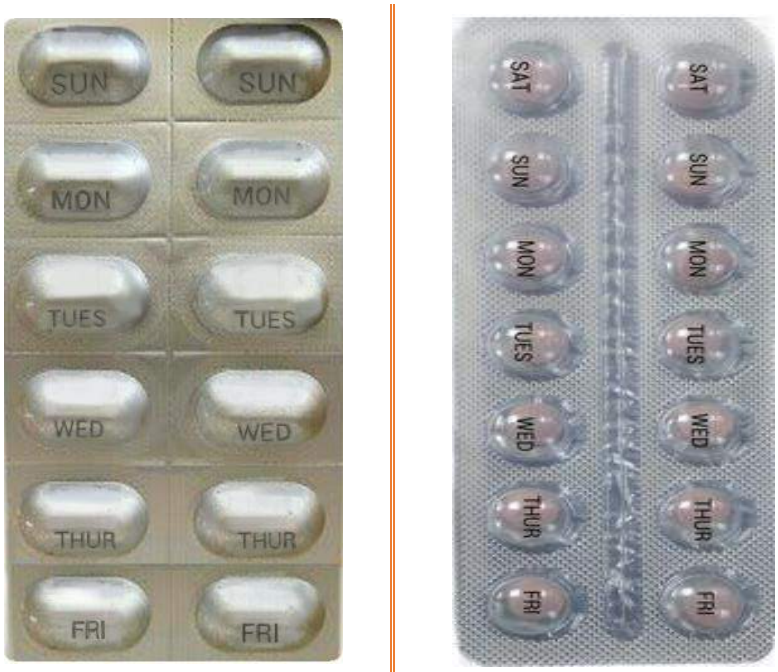


Figure 2

In certain cases (such as: small blister) it may not be possible to design the packaging to accommodate all critical information on each blister cell. In such circumstances, important information can appear multiple times across the back of the blister or the important information should be displayed in such a manner that it is not destroyed or eliminated when dosage units are removed.

1.2 Blister strips foil

Use non reflective, matte material. Reflective foil can cause glare by light reflecting on the foil which reduces the legibility of any information.

Figure 3

1.3 Type and background color

Type color should contrast strongly with background color. Legibility can be reduced by the combined effect of the foil material, a small font size and a background color that does not sufficiently contrast with the font color.

Figure 4

1.4 Type size and font color

Use bold or semi-bold type and avoid lightweight type. Maximize the font size to a size that is appropriate for the size of the container. Small type size and a lightweight font on a foil background impairs legibility.

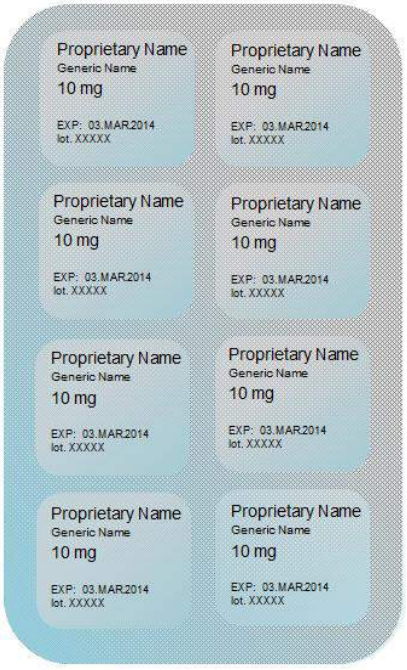


Figure 5

1.5 Match the styles of primary and secondary packaging [optional]

A product's primary and secondary packaging may have an identical or linked visual style.

Figure 6

IV. DESIGN RECOMMENDATIONS FOR SECONDARY PACKAGING

Secondary packaging describes the outer package of a pharmaceutical product. It serves to hold the primary packaging and is not in contact with the product. The combined impact of all design elements, such as color and typography, should be evaluated.

Company's pharmaceutical products should not have the same theme for outer package and should differentiate between them, to avoid similarity between products and prevent medication error.

1. Allocate white space for the dispensing label [optional]

Have a clearly designated white space for the dispensing label if possible. Label dimensions vary but a minimum of 70 x 35 mm is suggested, as this is the most common size for dispensing. The white space should not interfere or cover the legibility of the critical information on either side.

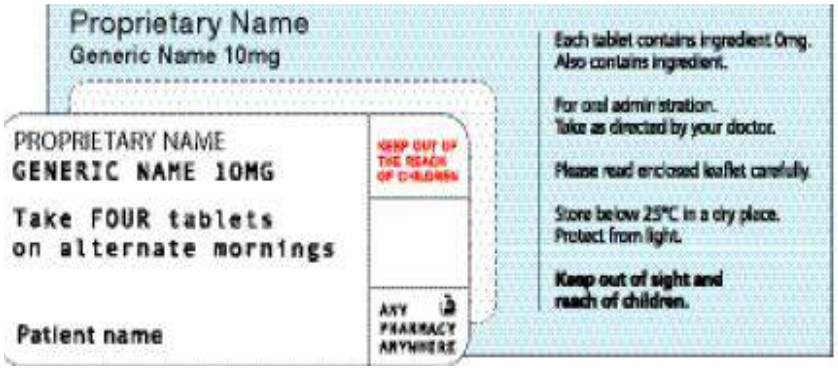


Figure 7

1.1 Brand name, generic name and strength position

The brand name, generic name and strength of the product should be directly above or beside the space provided for the dispensing label. Pharmacy staff can then easily check that the product description on the dispensing label correctly matches that on the secondary packaging.

Figure 8

2. PUT CRITICAL INFORMATION IN THE SAME FIELD OF VISION ON AT LEAST THREE NON-OPPOSING FACES (ONE SIDE FOR ARABIC & ONE SIDE FOR ENGLISH)

A standard packaging container has six faces on which information can be displayed. Critical information should be in the same field of vision on at least 3 of the non-opposing faces of the secondary packaging. This means putting the information on the top or bottom face, one of the side faces, and one of the end faces. If it is feasible, display a product description (the brand name, generic name and dosage strength of the product) on more than three non-opposing faces.

Figure 9

3. ORIENT TEXT IN THE SAME DIRECTION [OPTIONAL]

The text on every face, excluding the ends, should be oriented in the same direction in a way to easily read the information when the product is placed at any side on the shelf.

Figure 10

4. USE BLANK SPACE TO EMPHASIZE CRITICAL INFORMATION

Leave sufficient space around critical information, so that it can be easily seen. If the secondary packaging is cluttered with text and images, it can be difficult to recognize important information and identify the correct packaging.

Critical information include:-

1. Trade / brand / proprietary name
2. Generic Name
3. Strength /concentration
4. Route(s) of administration
5. Dosage form
6. Total volume or net quantity.
7. Warning statements in some cases.
8. Indications for OTC only.
9. Storage conditions must be added in both Arabic and English languages.

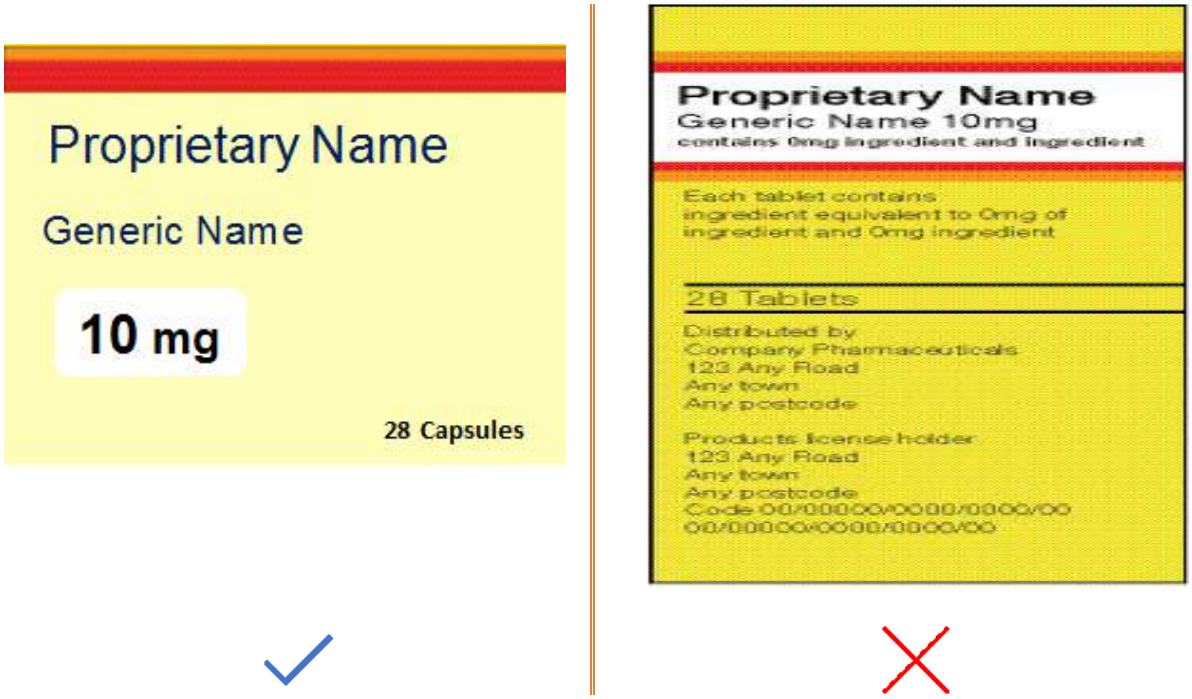


Figure 11

5. ENSURE THE GENERIC PRODUCT NAME IS SUITABLY CLEAR

The generic name should be at least 50% the size of the brand name. Patients may be (mistakenly given) two generic products (with the same active ingredient). Patients may take concomitantly two products with the same active substance, putting them at risk of exceeding the safe dose

Figure 12

6. DIFFERENTIATE BETWEEN STRENGTHS OF THE SAME PHARMACEUTICAL PRODUCT

Make pharmaceutical product strengths stand out through typeface, type weight, color and shape. This is particularly important if all secondary packaging from a manufacturer looks similar.

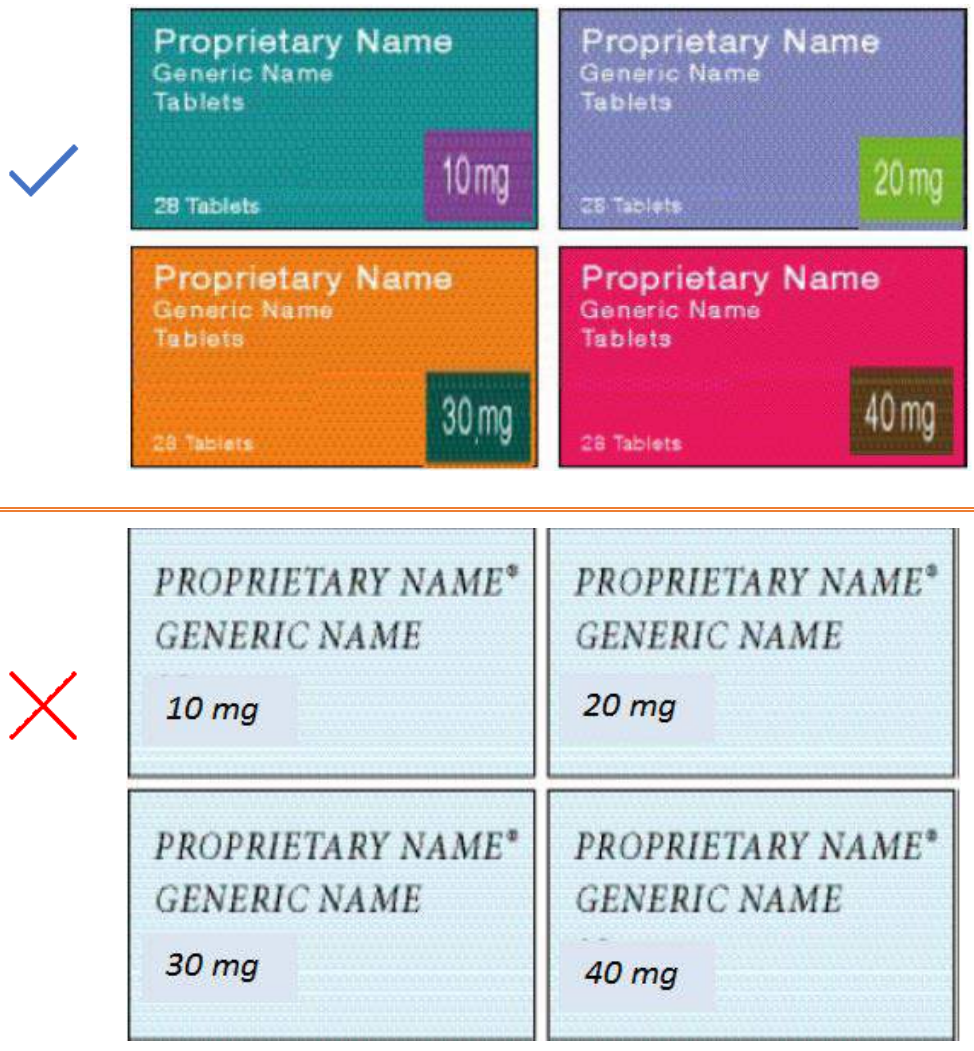


Figure 13

7. DO NOT ADD TRAILING ZEROS TO NUMBERS

Do not add trailing zeros to numbers; always use whole numbers. If numbers have a trailing zero (a decimal point followed by a zero, for example 5.0 mg) it is easy to miss the decimal point and dispense a tenfold overdose. For example, a practitioner could administer 50 mg instead of 5 mg.

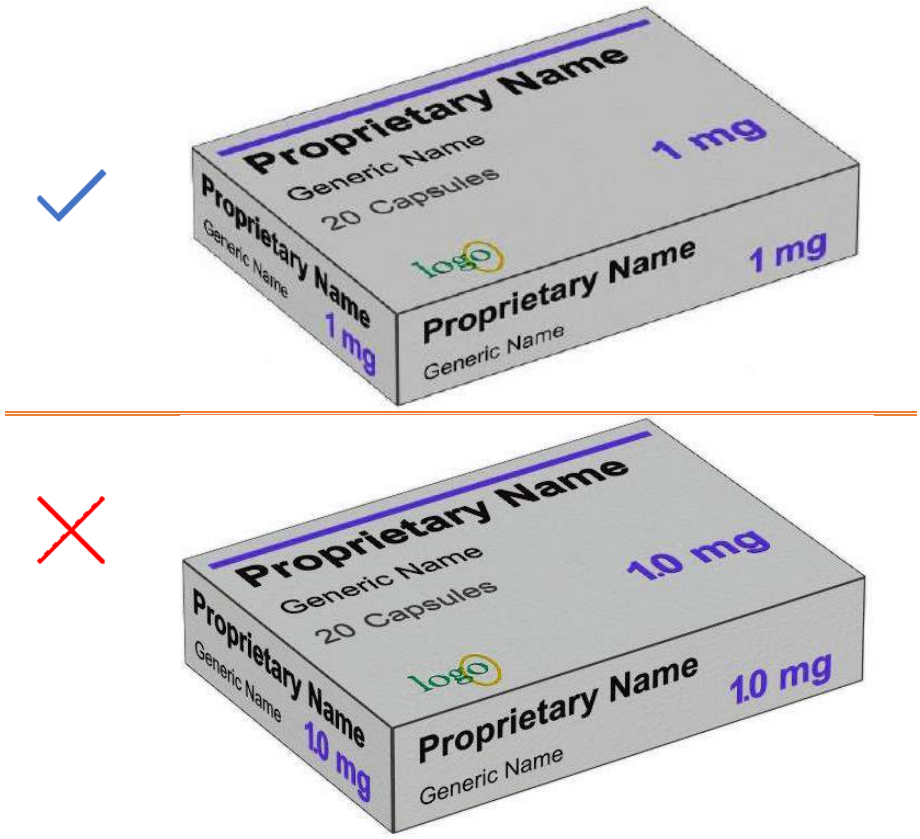


Figure 14

8. USE THE SAME UNIT FOR ALL DIFFERENT STRENGTHS FROM THE SAME PHARMACEUTICAL PRODUCT

In addition, different strengths of the same pharmaceutical product should be expressed in the same way, such as 250 mg, 500 mg, 750 mg. (e.g., 500 mg, not 0.5 g)

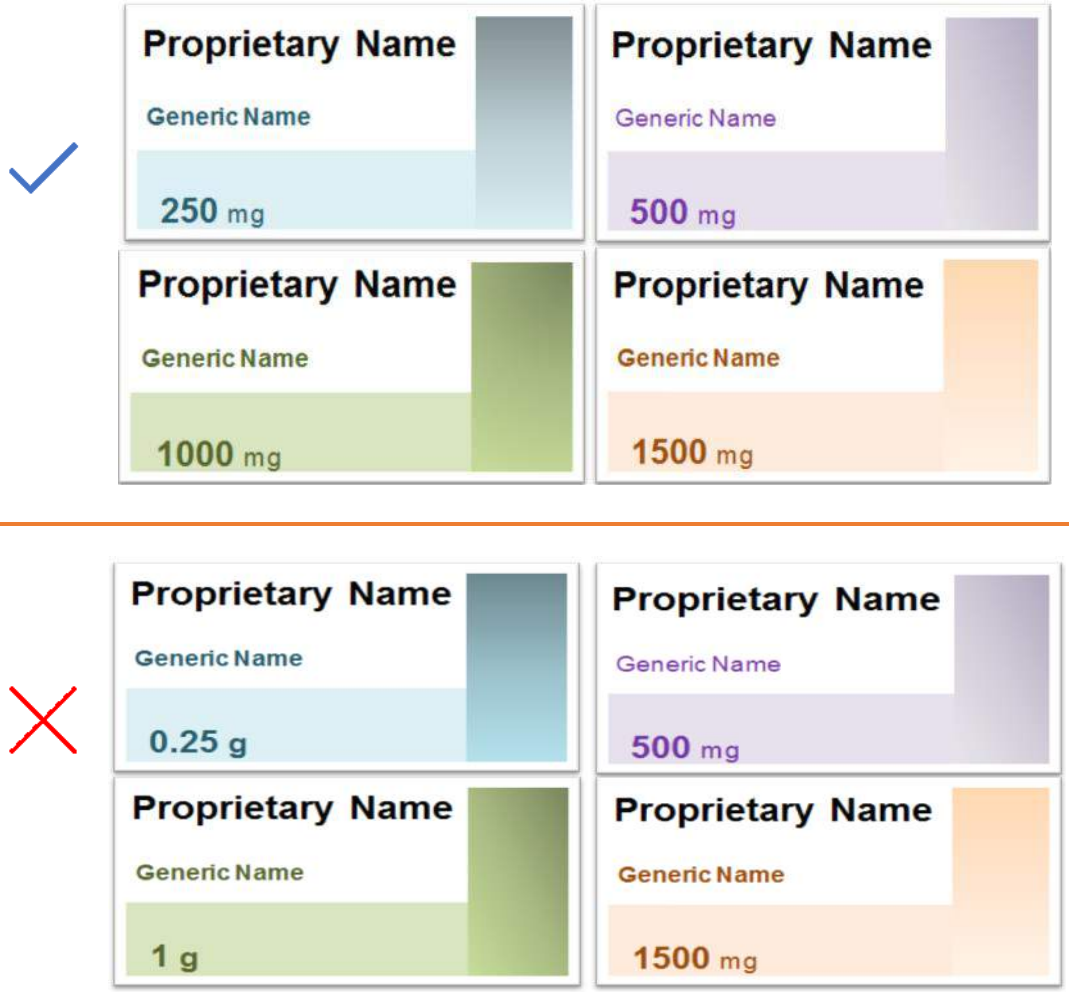


Figure 15

9. USE OF LEADING ZERO

For an amount less than one, always use a leading zero to avoid any confusion in the concentration (for example use 0.25 not .25).

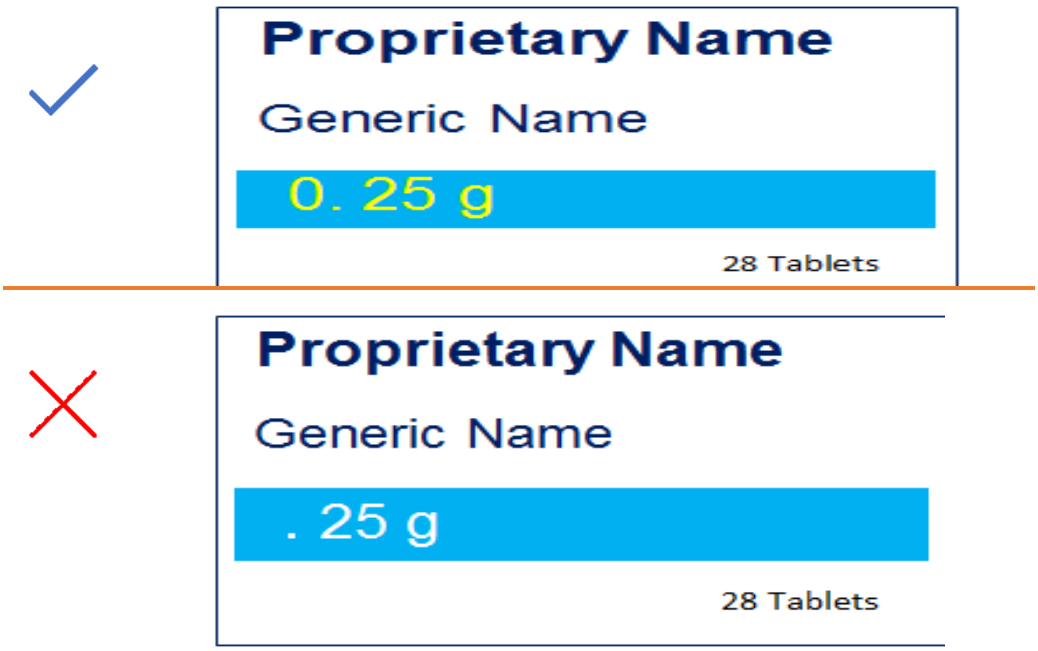


Figure 16

10. CRITICAL INFORMATION SIZE

Use the largest size font possible for that package size so that the information is readable and clear.

Figure 17

11. USE UPPER AND LOWER CASE LETTERING

Entire sentences written in upper case letters or italic type are hard to read. Use the lower case except for the first letter of the generic names, brand names, sentences or paragraphs. Italic types should not be used where there is an alternative method of emphasis such as bold type. Mixed case lettering should always be used for sentences.

Figure 18

12. TALL MAN LETTERING

Changing the appearance of look-alike drug names to draw attention to their dissimilarities by using TALL Man Letters (bolded uppercase letters)

Generic names Before	Predniso**lone**	vs	Predni**sone**
After tall man lettering	predniso**LONE**	vs	predni**SONE**

13. USE SANS SERIF TYPEFACES

Use a sans serif typeface, such as Arial, Helvetica or Universe. The choice of typeface influences legibility. Ornate typefaces are difficult to read. They are not suitable for medication packaging, where clarity, accuracy and legibility must be paramount.

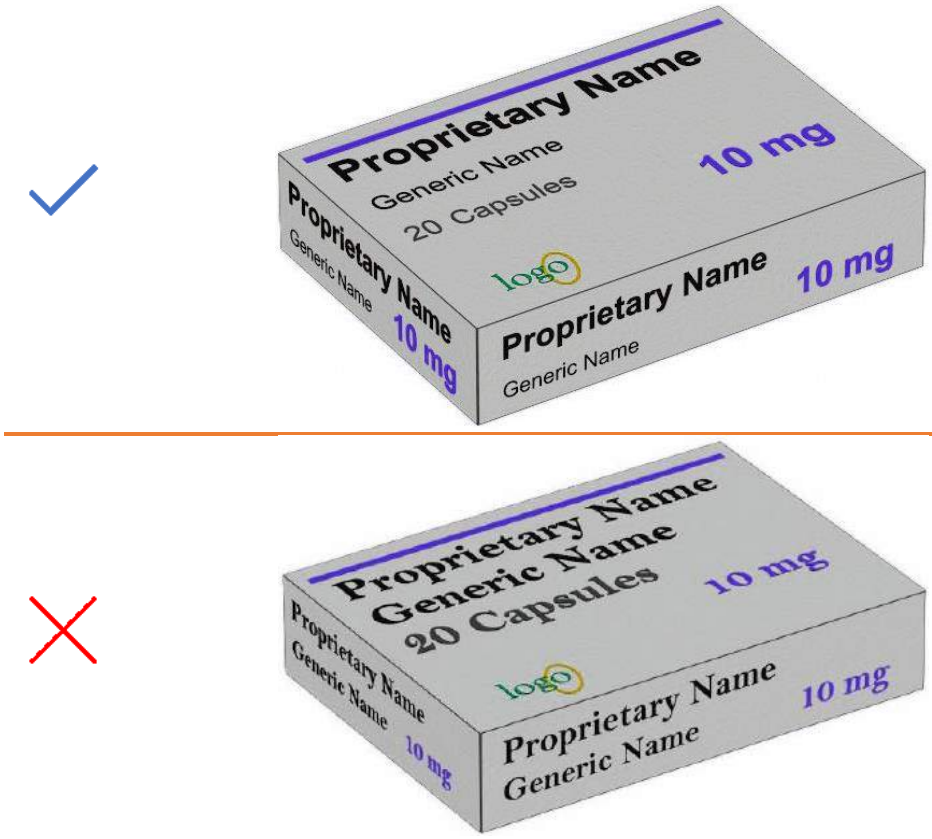


Figure 19

14. USE BOLD OR SEMI-BOLD TYPE

Lightweight type reduces legibility. Patients, especially those who are partially sighted, find bolder type easier to read. Use bold or semi-bold type and avoid lightweight type for all critical information.

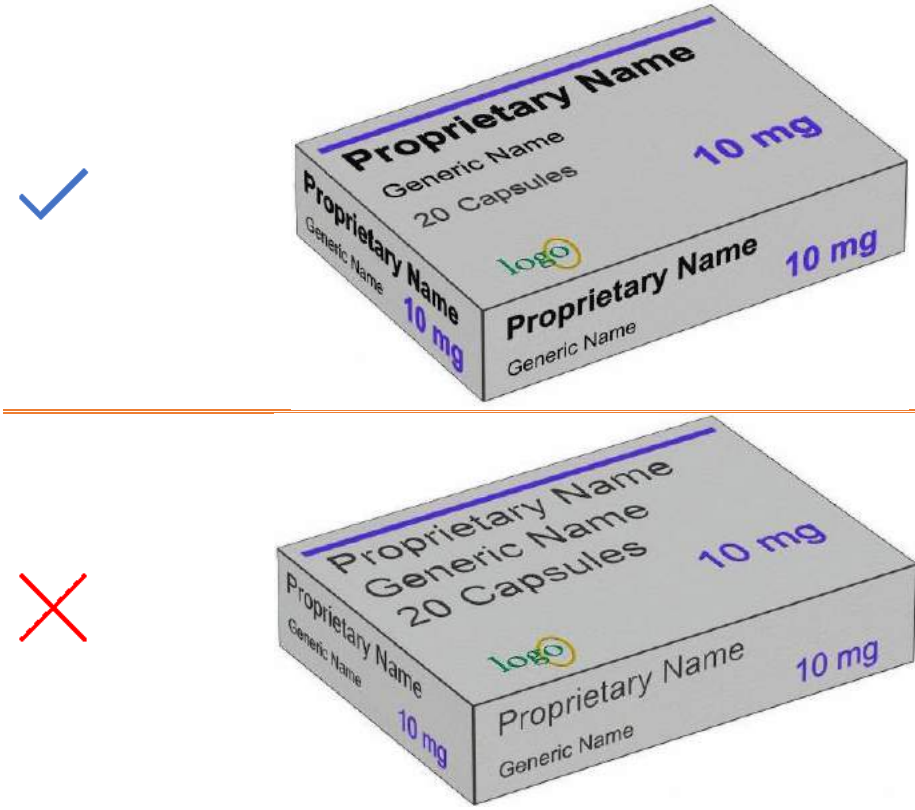


Figure 20

15. CONDENSED TYPEFACES

Do not use condensed typefaces when possible. Condensed typefaces reduce legibility and increase the chance of error. Condensed typefaces may be necessary on blister packs on each pocket and on small vials to fit all the required information, but should not be used when there is adequate space for normal typeface.

Figure 21

16. DO NOT COMPRESS LINES OF TEXT CLOSE TOGETHER OR ADJUST THE SPACE BETWEEN LETTERS

Reducing the space between lines, known as the leading, and reducing the space between letters, known as the kerning, affects legibility. Do not compress lines of text close together. Leave enough space between lines and letters.

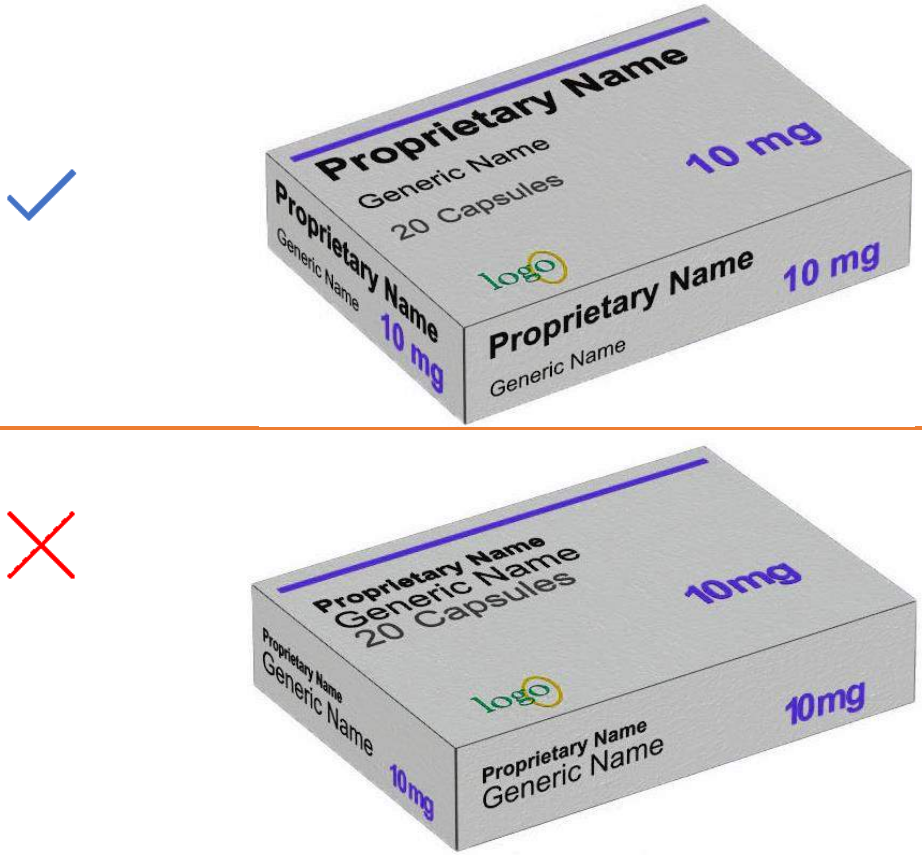


Figure 22

17. ALIGN TEXT TO THE LEFT FOR ENGLISH & TO THE RIGHT FOR ARABIC

An irregular amount of space between words affects legibility. Align text to the left hand margin and do not center justify text. Align all English text including the critical information to left side (left justified) and for the Arabic version, it should be aligned to the right side (right justified).

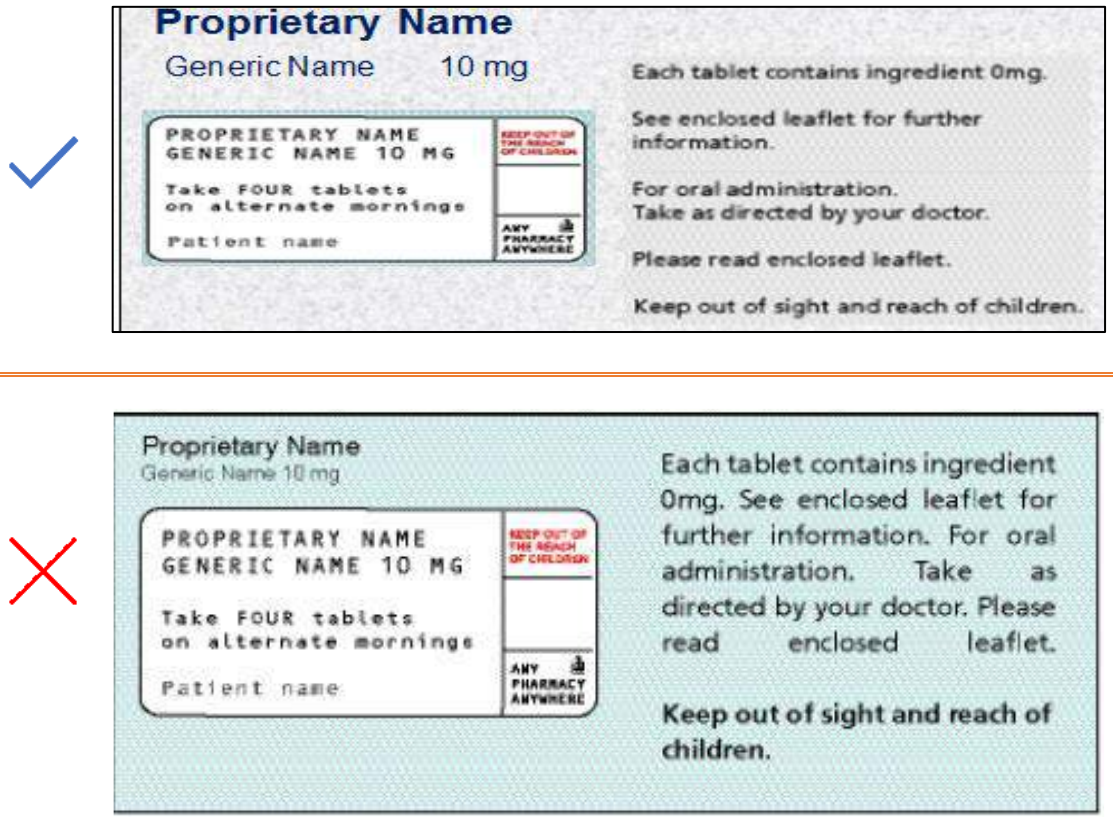


Figure 23

18. IMAGES AND LOGOS

Images or logos should not be near the text, as it could interfere with reading it, or it may look like it is part of the text. Text should remain unbroken. Fitting text around or over images or logos breaks the flow of information.

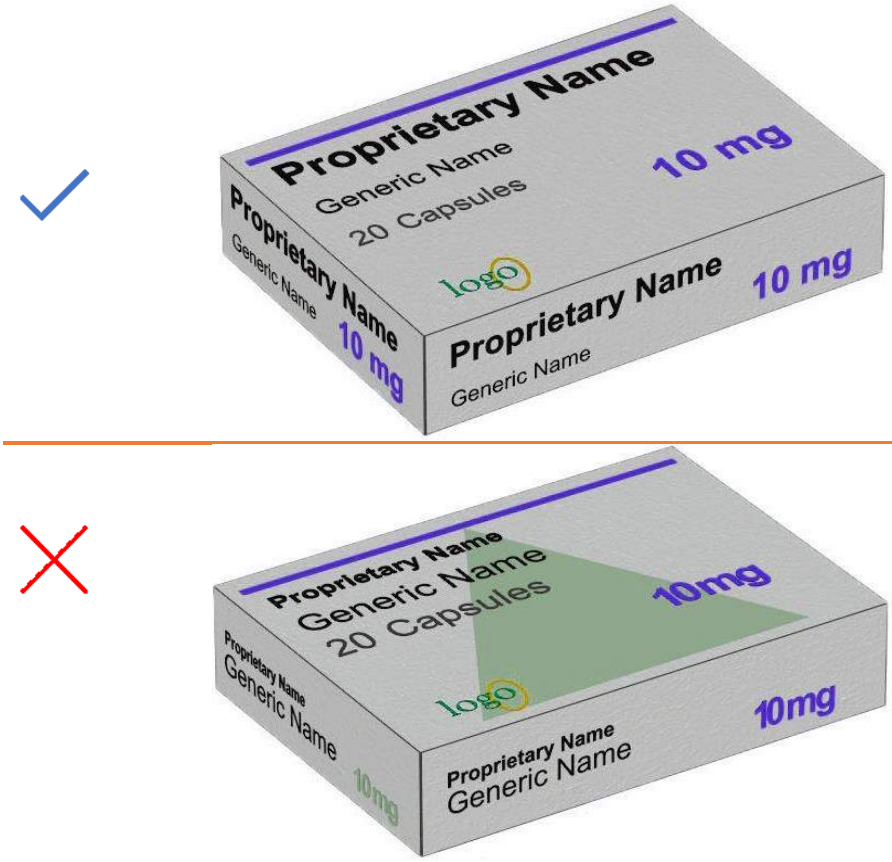


Figure 24

19. CREATE A STRONG CONTRAST BETWEEN TYPE AND BACKGROUND COLOR

There should be a strong color contrast between the type and background colors. Dark colored type (e.g. black, dark blue) should be on a light colored background (e.g. white, pale pink, pale yellow). The reverse is true as well. Insufficient contrast between the background and the type reduces legibility.

Figure 25

V. USING COLOR

Secondary packaging describes the outer package of a pharmaceutical product. It serves to hold the primary packaging and is not contact with the product. The combined impact of all design elements, such as color and typography, should be evaluated.

1. USE COLOR DIFFERENTIATION TO HIGHLIGHT INFORMATION OF THE SAME PHARMACEUTICAL PRODUCT

Use color to distinguish between, for example, different strengths of the same pharmaceutical product and between similarly named pharmaceutical products.

Figure 26

Do not color code packaging. A color coding system allows people to memorize a color and match it to a particular product. However, creating a shortcut for identifying a pharmaceutical product without having to read the label can lead to mistakes. It is important that practitioners do not rely on color as a means to identify a specific product, as many manufacturers may use the same color for different products, or different strengths of the same product.

Packaging Design Summary

Issues	Recommendations
Primary packaging	
Glare caused by light reflecting on the foil	Use non-reflective foil
Text damaged when blister strip is cut	Put pharmaceutical product name and strength clearly on each pocket
Reduced legibility due to combined effect of foil material, small type size and background color	Create a strong contrast between type and background color
Reduced legibility due to combined effect of a small type size and lightweight font on a foil background	Use bold or semi-bold type
Blister strip with the wrong secondary packaging	Match the styles of primary and secondary packaging
Secondary packaging	
Pharmaceutical product name and strength obscured	Allocate 70 x 35mm white space for dispensing label
Dispensing label and pharmaceutical product name mismatched	Position the generic name and pharmaceutical product strength above or next to the space for the dispensing label
Critical information does not appear in the same field of vision	Put critical information in the same field of vision on at least three non-opposing faces
Compressing lines of text close together or reducing the distance between individual letters makes text difficult to read	Do not squash lines of text closer together or adjust the spaces between letters
Irregular amount of space between words	Align text to the left for English, and right for Arabic
Text illegible over an image or logo	Logo should not be placed near text
Insufficient contrast between background and type	Create a strong contrast between type and background color
Using color	
Color differentiation inadvertently associated with a particular feature	Use color differentiation to highlight information
Color does not help distinguish between products in a manufacturer's range	Use opposing, meaningless colors

VI. A GUIDE TO LABELING AND PACKAGING OF INJECTABLE PHARMACEUTICAL PRODUCTS

1. PRINCIPAL DISPLAY PANEL FOR CARTON (PDP): (IN THE RED BOX BELOW)

1.1. Features of front panel

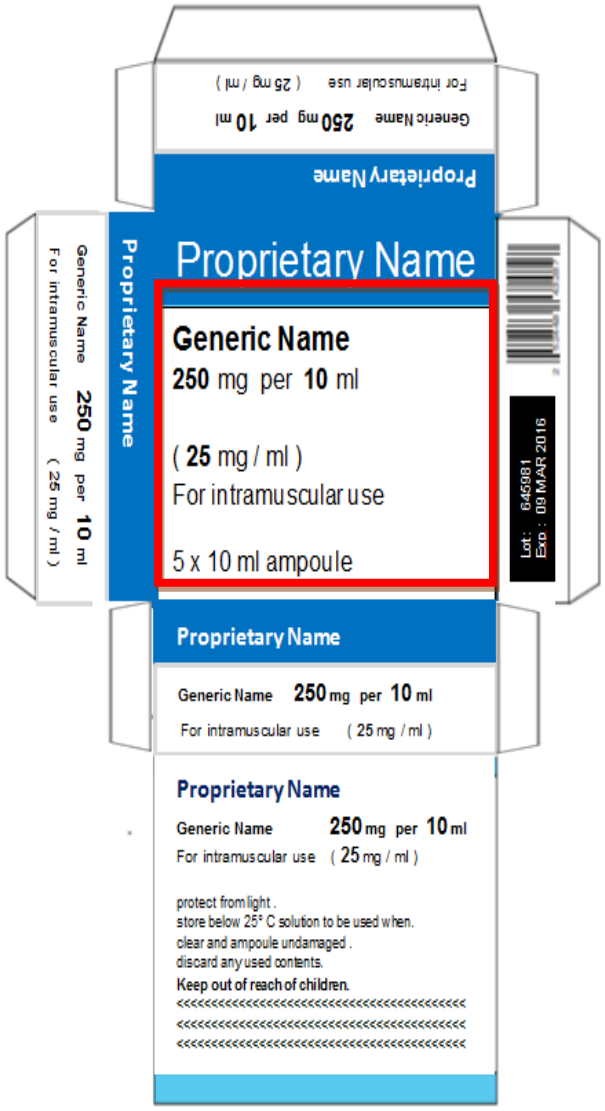
Create a front panel that features only the critical information. Subsequent (noncritical) information can be shown on the back panel.

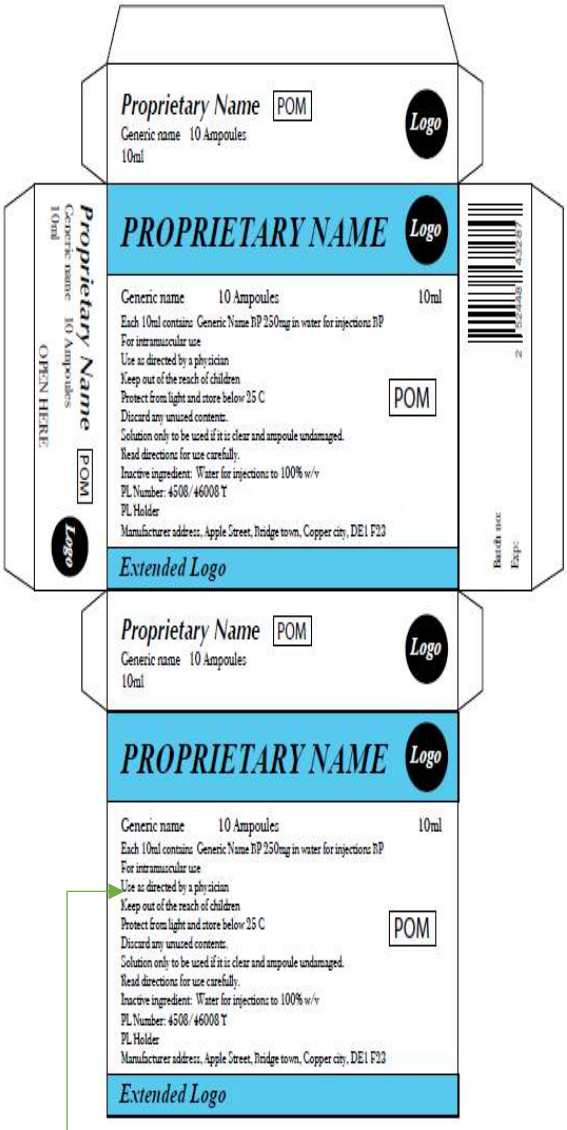
Minimum information consists of:

- Trade name
- Generic drug name
- Concentration of the pharmaceutical product:
  - Total quantity in the container (large font)
  - Concentration per unit volume (smaller font).
- Administration route(s)
- Significant Warnings
- Type of containers based on:-

  the number of doses i.e. (multiple-dose or single-dose containers)

  – the number of users i.e. single patient use.





Key information becomes difficult to find when information is printed on packaging in a dense block using text in a small font.

Figure 27

1.2. Use of color

Use color to highlight key differences in information: the drug name, the quantity concentration or warning if appropriate.

Apply the color scheme consistently throughout the primary and secondary packaging.

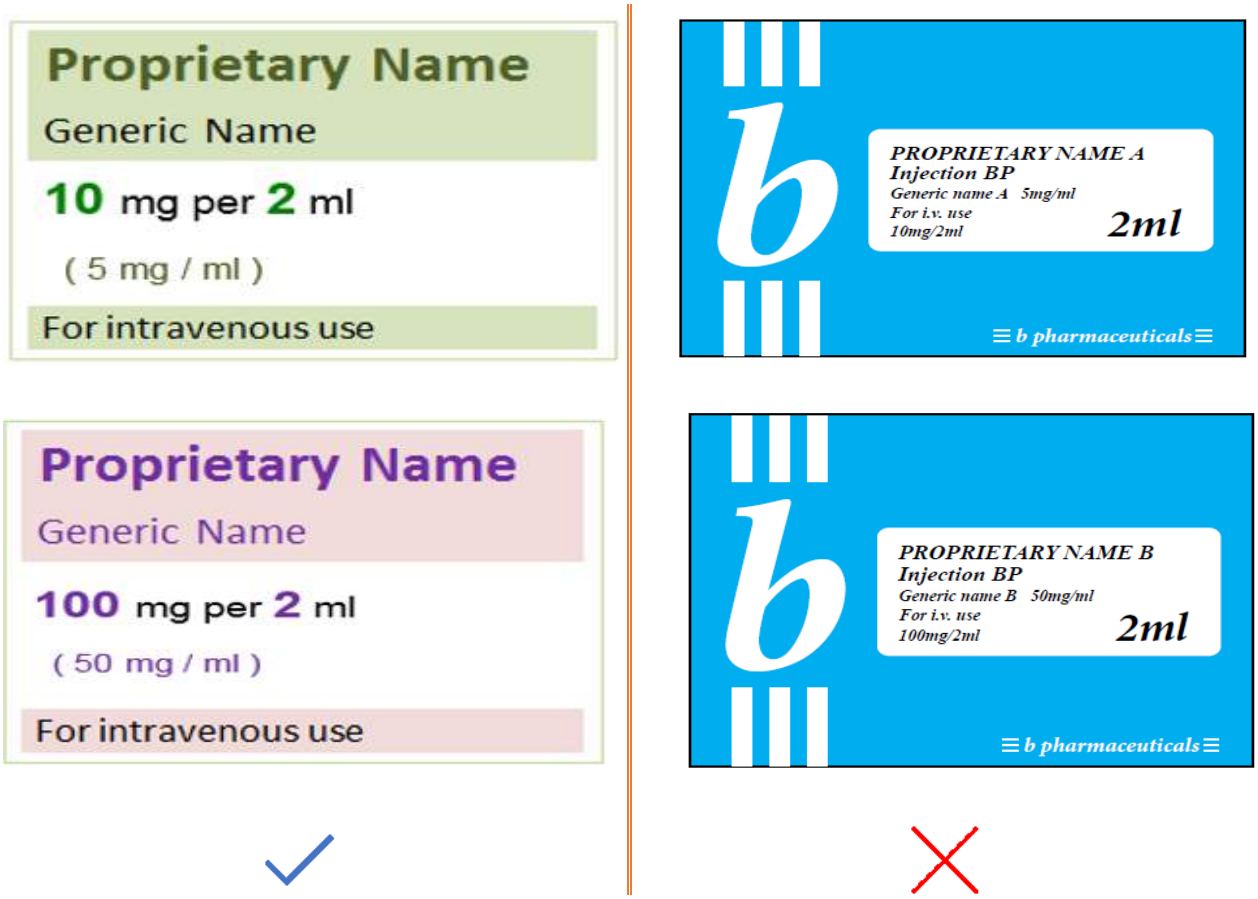
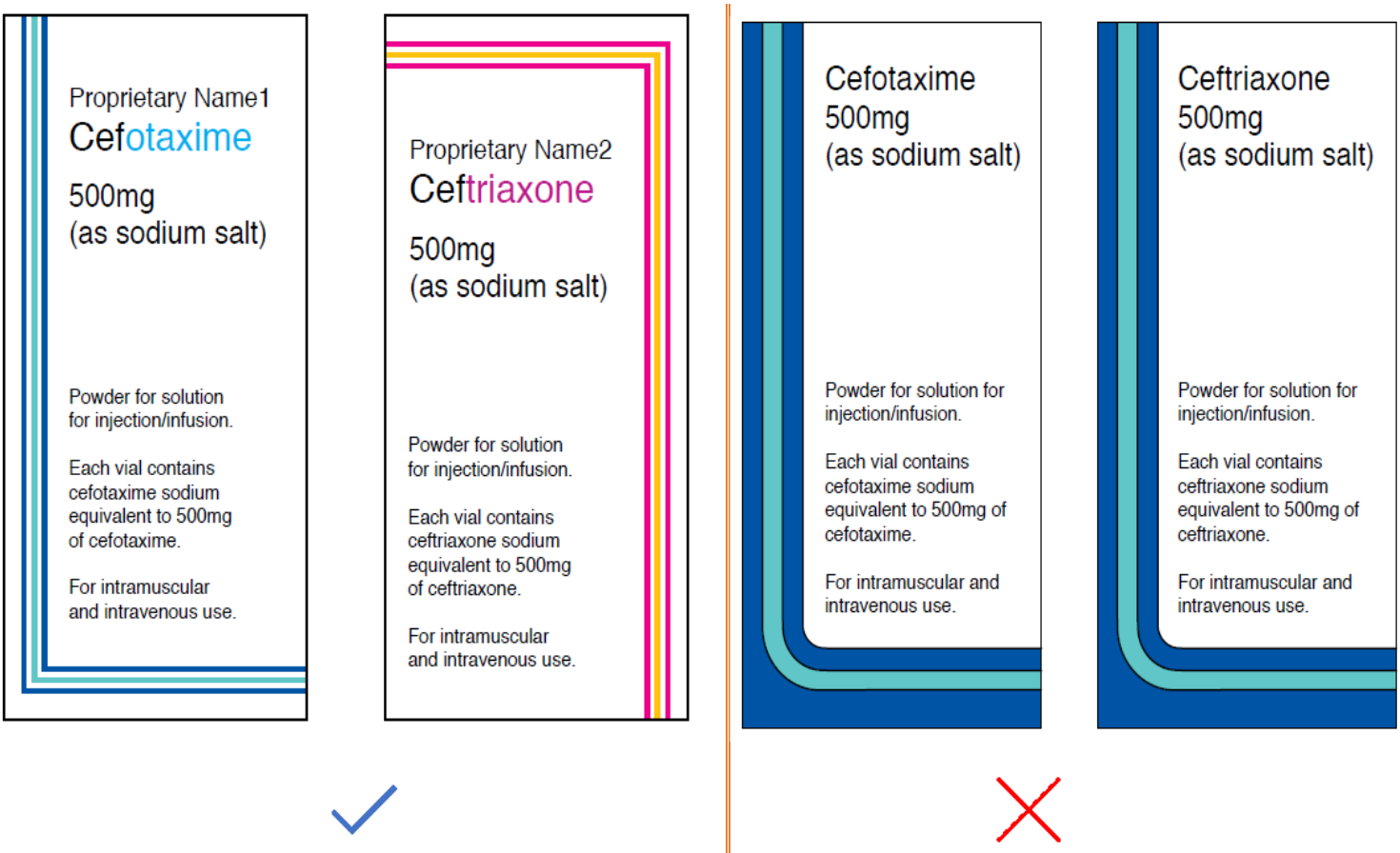


Figure 28

1.3. Similar drug name

Highlight the differences between similar generic or brand names from the same company. This could be done through the use of color, or font sizes, or by using TALL Man Letters (bolded uppercase letters).

Change the graphic component to ensure an added element of differentiation; for example this can be done by using different colors.



- Use Different colors or font size to differentiate between generic names of look-alike and sound-alike products from the same company
- Changing the appearance of look-alike drug names to draw attention to their dissimilarities by using TALL Man Letters (bolded uppercase letters)

Figure 29

1.4. Strength/Concentration

Include a representation of the full volume strength, i.e. total quantity in total volume, as well as amount per unit volume (e.g., 25 mg per 5 mL, then directly underneath and in parentheses 5 mg/mL).

Care should be taken with the spacing between mg and ml. Adjust the kerning so as to leave sufficient space around the "/" to achieve maximum legibility. It is acceptable to use the slash mark (/) if the number after the slash is a 1, as in 1 mL. If the number is something else, then use the "per" (for example, 50 mg per 2 mL, not 50 mg /2 mL). A slash can be mistaken for the number 1, so the concentration could be misread (for the above example, could be read as 50 mg in 12 mL, instead of 2 mL).

Quantity and Total Volume for Injectable Drug Products Packaged in Single- and Multiple-Dose Containers For injectable drug products greater than 1 mL, whether packaged in single- or multiple-dose containers, the quantity per total volume should be the primary and prominent expression on the principal display panel of the label, followed in close proximity by quantity per milliliter enclosed by parentheses (quantity/mL). For containers that hold a volume of less than 1 mL, the quantity per fraction of a milliliter should be the only expression of strength. For containers that hold a volume equal to 1 mL, the strength should be expressed as quantity per milliliter (quantity/mL), not quantity/1 mL. The following example formats are acceptable:

1. For containers less than 1 mL: 12.5 mg/0.625 mL
2. For containers equal to 1 mL: 5 mg/mL (not 5 mg/1 mL)
3. For containers greater than 1 mL: Example 1: 500 mg/10 mL (50 mg/mL) Example 2: 25,000 Units/5 mL (5,000 Units/mL) C226732-M4908-NL2015, rev. 00 20200731

Dry solids that must be constituted should follow the same format with the exception that only the quantity of the drug in the container should be listed as the primary expression of strength, not the quantity per total volume or quantity per milliliter (quantity/mL). Example: 500 mg/vial

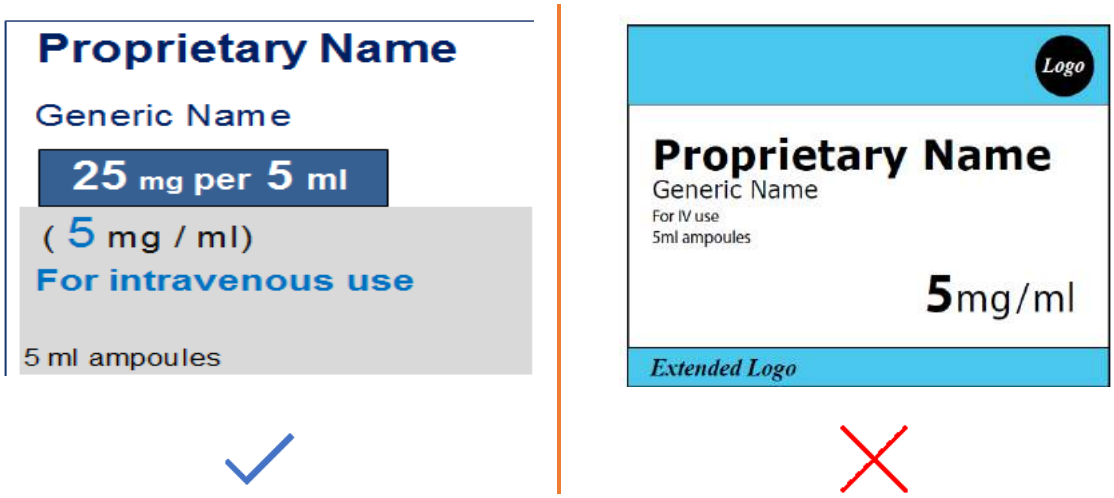


Figure 30

In certain cases, the primary and prominent expression of the total drug content per container is not effective in preventing medication errors and therefore in those cases, the total drug content per container should not be the primary and prominent expression of strength. Insulin products are an example of a product class that is an exception from the total drug content per container requirement. Another exception to expressing strength as quantity per total volume is lidocaine (or similar drugs for local anesthesia) where the product may be ordered and administered by percentage (e.g., 1% or 2%). In such cases, the percentage strength as well as the quantity per total volume followed in close proximity by quantity per milliliter enclosed by parentheses must be used.

Example 1:

1% (100 mg/10 mL) (10 mg/mL)

Example 2:

2% (1000 mg/50 mL) (20 mg/mL)

Display concentration in total quantity /total volume, even if other units of concentration such as percentage and ratios (for example '1 in 1,000') are also present.

When using numbers of 1,000 and above, use commas to help prevent misreading.

Do not superimpose information on other information.

Single-entity injectable drug products must be labeled in terms of quantity per milliliter (quantity/mL) and not as a ratio expression. Examples: Epinephrine Injection, 1:1000 must be expressed as 1 mg/mL. Epinephrine Injection, 1:10,000 must be expressed as 0.1 mg/mL. Isoproterenol Hydrochloride Injection, 1:5000 must be expressed as 0.2 mg/mL. Neostigmine Methylsulfate Injection, 1:1000 must be expressed as 1 mg/mL. Single-entity injectable drug products greater than 1 mL should be formatted as quantity per total volume on the principal display panel of the label followed in close proximity by quantity per milliliter (quantity/mL) enclosed by parentheses. When combined with a local anesthetic, the concentration of epinephrine will be expressed as a ratio. Examples: Lidocaine Hydrochloride and Epinephrine Injection 1%/1:100,000 or Lidocaine Hydrochloride 1% and Epinephrine Injection 1:100,000

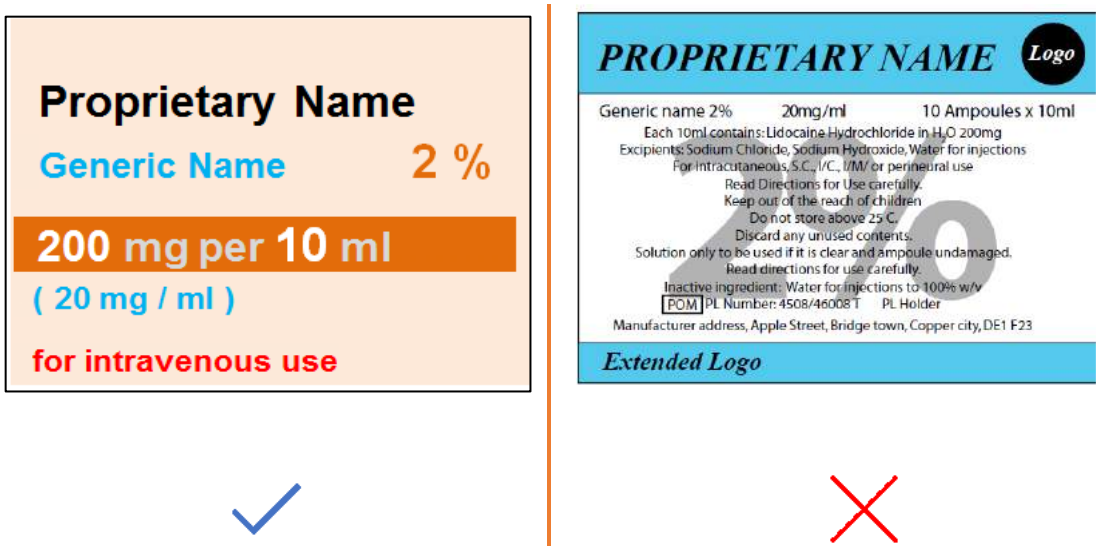


Figure 31

1.5. Administration route

Make positive statements- use ‘do’s’, rather than ‘do not’s’ as much as possible.

Use specific directions and avoid using technical terms that are not well understood. (e.g. ‘For Parenteral Use’ meaning: For intravenous, intramuscular, intradermal, subcutaneous, intrathecal).

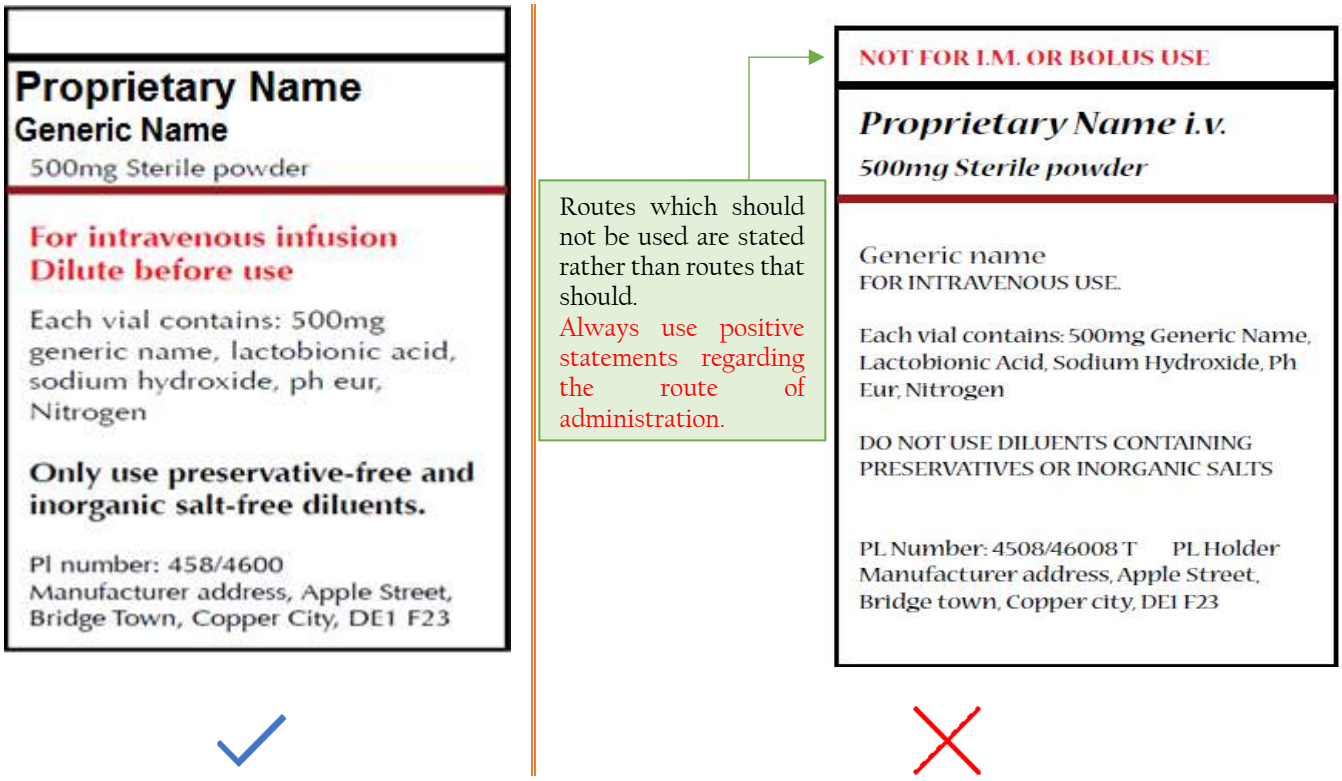


Figure 32

1.6. Warnings

-Use separate warning notices from the main part of the text and highlight the warning.

- Use positive affirmative language always.

Proprietary Name	Proprietary Name
Generic Name **500 mg**	**Generic Name** **500 mg**
Must be diluted before use. For injection or infusion as sodium salts. Read directions for use carefully. Store below 25°C.	Must be diluted before use. For injection or infusion as sodium salts. Read directions for use carefully. Store below 25°C.
✓	✗

Warning about unusually high doses or potential allergies, for example, are often not highlighted and become lost in dense blocks of text

Figure 33

Neuromuscular Blocking and Paralyzing Agents All injectable neuromuscular blocking agents and paralyzing agents must be packaged in vials with a cautionary statement printed on the ferrules and cap overseals. Both the container cap ferrule and the cap overseal must stand out in black or white print (whichever provides the greatest color contrast with the ferrule or cap color) the words: “Warning: Paralyzing Agent” or “Paralyzing Agent” (depending on the size of the closure system). Alternatively, the overseal may be transparent and without words, allowing for visualization of the warning labeling on the closure ferrule[1].

- Ampules containers are not recommended for paralyzing agents since they tend to be very small for the warning to be visible and usually ampules have similarity with other ampules, and many other disadvantages.

[1] Implementation Date 1-1-2023

1.7. Injectable pharmaceutical products intended for use by patients [optional]

For injectable pharmaceutical products that are intended for use by patients, leave a clearly designated blank space for the pharmacy label that is a minimum size of 70 x 35 mm. Position the drug name and strength near the space.

For injectable pharmaceutical products that come in a multi dose format as insulin, it is recommended that the drug concentration be represented as strength per unit volume.

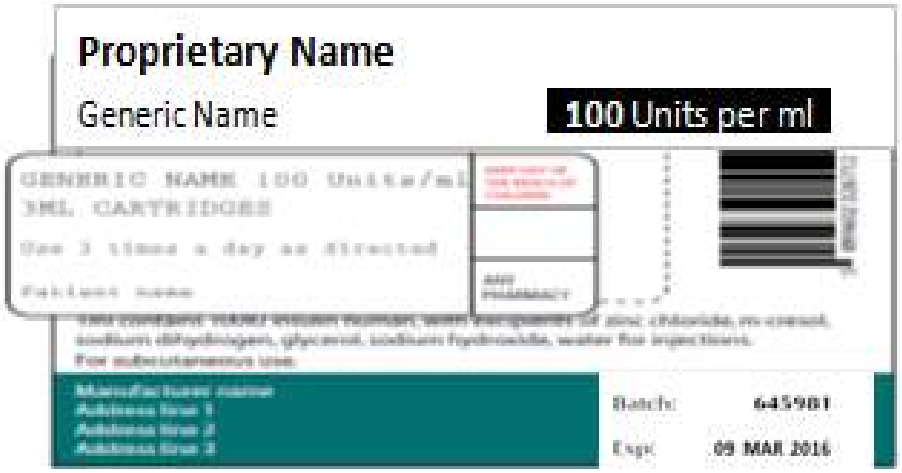


Figure 34

2. AMPOULES

2.1. Text orientation

Print the pharmaceutical product name longitudinally, along the length of the ampoule. A good rule of thumb is: if the visible width of the label is less than the height of the label then the name should be printed longitudinally.

- The information listed below is the minimum and must be present on containers more than 10 ml (the small container **exceptions** apply to containers of 10 ml or less):

1. Pharmaceutical product name (brand name and nonproprietary name)
2. Expression of strength
3. Route of administration
4. Warnings, where important
5. Expiry date
6. Batch number
7. Marketing authorization holder

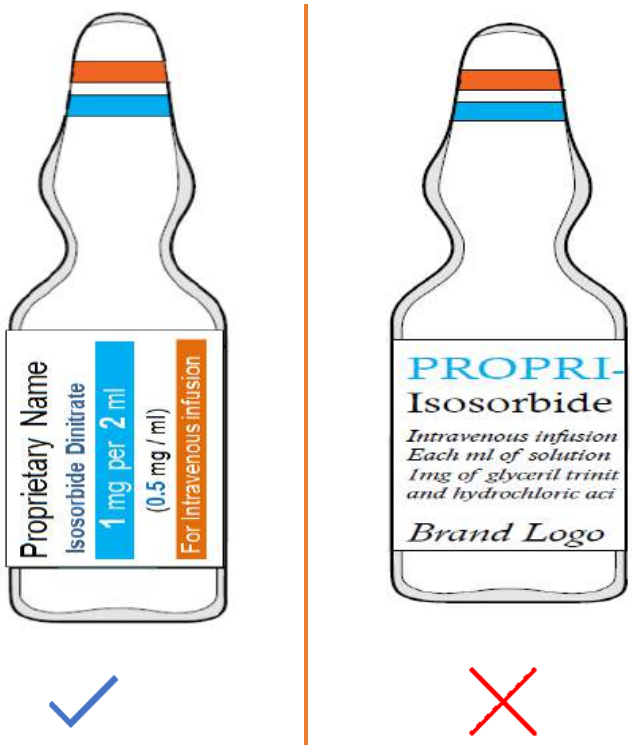


Figure 35

2.2. Labeling methods

- Use paper labeling where possible, and ensure that the label does not wrap completely around the ampoule to allow for inspection of contents.

  If ceramic or clear plastic labeling must be used, highlight key information by inverting the text color.

  Keep information to a minimum and reduce overlapping with text from the reverse side as much as possible.

  Labels should not come off in use and should be printed with ink that does not run when sprayed with alcohol to disinfect the ampoule surface in the pharmacy or during clinical procedures.

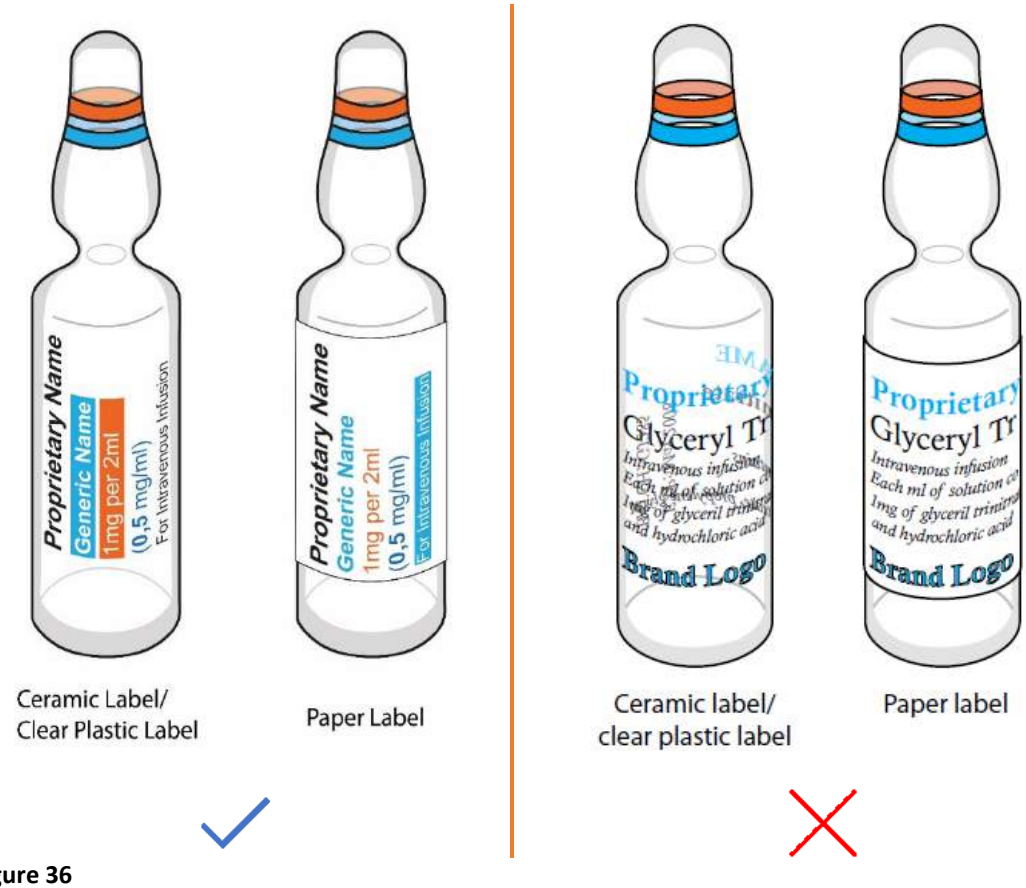


Figure 36

- We recommend the addition of a peel-off label on ampoules or vials, which can be transferred to a syringe in practice, will help practitioners avoid selection errors. All syringes containing pharmaceutical products should be labeled if they leave the operator's hands.

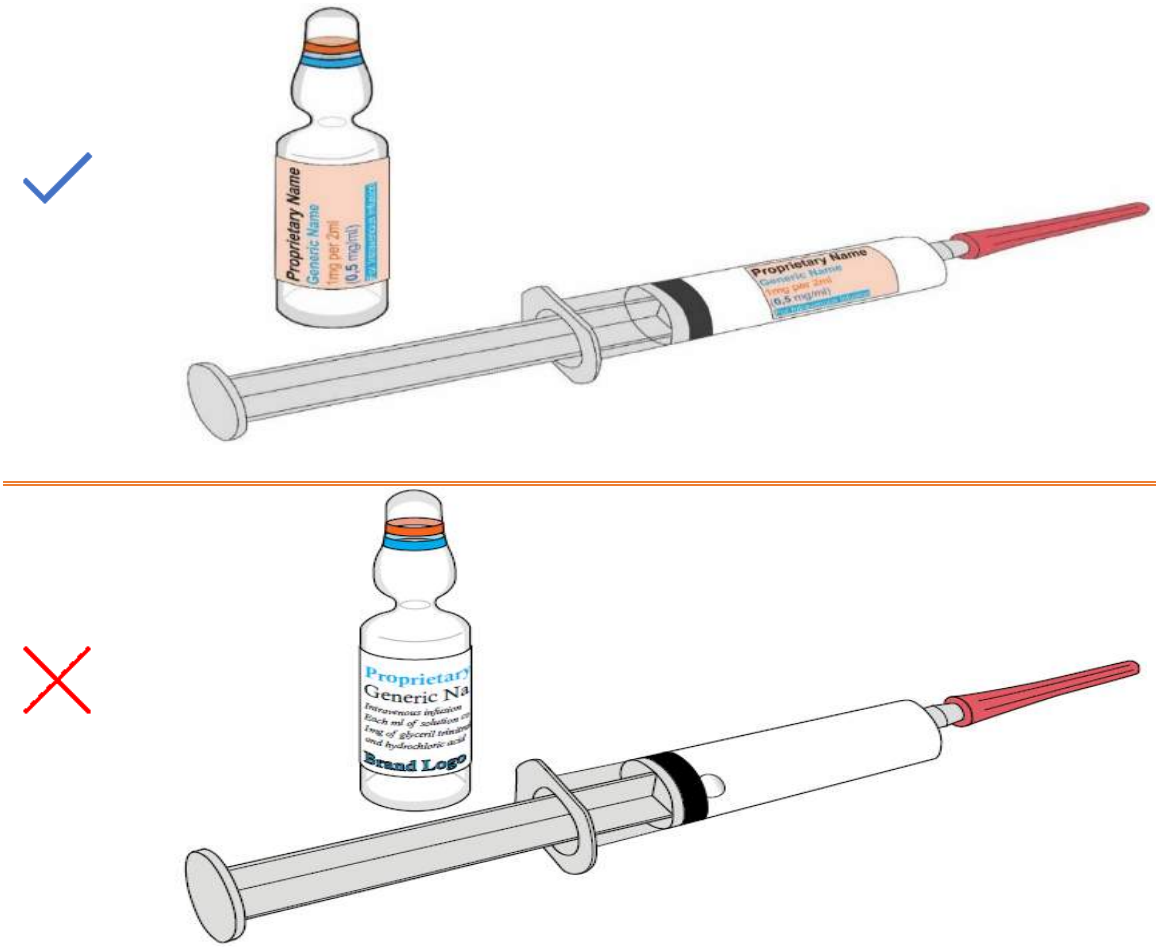
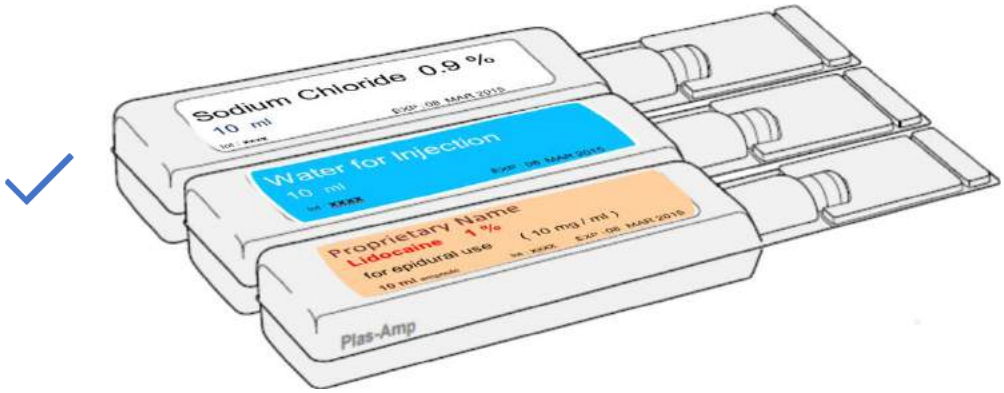


Figure 37

2.3. Plastic ampoules

- Use a clear font size.
- Information should be printed on paper label, if possible or direct on the ampoule with good contrast color.
- Use color to help to differentiate between products of the same company.
- Eliminate or reduce emphasis on the name of the container type such as ‘Plas-Amp’.
- Expiry dates and batch numbers should be easy-to-read and printed on the main body of the container, not on rip-off tabs.
- Where concentrations are shown, they should be expressed as total quantity in total volume (e.g., 20 mg per10 ml) as well as the per unit volume (e.g., 2 mg/ mL).
- Highlight the route of administration to avoid wrong route errors between products packed in plastic containers.



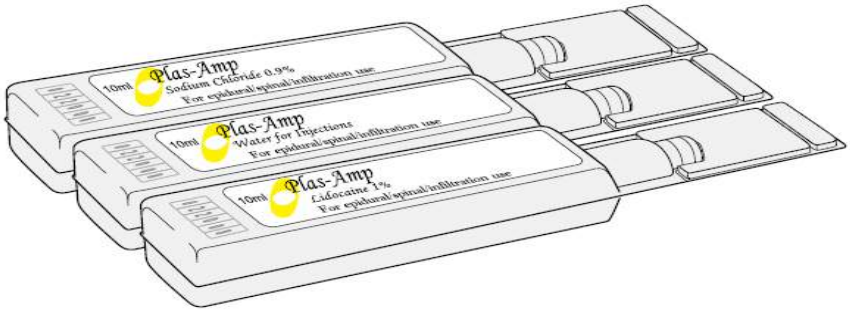


Figure 38

3. VIALS

3.1. Critical information panel

Create an area, which highlights the critical information. This area should not be wider than the width of the bottle in order to allow seeing the critical information without the need to turn the vial (i.e., along a single line of vision).

Use appropriate font size and formatting to enable the generic drug name to be read in one glance. The generic name should be at least 50% the size of the brand name.

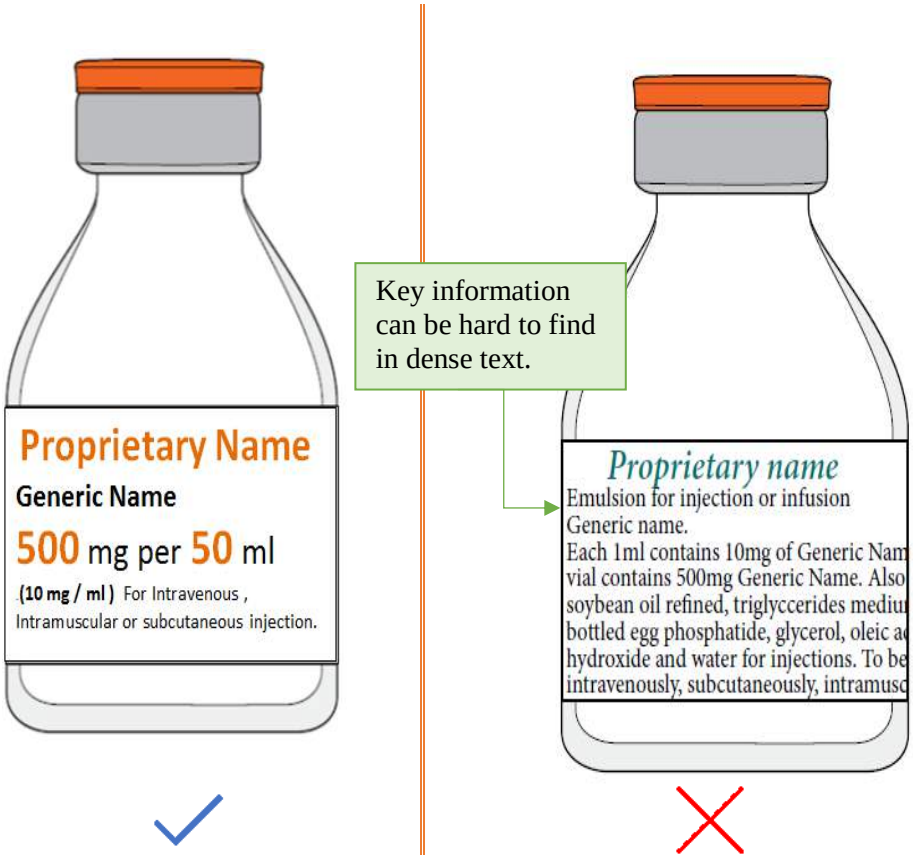


Figure 39

Neuromuscular Blocking and Paralyzing Agents All injectable neuromuscular blocking agents and paralyzing agents must be packaged in vials with a cautionary statement printed on the ferrules and cap overseals. Both the container cap ferrule and the cap overseal must stand out in black or white print (whichever provides the greatest color contrast with the ferrule or cap color) the words: “Warning: Paralyzing Agent” or “Paralyzing Agent” (depending on the size of the closure system). Alternatively, the overseal may be transparent and without words, allowing for visualization of the warning labeling on the

closure ferrule[2]

- Ampules containers are not recommended for paralyzing agents since they tend to be very small for the warning to be visible and usually ampules have similarity with other ampules, and many other disadvantages).

[2] Implementation Date 1-1-2023

3.2. Text orientation

The drug name should be able to be seen in a single line of vision. If the full drug name cannot be seen when the vial is upright, then the label should be oriented in a longitudinal fashion, in order to have the drug name in a single line of vision.

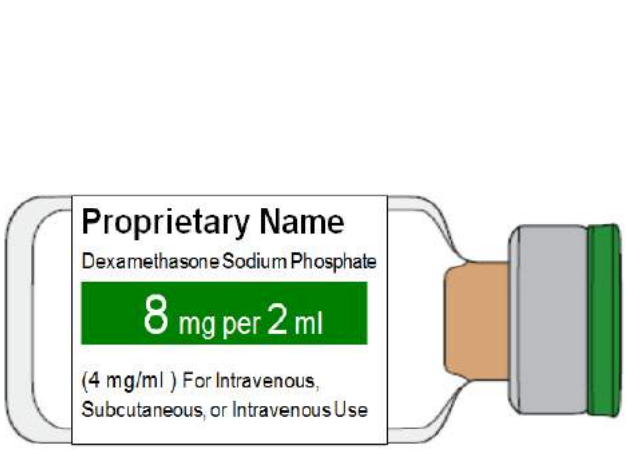


Figure 40

3.3. Color schemes

Match the design of the vial label to that of the carton.

Where the flip cap is colored, use the predominant differentiating color that has been used on the label and carton if possible.

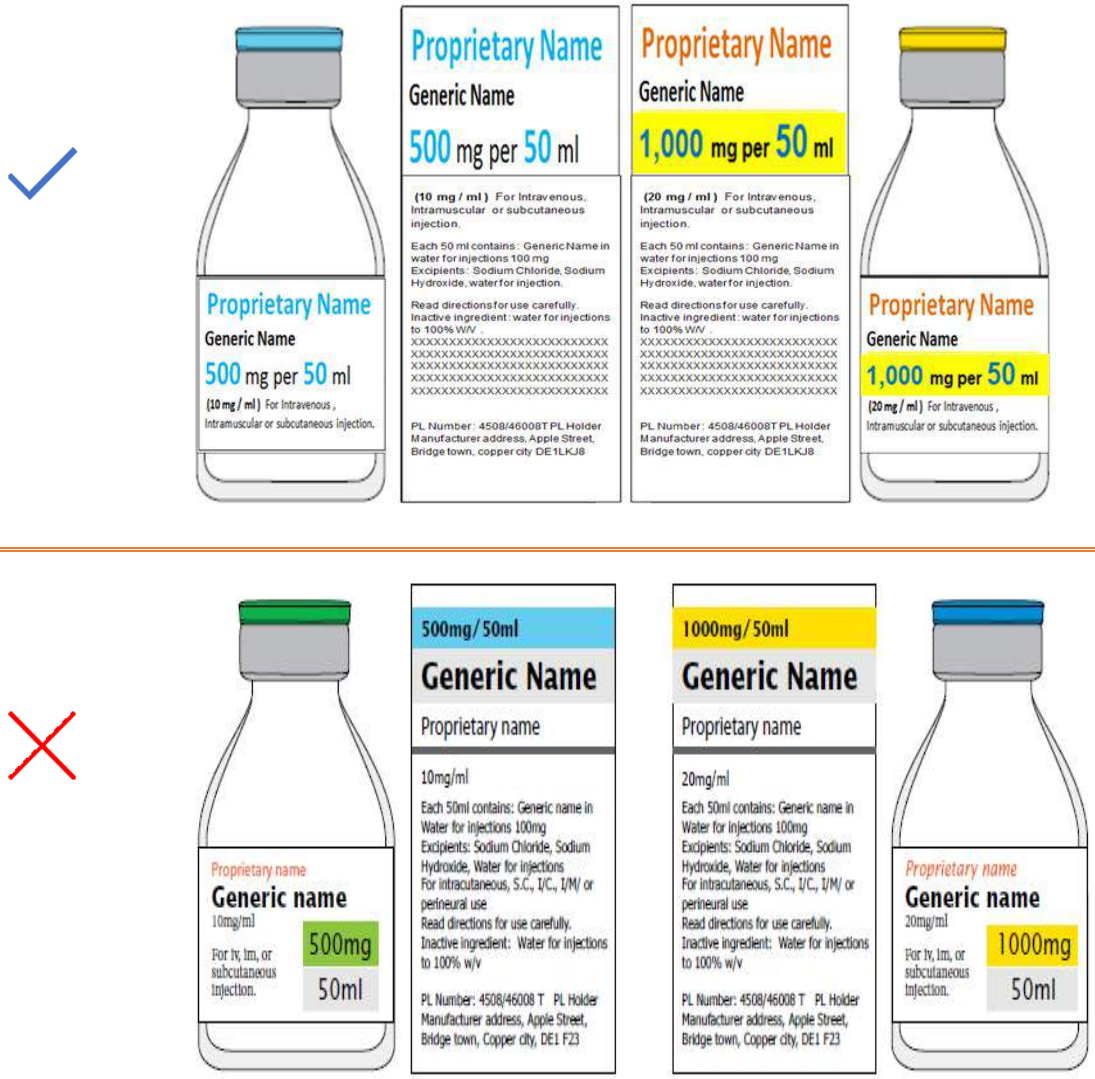


Figure 41

4. PRE-FILLED SYRINGES

4.1. Secondary packaging

Vary the design of the secondary packaging of similar products to enable easy identification. Pre-filled syringes that may be required during a medical emergency can be easily confused, especially when there is minimal differentiation on the outer packaging.

Consider the use of different colored components, for example, plungers or caps, to emphasize differences. Pharmaceutical products that come in a wide range of concentrations and doses can also be mistaken for each other.

Outer packaging, once opened, should not be easily re-sealable and should clearly indicate that the pre-filled syringe has been removed to prevent a delay in treatment if the empty pack is placed back into stock.

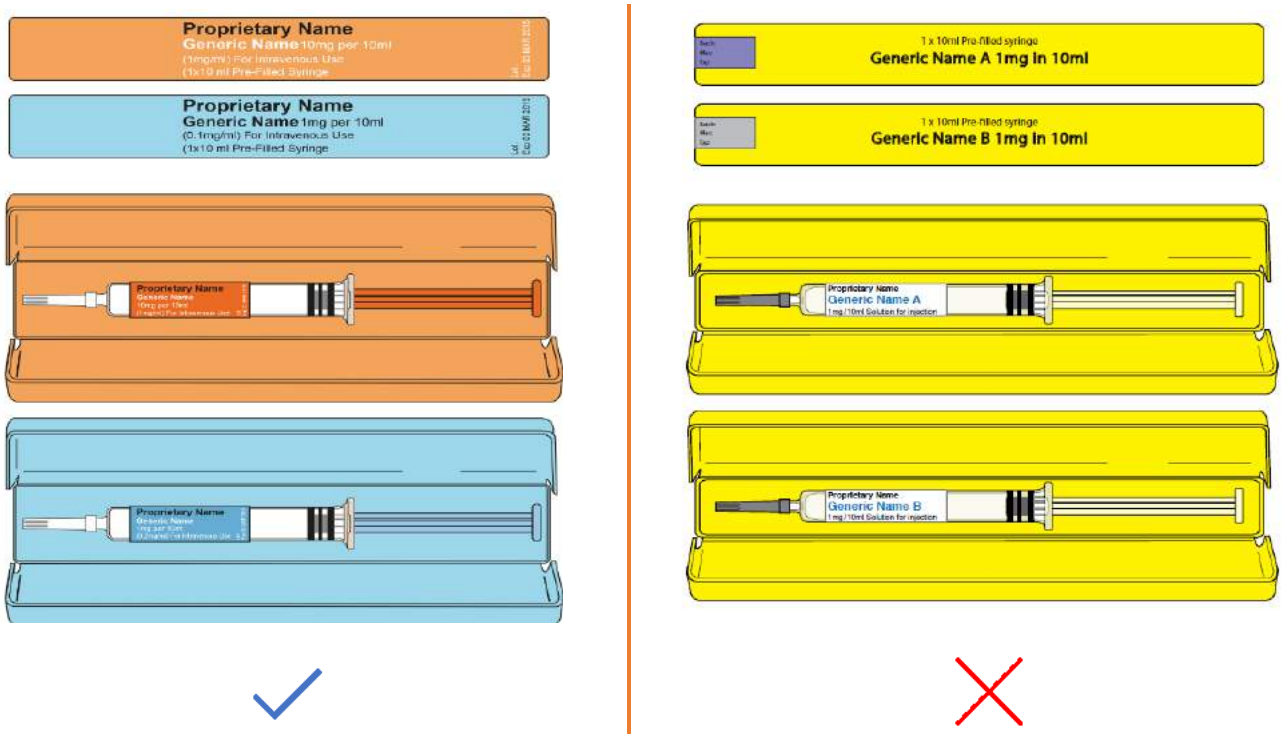


Figure 42

4.2. Text orientation on syringe

Orient text along the length of the syringe so critical information can be read holding it in the right hand, without rotating the syringe. When text is oriented around the syringe it necessitates a small font size which can be difficult to read.

Invert text color or use a background color to prevent text showing through.

Volume markings should always be visible and not covered by labels.

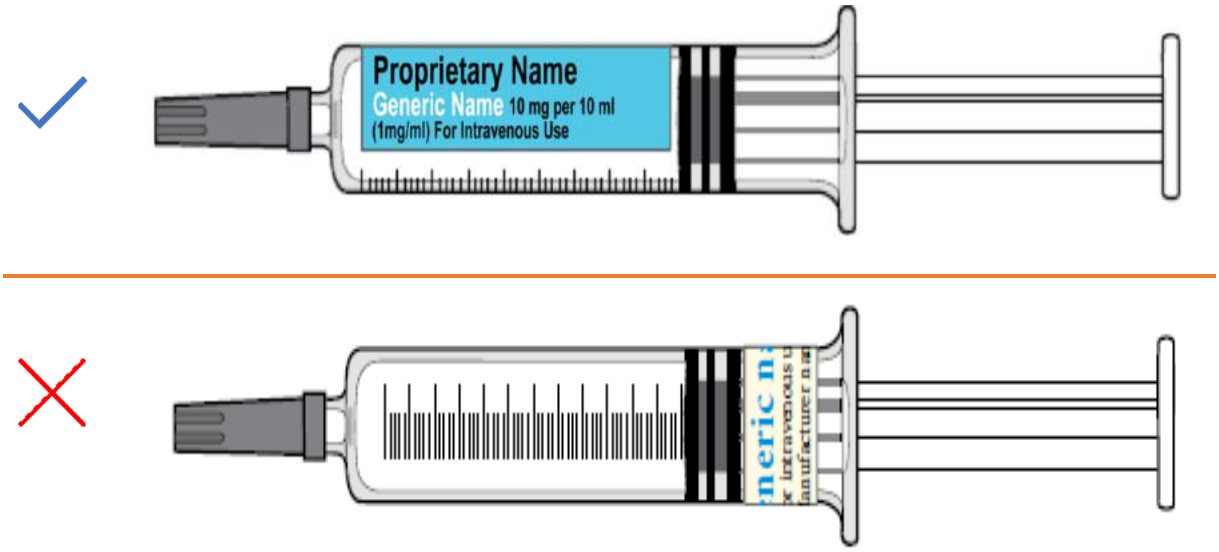


Figure 43

5. INFUSION BAGS

5.1. Text positioning

The critical information should be placed at the top of the bag; this information (especially the drug name and strength/concentration) should be repeated at the bottom of the bag so that as the bag empties it can still be visualized.

Position the batch number and expiry date close together.

Invert the key information text to draw the eye to it. Key information is lost in dense blocks of text.

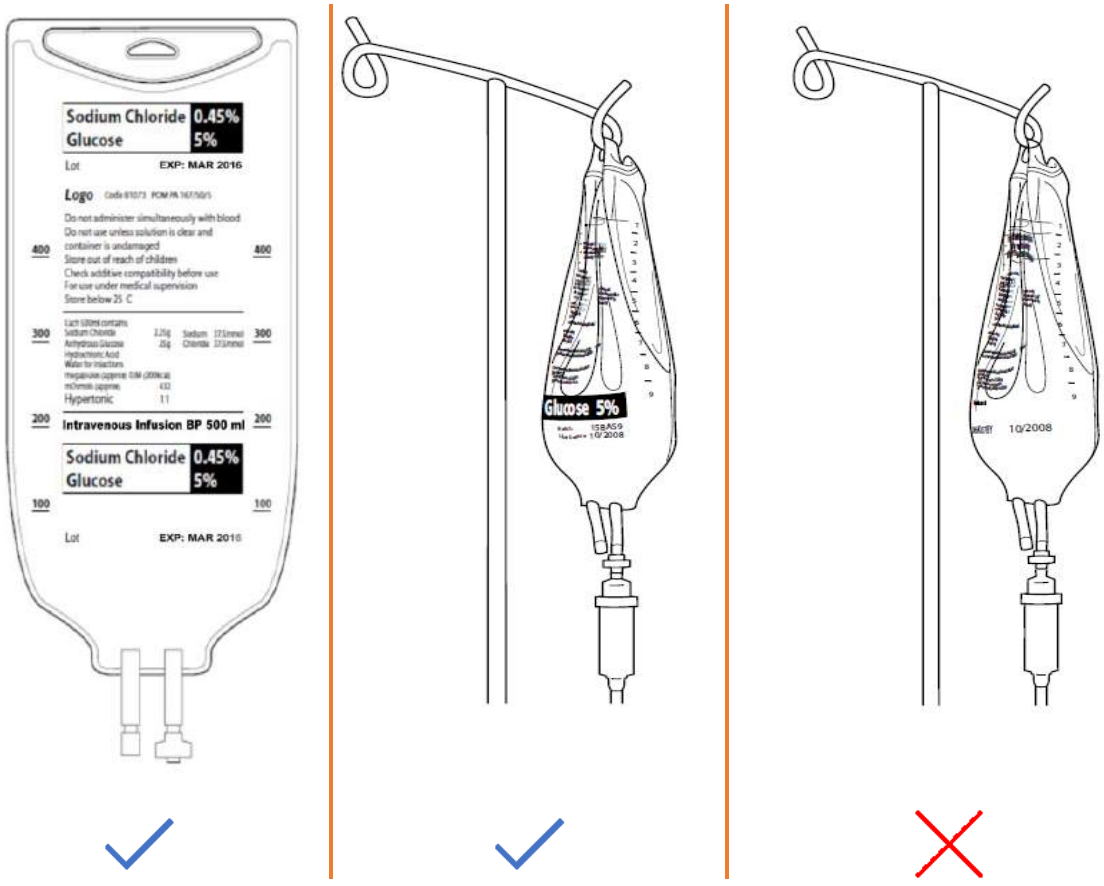


Figure 44

5.2. Font

The choice of font should be carefully considered to ensure adequate spacing between letters also the ink should not bleed. Use a san serif font as with other labels.

For multi-ingredients products, list the ingredients in table format if possible.

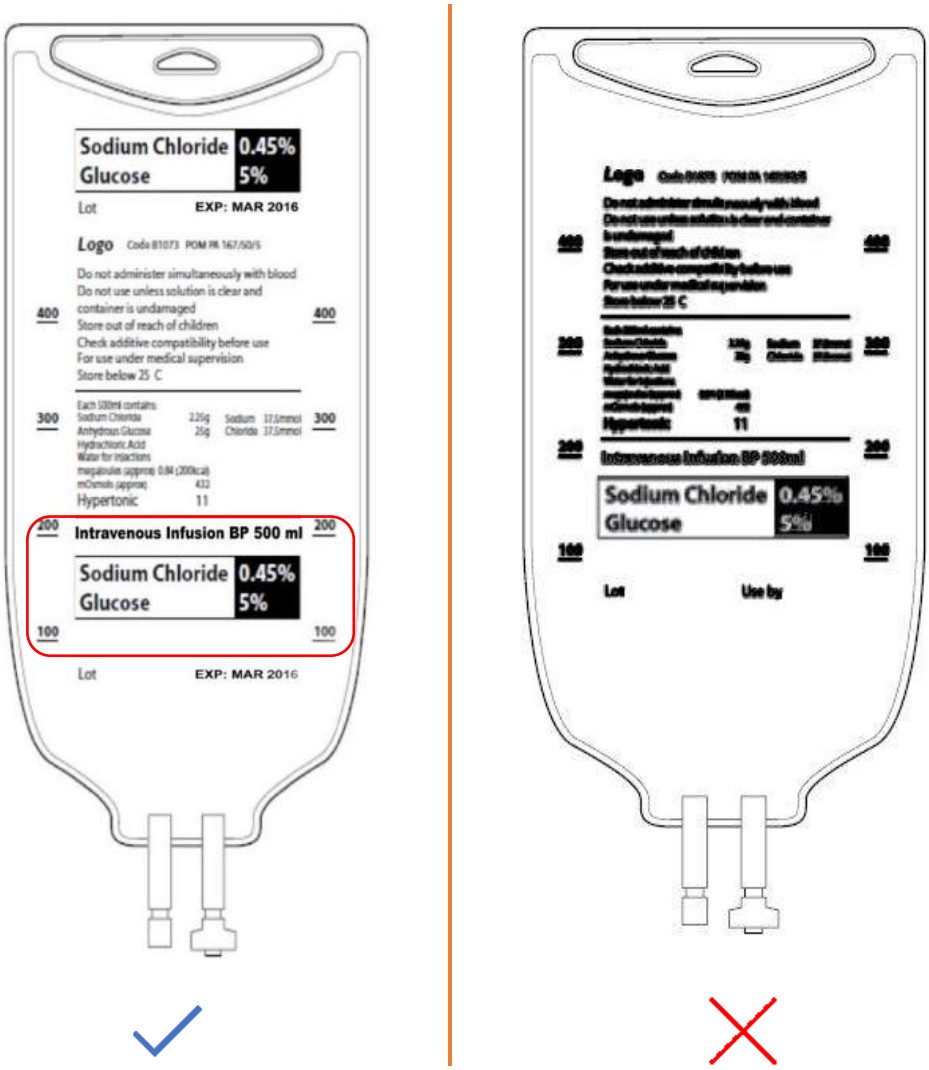


Figure 45

5.3. Bag volume

For fluids that comes in different volume sizes, give emphasis to the volume of infusion.

Vary other elements of the design to increase differentiation between labels.

When listing ingredients on the infusion bags, the strength should be represented as quantity per container.

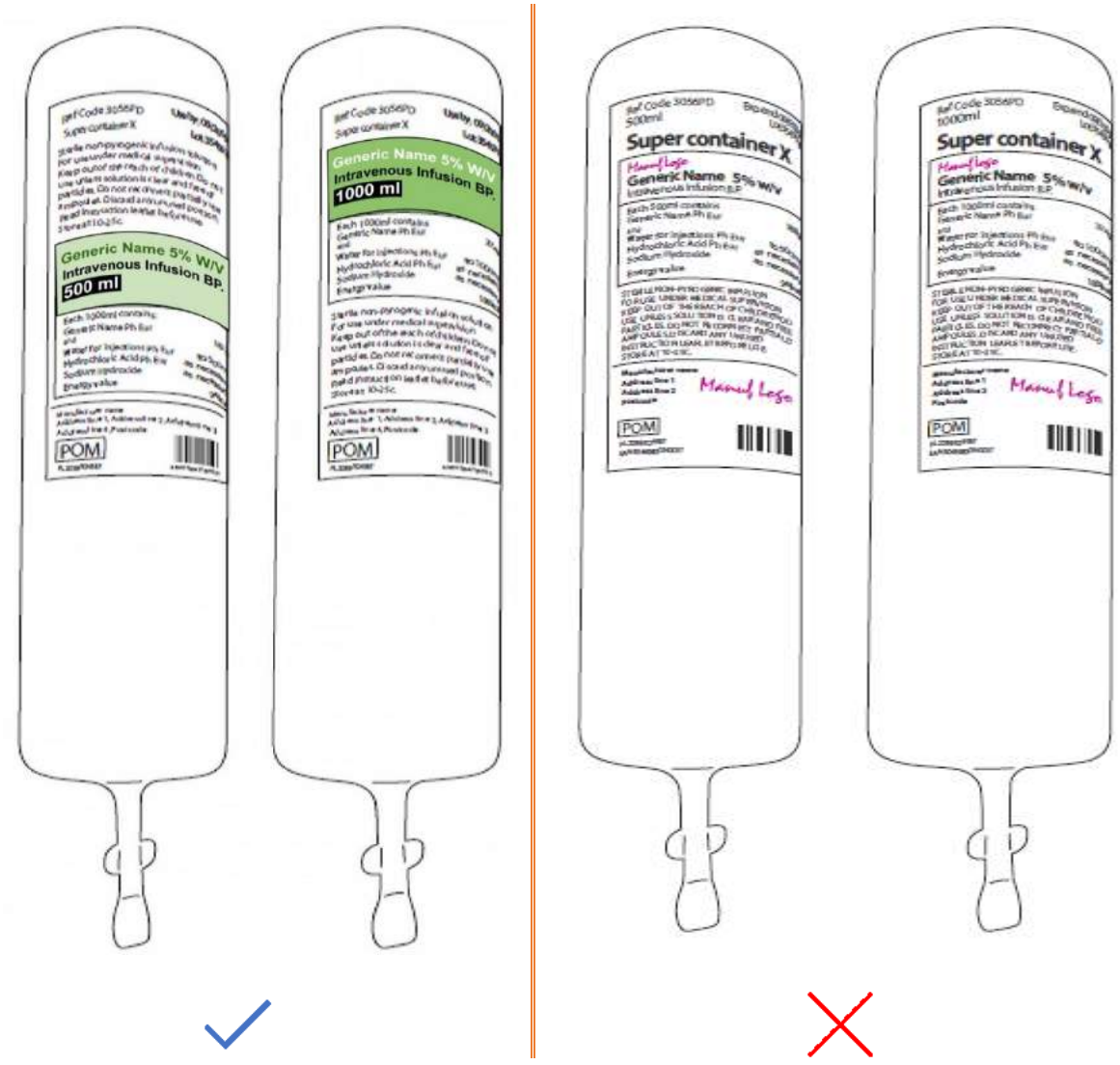


Figure 46

5.4. Use of color

It is important to differentiate between identified high-alert infusions.

Use bold blocks of color that stand out and draw the eye to the critical information and warnings.

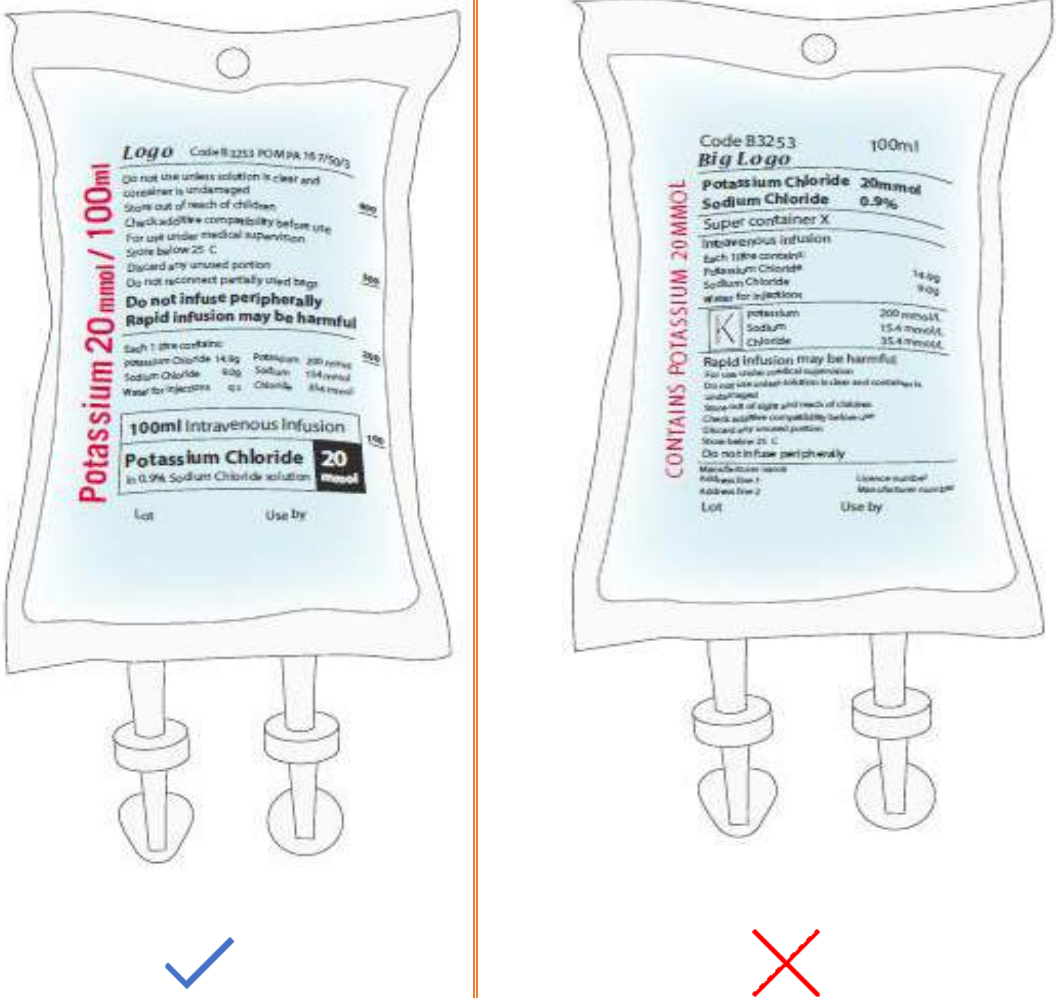


Figure 47

5.5. Bag Unit

Where the strength of pharmaceutical product is expressed in mmol, it should be represented as mmol/container volume.

5.6. Route of administration

Highlight the route of administration, particularly if it is different from the norm.

Figure 48

5.7. Product differentiation

Ensure there is an additional differentiator in addition to the text. For example, use color or, if this is not possible, vary the graphic components.

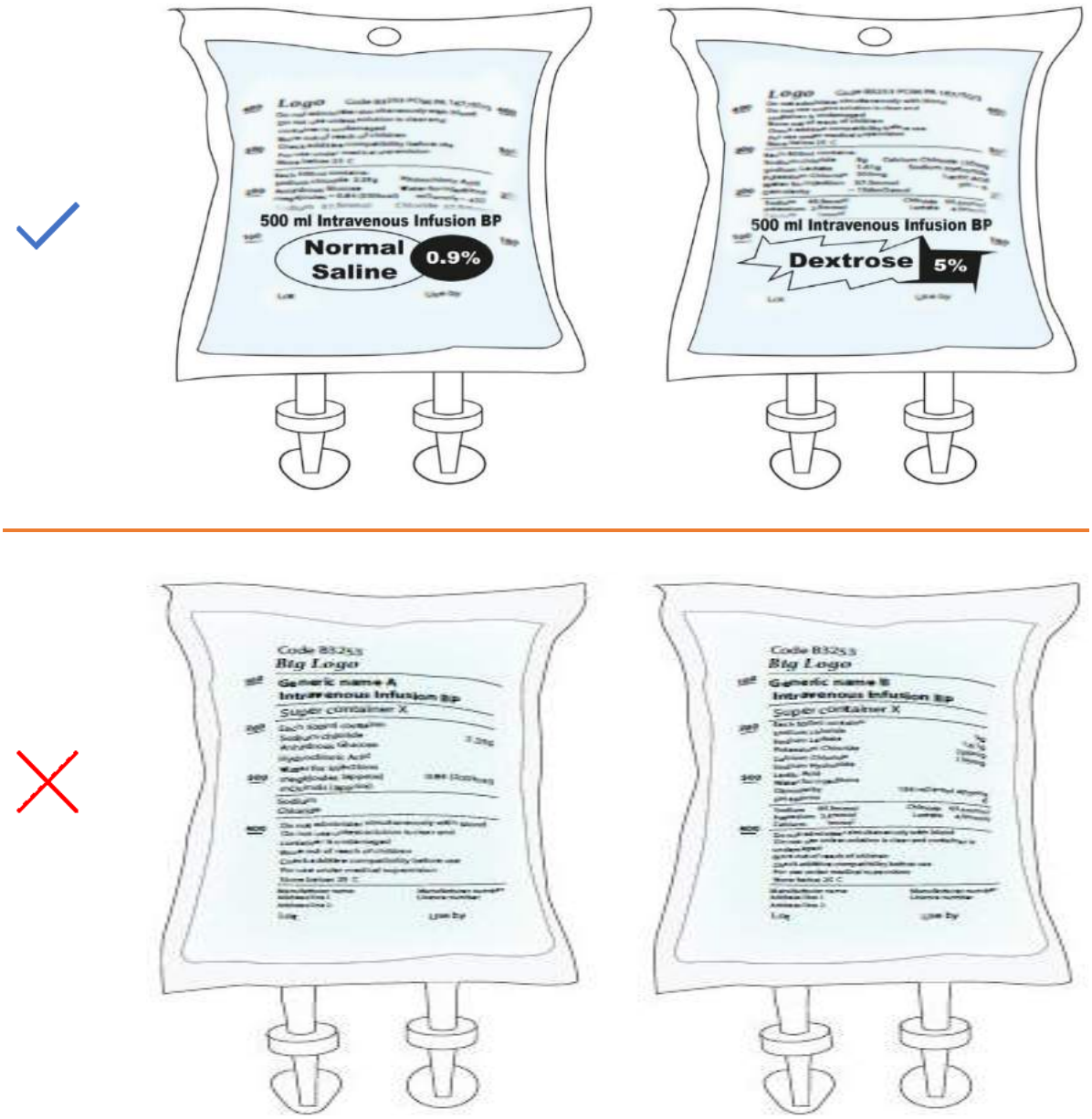


Figure 49

5.8. Surface finish

Use matte materials where possible to improve legibility. If materials used for the fluid bags and overwraps are reflective, the combination of the two materials can lead to impaired visibility of key information.

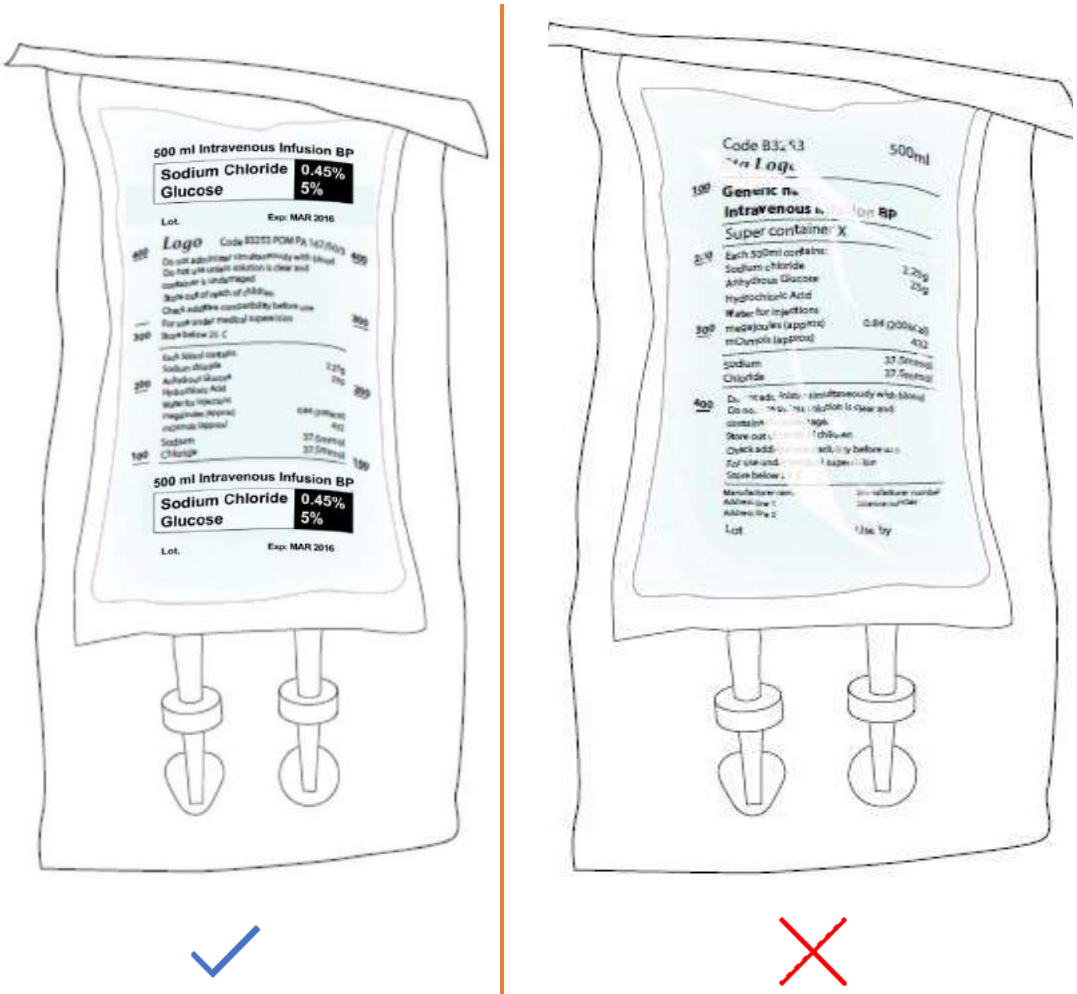


Figure 50

VII. MEDICATION ERRORS REPORTS AND CORRECTIVE ACTIONS

1. Reporting Of Medication Errors

All product-related medication errors should be reported to the relevant authorities SFDA and other relevant stakeholder. – i.e. product-related medication errors includes poorly designed packaging, similarity between products names, Design similarity between two or more products from the same company, unclear labels, etc.

Via vigilance system https://ade.sfda.gov.sa/Organization/Login

2. Handling Corrective Actions

Companies have an ongoing responsibility to guarantee that each marketed product fulfills the applicable requirements, such as guaranteeing that its labeling isn't false or misleading in any specification. In case a marketed product's proprietary name, packaging design or labeling causes or contributes to medication errors, the Company of that product should work expeditiously with SFDA to resolve the incident. In the event that the product does not comply with applicable requirements and the company is unwilling to address or resolve an issue voluntarily, the company may be subject to enforcement actions.

VIII. CONCENTRATION DESIGNATION & RECOMMENDATIONS

1. Elimination Of Ratio Expression

Quantity per milliliter (quantity/mL) must be indicated on single-entity injectable drug products, not as a ratio expression.

Examples: Epinephrine Injection, 1:1000 must be expressed as 1 mg/mL. Epinephrine Injection, 1:10,000 must be expressed as 0.1 mg/mL. Isoproterenol Hydrochloride Injection, 1:5000 must be expressed as 0.2 mg/mL. Neostigmine Methylsulfate Injection, 1:1000 must be expressed as 1 mg/mL.

Quantity per total volume on the main display panel of the label followed by quantity per milliliter (quantity/mL) enclosed by parentheses for single-entity injectable drug products more than 1 mL. The concentration of epinephrine will be expressed as a ratio when mixed with a local anesthetic.

Examples: Lidocaine Hydrochloride and Epinephrine Injection 1%/1:100,000 or Lidocaine Hydrochloride 1% and Epinephrine Injection 1:100,000.

IX. A GUIDE TO LABELING AND PACKAGING OF OPHTHALMIC PREPRATION

1. Deletion of the Arabic Term معقم/ـة.

We received reports of wrong use of sterile ophthalmic preparations the Arabic term مُعَقَّم of the sterile dosage form has been perceived as an indication antiseptic مُعَقِّم . Therefore, to avoid the confusion delete the Arabic term معقم/ة .

References:

- A guide to labeling and packaging injectable medicine , edition 1, 2008 National patient Safety Agency (NHS)
- A guide to the graphic design of medication packaging, 2nd edition , 2007 , National Patient Safety Agency (NHS)
- A guide to the design of dispensed medicines, 1st edition, 2007, National Patient Safety Agency (NHS)
- The US Draft guidance, “Safety Considerations for Container Labels and Carton Labeling to Minimize Medication Errors ”, April 2014
- US FDA Best Practices in Developing Proprietary Names for Human Prescription Drug Products; Guidance for Industry_ Guidance for Industry (December 2020)
- USP General Chapter <7> Labeling - US Pharmacopeia