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Group standard

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Guideline of labeling design for injections

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China Pharmaceutical Packaging Association Release

Content

Foreword

This standard is one of the series standard “Guide to Pharmaceutical Packaging Design” which consists of “Guide to Pharmaceutical Packaging Design” “Oral Formulation Packaging Design Guide” “Eye Drops Packaging Design Guide” “Inhalation Formulation Packaging Design Guide” and “External Drug Packaging Design Guide” etc.

This standard is drafted in accordance with the rules given in GB / T.1. 1-2009.
This standard is attributed to the China Pharmaceutical Packaging Association.
Participating organizations：Zhejiang Pharmaceutical Cosmetics Evaluation Center，Beijing Shield Public Welfare Foundation, Expert Group on Drug Safety of Hospital Pharmacy Committee of Chinese Pharmacy Association.
Chief drafting staff: Jin Hong, Zhang Xiaole, Liu Fang, Zhang Weimin, Zhang Lihui.

Introduction

This standard is intended to guide the drug licensor, clinical institution, label design, and production unit to reduce the clinical drug error and ensure the patient medication safety by normative applying the elements such as font, pattern, color and layout etc. during drug label design and production.

This standard is set according to injection characteristics but based on the guidelines of Infusion label and Packaging issued by National Patient Safety Agency (NPSA) of the United Kingdom

This standard can be used for reference by licensor, clinical institution, label design and label producer in accordance with the relevant national regulations.

All the drawings in the standard are diagrammatic sketch, and the names of drugs appeared in the drawings are only used for auxiliary description and have no concern with the properties of the actual drugs.

Guideline of labeling design for injection

1. Scope

This standard defines terms and definitions, injection label design principles.

This standard is applicable to guide the design and making of the label and labeling of injection, Which includes making (or printing) lable directly on the surface of the injection packaging, and affixing them on the surface of the injection packaging after making (or printing).

2 Terms and definitions

The following terms and definitions are applicable to this standard.

2.1 Labeling

The contents printed or affixed on the package of medicines can be categorized into inside label and outside labeling. Injection label includes the contents making (or printing) directly on the surface of the injection packaging, and affixing on the surface of the injection packaging after making (or printing)

2.2 Label

Inner label can directly contact with the pharmaceutical packaging container.

2.3 Labeling

All the Labels except inner label can be categorized as labeling. Labeling usually includes the minimum package labels, the shipping labels and storage packaging labels. In this standard, labeling only refers to the minimum packaging label on the market.

2.4 Specified information

Warning content that appears in the drug instructions, such as black box warnings (see Fig.1 and Fig.2), contraindications, special instructions and methods etc.

Fig 1

Fig 2

2.5 High alert medication

High alert medication is the drugs that cause serious injury or death to the patient in the event of improper use. Although the probability of drug ordering errors in high alert medication is similar with the other drugs, the consequences are extremely serious. More information please refer to Appendix A.

2.6 Traceability code

The unique code assigned by the pharmaceutical manufacturer on the minimum packaging of the drug. It can be one-dimensional code, two-dimensional code, or RFID technology. You can obtain manufacturing enterprises, drug specifications, approval number and expiration date and other information by reading the drug traceability code. Traceability code is mainly used for drug safety tracing and anti-counterfeiting.

2.7 Specified label

Specified label includes the prescribed labeling of the special drugs listed in the national specified list (Fig.3-Fig.8) , and the labels appeared in the fixed position (For example, the labels marked in the upper right corner for narcotic drugs, psychotropic drugs, toxic drugs and radiopharmaceuticals (Fig.9).

Fig3.Narcotic drug mark

Fig4. Psychotropic drug mark

Fig5. Toxic drug mark

Fig6.Radiopharmaceutical label

Fig7. High warning drug mark

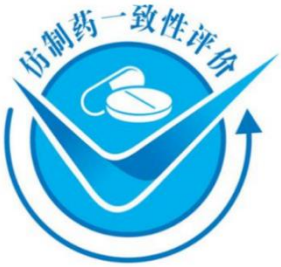


Fig8.Mark by generic drug conformity

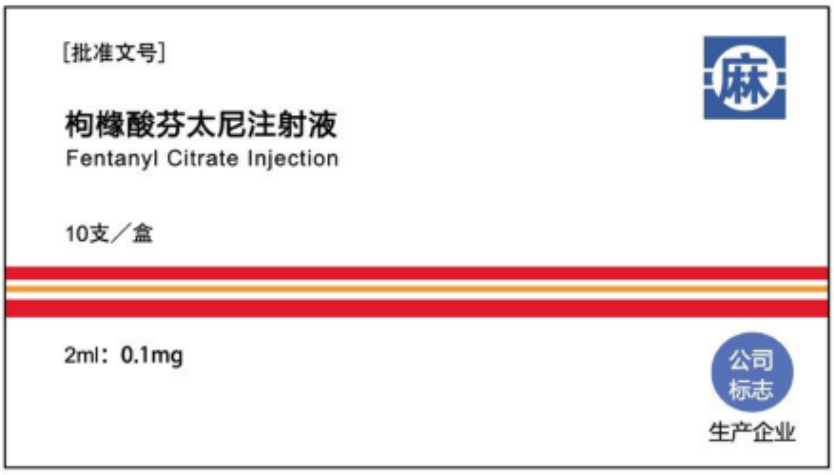


Fig 9

3. Design principle of injection label

3.1 Summary

Injections are aseptic agents made of raw materials and with suitable excipients for injection into the human body. Injections can be divided into injection solution, sterile powder for injection and concentrated solution for injection etc. In clinical application, it is directly injected into the tissues, blood vessels or organs of the human body in a liquid state, and the absorption is fast and the effect is direct. Especially for intravenous injection, the liquid can directly enter the blood circulation, which is more suitable for the rescue of critical illness. Dispensing and injecting drugs is a high-risk treatment process for patients and hygeian professionals. Optimized label design reduces errors and the risk of damage. In the development and design of drug labeling and packaging, the end user and its use environment should be considered. Drug manufacturers should evaluate and minimize the risk of drug errors caused by design problems of label and labeling, and the label design should be reviewed or approved in accordance with relevant national regulations.

In addition to the basic requirements of various types of labels, injection labels should also pay attention to the specificity of the injection label. In addition to the product name (if any), the generic name (if have English name or pinyin name), specifications, route of administration (intramuscular injection default), and special identification (if any), other label information, such as: locations can be adjusted for component, storage, manufacturing companies, expiration dates, approval numbers, etc. See Fig.10:

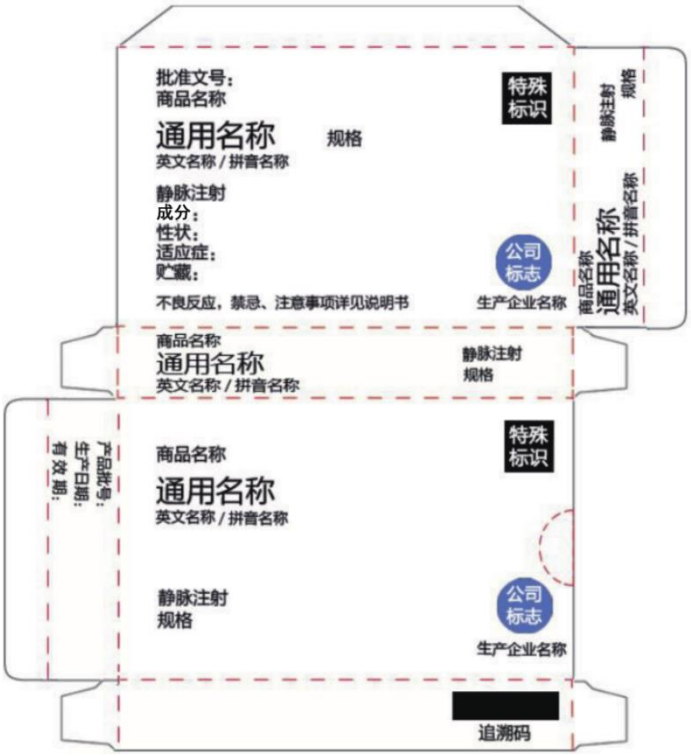
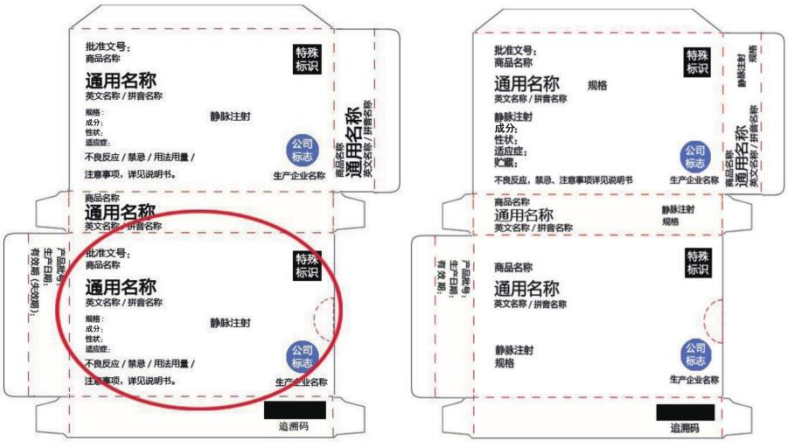


Fig10

3.2 General principle

3.2.1 Main information panel

Important information should be highlighted when designing the front panel [generic name of the drug, special identification, specification, product lot number, expiration date (invalidity period), mode of administration, and information that requires special prompts]. Other information can be displayed on the rear panel. See Fig.11.



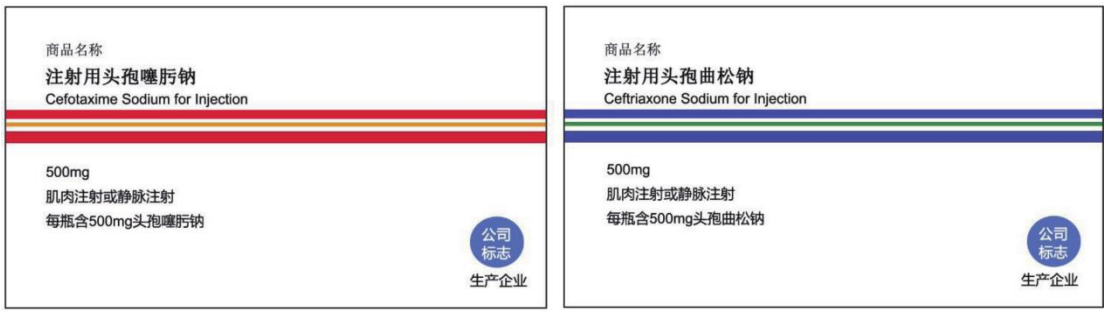
a）Problem diagram　　b)Suggestion diagram

Fig11

3.2.2 Drug name is similar

When designing the generic name and trade name used in the label, special attention should be paid to different drugs that look similar (seemingly) and sound similar (listening). In particular, the “seemingly” and “listening” drug labels produced by the same company should have obvious differences, such as printing ribbons or other different ways. See Fig.12.

a) Problem diagram

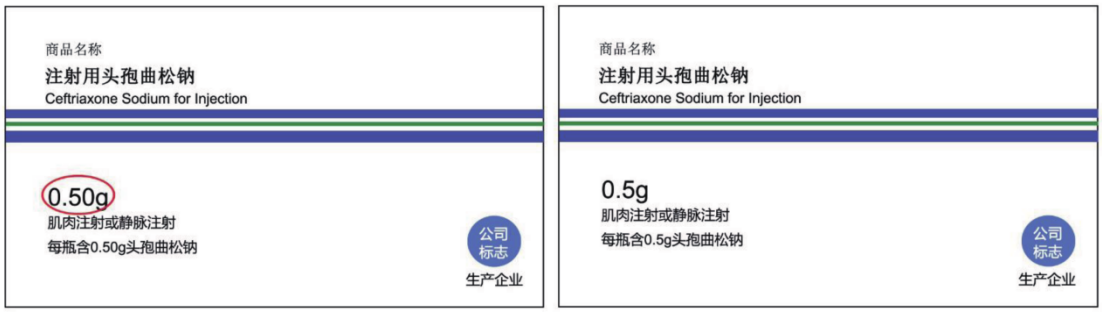


b) Suggestion diagram

Fig12

3.2.3 Specification

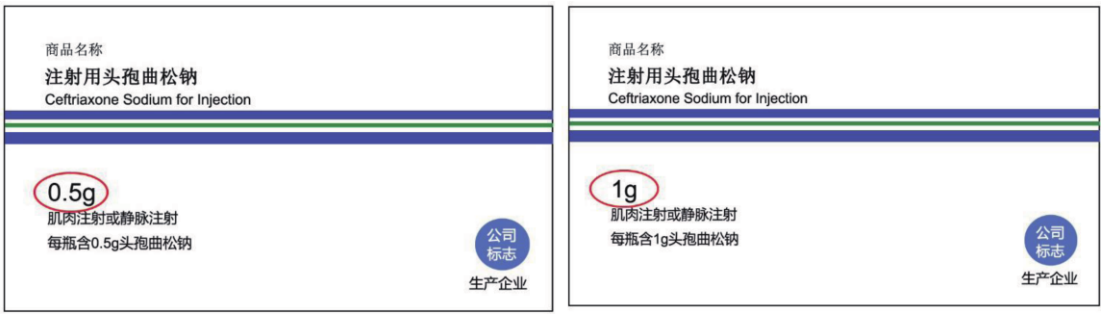
3.2.3.1 The minimum packaging label of marketed drugs does not need to express the precision of concentration, and do not add "0" to the specification number. See Fig.13.



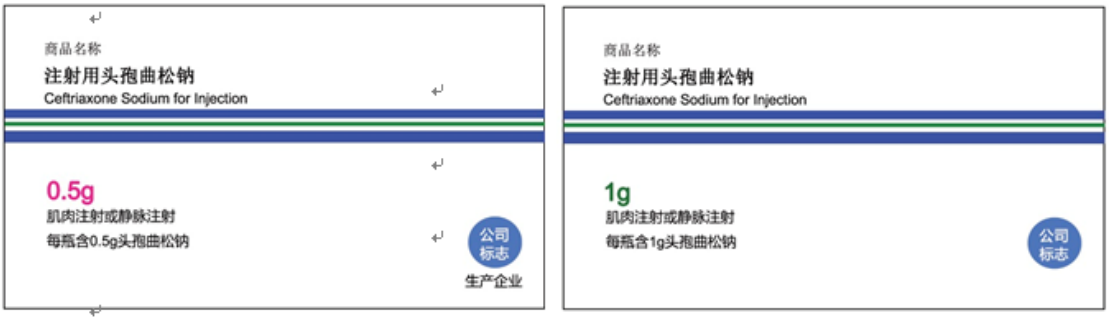
a) Problem diagram b)Suggestion diagram

Fig13

3.2.3.2 For different specifications of the same product of the same manufacturer, should be clearly differentiated. See Fig.14.



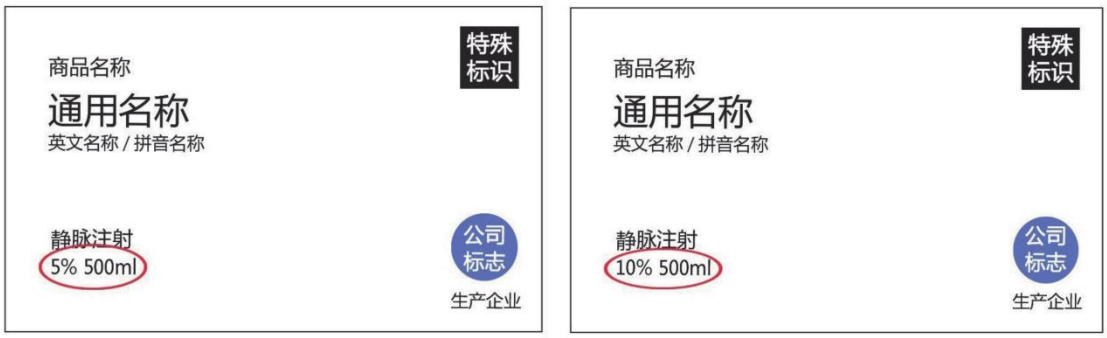
a) Problem diagram



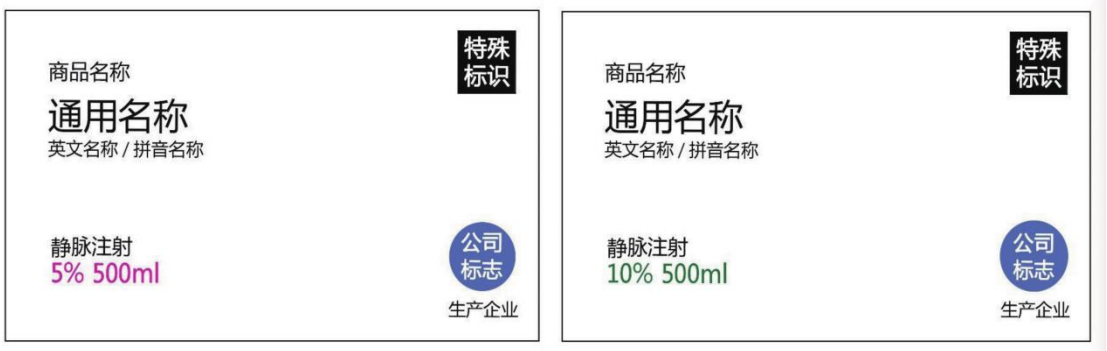
b) Suggestion diagram

Fig14

3.2.3.3 The specifications of liquids should be clearly differentiated. See Fig.15.



a) Problem diagram



c) Suggestion diagram

Fig15

3.2.4 Route of medication

3.2.4.1 Use definite information to identify the correct delivery routes and avoid negative or incomprehensible terms. See Fig.16.

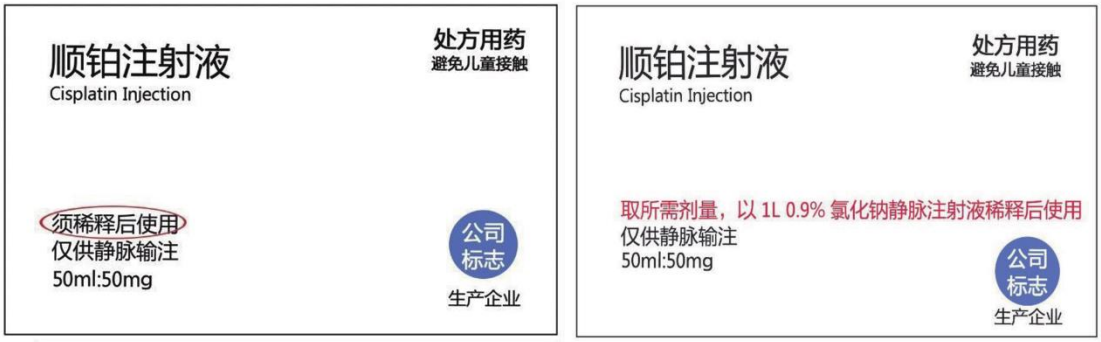
a) Problem diagram b)Suggestion diagram

Fig16

3.2.4.2 The drugs strictly forbidden to inject into the sheath should usea black alerting box according to, chapter 3.2.4.1.

3.2.5 Drug dilution

The drugs that must be diluted should be clearly labeled and marked with the appropriate minimum dilution volume. See Fig.17.

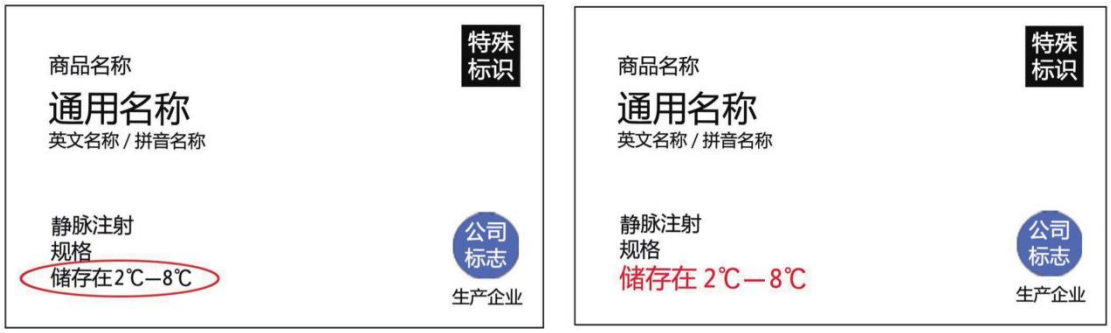


a) Problem diagram b)Suggestion diagram

Fig17

3.2.6 Storage condition

Storage conditions should be specified on the label. In particular, special instructions should be made for preparations that cannot be frozen. Special requirements for storage conditions should be highlighted, and users should be prompted in definite language. See Fig.18.



a) Problem diagram b)Suggestion diagram

Fig18

3.2.7 Injection drugs for use by patients

For multi-dose, multiple-use injection drugs, such as insulin, in addition to the indicated packaging specifications, the content can be expressed as: dose/ unit volume, unit/ ml, or mg/ ml. Braille shall be marked on the package if braille is available. Make sure that braille does not interfere with other design elements. See Fig.19.

a）Problem diagram b)Suggestion diagram

Fig19

3.2.8 Multiple injection drugs

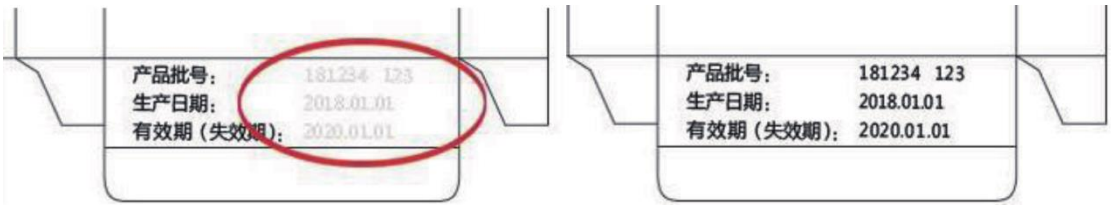
The dosage and quantity should be labeled in specifications. See Fig.20.

a) Problem diagram b)Suggestion diagram

Fig 20

3.2.9 Validity period (period of invalidity)

Validity period should be printed on the clear and recognizable position of label and labeling (using ink as much as possible). If drugs are often used in sterile environments, digital embossing is also feasible, just make sure the numbers are clearly identifiable. See Fig.21.



a) Problem icon b)Suggestion icon

Fig 21

3.2.10 Precautions

When there are more than 2 points for attention, it should be written in sections to make it easy for users to read. See Fig.22.

a) Problem diagram b)Suggestion diagram

Fig 22

3.2.11 Bar code (traceability code)

All kinds of bar codes (traceability codes, etc.) used by drug manufacturers can be placed in a secondary position, leaving as much space as possible for clinical bar codes. See Fig.23.

a) Problem diagram b)Suggestion diagram

Fig 23

3.2.12 Important information

Important information about drugs (at least) should be represented on the three non-relative outer surfaces of the minimum package on sale, but the main plane should contain all important information. Such as: generic name, specifications, usage, etc., and leave a certain blank area for pharmacists to add labels if need. See Fig. 24.

Fig 24

3.2.13 Background requirement

The text, image or logo should be separated and placed in a blank space. See Fig. 25.

Fig 25

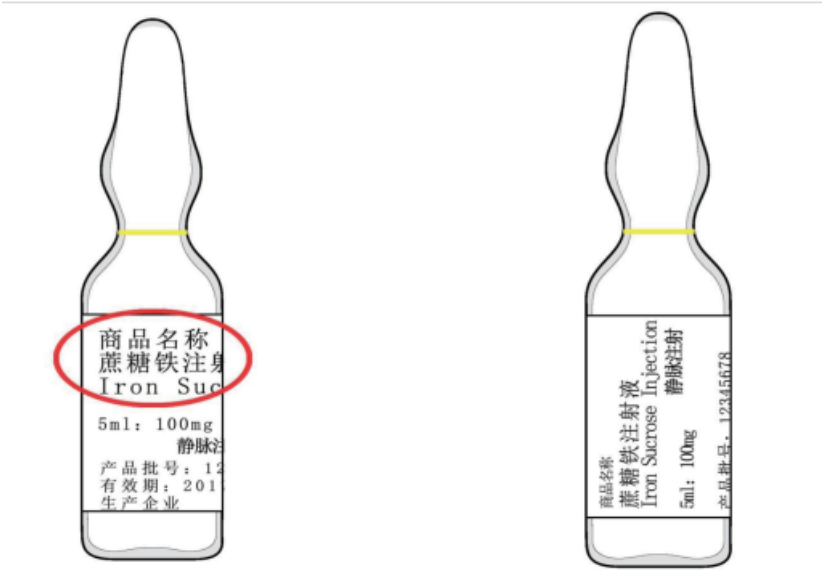
3.3 Design principles of Ampoule bottle label

3.3.1 Written content

Should include at least the generic names, specifications, method, batch number or the period of validity.

3.3.2 The text direction

Because ampoule bottle is small, label text should choose suitable position and direction for complete printing important information without rotation (or move) . If ampoule bottle is too small to laterally print, other appropriate ways, such as vertical print (along the length of the ampoule direction) or multilayer tags (single/double side printing), etc. can be used for making sure the full of important information to be readed. As shown in Fig. 26.



a) Problem diagram

b) Suggestion diagram

c) Single/double-sided printing graphic

Fig26

3.3.3 Label form

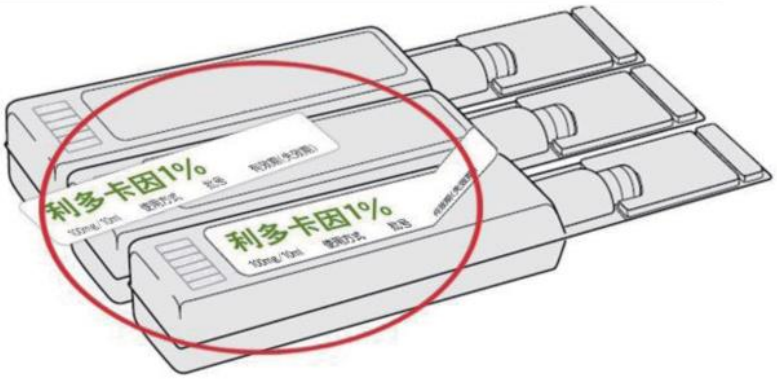
Glass ampoule usually use direct printing (also suitable for other glass packed injection label), pay more attention to the text loss risk during clinical preparation and sterilization. Using paper labels if possible. if have to direct print or use transparent plastic labels, the important information should be highlighted and try to avoid seeing reverse overlapping information As shown in Fig.27.

a) Problem diagram b) Suggestion diagram

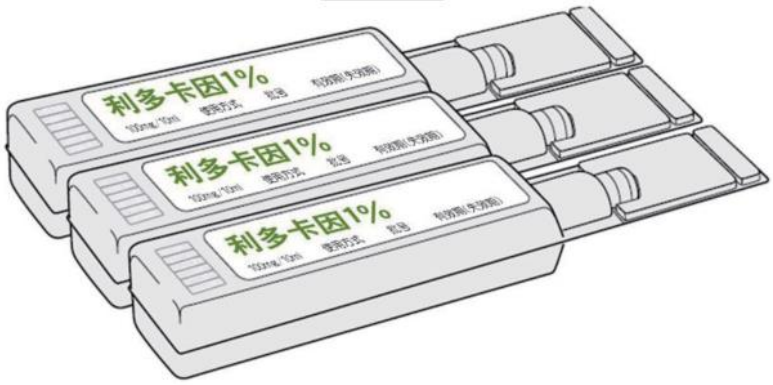
Fig 27

3.3.4 Plastic ampoules

When using the adhesive label, make ensure that the label will not peel off, at the same time focus on label adhesive migration to the solution.



a) Problem diagram



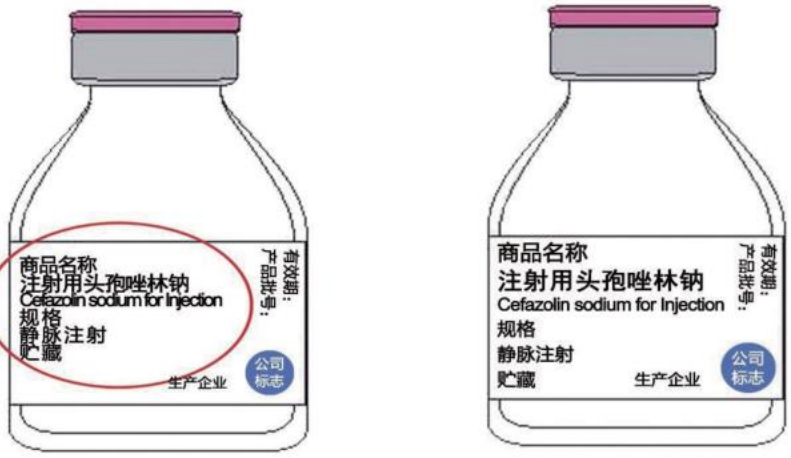
b) Suggestion diagram

Fig28

3.4 The design principle of glass bottle label

3.4.1 Important information on the bottle

Bottle label should highlight the important information, such as generic names, specifications, delivery way, batch number and the period of validity which shall not be less than 12 (four) font, can use song typeface, regular script, bold etc. and English and pinyin labels can use case and bold. Never use dense text word, keep the appropriate word spacing, the letter spacing and row spacing, and avoid the text crowded together. As shown in Fig. 29.

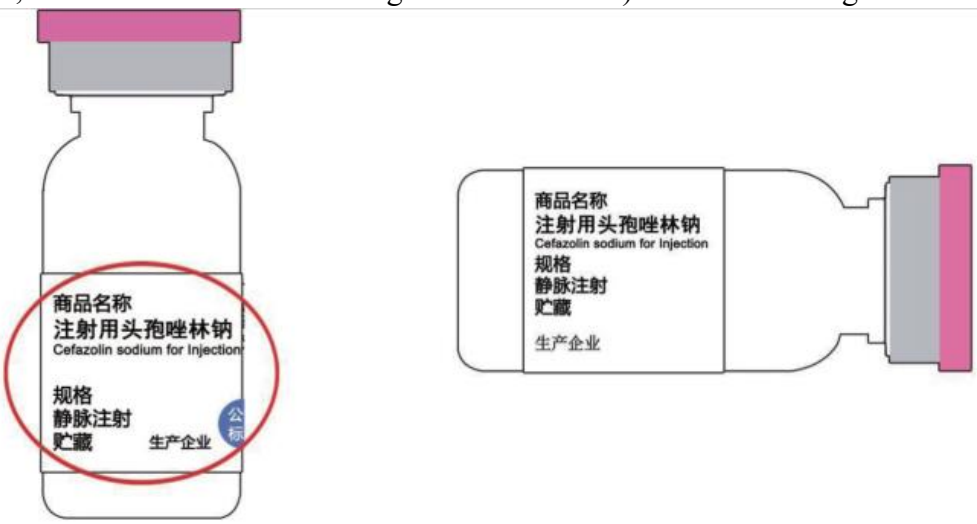


a) Problem diagram b) Suggestion diagram

Fig 29

3.4.2 The text direction

Same as the chapter 3. 3. 2, (if the width of the bottle is less than the height of the label, the text should be in the longitudinal direction). As shown in Fig. 30.



a) Problem diagram b) Suggestion diagram

Fig 30

3.4.3 Tonal collocation

The design of label should match with the design of labeling. Cap color should be consistent with the main color of label and labeling. As shown in Fig. 31.

a) Problem diagram b) Suggestion diagram

Fig 31

3.4.4 Multi-dose vial

The drug storage time and the key requirements after unpacking should be highlighted, and leave space for recording the opening date. As shown in Fig. 32.

a) Problem diagram b) Suggestion diagram

Fig 32

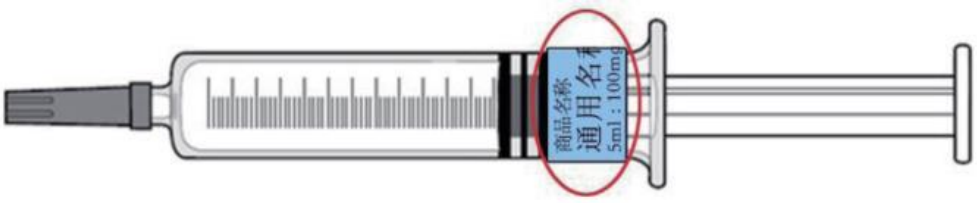
3.5 Potting syringe label design principles

3.5.1 Written content

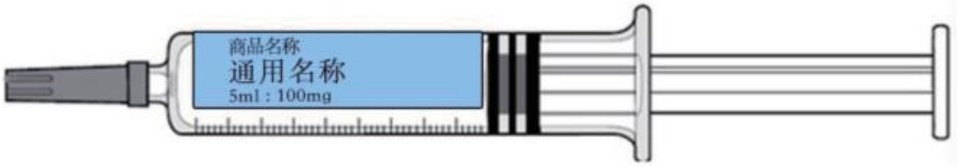
Written content should include at least the generic names, specifications, method, batch number or the period of validity.

3.5.2 The text direction

It's better to set label text direction along the direction of the injector length, and leave a blank area for inspecting the content inside. The font color shall not interfere with the observation of the content. Volume calibration markings shall be visible, and should not be covered by the label. As shown in Fig. 33.



a) Problem diagram



b) Suggestion diagram

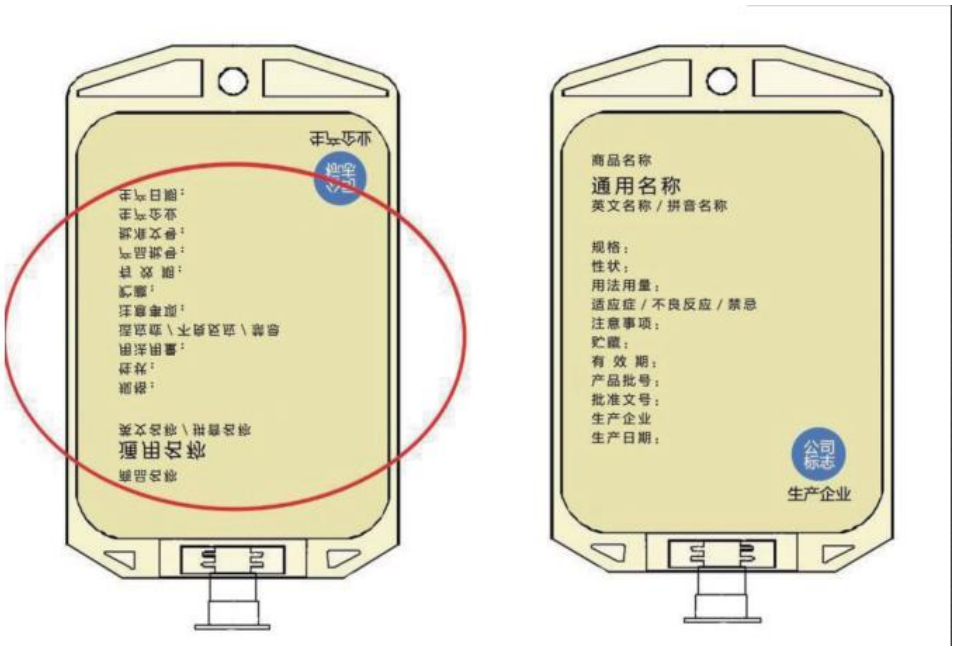
Fig 33

3.6 The design principle of infusion bag tag

3.6.1 Writing principles

3.6.1.1 In order to ensure legible information printed directly on the IV bags, the background color should avoid to interfere with text messages. The text color lightness on the IV bag color should not affect the text reading (such as: bright yellow). Similar packaging of different drugs, suggest to use different colors to distinguish. The text and pattern on the basic IV bags, suggest to choose different color according to different varieties of drugs,, for example warm color (red, orange and yellow etc.) for glucose solution bag, cool color (green, blue and purple) for sodium chloride solution bag. Particularly recommend the design method of black font with the corresponding color lumps for achieving better reading and distinguishing. The important information need to be emphasized, can be marked by different color , in order to highlight its visual display; Text direction should be comply with the using direction As shown in Fig. 34.

3. 6. 1. 2 High alert drugs (such as: potassium chloride, etc.) should have alert label.

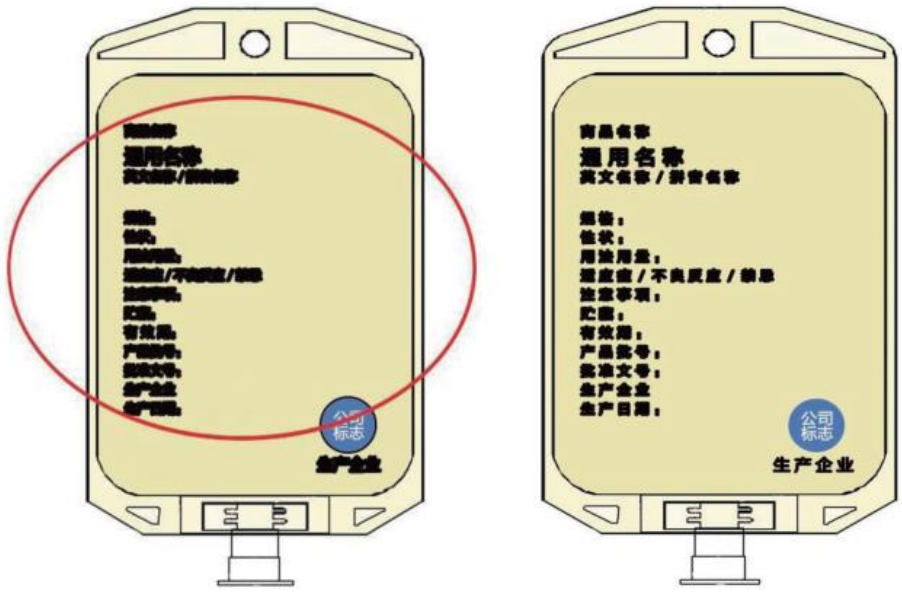


a) Problem diagram b) Suggestion diagram

Fig 34

3.6.2 Printed word

Choice of font should guarantee the space between the words, make sure the handwriting still can be recognized even erasing. As shown in Fig. 35.



a) Problem diagram b) Suggestion diagram

Fig 35

3.6.3 Other requirements

Better to use matte material in order to improve the identification and avoid reflective phenomenon.

Appendix A

Informative appendices

High-Alert Medications Recommended Directory

Form A.1 High alert drugs recommended directory

Serial number	Name
Drug types (without remark of American ISMP high alert drug directory)	
1	100 ml or larger volume of sterilizing water for injection (for injection, inhaled or flushing)
2	Theophylline drugs, intravenous route
3	Parenteral nutrition preparation
4	Parenteral and oral start
5	Fluid of peritoneal and hemodialysis
6	Hypertonic glucose injection (20% or above)
7	Anti-arrhythmic drugs, intravenous (such as amiodarone, lidocaine)
8	The antithrombotic drugs (including anticoagulant drugs, Xa factor antagonists, direct thrombin inhibitor and glycoprotein II b/III a inhibitor)
9	Oral medications
10	Sodium chloride injection (high permeability, concentration > 0.9%)
11	Anesthetics, ordinary, inhaled or vein (such as propofol)
12	Strong heart medicine, intravenous injection (such as rice farmers)
13	Neuromuscular blocking agents (such as succinyl choline, the interaction between rocuronium, vecuronium bromide)
14	Adrenaline receptors excited drugs, intravenous (e.g., epinephrine)
15	Adrenaline receptor antagonist drugs, intravenous (such as propranolol)
16	The medium of children with oral sedatives (e.g., chloral hydrate)
17	Fluid of cardiac arrest
18	Insulin, subcutaneous or intravenous injection
19	Epidural or intrathecal injection of drugs
20	On the people of child-bearing age have reproductive toxicity of drugs, such as avi A capsule, vitamin A acid etc
21	Contrast agent, the intravenous injection
22	Analgesic/opioids, intravenous injection, percutaneous and oral (including liquid concentrate, quick release and slow release preparation)
23	Liposomes drugs (e.g., amphotericin B liposomes) and the traditional similar drugs (e.g., amphotericin B to oxygen cholic acid salt)
24	Moderate sedatives, intravenous (e.g., midazolam)
Drug varieties (without remark of American ISMP high alert drug directory)	

1	Opioid tincture
2	Atropine injection (specifications 5 mg/mL)
3	Potassium permanganate external preparation
4	Vasopressin, intravenous injection or bone
5	Methotrexate (oral, non tumor purposes)
6	Magnesium sulfate injection
7	Concentration of potassium chloride injection
8	Thrombin producing
9	Adrenaline subcutaneous injection
10	Oxytocin, intravenous injection
11	Nitrate, sodium injection
12	In accordance with the aforementioned alcohol, intravenous injection
13	Promethazine, intravenous injection
14	Arsenic trioxide for injection

Note 1: Based on compliance with the original English semantic (High-Alert Medications), suit management culture, and is convenient for patients to use replacement, avoid ambiguity and so on many aspects to consider, in our country in recent years, continue to use the "high-risk drug", renamed "high warning drug".

Note 2: By 23 medical personnel to participate in medical institutions of the country's "high alert drugs directory selected research project", draw lessons from the American institute of drug safety warning drugs (ISMP) high directory, and combining with China's national conditions, added to the reproductive toxicity of childbearing age crowd of drugs (such as avi A), venous pathway to drug theophylline class two classes and atropine injection (5 mg/mL), potassium permanganate preparation for external use only, and clotting enzyme producing and arsenic trioxide four drugs for injection.

Note 3: Hospital pharmacy professional committee of China medicine institute drug safety experts are studying to formulate high warning catalogue of drug classification management and management SOP, relevant results will be released in due course.

Note 4: High warning about Chinese medicine yinpian and traditional medicine directory, hospital pharmacy professional committee of China medicine institute jointly with the relevant institute is to organize the study.