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Paperboard folding carton for pharmaceutical package

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Foreword

The *Standards* supersedes *Paperboard Folding Cartons for Pharmaceutical Package (YBX 2001－2009).* Compared with YBX 2001－2009, besides the editorial revisions, major technical modifications are as follows:

——Requirement on quality of Braille is added, with regulation for key technical requirements (set out in 5.10);

——Requirement on drug traceability code is added, with regulation for key technical requirements (set out in 5.11);

——Relevant description on children-resistant packaging is added, with instructive requirements involved (set out in 9);

——Relevant description on self-destructive packaging is added, with instructive requirements involved (set out in 10);

——Relevant description on paperboard folding carton cold chain transportation packaging is added, with instructive requirements involved (set out in 11);

The Standards is put forward by and subject to China National Pharmaceutical Packaging Association.

The Standards is drafted by Xi'an Global Printing Co., Ltd., Xian Janssen Pharmaceutical Ltd., China Resources Double-crane Pharmaceutical Co., Ltd., Beijing Edelmann Packaging & Printing Co., Ltd., Department of Pharmacy, Xin Hua Hospital Affiliated to Shanghai Jiao Tong University School of Medicine and Partnership for Safe Medicines (PSM).

The Standards is mainly drafted by: Meng De, Sun Xuejun, Zhang Qianqian, Shi Ying, Zhang Ruijuan, Li Xiaoguang, Lu Xiaotong, Zhao Caiwen, Guo Pengxiang, Feng Guoping, Ji Wei and Zhang Weimin.

The historical issuance of the Standards is YBX 2001－2009.

Introduction

The *Standards for Paperboard Folding Cartons for Pharmaceutical Package* (the Standards) issued by China National Pharmaceutical Packaging Association in 2009 has been in effect for five years. The above Standards is revised in accordance with *Regulations of Working Committee on Standardization of China National Pharmaceutical Packaging Association* and *Procedures on Formulation of and Amendments to Standards of China National Pharmaceutical Packaging Association*.

The purpose of preparation of the *Standards* is to improve pharmaceutical security, convenience and patient compliance, and improve printing quality of paperboard cartons for pharmaceutical package, shorten cycles for placing order and producing, reduce the waste of resources, lower costs of producing pharmaceutical cartons, and improve efficiency of production and storage and transportation at the same time.

Paperboard Folding Carton for Pharmaceutical Package

1 Scope

The *Standards* specifies the classification, dimension and specification, structure, technical requirements, quality requirements, inspection method as well as requirements for packaging, transportation and storage of paperboard folding cartons for pharmaceutical package.

The *Standards* is applicable to the design, production and inspection of plug-in folding cartons with base material of paperboard sized at 200g/m2 to 500g/m2. In regard of bottom lock folding cartons and auto bottom lock folding cartons, the *Standards* may also be a reference.

2 Normative references

Original provisions in the following documents are referenced and become provisions of the *Standards*. Parties reaching agreements in accordance with the *Standards* are encouraged to adopt the latest version of these documents.

GB/T 10335.3 Coated paper and board--Coated ivory board

GB/T 10335.4 Coated paper and board--Coated folding board

GB/T 450 Paper and board--Sampling for testing

GB/T 451.1 Paper and board--Determination of size and deviation

GB/T 451.2 Paper and board--Determination of grammage

GB/T 451.3 Paper and board--Determination of thickness

GB/T 452.1 Paper and board--Identification of machine and cross direction

GB/T 453 Paper and board--Determination of tensile properties (constant rate of loading method)

GB/T 454 Paper--Determination of bursting strength

GB/T 455 Paper and board--Determination of tearing resistance

GB/T 456 Paper and board--Determination of smoothness (Bekk method)

GB/T 457 Paper--Determination of folding endurance (Schopper method)

GB/T 462 Paper and board--Determination of moisture content

GB/T 2679.3 Paper and board--Determination of resistance to bending

GB/T 2679.8 Paper and board--Determination of compressive strength (Ring crush method)

GB/T2828.1 Sampling procedures for inspection by attributes -- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

GB 6543 Corrugated box

GB/T7706 The relief prints for decorating

GB/T 10739 Paper, board and pulps--Standard atmosphere for conditioning and testing

GB 11680 Hygienic standard of paper used for food packaging

GB/T 18722 Graphic technology--Application of reflection densitometry and colorimetry

CY/T 3 Color evaluation lighting and observation conditions

GB/T 12905 Bar coding terminology

3 Terminology and definition

3.1 Folding carton

The paperboard can be convertible to a carton when using, in the process, it can be folded into a sheet-like pattern through die-cutting and creasing, folding and gluing.

3.2 Plug-in folding carton

It refers to cover or bottom structure with flap plugging in carton and sealing up by friction between paperboard.

3.3 Bottom lock folding carton

It is bottom structure which is arranged by taking use of the crossing and inlaying of sides at the bottom of a box. When the bottom is pressed against the side with the hook and the bolt is plugged in the fore edge, it can be locked.

3.4 Auto bottom lock folding carton

It is bottom structure which is arranged by taking use of the crossing and inlaying of sides at the bottom of a box. When the box takes shape, the bottom can be automatically locked up.

4 Classification

They are classified into three categories based on base structure of the carton: the plug-in folding carton, the bottom lock folding carton and the auto bottom lock folding carton.

5 Technical requirements

5.1 General rules

The design and production of paperboard folding carton for pharmaceutical package shall be safe, convenient, economical and environment-friendly.

Paperboard materials of folding carton for pharmaceutical package shall meet relevant quality criteria in (China's) national standards, industrial standards and contractual stipulation.

It must keep clean in the processes of production and transportation of paperboard folding carton for pharmaceutical package, while avoiding foreign body pollution including dust and oil stain and eradicating biological contamination.

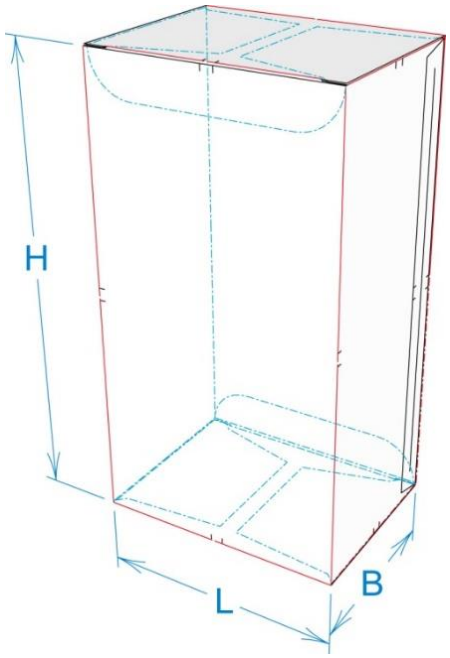
Necessary measures shall be taken in the processes of production, transportation and utilization of paperboard folding carton for pharmaceutical package to avoid mixing up cartons of different specifications and uses.

5.2 Structure of common paperboard folding carton for pharmaceutical package

5.2.1 *General description of the dimension*

Illustration of folding carton is as in Figure 1.

The dimension of the layout of a folding carton structure is the dimension ranging from the middle of the creasing round edge of carton plate, the intermediate line of the creasing round edge to die-cutting line.



Description:

L—the dimension of the line which is parallel to the line connecting the plug-in carton cover;

B—the dimension of the sealing strip of the carton base;

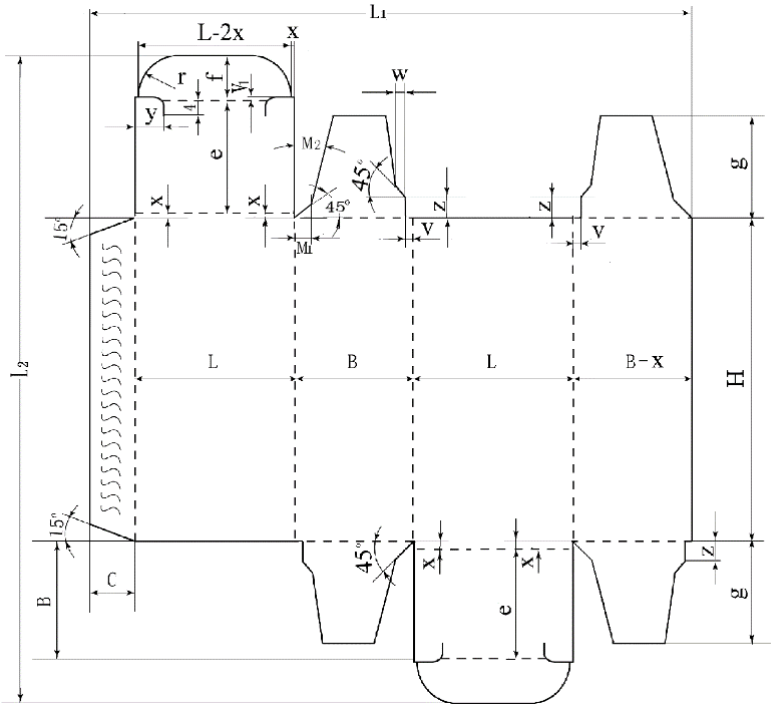
H—he distance between the carton cover and the intermediate line of the creasing round edge at the bottom of the carton.

Figure 1 Illustration of folding carton

5.2.2 *The dimension of structure with plug-in cover and bottom*

The layout of structure with plug-in cover and bottom for a plug-in folding carton is set out in Figure 2.

Unit: millimeter



Description:

L1—the total dimension of carton sheet which is parallel to the Line L, B and c;

L2—the total length of carton sheet which is parallel to the Line H;

r—arc radius of the flap;

v、 v_1、 w、x—indent;

c—the width of the edge with glue;

y—the length of joint-cutting, which is dustproof and self-locking;

d—the thickness of paperboard;

z—the width of dustproof side cover fastening edge;

e—the length of carton cover;

f—the depth of flap;

M1—the length of dustproof side cover（M1 =2.5mm）;

M2—the length of dustproof side cover (8 ≤M2≤15)。

Note: The magnitude of L, B and H of the carton main body is determined based on the design of the product.

Figure 2 Illustration of layout of folding carton structure with plug-in cover and bottom

The dimension of main body of the plug-in folding carton and other parameters of carton is better maintain the accounting relationship existed in Table 1, 2 and 3.

Table 1 Correspondence table between g, w, y, z and the dimension L

Unit: millimeter

L	w	y		z		g[a)]	
15＜L≤18	2	4	±0.2	2.5	±0.2	12≤g≤30	±0.5
18＜L≤30	2	5		3			
30＜L≤60	2	6		3.5			
L ＞60 且 B＜20	3	6		3.5		g≤0.5L-2	
L＞60 且 B≥20	3	7.5		5		g≥0.5L+2	
a）$g=\frac{e+f+x}{2}$							

Table 2 Correspondence table between f, r, c and the dimension B

Unit: millimeter

B	f		r		c
B≤12	B/2+2	±0.3	f+2	±0.3	B-2

12＜B≤13	8		10		
13＜B≤16	9		11		
16＜B≤19	10		12		
19＜B≤23	11		13		
23＜B≤26	12		14		
26＜B≤29	13		15		10≤c≤16
29＜B≤33	14		16		
33＜B≤36	15		17		
36＜B≤80	16		19		
80＜B≤100	18		21		
B＞100	20		24		

Table 3 Correspondence table between e, v, v1, x and the thickness d

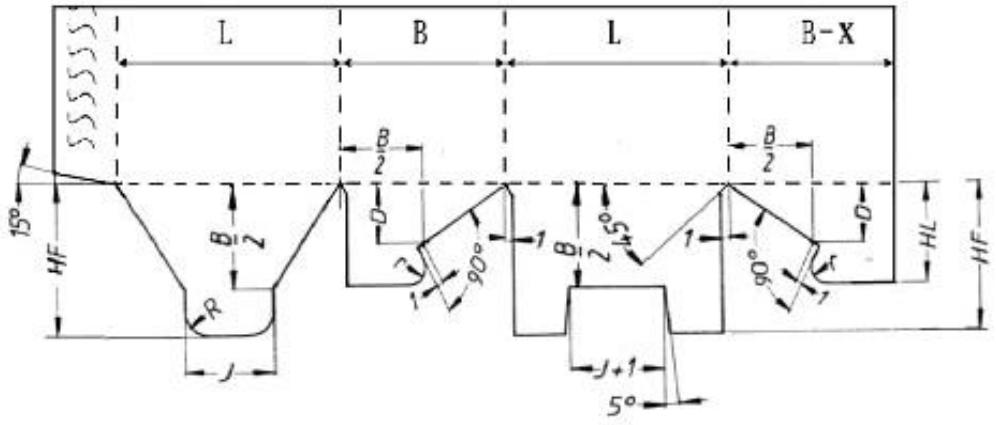
Unit: millimeter

d	e		v		v_1		x	
≤0.65	B-1.5	±0.3	0.75	±0.2	0.75	±0.2	0.5	±0.2
＞0.65	B-2.0		1.25		1.25		1.0	

5.2.3 Structure and dimension of base of bottom lock carton

The layout structure of bottom lock carton is as illustrated in Figure 3.

Unit: millimeter



Description:

J—the length of the flap; the relationship with dimensions is:

D—the length of the baffle plate of the lock plate; J=L/2

HF—the width of the lock floor; D=(L+1-J)/2

HL—the length of the lock plate； HF=0.6B+8

x—indent; HL=0.1B+D+6 ≤L/2

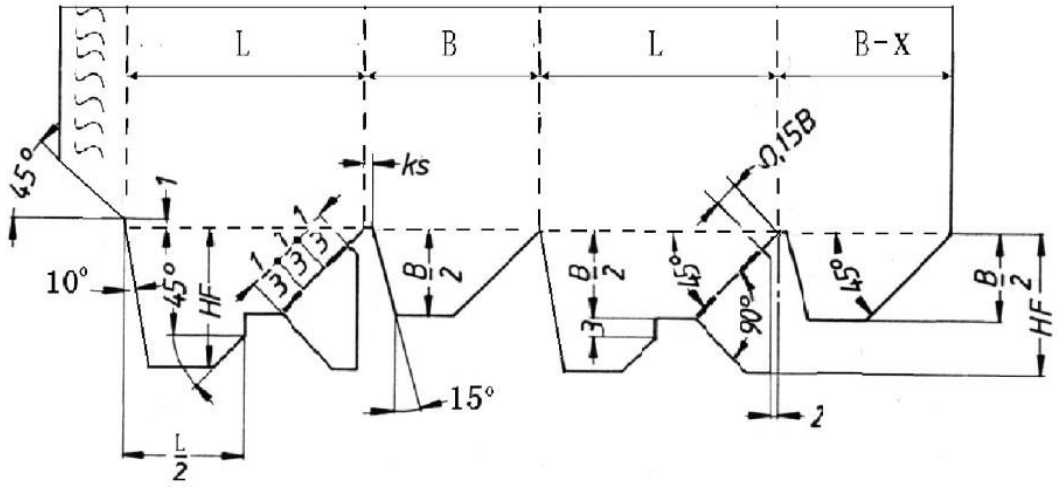
R, r—arc radius.

Figure 3 Illustration of structure layout of base of bottom lock carton

5.2.4 Structure and demensions of base of auto lock bottom folding carton

The layout structure of base of auto bottom lock folding carton is as illustrated in Figure 4.

Unit: millimeter



Description:

F—the width of the lock plate; the relationship with dimensions is:

x—indent; HF=0.6B+8

ks—indent. ks=1.5~2.0 mm

Figure 4. Illustration of layout structure of base of auto lock bottom folding carton

5.3 Dimension and specification

It is advised to choose with reference to dimension and specification in Table 4 regarding grammage and material quality of paperboard for the design and production of the plug-in paperboard folding carton for pharmaceutical package. Table 4 may be a reference for bottom lock folding carton and auto bottom lock folding cartons as well.

Table 4 Physical dimension of common plug-in paperboard folding carton for pharmaceutical package

Serial No.	Dimension (L*B*H） mm	Limit deviation mm	Lateral stiffness of paperboard mN.m (recommended)	Material quality (recommended)	Content (recommended)
1	36*18*85	±0.5	≥4.8	Ivory board	Tablet
2	38*38*70	±0.5	≥2.3	Folding board	Injection
3	45*20*105	±0.5	≥4.8	Ivory board	Tablet
4	50*30*95	±0.5	≥3.9	Ivory board	Bottled
5	55*18*105	±0.5	≥3.9	Ivory board	Tablet

6	58*12*98	±0.5	≥6.4	Ivory board	Tablet
7	60*20*90	±0.5	≥4.1	Folding board	Tablet
8	65*15*105	±0.5	≥9.4	Ivory board	capsule
9	68*20*130	±0.5	≥6.4	Ivory board	Tablet
10	70*15*90	±0.5	≥9.4	Ivory board	Tablet
11	75*15*130	±0.5	≥3.5	Ivory board	Tablet
12	82*55*65	±0.5	≥6.4	Ivory board	Packet
13	85*18*110	±0.5	≥4.8	Ivory board	capsule
14	90*65*60	±0.5	≥6.4	Ivory board	Packet
15	90*80*68	±0.5	≥6.4	Ivory board	Packet
16	102*70*16	±0.5	≥3.9	Ivory board	Tablet
17	132*48*35	±0.5	≥6.4	Ivory board	Tablet
18	105*65*16	±0.5	≥3.9	Ivory board	Packet
19	125*75*42	±0.5	≥6.4	Ivory board	Tablet
20	140*80*22	±0.5	≥6.4	Ivory board	Pill
21	140*80*30	±0.5	≥6.4	Ivory board	Pill
22	140*90*35	±0.5	≥6.4	Ivory board	Packet
Note: The size and specification of the content recommended (unit: mm): l=L-3，b=B-3，h=H-5					

5.4 Appearance quality

The finished goods shall be clean on the surface, without any obvious scratch, creasing, scoring, smear and fading by friction.

In regard of the fold line and four corners of the finished goods, damages bigger than 1mm are intolerable.

Smear: On the surface of the package, regarding words of key information for the identification of performances and dosages of products, there should be no ink or spots which may give rise to ambiguity; the allowable area for spots in other places is set out in Table 5.

Table 5 Allowable area for spots

Place / Content	Front	Side
The area of spots	≤0.25mm^2	≤0.5mm^2
The number of spots	No more than two on the top of a carton; no more than three for the overall layout of a carton.	

5.5 Printing quality

5.5.1 General requirements for printing

For text printing, it shall be clear and complete, without any missing stroke and texts smaller than 6 pt.

shall not be misread.

As there is friction between printing surfaces of the carton, ink shall not fade due to friction.

5.5.2 Registration deviation

Registration deviation shall meet criteria in Table 6.

Table 6 Registration deviation

Trapping part	Limit deviation
Prime section	≤0.2mm
Subprime section	≤0.25mm
Note: The prime section refers to the part that reflects the theme, i.e. the pattern, text or symbol etc.	

5.5.3 Solid color difference

Solid color difference shall meet criteria in Table 7.

Table 7 Solid color requirements

Indicator	Unit	Symbol	Requirements	
Color difference of same batch and same color	CIEL*a*b*	△Eab	when L*＞50.00	when L*≤50.00
			≤3.50	≤3.00

5.5.4 Requirements for barcode quality

Neat and clean on the surface of barcode, without any obvious smear, fold or damage.

Numbers, characters, special symbols are printed complete and clear.

There is no obvious stripping, smear (deviations shall be smaller than 0.4 time of bar width), or broke line.

The edge of a bar code shall be tidy, without any obvious curvature or deformation.

Upon printing, dimension of bar code is accurate, without any deformation, stretch, having no impact on reading and identification.

5.6 Quality of die-cutting

5.6.1 Requirements for creasing round edge

Creasing round edge shall satisfy clients, without any omission.

Creasing round edge shall be full, centered, un-cracked, flat and straight without curvature.

5.6.2 Requirements for precision of die-cutting

Dimension deviation of die-cutting finished goods shall be controlled with ±0.5mm.

5.7 Quality of pasting

Pasting edge shall be glued solidly, not being tackles or squeezed out. Quality of gluing shall meet the following criteria:

a) When tearing off the pasting edge of a carton, ensure that 80% of the edge with glue sees paperboard fiber cracking.

b) The length of fiber of the edge with glue on the base of an auto-lock folding carton which cannot be cracked shall be shorter than 5mm.

5.8 Force for opening carton

Force for opening a carton refers to the minimum strength needed for a folding carton to be opened after being printed and glued.

For a paperboard folding carton of the automatic packaging streamline, force for opening shall satisfy requirements of the automatic packaging equipment.

5.9 Surface friction coefficient

For a paperboard folding carton of the automatic packaging streamline, surface friction coefficient shall be reasonably determined based on requirements of pharmaceutical packaging equipment.

5.10 Quality of Braille

5.10.1 General requirements

No missing Braille dots, no connections between Braille dots.

5.10.2 Requirements for Braille size

Braille size shall meet the following criteria:

a) The diameter of Braille dots: 1.6mm±0.1mm.

b) The spacing between Braille dots (center-to-center spacing of two dots next to each other): 2.5mm ±0.1mm.

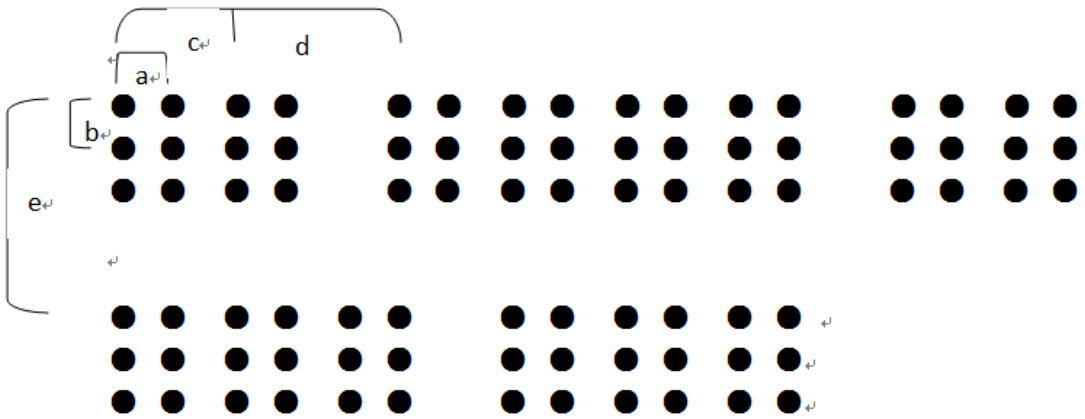
c) The spacing between Braille characters: 6.0mm±0.1mm.

d) The connection between Braille characters: 12mm±0.1mm.

e) The leading of Braille: 10.0mm±0.1mm.

f) The height of Braille: 0.12mm～0.2mm.

g) Specifications of Braille dots are as illustrated in Figure 5.



Description:

a, b—The spacing between Braille dots.

c—The spacing between Braille characters.

d—The connection between Braille characters.

e—The leading of Braille.

Figure 5 Illustration of braille specification

5.10.3 Requirements for height of Braille

In the process of production, the number of products with height of Braille in excess of 0.2mm shall not exceed 5% of the total number, while that of products with height of Braille lower than 0.12mm shall not exceed 1% of the total.

5.11 Drug traceability code

A drug traceability code, represents an electronic label which enables drug traceability service and big data service by tracing the full lifecycle of the drug.

5.11.1 General requirements for drug traceability code

5.11.1.1 Based on the requirement for uniqueness regarding traceability ID verification, a drug has its sole code, without any repetition.

5.11.1.2 Determination of location for drug traceability code is based on principles including relatively uniformed symbol location, difficulty in deformation for symbols, easiness for scanning and identification, with prohibition of covering key explanatory information of drugs, i.e. trademark of package, name of drug, approval number, date of production, batch number of production and expiry date, and contradict with China's laws and regulations regarding pharmaceutical package.

5.11.2 Technical regulations for one-dimensional code

5.11.2.1 Data parameters of one-dimensional code

Name	Value
Type of barcode	Code 128C
Density of barcode	≥7mils(recommended≥10mils)
Type of data	Number
Format of data	TXT database
Length of data	20 (or 16) bit
Height of barcode	≥8mm

5.11.2.2 Color of one-dimensional code

The drug traceability code is black, while its blank space can be white, yellow, orange or red. The color is suggested to be a match of black and white. Work out a sample and test the sample before print out Code 128C barcode in a colorful background mentioned above.

5.11.2.3 Printing direction of one-dimensional code

a) In the case where the curvature and area of the product packaging surface permit, it is suitable for barcode symbols to be horizontal with characters read from the left to the right.

b) If it is not practicable for placing horizontally, on the premise that printing quality is ensured, barcode symbols may be vertical with characters read from the upside to the downside.

c) In regard of special reflective material for printing, it is advised to adopt the extinction craft to prevent barcode symbols from being impacted. For special thermal shrinkage film, direction of barcode symbols shall be consistent with that of maximum shrinkage of the film.

5.11.2.4 Size of blank area of one-dimensional barcode

The blank area on the two sides of barcode symbols ≥ 10 times of minimum module width (10X)

Examples on calculation: if the total width of the barcode is 37mm (10mils), X=37mm÷145=0.2552mm, 10X=0.2552mm×10=2.552mm

Meaning: the minimum width for the left and right side of the barcode is no less than 2.552mm.

5.11.3 Technical regulations for two-dimensional barcode

5.11.3.1 Color of two-dimensional barcode

Two-dimensional barcode is composed of two modules in dark and light colors. The module in dark color and light color respectively represent 1 and 0 in binary system. The color is suggested to be a match of black

and white.

5.11.3.2 Size of blank area of two-dimensional barcode

a) The size of blank space around QR Code ≥4 times of minimum module width (4X)

b) The size of blank space around DM Code ≥1 time of minimum module width (1X)

c) The size of blank space around Hanxin Code≥3 times of minimum module width (3X)

5.11.4 Appearance requirements for drug traceability code

5.11.4.1 Neat and clean on the surface, no wrinkles or damages; characters, special symbols are printed completely, with bar edge clear.

5.11.4.2 No obvious stripping, smear, broken line or blur, edge of code even without burr, no obvious curvature and deformation, no more than two the thin white lines throughout the traceability code, identifiable and legible.

5.11.4.3 Correct code size, no deformation or stretch, legible

5.11.4.4 Characters for identification purpose cannot be printed over the drug traceability proper or in the blank area.

5.11.5 Character grading and decoding requirements for drug traceability code

5.11.5.1 Quality level of drug traceability code characters shall be above C (1.5).

5.11.5.2 Code information identified and information in loading and information for identification below the code shall be in agreement.

6 Inspection method

6.1 Inspection condition

Regarding quality inspection of finished carton, the following conditions shall be satisfied:

a)Working environment is white.

b)Working environment is dust-proof and tidy and clean.

Temperature and moisture of workshop shall be 18℃—28℃ and 50%—75% respectively.

Light source for sample observation shall meet criteria in CY/T3 Color Evaluation and Observation Condition.

6.2 Appearance inspection

Visual inspection is adopted, the distance from the checker's eyes to the visual site is about 400mm.

6.3 Registration deviation inspection

Place a sample under the standard illuminant, test each 3 points of registration deviation for any two colors on the prime section and the subprime section of the sample respectively with a 20 times scale microscope (precision accuracy at 0.01mm), the average is determined as registration deviation for the prime section and the subprime section.

6.4 Quality inspection of color of solid print

Inspect color difference between a sample and the standard color in accordance with Graphic technology-Application of reflection densitometry and colourimetry to process control in graphic arts.

6.5 Friction resistance inspection

The above inspection is carried out according to GB/T7706 The Relief Prints for Decorating.

6.6 Quality inspection of die-cutting

Measure with a steel ruler with 0.5-mm divider and minimum scale.

6.7 Quality inspection of pasting

Tear the place where the carton is glued by hand, over 80% of paper fiber shall be cracked.

6.8 Quality inspection of Braille

Items related to Braille data are inspected with a steel ruler of exactitude at 0.5mm.

The height of Braille is measured using a thickness gauge with anvil. When measuring, three different areas shall be selected with each area for measurement at least including three Braille dots.

6.9 Quality inspection of drug traceability code

Barcode appearance, font and color: visual inspection.

Size of barcode: measure by a steel ruler with exactitude at 0.5mm.

Consistency of barcode: identify and inspect with a barcode verifier, data displayed by the instrument are completely consistent with codes below the barcode without any hidden code.

Barcode grade: Inspect the barcode with a barcode verifier which is coverable of grading. The same symbol is scanned ten times, with the highest rank of symbol most frequently displayed representing the grade of the barcode.

Data length: inspect with a barcode verifier which is coverable of grading.

7 Inspection rules

7.1 Batch inspection

Products are inspected and accepted on a batch basis. Products of the same specification, craft and raw material and produced in series are classified into the same batch.

7.2 Sampling inspection

Outgoing quality control is conducted in accordance with GB/T2828.1 Sampling Procedures for Inspection by Attributes - Part 1: Sampling Schemes Indexed by Acceptance Quality Limit (AQL) for Lot-by-lot Inspection. Unqualified items and classification are determined based on different products or contractual agreements with determination of sampling times, inspection quality and AQL etc.

8 Packaging, transport and storage

8.1 Requirements for packaging

Corrugated box is used for packing paperboard folding carton for pharmaceutical package. Technical requirements for corrugated box shall be in accordance with criteria in GB6543 Corrugated Box.

8.2 Requirements for storage

In the warehouse of medicine packages, rat and insect proof measures shall be taken to prevent damages caused by rats and insects.

Regarding storage of medicine packages, moisture and contamination shall be prevented with packing chest over 100mm away from the ground and the wall.

8.3 Requirements for transport

In the process of transport, avoid being watered by rain, strongly exposed to the sun or hardly pressed;

The fully enclosed box van shall be used for transportation.

9 Child-resistant packaging of paperboard folding carton

9.1 Basic concept of child-resistant packaging of paperboard folding carton

Children-resistant pharmaceutical package is a kind of relatively simple protective packaging method or case which is based on consumers' satisfaction and people-orientated packaging and for the purpose of avoiding harm or causalities from children's intake of poisonous drugs or chemicals by mistake. Precisely

speaking, it is a safe package or packaging method which restrains children from opening the package independently while allows adults to open the package without difficulty and utilize it properly.

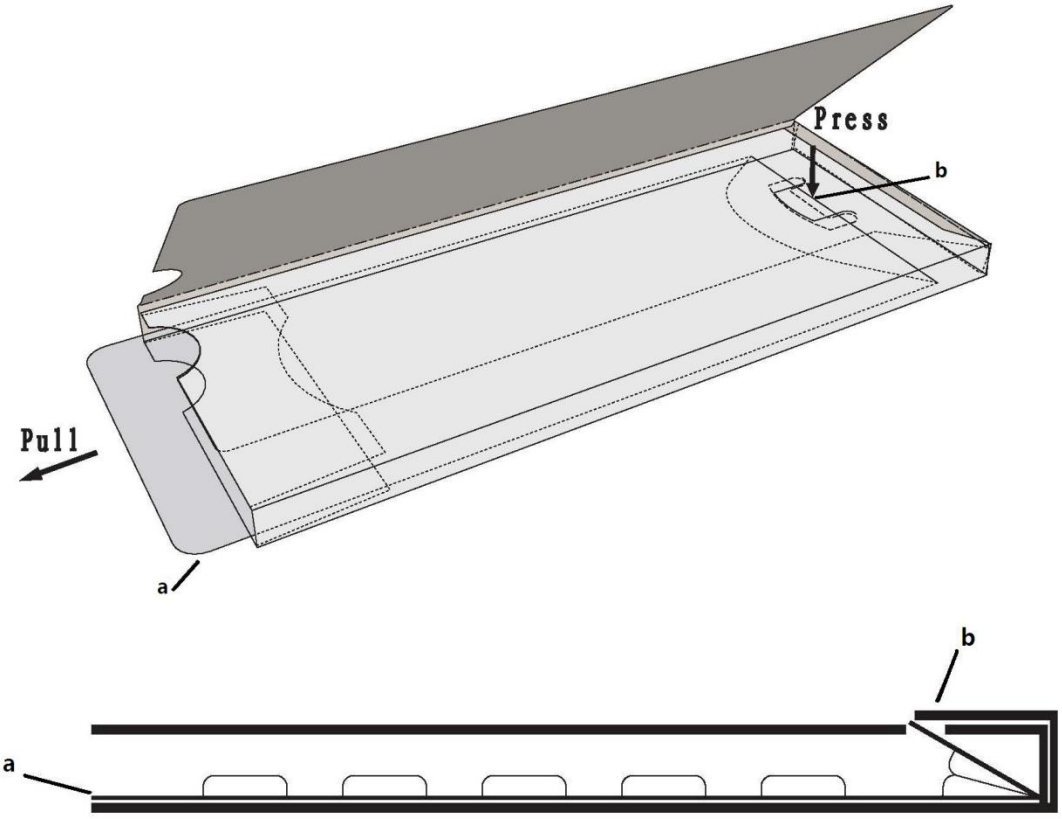
In regard of China's child-resistant pharmaceutical package, it is suggested that packaging form of certain kinds of drugs for children or adults, including drugs for cardio cerebral vascular treatment, hypertension treatment and psychotropic substance should be difficult for children to open or tear off so as to prevent children's intake by mistake and avoid any harm.

The function to protect children may be demonstrated in various ways and reflected in various links of pharmaceutical packaging, including both package that is directly in contact with drugs (blister and plastic covers) and indirectly in contact with drugs (paperboard folding carton).

9.2 Main structure of child-resistant packaging of paperboard folding carton

Lock structure is added into paperboard folding carton for pharmaceutical package, requiring collaboration work of one hand or two hands to restrain children from opening the carton. Two types of design of auto lock structure are illustrated in Figure 9 and 10.

Illustration:



Description:

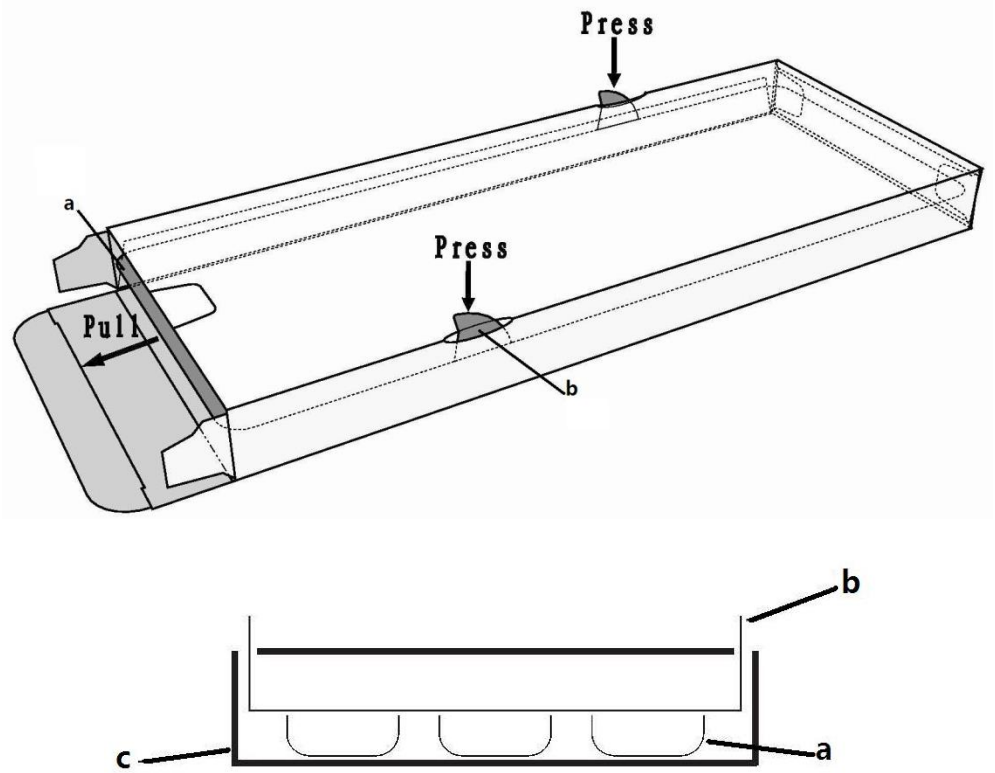
a— Plastic blister with auto springback wings on the base;

b—Auto lock structure;

Note: Only draw out the medicine plate when pressing b and keeping springback lock remaining within the carton body.

Figure 9 Auto lock folding carton I

Illustration:



Description:

a—Plastic blister with auto springback wings on both sides;

b—Auto lock structure;

c—Pharmaceutical package

Note: Only draw out the medicine plate when pressing b and keeping springback lock remaining within the carton body.

Figure 10 Auto lock folding carton II

9.3 Testing method of children-resistant packaging of paperboard folding carton

9.3.1 Domestic testing

At present, no testing method regarding children safety on paperboard folding carton for pharmaceutical package is formulated in China. Enterprises may carry out its internal control standards based on clients' requirements, with reference to 9.3.1 Foreign testing criteria of the *Standards*.

9.3.2 Foreign testing

In Europe, testing of protective cover is carried out based on criteria of ISO 8317 and CFR 1700.20 in Europe and the US respectively.

9.3.2.1 Testing principle

Tests should take account of adults' participation.

Initially, the protective cover shall be opened, and then adults will shut the case to test if children are able to open the case shut by adults.

9.3.2.2 Requirements for the design of testing method

Every 50 children as group would participate in the test, analysis of children's age is as follows:

a) 30% of children are required to be 42-to-44-month old
b) 40% of children are required to be 45-to-48-month old
c) 30% of children are required to be 49-to-51-month old

As for the male-female proportion of three age groups mentioned above, the number difference between girls and boys shall not exceed 10% of the total number of children.

10 Self-destructive packaging of paperboard folding carton

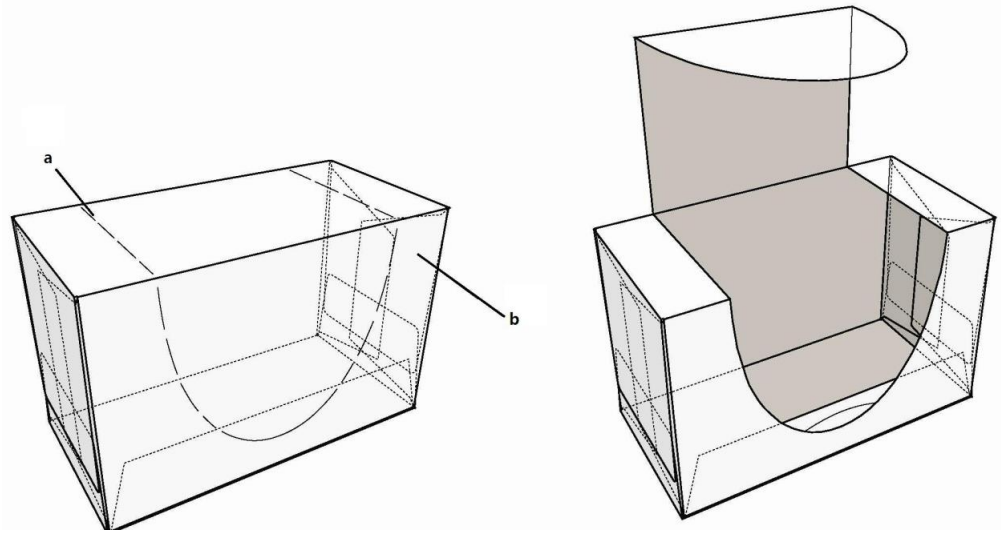
10.1 Basic concept of self-destructive packaging of paperboard folding carton

It represents disposable paperboard folding packaging carton which prevents itself from being used repeatedly.

10.2 Main structure of self-destructive packaging of paperboard folding carton

Dotted cutting line is added in the original design of carton, which entitles the carton to be opened easily and destroyed upon opening. When opening the original packaging carton, pressing on the dotted cutting line area with external forces or fingers may destroy the package and make it unrecoverable and avoid being used repeatedly, illustration of relevant design is set out in Figure 11.

Illustration:



Description:

a—Die-cut line;

b—the major side with patterns and texts;

Note: When the cover is opened, the die-cut line (a) cracks and damages the major side of the package (b), thus the package achieves self-destruction.

Figure 11 Structural self-destructive packaging

11 Paperboard folding carton for cold chain transportation packaging

The above packaging refers to carton for pharmaceutical package which need to be kept in cold temperature, with drugs inside usually stored and transported between 2℃ and 8℃.

11.1 General requirements for paperboard folding carton for cold chain transportation packaging

The above packaging shall be well airtight, moisture-resistant and able to protect drugs against the low-temperature and constant-temperature environment.

11.2 Major craft of paperboard folding carton for cold chain transportation packaging

Film laminating can be adopted for paperboard folding carton for cold chain transportation packaging.

With enhancing requirements for environment protection and improvements in relevant laws and regulations, when manufacturing products demanding for paperboard folding carton for cold chain transportation packaging, in the process of film laminating, relevant pollution generated and difficulty in recycling wastes of film laminating products, and risk related to long-time penetration of glue used in film laminating resulting in dissolving with drugs shall be identified.

It is advised to using UV coating or PE coated paper to replace film laminating of paperboard folding carton for cold chain transportation packaging.