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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.

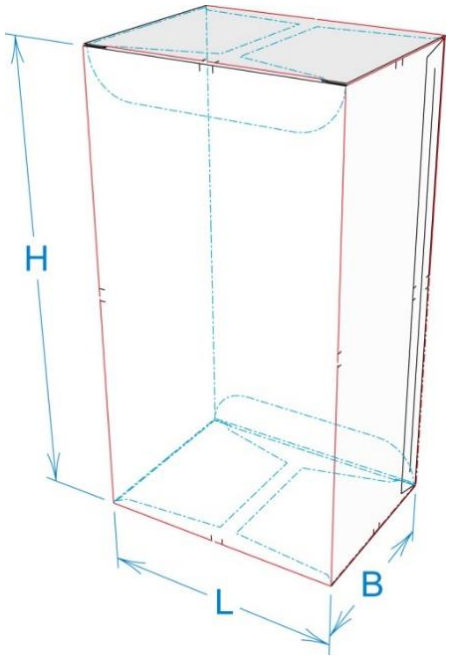
Necessary measures shall be taken in the processes of production, transportation and utilization of paperboard folding carton for pharmaceutical package to avoid mixing up cartons of different specifications and uses.

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;

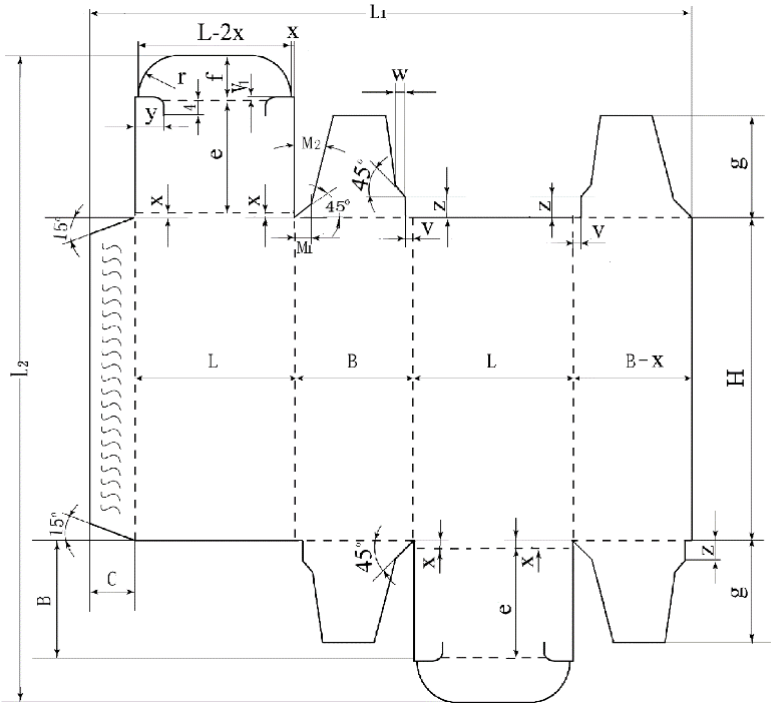
H—he distance between the carton cover and the intermediate line of the creasing round edge at the bottom of the carton.

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

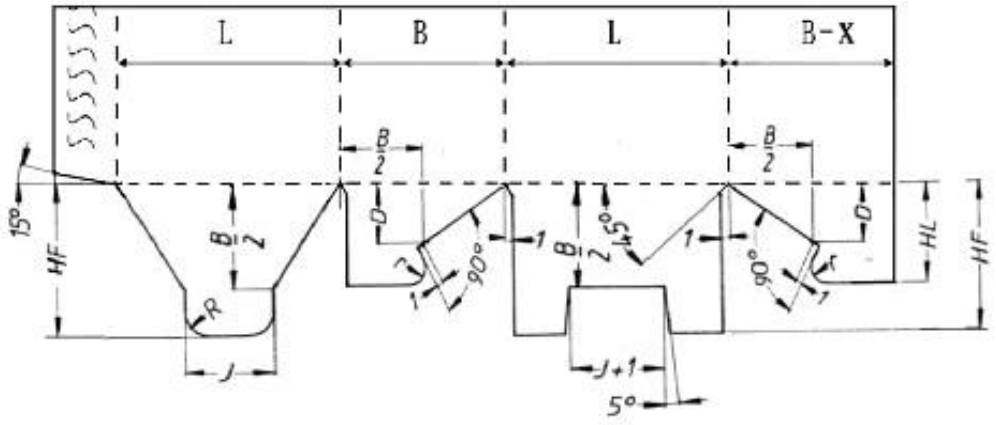
Unit: millimeter

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

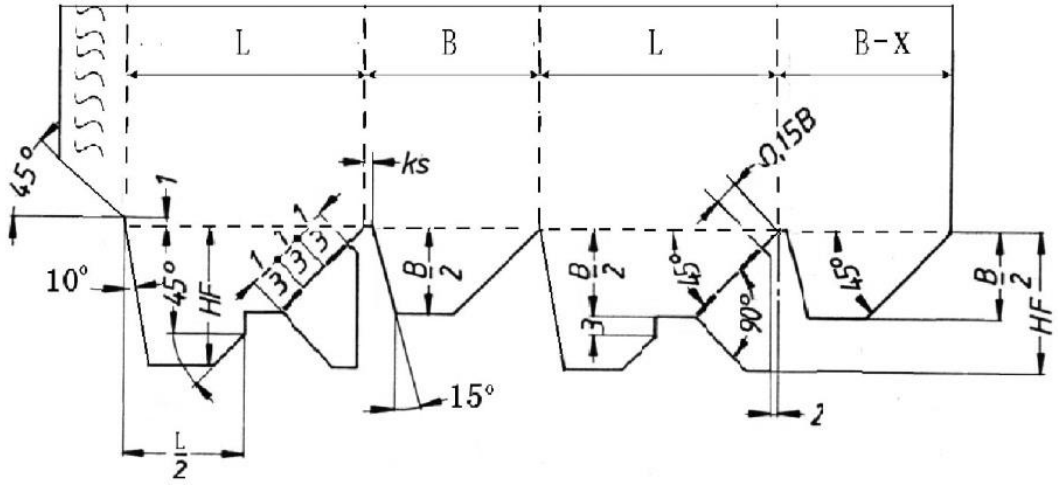
R, r—arc radius.

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

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