行政院衛生署食品藥物管理局管制藥品製藥工廠

材料規格

文件名稱	1毫升茶色玻璃安瓿			頁　碼	第 3 頁 共 6 頁
文件編號	P101	版次	9	生效日期	100. 5. 10

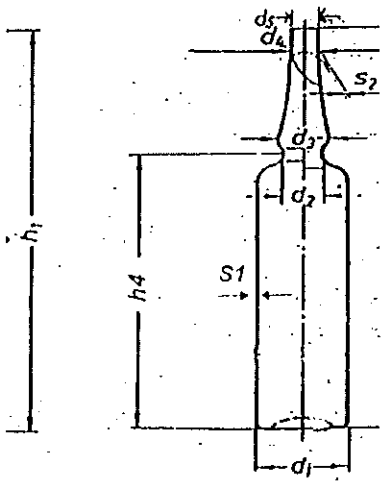
1. 材　　質：注射劑玻璃容器依最新 USP 規定為 Type I ，硼矽質硬質玻璃容器（High resistant, borosilicate glass），其玻璃管厚度為 0.45 ± 0.03 mm，由廠商提供材質證明。

2. 包　　裝:每 400~800 支裝一紙盒，紙盒雙面開口，寬度 26 公分，瓶口向上，外箱應標明品名、數量、批號或製造日期及廠名，紙箱內外應清潔，不得有異物污染。

3. 外　　觀：

	項　　目	樣本數	AQL	Ac	Re
1	本品為茶褐色玻璃安瓿，以安瓿用玻璃管加工製成之直筒型，外型平滑完整，瓶口鍛燒平整呈圓形，色澤均勻，不得有深淺不一。	125	1.5	5	6
2	本品不得有底歪頸斜，中心線不正，影響藥液充填作業情形。一次取 10 支安瓿使站立排列成直線，旋轉不同角度檢視，挑出瓶身異常傾斜者，測量瓶身中心線（瓶口圓心至瓶底圓心）之傾斜角度，不得大於 5°。	125	0.65	2	3
3	本品不得有肉眼可查覺之雜物、絲紋、氣泡及裂痕。	125	1.5	5	6
4	本品不得有直徑大於 1mm 之污點。	125	0.25	1	2
5	本品為 One-point 預割產品，不得有無預割之情形。	125	0.65	2	3
6	本品為 One-point 預割產品，有預割但無標示，或位置標示不當。	125	1.5	5	6
7	本品不得混雜任何他廠已印字之安瓿。	1250	0.010	0	1

4. 重量及尺寸單位：重量為 gm，尺寸為 mm（廠商需附每生產批之品質管制紀錄）。口徑 d4 及頸壁厚 S2 之量測點為安瓿開口下方 15 mm 處（約熔封點）。



項　目	代號	範　圍	樣本數
重量	W	1.34～1.64	32
胴徑	d1	9.75～10.30	32
絞徑	d2	5.3～6.1	32
玉徑	d3	6.0～7.0	32
口徑	d4	5.0～6.0	32
全長	h1	63～66	32
胴高	h5	27～29	32
管壁厚	S1	0.42～0.48	10
頸壁厚	S2	0.25～0.40	10

標準書發放章
101.07.03
高郁琪

註：尺寸及重量如不合格數 ≥ 2 支即判不合格。如不合格數為 1 支，則加倍取樣，兩次量測如不合格數 ≥ 3 支即判不合格。

5. 折斷面平整度測試：折斷時安瓿瓶身不得破碎。(樣本數 125, Ac=0, Re=1)

6. **CHEMICAL RESISTANCE**：詳見 2011 USP 34 〈660〉**CONTAINERS—GLASS**

6.1 Powdered Glass Test：安瓿清潔乾燥後，將之折斷，棄去有預割標示點之上半截，保留下半截進行本試驗。

Table 2. Test Limits for Powdered Glass Test

			Limits	
Type	**General Description**[a]	**Type of Test**	**Size,**[b] **mL**	**mL of 0.020 N Acid**
I	Highly resistant, borosilicate glass	*Powdered Glass*	All	1.0
III	Soda-lime glass	*Powdered Glass*	All	8.5

[a] The description applies to containers of this type of glass usually available.
[b] Size indicates the overflow capacity of the container.

6.2 Surface Glass Test

Table 3. Volume of Test Liquid and Number of Titrations

Filling Volume (mL)	**Volume of Test Liquid for One Titration (mL)**	**Number of Titrations**
Up to 3	25.0	1
Above 3 and up to 30	50.0	2
Above 30 and up to 100	100.0	2
Above 100	100.0	3

標準書發放章
101.07.03
高郁琪

Table 4. Test Limits for Surface Glass Test

	Maximum Volume of 0.01 M HCl per 100 mL of Test Liquid (mL)	
Filling Volume (mL)	**Types I and II**	**Type III**
Up to 1	2.0	20.0
Above 1 and Up to 2	1.8	17.6
Above 2 and Up to 5	1.3	13.2
Above 5 and Up to 10	1.0	10.2
Above 10 and Up to 20	0.80	8.1
Above 20 and Up to 50	0.60	6.1
Above 50 and Up to 100	0.50	4.8
Above 100 and Up to 200	0.40	3.8
Above 200 and Up to 500	0.30	2.9
Above 500	0.20	2.2

7. 砷(Arsenic)：限量 0.1 ppm 。

檢品試液取自 Surface Glass Test。

測定法：以原子吸收光譜儀測定之。

8. **LIGHT TRANSMISSION TEST**：詳見 2011 USP 34〈**671**〉

CONTAINERS—PERFORMANCE TESTING

標準書
發放章
101.07.03
高郁琪

Table 2. Limits for Plastic Classes I–VI and

Glass Types I, II, and III

	Maximum Percentage of Light Transmission at Any Wavelength between 290 and 450 nm	
Nominal Size (in mL)	**Flame-sealed Containers**	**Closure-sealed Containers**
1	50	25
2	45	20
5	40	15
10	35	13
20	30	12
50	15	10

9.附件：

(1)2011 USP 34版（660）Containers-Glass。

(2)2011 USP 34版（671）Containers-Performance Testing。

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〈 660 〉 CONTAINERS—GLASS

Glass containers for pharmaceutical use are intended to come into direct contact with pharmaceutical preparations. Glass used for pharmaceutical containers is either a borosilicate (neutral) glass or a soda-lime glass. Borosilicate glass contains a significant amount of boric oxide, aluminum oxide, and alkali and/or alkaline earth oxides. Borosilicate glass has a high hydrolytic resistance due to the chemical composition of the glass itself; it is classified as Type I glass. Soda-lime glass is a silica glass containing alkali metal oxides. Soda-lime glass has a moderate hydrolytic resistance due to the chemical composition of the glass itself; it is classified as Type III glass. The inner surface of glass containers may be treated, for example, to improve hydrolytic resistance. The treatment of Type III soda-lime glass containers will raise their hydrolytic resistance from a moderate to a high level, changing the classification of the glass to Type II.

The outer surface of glass containers may be treated to reduce friction or for protection against abrasion or breakage. The treatment of the outer surface does not come into contact with the inner surface of the container. Glass may be colored to provide protection from light or may have a coating applied to the outer surface. Such containers will meet the requirements for *Light Transmission* under *Containers—Performance Testing* 〈 671 〉. A clear and colorless or a translucent container that is made light-resistant by means of an opaque enclosure (see *Light-Resistant Container* in *Preservation, Packaging, Storage, and Labeling* under the *General Notices*) is exempt from the requirements for *Light Transmission*.

The quality of glass containers is defined by measuring their resistance to chemical attack. In addition, Type I containers for aqueous parenteral preparations are tested for arsenic release, and colored glass containers are tested for light transmission.

CHEMICAL RESISTANCE

The following tests are designed to determine the resistance to water attack of new (not previously used) glass containers. The degree of attack is determined by the amount of alkali released from the glass under the influence of the attacking medium under the conditions specified. This quantity of alkali is extremely small in the case of the more resistant glasses, thus calling for particular attention to all details of the tests and the use of apparatus of high quality and precision. The tests should be conducted in an area relatively free from fumes and excessive dust.

Glass Types— Glass containers suitable for packaging Pharmacopeial preparations may be classified as in *Table 1* on the basis of the tests set forth in this section. Containers of Type I borosilicate glass are generally used for preparations that are intended for parenteral administration. Containers of Type I glass, or of Type II glass (i.e., soda-lime

glass that is suitably dealkalized) are usually used for packaging acidic and neutral parenteral preparations. Type I glass containers, or Type II glass containers (where stability data demonstrate their suitability), are used for alkaline parenteral preparations. Type III soda-lime glass containers usually are not used for parenteral preparations, except where suitable stability test data indicate that Type III glass is satisfactory for the parenteral preparations that are packaged therein.

Table 1. Glass Types

Type	General Description	Type of Test
I	Highly resistant, borosilicate glass	*Powdered Glass*
II	Treated soda-lime glass	*Water Attack*
III	Soda-lime glass	*Powdered Glass*

Apparatus—

Autoclave— For these tests, use an autoclave capable of maintaining a temperature of 121 ± 2.0°, equipped with a thermometer, a pressure gauge, a vent cock, and a rack adequate to accommodate at least 12 test containers above the water level.

Mortar and Pestle— Use a hardened-steel mortar and pestle, made according to the specifications in *Figure 1*.