Vacant capsules Size and Appearance Quality

T/CNPPA 3008-2020

Contents

Preface

This standard is drafted in accordance with GB/T1.1.

This standard is proposed by the Capsule Committee of China National Pharmaceutical Packaging Association.

This standard is administered by China National Pharmaceutical Packaging Association.

This standard was drafted by: Qingdao Yiqing Biotechnology Co.,LTD. Anhui Huangshan Capsule Co.,LTD. Jiangsu Lefan Capsule Co.,LTD. Suzhou Capsugel LTD.Shanxi Guangsheng Medicinal Capsule Co.,LTD. Guangdong Kaiping Kingly Capsule Co.,LTD. Shaoxing Kangke Capsule Co.,LTD. Zhejiang Yili Capsule Co.,LTD. Zhejiang Huaguang Capsule Co.,LTD. Jiujiang Angtai Capsule Co.,LTD. Shanghai Guangdeli Capsule Co.,LTD.

Main drafters: Li Tongjie, LiuSonglin, Yun Xianyu, Guo Xiangyong, Qiao Xueqing, Zhou Tao, Li Xiaofei, Weng Lihong, Zhu Shuaihui, Fu Jianbo, Xu Zhenying, Liu Tianshi, Pan Shaoying, Yu Yu, Han Xiao

As of the date of publication of this Standard, content related to size and appearance in YBX-2000-2007 Vacant Gelatin Capsules should be repealed.

Introduction

The quality of vacant capsules depends on the whole process quality control, including the raw materials, production technology, production environment, batch division, packaging, storage, transportation and other factors affecting product quality should meet the corresponding technical specifications.

This standard is applicable to the size and appearance quality of vacant capsules. In addition to meeting the relevant technical requirements of this standard, the quality of vacant capsules should also meet the relevant national and association regulations such as the *Good manufacturing practice for pharmaceutical excipients,, the Pharmacopoeia of the People's Republic of China and the General Requirements for vacant capsules*, to ensure the quality and safety of vacant capsules.

Vacant capsules Size and Appearance Quality

1. Scope

This standard specifies requirements on Specifications and varieties, general requirements, detection methods, inspection rules, decision rules, as well as package, label, storage and transportation of vacant capsules.

This standard is applicable to vacant capsules used for Oral dosage form.

2. Normative reference

The following documents are essential to the application of this standard. For reference documents with date, only the dated version applies to; for reference documents without date, the latest version (including all amendments) applies to this standard.

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

3. Character, specification and variety

3.1 Character

Vacant capsules(Hereinafter referred to as the "Capsule") are cylindrical, hard, elastic empty capsules, which consist of telescoping cap and body pieces. Vacant capsules should have a clean, smooth and uniformly coloured surface, well trimmed , shaped without deformation and odourless.

3.2 Specification

Capsules can be categorized to 00#, 0#, 1#, 2#, 3#, 4#, 5# and other special size according to capacity. Elongated capsules are described as *el*, for example, 0# el. Enterprises Standard to special size can be made by manufacturer.

3.3 Variety

Capsules are categorized as three types, transparent (no opacifying agent in both pieces), opaque (opacifying agent in both pieces), half transparent (opacifying agent in either piece).

4. Technical requirements

4.1 Dimension

Dimensions of capsules with different sizes in table 1.

Table 1 Dimension

Size	Length mm	Single wall thickness mm	External diameter	Weight Difference

		Dimensions	Tolerance	Dimensions	Tolerance	mm	mg
00#	cap	11.50～11.90	±0.40	0.090～0.120	±0.020	8.45～8.65	±9.0
	body	20.00～20.40		0.090～0.120		8.10～8.30	
0#	cap	10.70～11.10		0.085～0.115		7.55～7.75	±8.0
	body	18.40～18.80		0.085～0.115		7.25～7.45	
1#	cap	9.60～10.00		0.085～0.115		6.85～7.05	±7.0
	body	16.40～16.80		0.080～0.110		6.55～6.75	
2#	cap	8.80～9.20		0.080～0.110		6.27～6.45	±6.0
	body	15.20～15.60		0.080～0.110		6.00～6.18	
3#	cap	7.90～8.30		0.080～0.105		5.74～5.92	±5.0
	body	13.40～13.80		0.080～0.105		5.48～5.66	
4#	cap	7.00～7.40		0.080～0.105		5.23～5.41	±4.0
	body	12.00～12.40		0.075～0.100		4.95～5.13	
5#	cap	6.00～6.40		0.070～0.105		4.83～4.98	±3.0
	body	9.20～9.60		0.065～0.100		4.61～4.75	

Central Value of length and single wall thickness can be revised within specified range. But maximum tolerance should within the specific value.

The dimensions above are for reference only, and should not be considered as an accept/reject criteria. The specific dimensions can be negotiated by supplier-user according to the filling requirements.

4.2 Appearance quality

4.2.1 Visual Defects

Description of visual defects in Table 2.

“Class A defects” refers to defects which cause loss of container properties of the capsule, or cause a low dosage weight of the capsule or cause a major filling machine stoppage or production operation delay.

“Class B defect” refers to defects which may cause problems in the filling operation, such as non-opening, failure to rectify or incorrect closure.

“Class C defect” refers to defects which do not affect the filling operation but detract from the visual or cosmetic appearance of the capsule.

Table 2 Visual Defects

Classification	Defect	Description
Class A defect	Hole	A hole caused by various reasons.
	Uncut/Trims	The trims of the cap or body remains attached to or in the capsule.
	Crack/Split	Cut edge crack is more than 2 mm/split is more than 2 mm.
	Short body	The length of the body is more than 1mm shorter than the specified length.
	Mashed	The body or cap is squashed or deformed.
	Bad join	When the capsule is joined, the overlaps of the cap and body are inserted into each other.
	Trims	Any excised portion of a body or cap left after cutting.
	Crack/Split	Cut edge crack is more than 1 mm/split is more than 1 mm.

Class B defect	Loose pieces	A detached body or cap.
	Collet pinches	The length of single longitudinal fold on the capsule is greater than 5mm, and the degree of concave-convex is greater than 1mm.
	Closed capsule	The capsule cap body has reached the final lock position.
	Double cap	An additional cap is attached to the capsule body.
	Punched ends	Diameter of punched ends: 00# and 0# capsules > 5.0mm;Capsules 1#, 2#, 3#, 4# and 5# are greater than 4.0mm.
	Thin spots	Thin spot on Cap or body of a single wall thickness is less than or equal to 0.03mm.
	Short cap/long cap	The length of the cap is more than 1mm shorter or longer than the specified length.
	Long body	The length of the body is more than 1mm longer than the specified length.
Class C defect	Crack/Split	Cut edge crack is less than or equal to 1 mm, split is less than or equal to 1 mm.
	Bubbles	There are bubbles with a diameter greater than 0.5mm or more than three (including three) bubbles with a diameter greater than 0.3mm on the capsule.
	Collet pinches	The length of longitudinal fold on the capsule is greater than 3mm.
	Punched ends	Diameter of punched ends: 00# and 0# capsules > 3.0mm;1#, 2#, 3#, 4# and 5# capsules greater than 2.0mm.
	Black dots/ Specks	Black dots or foreign dots/with a diameter greater than 0.3mm on the capsule.
	Star ends	Top stellate fold diameter: 00#, 0#, 1# capsules greater than 5.0mm, 2#, 3#, 4# and 5# capsules greater than 4.0mm.
	Scrapes	Capsule external surface is scraped longer than or equal to 2 mm.
	Wrinkle	The fold on the capsule wall is greater than (5×3) mm.
	Strings	Cutting edge with strings: 00#, 0#, 1# capsule greater than or equal to 3mm;2#, 3#, 4# and 5# capsules are greater than or equal to 2mm.

4.2.2 Print defects

Table 3 describes various defects in capsule printing.

“Critical print defect” means defects which results in non-identification of the printing design (including texts, letters, similarly hereinafter); “Major print defects” means defects which do not affect the identification of print design but it’s illegible or position reversed; “Minor print defect” means defects which do not affect the legibility of the printing design, but detract from the visual appearance of the capsule.

Table 3 Print defect

Defects classification		Description
Critical defect	unprinted	There is no pattern on the capsule.
	Multiple print	The design on the capsule is repeatedly printed.
	Print interruption	important parts of the pattern are incomplete, resulting in non-identification or incorrect identification.
Major defect	Reverse	The pattern on the cap and body is opposite to the prescribed direction.
	Print smeared	The handwriting of the pattern is blurred, resulting in the unclear pattern.
	Print off-set	More than a quarter of the pattern is covered by the cap after the final lock or the pattern on the cap is missing.
	ink spot	The ink spot on the capsule is greater than 0.5mm.
	ink line	The ink mark on the capsule is greater than or equal to 3mm.
Minor defect	Print interruption	The text (letter) on the pattern is missing, the pattern can be recognized (except the missing mark on the lock spot).
	Print smeared	Some part of the pattern is illegible, but the pattern is recognizable.
	Print off-set	Less than a quarter of the pattern is covered by the cap after the final lock or the pattern on the cap is missing.
	ink spot	The ink spot on the capsule is within 0.3 and 0.5mm.
	ink line	The ink line on the capsule is greater than or equal to 1 mm and less than 3mm.

5. Detection method

5.1 Dimension

5.1.1 Length

The length of cap and body shall be respectively measured by length measurement tool with accuracy of 0.01 mm.

5.1.2 Single wall thickness

The single wall thickness of cap (1 mm from the cut edge) and body (1 mm within the lock ring) shall be respectively measured by single wall thickness measurement tool with accuracy of 0.001 mm.

5.1.3 External diameter

The external diameter of cap and body shall be measured by standard orifice plate with accuracy of 0.01 mm or other effective methods, gently push samples through the orifice during measuring. Micrometers and Vernier calipers shall not be used.

5.2 Weight difference

5.2.1 Instrument

Analytical balance: accuracy of 0.1mg.

5.2.2 Determination

20 capsules were weighed by an analytical balance with accuracy of 0.1mg. Then weigh each capsule separately.

5.2.3 Calculation

Calculate average weight of 20 capsules and compare the weight of each capsule to the average weight. The maximum positive difference and minimum negative difference are regarded as weight difference.

Calculate the result to one decimal.

5.3 Appearance quality

5.3.1 Instrument

Inspection table with Ground-glass lamp

5.3.2 Determination

Place the capsule on the inspection table. The test shall be performed at a distance of 30cm (the light intensity is recommended to be controlled within 600-900lux) by persons with visual acuity 1.0 and above (including corrected visual acuity), or by other automatic detection devices.

6. Inspection Rules

6.1 Batch division

The production batch should be identified based on the traceability and quality uniformity of the products.

Generally, production batch should be defined as products continuously manufactured at a certain interval with same formula, process and specification.

6.2 Sampling

After the inspection of the outer packaging, a certain number of samples can be randomly gathered from the same batch of products according to table 4.

Table 4 Number of samples

Number of packages per lot	Number of samples
2～15	2
16～50	3
51～150	5
151～500	8

Equal amount of samples are taken from each package and mixed to a sample with a total quantity of not less than 1250 pieces. Then the sample was determined according to GB/T2828.1.

6.3 Acceptance quality limit

The inspection level and acceptance quality limit (AQL) for the dimensions, appearance quality, weight tolerance of capsules should comply with the provisions in Table 5.

Table 5 Acceptance quality limit

Technical requirements	Items		Test level	Number of samples,	Acceptance quality limit and decision		
					AQL	A_C	R_e
Dimension	length		S-4	125	0.65	2	3
	Single wall thickness						
	Capsule weight tolerance		—	20	Meet the requirements in Table 1	2	3
Appeara	Visual	Class A defect	Ⅱ	1250	0.04	1	2

nce quality	Defects	Class B defect			0.15	5	6
		Class B defect			1.0	21	22
	Defect of printing	Serious defect			0.04	1	2
		Major defect			0.65	14	15
		Minor defect			1.0	21	22

7. Decision rules

If any of the testing item fails to meet the requirements during the acceptance inspection, the receiving party shall conduct joint inspection with the manufacturer on the non-conforming items to determine whether they are qualified or not according to the inspection results.

8. Package, label, transportation and storage

8.1 Package

The inner package materials shall conform to the requirements of food or Pharmaceutical grade. Outer packaging shall be made of corrugated carton or negotiate by both supplier and user.

8.2 Label

Label should include but not limited: manufacturer name, product name , batch number, manufacturing date, expiration date, applied standard, quantity, transportation and storage conditions, etc.

8.3 Transportation

Products should be protected from pressure, sunshine, moisture and heat during transportation. Shipment with toxic or spoilage materials are forbidden.

8.4 Storage

The product should be airtight, stored in a clean, dry and ventilated warehouse. And storage outside of warehouse is not recommended. The storage environment should be controlled of temperature and humidity accordingly.