

A close-up photograph of a hand holding a clear glass ampoule. The ampoule has a white cap with a frayed edge and three colored bands (yellow, red, and white) around its neck. The background is a blurred blue surface with circular patterns.

CORNING

Tubing Specification
Pharmaceutical Ampoule Tubing

Dimensional Specification

All requirements and criteria applicable to dimensional characteristics are summarized in the table below. For details see “Tubing Specifications — Definition and Supporting Information”.

Sample size according to ISO 2859 unless specified otherwise. Reference volume = 1 pallet

Requirement	Definition Item	Unit Defect Spec / Limit		AQL	Remarks	
Outer Diameter	OD_{avg}	The individual tubing sample is defective if there is a 60 mm section out of tolerance over the entire length.		Cumulative AQL of 0.25	Standard tolerances see page 5	
Circularity	$NCR = 1/2 (OD_{max} - OD_{min})$	OD range	Limit for NCR			
		< 25.0 mm	0.3% of OD_{nom}			
		25.0 – 35.0 mm	0.5% of OD_{nom}			
Wall Thickness	WT_{avg}	The individual tubing sample is defective if there is a 60 mm section out of tolerance over the entire length.				See page 5
Wall Siding (Lop)	$WS = WT_{max} - WT_{min}$	Maximum siding value is 6% of the nominal wall thickness.				
Length	L_{max}	The individual tubing sample is defective if overall length is out of tolerance.				Standard tolerances see page 5
Bow	B_{center}	Defective if greater than 0.7 mm			Over a 1000 mm length	
Square Cut	SC	$OD < 25.0$	Not to exceed 8% OD_{nom}	2.5		
		$OD \geq 25$	Not to exceed 2.0 mm			
Glazing	GID_{max} as a percentage of OD_{nom}	Light	Sharp edges rounded with a minimum turn in	0.65	May be specified differently on the two tube ends.	
		Medium	80 – 90% of OD_{nom}			
		Heavy	65 – 75% of OD_{nom}			

Notes

OD, WT, NCR, WS, measurements are to be taken on the usable length of the tube. Any local deviation in each that corresponds with knots or stones or other dimensionally relevant visual characteristic shall not be evaluated with respect to the dimensional specification, but rather according to the relevant visual specification.

Visual Quality Specifications

Requirements applicable to visual characteristics are summarized in the tables below. For details see “Tubing Specifications — Definition and Supporting Information”.

Sample size according to ISO 2859 unless specified otherwise. Reference volume = 1 pallet

Requirement	Detail/Parameter	Individual Defect Definition	AQL/Criteria	Remarks		
Airlines	Single	W > 0.08mm	0.4	Defective if any airline in the tube exceeds limit length or width.		
	Aggregate length of airlines	Aggregate length of airlines L > 30 mm and W > 0.02 mm	≤ 7.5%	Of tested tubing length. Apply to both open and closed airlines.		
Inclusions	Size (S) / count	Tube is defective if inclusion count per 5 kg tubing exceeds the following limits.		Inclusions up to 0.5 mm are not a defect. AQL not specified. 5 kg tubing must be controlled.		
		S ≥ 0.8			0 allowed per 5 kg	
		S ≥ 0.5			Max 8 allowed per 5 kg	
Glass Particles	Size (S) / count	Tube is defective if the following maximum allowed numbers of glass particles is exceeded in any class.	0.4	Glass particles up to 0.2 mm are not considered. Cumulative size classes apply.		
		OD range [mm]			S ≥ 0.5	S ≥ 0.2
		OD < 15.0			0	5
		15.0 ≤ OD < 25.0			0	8
		OD ≥ 25			0	10
Cracks	Surface cracks	Any size, any length	0.025	End cracks ≤ 2 mm are not considered as defects, 20 mm from each side not considered.		
	End cracks	L > 2.0 mm	0.65			
Scratches Coated tubes	Longitudinal	W > 0.1 mm AND L > 30 mm	1.0	20 mm from each side not considered. Only for bundlepack		
	Aggregate length	W > 0.1 mm AND AL > 150 mm				
	Circular	W > 0.1 mm AND Arc > 1/2 circumference				
Scratches Uncoated Tubes	Longitudinal	W > 0.2 mm AND L > 100 mm	1.0	20 mm from each side not considered (applies also for all tubes in sleeve pack)		
	Aggregate length	W > 0.2 mm AND AL > 300 mm				
	Circular	W > 0.2 mm AND Arc > 1 circumference				
Surface Impurities	Outer surface	If impurities cannot be easily removed > 1.0 mm	0.1			
	Inner surface	> 0.5 mm	0.1			

Other Requirements

Requirements for other characteristics are summarized in the tables below.

Requirement	Detail	Defect Specification	AQL	Remarks
Residual Stress	Longitudinal	Stress > 4.0 MPa	2.5	
	Circular	Stress > 4.5 MPa		
Mix-Up	Delivered articles is not uniform in the pallet	E.g. different glass types, dimensions, coating level, different identification (label)	Not permissible	
Identification	Wrong data	Incorrect identification data on the bundle label. E.g. declared dimensions, bundle weight, pallet weight	Not permissible	Test unit = 1 bundle
	Missing bundle label	Missing bundle labels	Not permissible	
Certificates	Wrong or missing data	Missing certificate or pallet label	Not permissible	
Type I	EP 3.2.1 – Test B, USP660 – Glass grain test	> 0.1 ml of 0.02 M HCl per 1 g of glass	Not permissible	JP 7.01 Test For glass containers for Injections upon request
Paneling (Waving)	Long range optical anomaly due to deviation from circularity or glass inhomogeneity	Based on agreed upon limit samples	1.0 For printed ampoules: 0.25	Local deformation or inhomogeneity (e.g. knots) should not be considered a paneling defect

Standard Dimensions

Length standard tolerance is -0.0 +4.0 mm.

The following table defines the standard OD and WT tolerances depending on the OD and WT nominal values.

OD range (mm)	WT range (mm)	OD tol (mm)	WT tol (mm)
9.0 – 14.9	0.40 – 0.55	0.12	0.02
	0.60 – 0.75	0.13	0.03
15.0 – 17.9	0.45 – 0.60	0.14	0.03
	0.65 – 0.75	0.15	0.03
18.0 – 19.9	0.55 – 0.60	0.15	0.03
	0.65 – 0.75	0.18	0.04
20.0 – 24.9	0.65 – 0.80	0.19	0.04
25.0 – 29.9	0.75 – 0.90	0.20	0.04

Contact Information

Asia

Corning Pharmaceutical Glass Co., Ltd.
No. 1951 Zhongliang Avenue, High-Tech Zone
Bengbu, Anhui, China

Phone: +86 552-3733886-8702
E-mail: cpginfoas@corning.com

Europe

Corning Pharmaceutical Glass S.p.A.
Via Montelungo, 4
56122 Pisa, Italy

Phone: +39 050 56 66 11
E-mail: cpginfoeu@corning.com

North America

Corning Pharmaceutical Glass, LLC
563 Crystal Avenue
Vineland, NJ 08360-3257 USA

Phone: +1 856 794 7100
E-mail: cpginfousa@corning.com

www.corning.com

© 2023 Corning Incorporated. All Rights Reserved.

CORNING