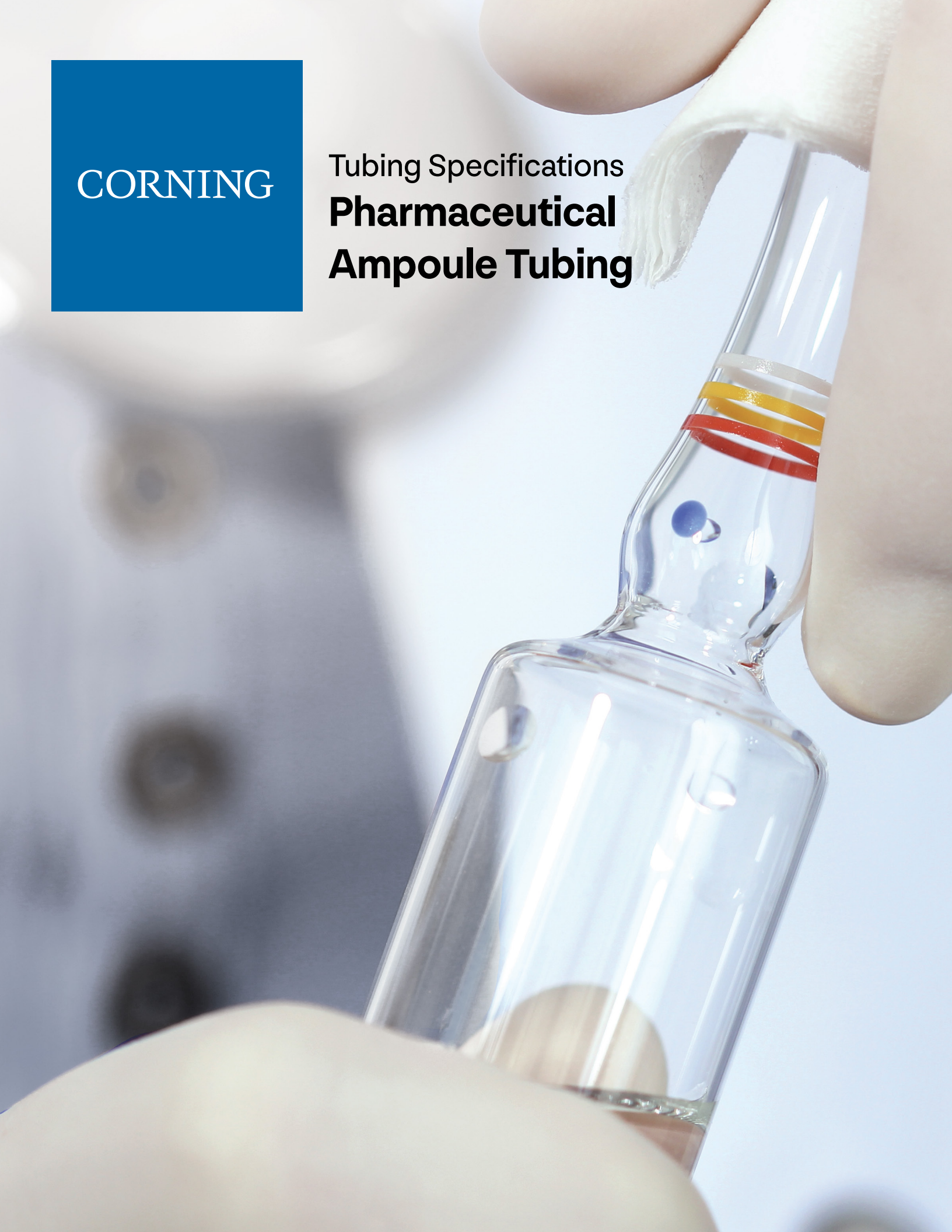
CORNING

Tubing Specifications

Pharmaceutical Ampoule Tubing



Dimensional Specifications

All requirements and criteria applicable to dimensional characteristics are summarized in Table 1.

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

Table 1. Summary of criteria applicable to dimensional characteristics.

Requirement	Definition	Unit Defect Spec/Limit		AQL	Remarks
Outer Diameter	OD_{AVG}	Defective if there is a 60 mm section out of the tolerance over the entire length		Cumulative AQL of 0.25	Standard tolerances, see Standard Dimensions
Circularity	NCR = ½ (OD_{max} - OD_{min})	**OD Range (mm)**	**Limit for NCR**		
		< 25.0	0.3% of OD_{nom}		
		25.0 - 35.0	0.5% of OD_{nom}		
Wall Thickness	WT_{AVG}	Defective if there is a 60 mm section out of the tolerance over the entire length			Standard tolerances, see Standard Dimensions
Wall Siding (LOP)	WS = WT_{max} - WT_{min}	Maximum siding value is 6% of the nominal wall thickness			
Length	L_{max}	Defective if overall length is out of tolerance			Standard tolerances, see Standard Dimensions
Bow	B_{center}	Defective if greater than 0.7 mm			Over a 1000 mm length
Square Cut	SC	**OD Range (mm)**	**Limit for NCR**	2.5	
		< 25.0	Not to exceed 8% OD_{nom}		
		≥ 25.0	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}		

NOTE: OD, WT, NCR, and 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 Table 2.

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

Table 2. Summary requirements applicable to visual characteristics.

Requirement	Detail/Parameter	Individual Defect Definition	AQL	Remarks
Airlines	Single	L > 150 mm or W ≥ 0.08 mm	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 %	As a percentage of tested tubing length. Apply to both open and closed airlines.
Inclusions	Size (S)/count	Defective if inclusion count per 5 kg tubing exceeds the following limits. **Size (mm)** — **Count** S ≥ 0.8 — 0 allowed per 5 kg S ≥ 0.5 — Max 8 allowed per 5 kg		Inclusions up to 0.5 mm are not considered defects. AQL not specified; 5 kg tubing must be controlled.
Glass Particles	Size (S)/count	Defective if the following maximum allowed numbers of glass particles is exceeded. **OD Range (mm)** — **S ≥ 0.5** — **S ≥ 0.2** < 15.0 — 0 — 5 15.0 ≤ OD < 25.0 — 0 — 8 ≥ 25.0 — 0 — 10	0.4	Glass particles up to 0.2 mm are not considered defects.
Cracks	Surface cracks	Any size, any length	0.025	End cracks ≤ 2 mm are not considered defects, 20 mm from each side not considered defects.
	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 are not considered defects. Only for bundlepack.
	Aggregate length	W > 0.1 mm and AL > 150 mm		
	Circular	W > 0.1 mm and Arc > ½ 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	Defective 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 Table 3.

Table 3. Summary requirements of other characteristics.

Requirement	Detail	Defect Specification	AQL	Remarks
Residual Stress	Longitudinal	Stress > 4.0 MPa	2.5	
	Circular	Stress > 4.5 MPa		
Mix-up	Delivered articles are not uniform in the pallet	Example: different glass types, dimensions, coating level, different identification (label)	Not permissible	
Identification	Wrong Data	Incorrect identification data on bundle (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	Ph. Eur. 3.2.1, Test B, USP <660> Glass grain test	> 0.1 mL of 0.02 M HCl per 1g 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 unprinted ampoules. 0.25 for printed ampoules.	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.

Table 4. Defines 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 0.60 - 0.75	0.12 0.13	0.02 0.03
15.0 - 17.9	0.45 - 0.60 0.65 - 0.75	0.14 0.15	0.03 0.03
18.0 - 19.9	0.55 - 0.60 0.65 - 0.75	0.15 0.18	0.03 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 Us

Corning Incorporated
Life Sciences, Pharmaceutical Technologies
www.corning.com/CPT

NORTH AMERICA
Corning Pharmaceutical Glass, LLC
t +1.856.794.7100
cpginfousa@corning.com

EUROPE
Corning Pharmaceutical Glass S.p.A.
t +39.050.56.66.11
cpginfoeu@corning.com

CHINESE MAINLAND
Corning Pharmaceutical Glass Co., LTD
t +86.552.3733886
cpginfoas@corning.com

INDIA
Corning Technologies India Private Limited
t +91.124.460.4000
Inquiriesin@corning.com