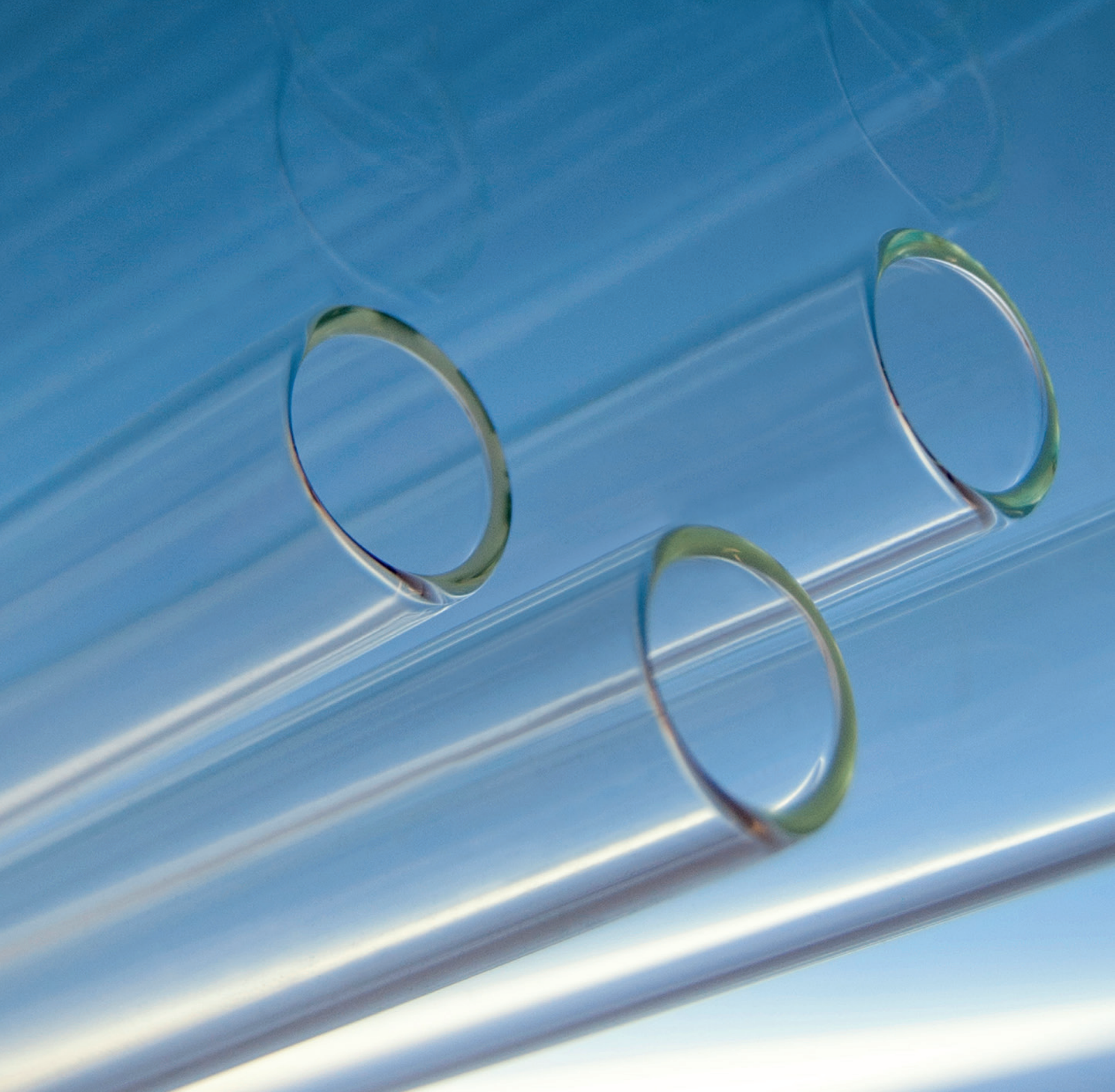
CORNING

Pharmaceutical Glass Tubing Specifications

Definition & Supporting Information



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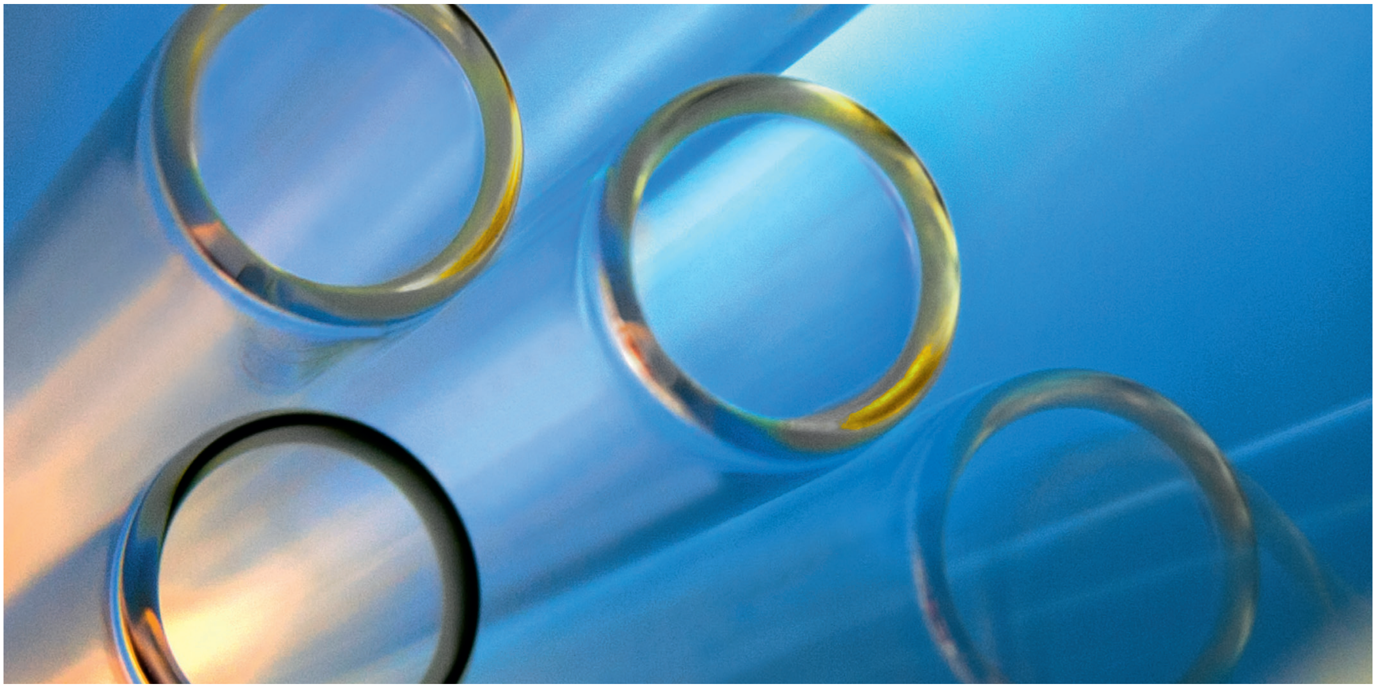
Introduction



About Corning

Corning is one of the world's leading innovators in materials science. For more than 160 years, Corning has applied its unparalleled expertise in specialty glass, ceramics, and optical physics to develop products that have created new industries and transformed people's lives. Corning succeeds through sustained investment in R&D, a unique combination of material and process innovation, and close collaboration with customers to solve tough technology challenges.

Corning Pharmaceutical Glass Tubing

Corning Incorporated operates two pharmaceutical glass tubing manufacturing sites: Corning Pharmaceutical Glass, LLC in Vineland, NJ (USA) and Corning Pharmaceutical Glass S.p.A. in Pisa, Italy. With over 160 years of experience in specialty glass and materials science innovation, Corning Pharmaceutical Glass is uniquely suited to supply high-quality clear and amber borosilicate glass tubing for use in pharmaceutical primary packaging.

Innovative Technologies

Corning has a long history of manufacturing highest-quality glass for a variety of applications. Through its sustained investment in research and development, Corning continues to innovate glass melting and forming technology. Corning Pharmaceutical Glass uses visual and dimensional quality specifications that are designed to exceed standards required for the production of pharmaceutical primary packaging. State-of-the-art furnace technologies guarantee a homogenous melting process which is monitored by control systems and regular chemical analysis.

Rigorous Process Control

From raw material preparation to final packaging, our tubing production process is seamlessly integrated. Automated computer controls maintain furnace stability and optimal melting conditions. Process variables are monitored and controlled automatically to meet specifications using online gauging equipment, which is part of a closed-loop system. This real-time process control ensures tight tolerances on key parameters such as tube OD, ID, wall thickness, siding and out-of-round.

Corning pharmaceutical borosilicate glass tubing is produced in ISO 9001:2008 certified facilities located in Vineland, New Jersey and in Pisa, Italy.

General Notations

Note 1: OD, WT, ID, OOR, WS, measurements are taken on the usable length of the tube.

Note 2: API or All Points In dimensions are available upon request.

Note 3: Diagrams may not be to scale. They are exaggerated to explain specifications and measurements.

Dimensional Quality Specifications

Outer Diameter

OD average

The average of the OD_{min} and OD_{max}:

$$OD_{ave} = (OD_{min} + OD_{max}) / 2$$

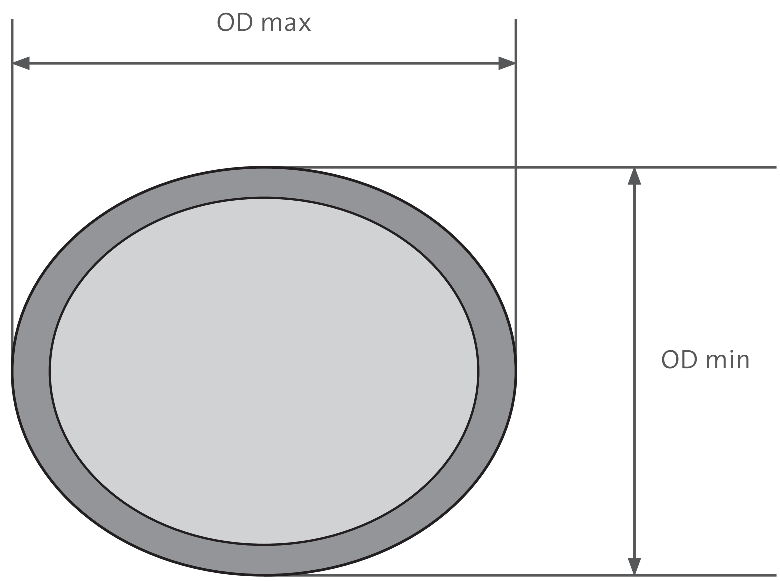
OD minimum

In any tube cross section, the ODmin is the minimum distance between two points on the annular cross section. This coincides with the minimum distance of two parallel lines touching the outer boundary of the annular cross section. Practically, a measurement can be obtained for any relative orientation of the cross section with respect to the parallel lines. The ODmin is the minimum value obtainable by orienting the tube in every direction.

OD maximum

In any tube cross section, the ODmax is the maximum distance between two points on the annular cross section. This coincides with the maximum distance of two parallel lines touching the outer boundary of the annular cross section. Practically, a measurement can be obtained for any relative orientation of the cross section with respect to the parallel lines. The ODmax is the maximum value obtainable by orienting the tube in every direction.

Outer Diameter



Diagrams not to scale

Circularity / Ovality

Ovality (OR)

An equivalent measurement takes the full swing of the OD, which defines the Ovality. As it is twice the circularity, the corresponding limit is also twice:

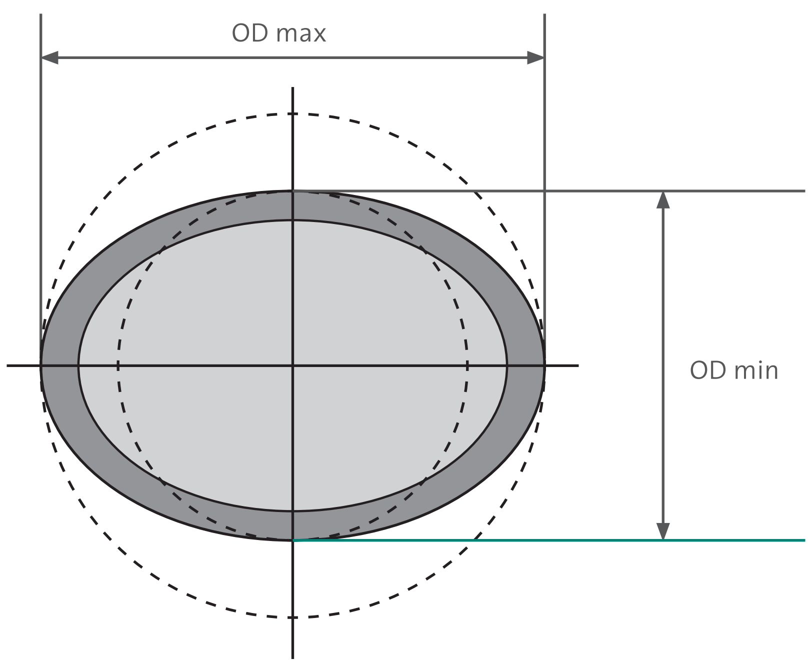
$$\text{Ovality (OR)} = OD_{max} - OD_{min}$$

Circularity (NCR)

The Circularity error is defined in any cross section as half the swing of the oriented OD:

$$\text{Circularity (NCR)} = (OD_{max} - OD_{min}) / 2$$

Ovality (OR)



Diagrams not to scale

Inner Diameter

ID ave

The average of the ID_{min} and ID_{max}:

$$ID_{ave} = (ID_{max} + ID_{min}) / 2$$

ID min

The minimum distance of two parallel lines touching the inner boundary of the annular cross section.

Maximum Inner Diameter (ID max)

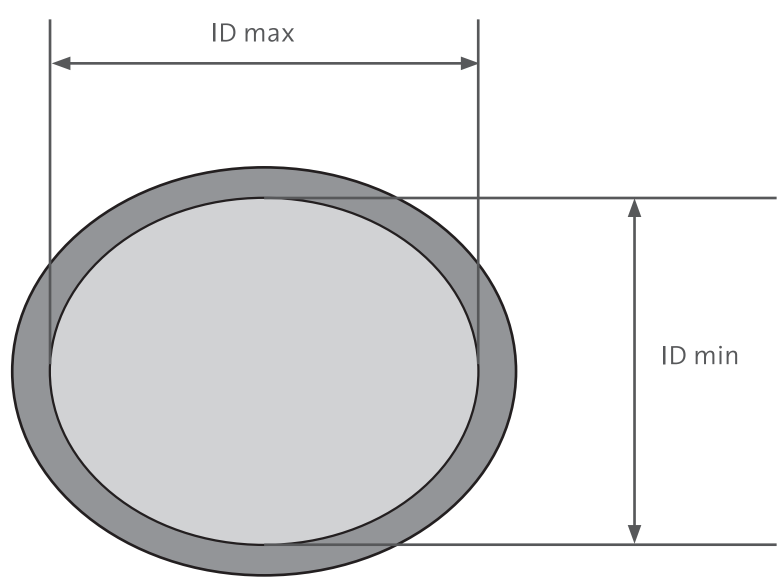
In any tube cross section, the IDmax is the maximum distance between two points on the inner surface. This coincides with the maximum distance of two parallel lines tangent to the inner boundary of the annular cross section. Practically, a measurement can be obtained for any relative orientation of the cross section with respect to the parallel lines. The IDmax is the maximum value obtainable by orienting the tube in every direction.

Notes

The IDmax and IDmin are obtainable by measuring with double-point snap gauge or micrometer suitable for internal measurements and rotating the tube, and then taking the max and min.

Note: When WT (wall weight/wall thickness) is specified, ID is not applicable.

Inner Diameter



Diagrams not to scale

Wall Thickness

WT ave

The average of WTmin and WTmax of a given cross section:

$$WT_{ave} = (WT_{max} + WT_{min}) \;/\; 2$$

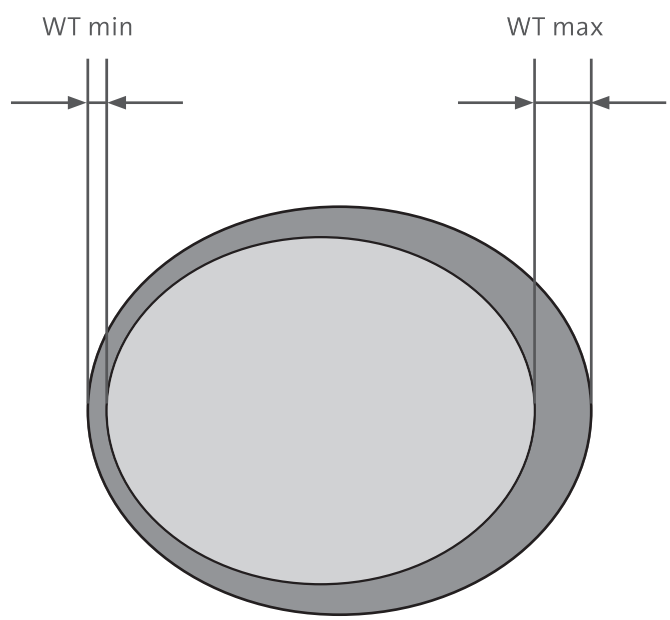
WT max

The maximum oriented WT obtainable in a given cross section.

WT min

In any tube cross section the OD is the shortest distance between two points on the inner and outer surfaces of the tube. Practically, a local measurement can be obtained for any angular position of the external point. The WTmin of the cross section is the minimum of such values.

Wall Thickness



Diagrams not to scale

Wall Siding (LOP)

Wall Siding (LOP)

The Wall Siding is the difference between the maximum and minimum Wall Thickness on a cross section of the tube:

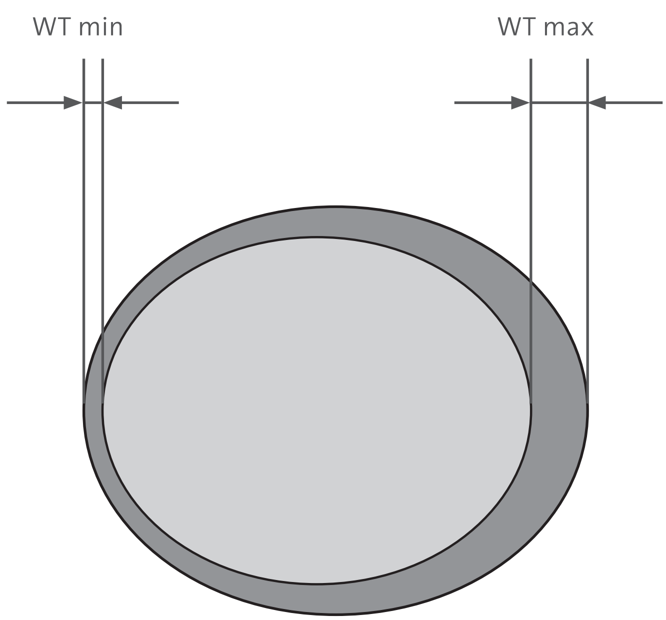
$$LOP = WT_{max} - WT_{min}$$

Notes

The WTmin and WTmax are practically obtainable by magnetic gauge with bead or with dial gauge with mandrel, the sample is rotated to obtain the max and min Wall Thickness. Wall Siding maximum acceptable value is specified depending on the nominal Wall Thickness, usually as a percentage of same.

When ID is specified, WT is normally not specified. The Wall Siding (LOP) requirement instead, applies anyway.

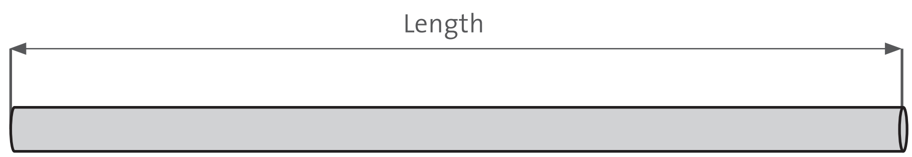
Wall Siding (LOP)



Diagrams not to scale

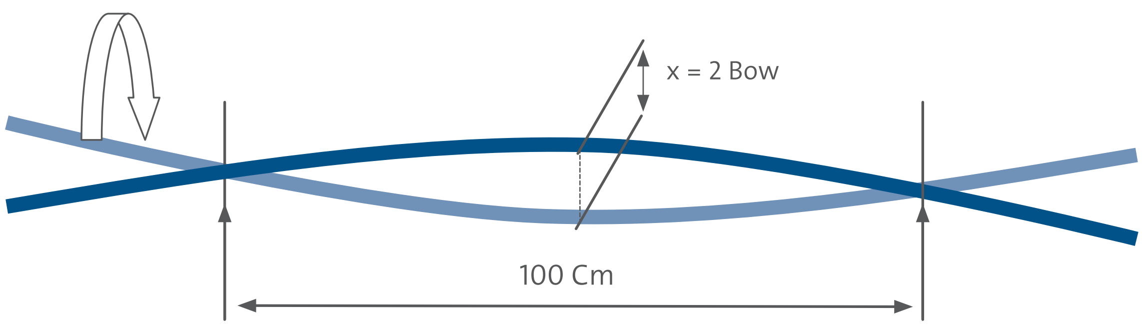
Length

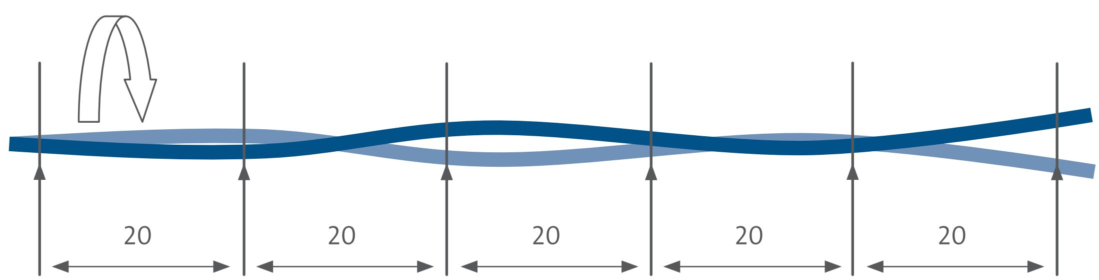
Length	The maximum distance between two planes perpendicular to the tubing axis, touching both tube ends.



Bow / Straightness

Bow (B_{center})	The Straightness is defined as longitudinal curvature of the tubing, and is measured at the maximum deviation from a straight line over 1000 mm length of the tube.
Notes	The Bow is obtained by laying the tube on two supports, 1000 mm apart from each other, and measuring half the swing of the position of its mid section axis, when it is rotated at least one complete turn around its axis.
Snaky Bow (B_S)	After initial visual observation, measurement is defined as longitudinal curvature of the tubing, and is measured at the maximum deviation from a straight line over agreed upon length of the tube as stated in individual agreed upon specifications.





Square Cut

Square Cut (SC)

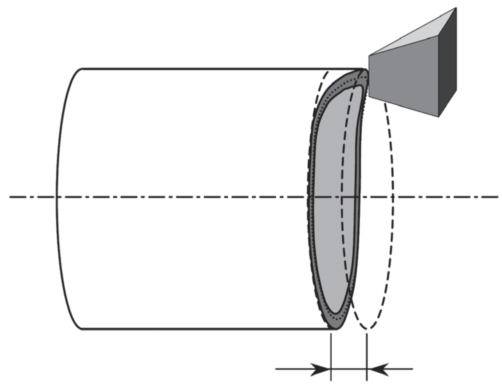
The Square Cut of a defined tube end, is the greatest absolute difference between two parallel planes, perpendicular to the tube axis, enclosing the whole end rim of the tube end. The end rim is defined by the point of contact of a linear probe, mounted perpendicularly to the tube axis and parallel to the tube radius, while the tube is rotated 360°.

Every tube provides two measurements of the Square Cut, one on each end.

Notes

The tube shall not translate along its axis while it rotates. This can be ensured by keeping the opposite end in contact with a suitably wide reference plane, perpendicular to the tube axis.

The Square Cut limit may be specified as a percentage of the nominal OD.



Diagrams not to scale

Glazing

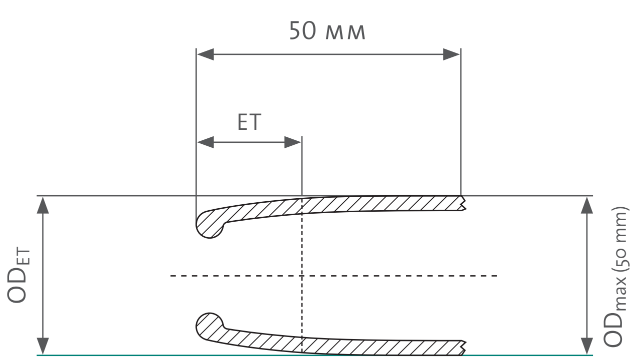
End Taper (ET)

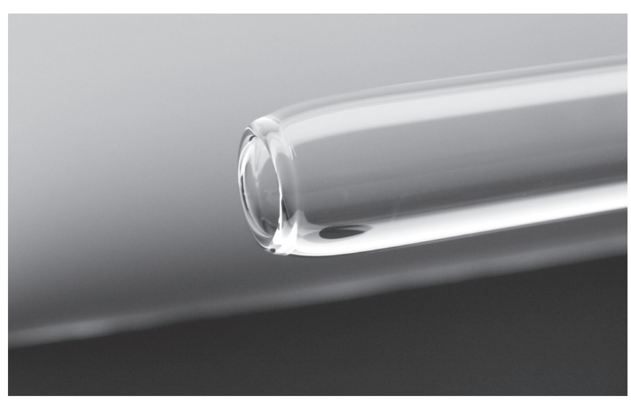
The End Taper of a defined tube end, is the distance between tube end and tube section where the ODmax is:

$$OD_{ET} = OD_{max}\ (50mm) - OD_{tol}$$

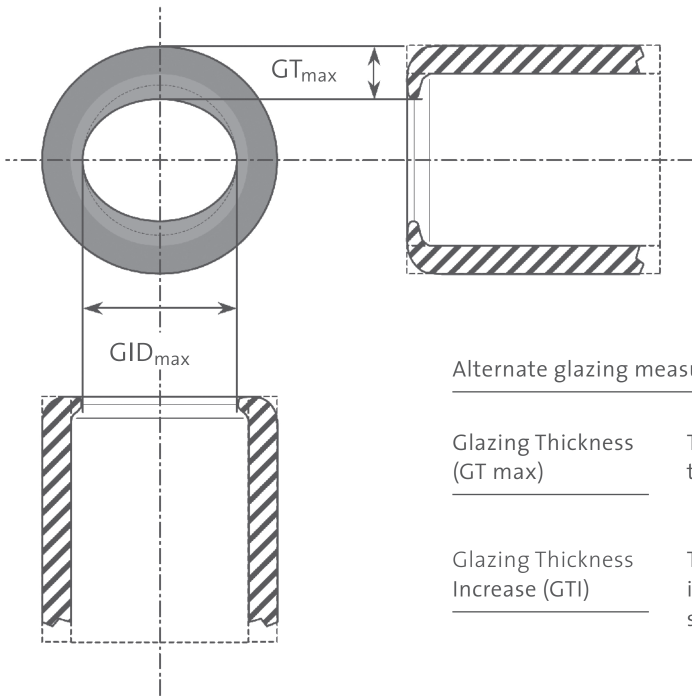
Notes

Only for Customer-specific agreements.





End Finishing — Glazing



Glazed ID (GID max)	The Glazed ID of a defined tube end, is the internal diameter measurement that can be taken at the glazed tube end.

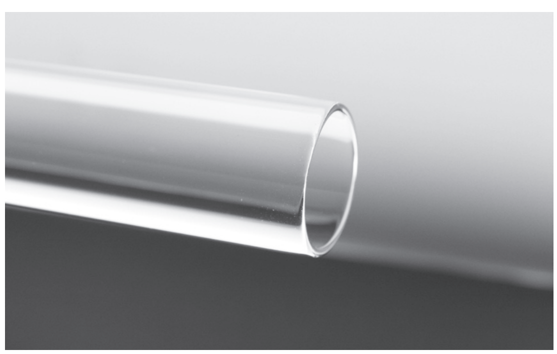
Alternate glazing measurements:

Glazing Thickness (GT max)	The Glazing Thickness of a defined tube end, is the maximum thickness of glazing measurable at one end along a radius.
Glazing Thickness Increase (GTI)	The Glazing Thickness Increase is defined as the increase in thickness due to glazing with respect to the WT at the same point.

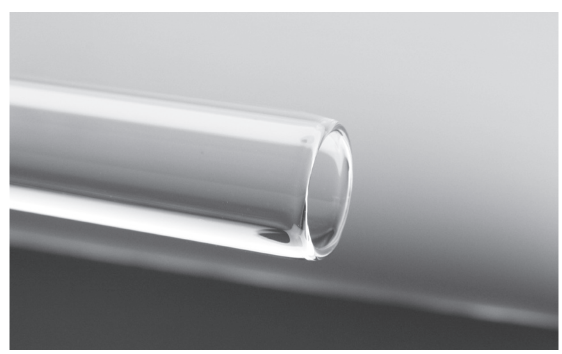
Diagrams not to scale

End Finishing — Glazing

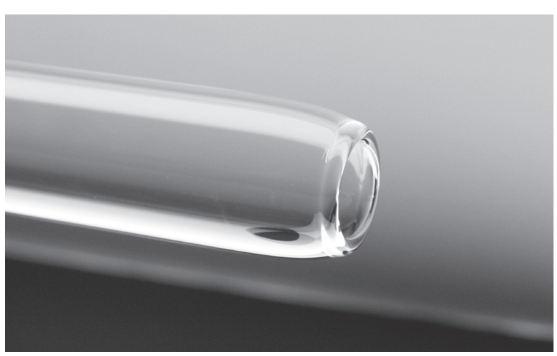
Light



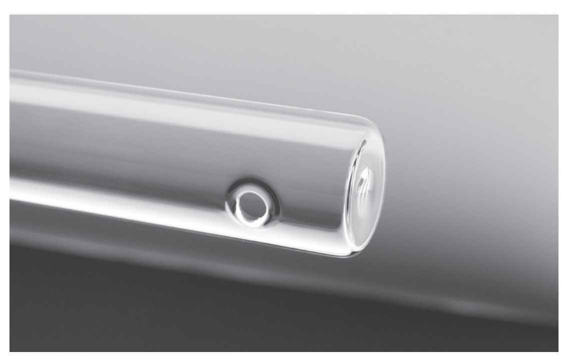
Medium



Heavy



Bottoming



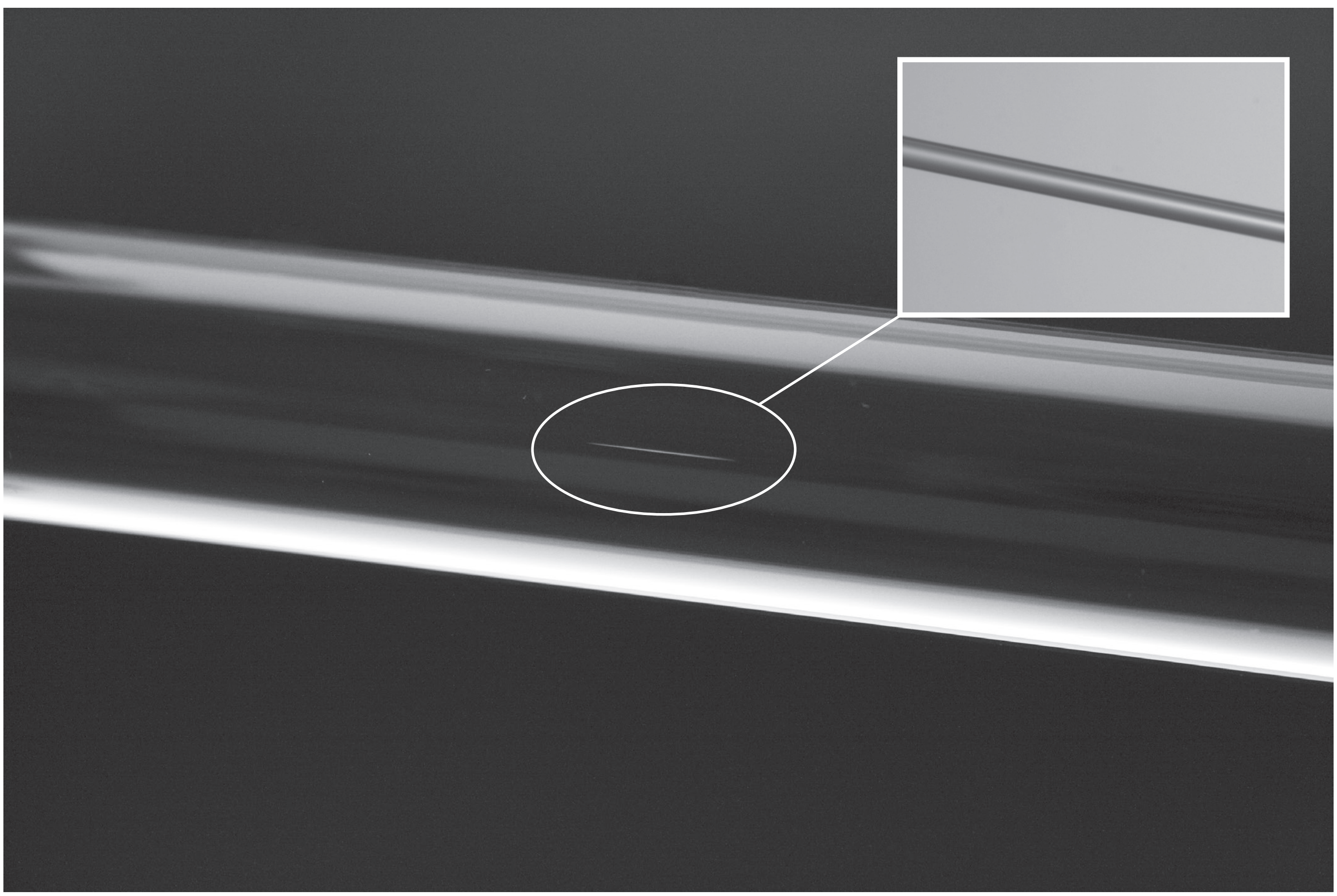
Visual Quality Specifications

Air Lines

Definitions

Closed Airline	The elongated gaseous inclusion in the tubing, completely surrounded by glass.
Open Inside Airline	The elongated cavity in the tubing that physically breaks the inner surface.
Airline Width (W)	The Airline Width is the maximum width over the whole airline as apparent from outside the tube.
Aggregate Length %	The Aggregate Length is the fraction of tubing length which is occupied by airlines, expressed in a percentage. It is the sum of the lengths of all airlines exceeding a certain dimension (Length and Width thresholds), divided by the total length of tubing inspected.

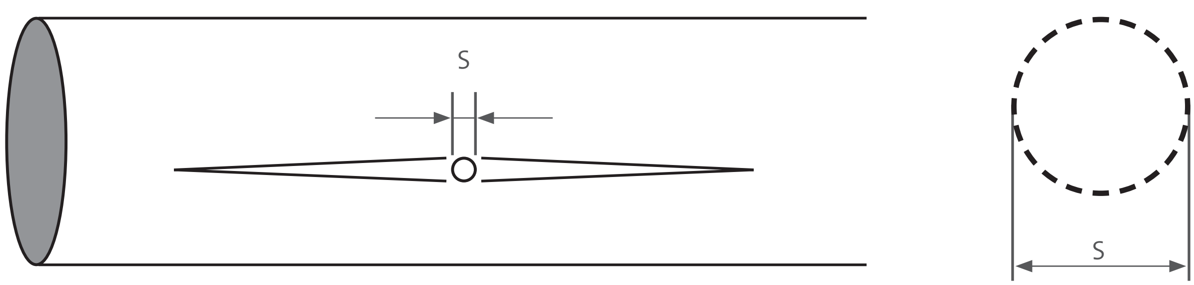
Air Lines



Knots & Stones (Inclusions or Rough)

Definitions	Inclusion	The material that differs in composition from the rest of the glass and is trapped in the glass mass. Usually shaped in a central core, which gives rise to elliptical or streaky shaped tails in the longitudinal direction.
	Knot	The transparent inclusion
	Stone	The opaque inclusion
	Size (S)	The Stones are the apparent diameter of the opaque core. The Knots are the apparent diameter of the transparent core, to be measured as indicated in the figures below.

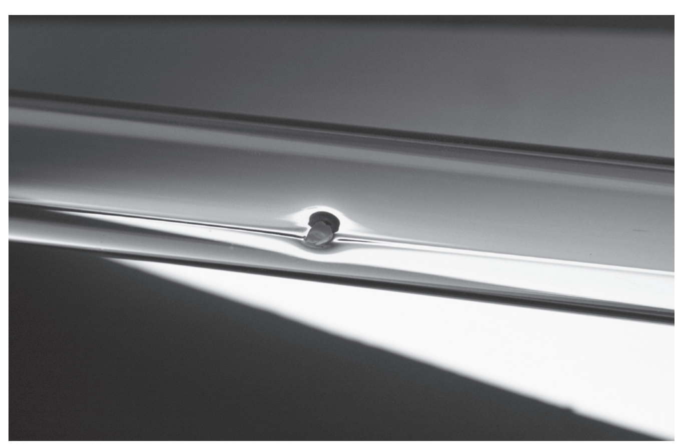
Knots & Stones



Diagrams not to scale

Knots

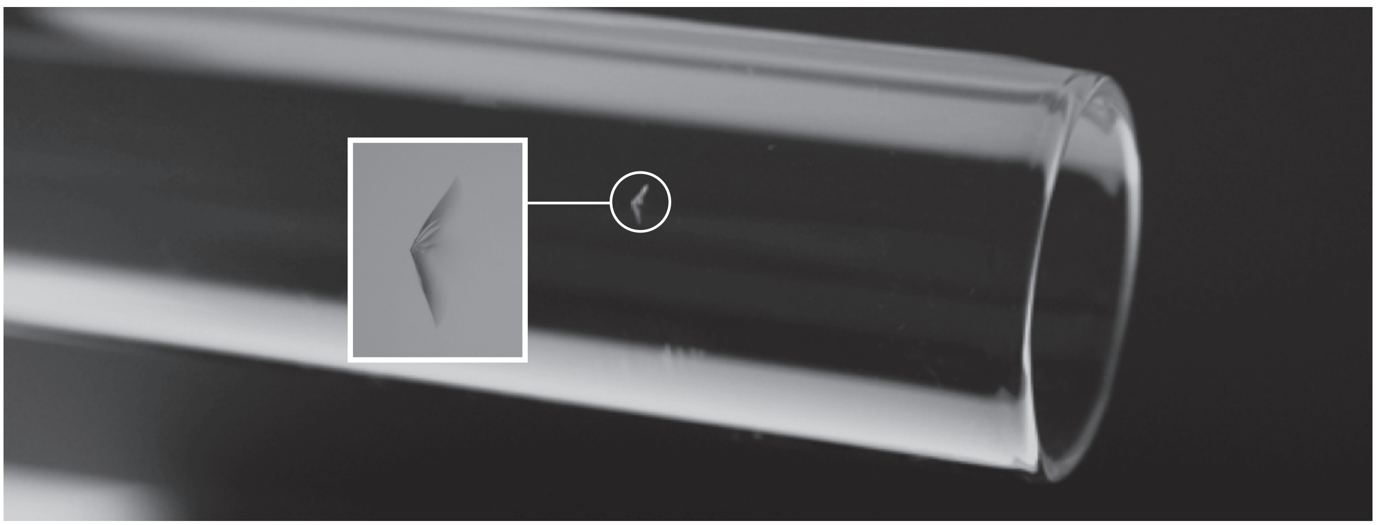
Stones



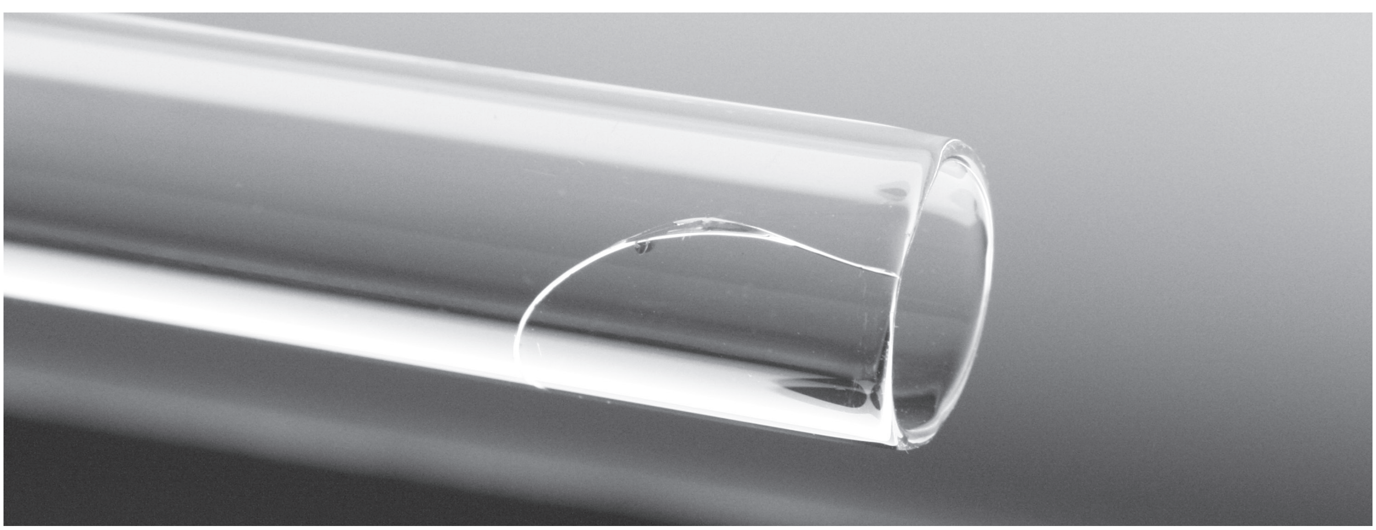
Cracks

Definitions	Cracks	Fractures that penetrate completely through the glass wall. Cracks significantly weaken the mechanical robustness of a tube.
	End Cracks (Fissures)	The cracks originating from the tube end, or entirely laying within 20 mm from the tube end.
	Surface Cracks	All other cracks.
	Length (L)	The Length of the crack line measured at the tube outer surface.

Cracks



End Crack

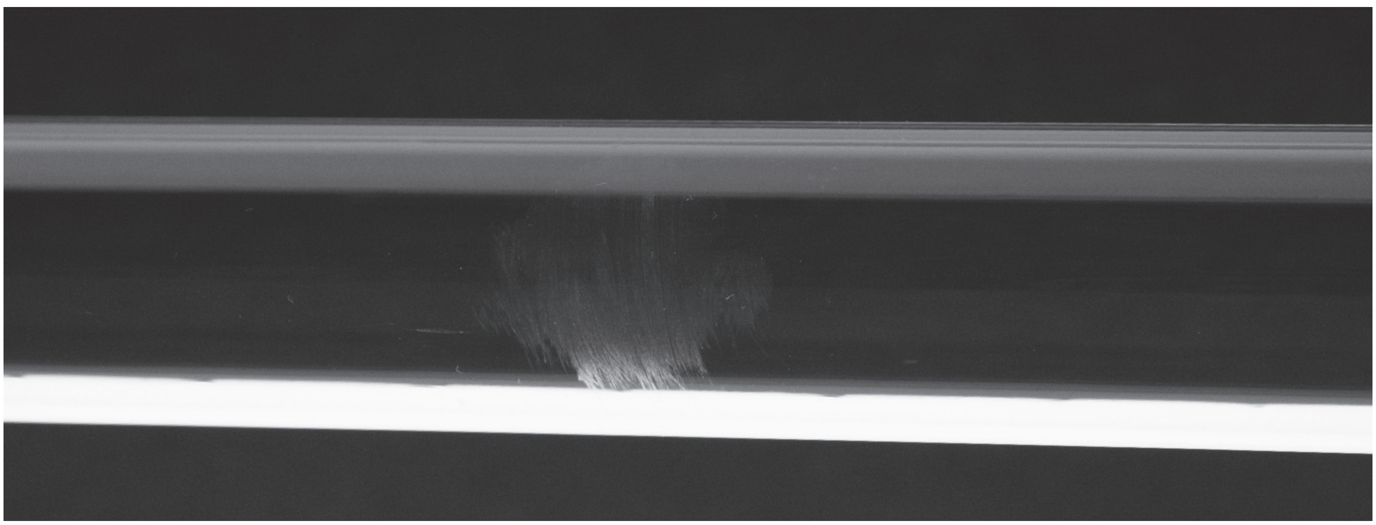


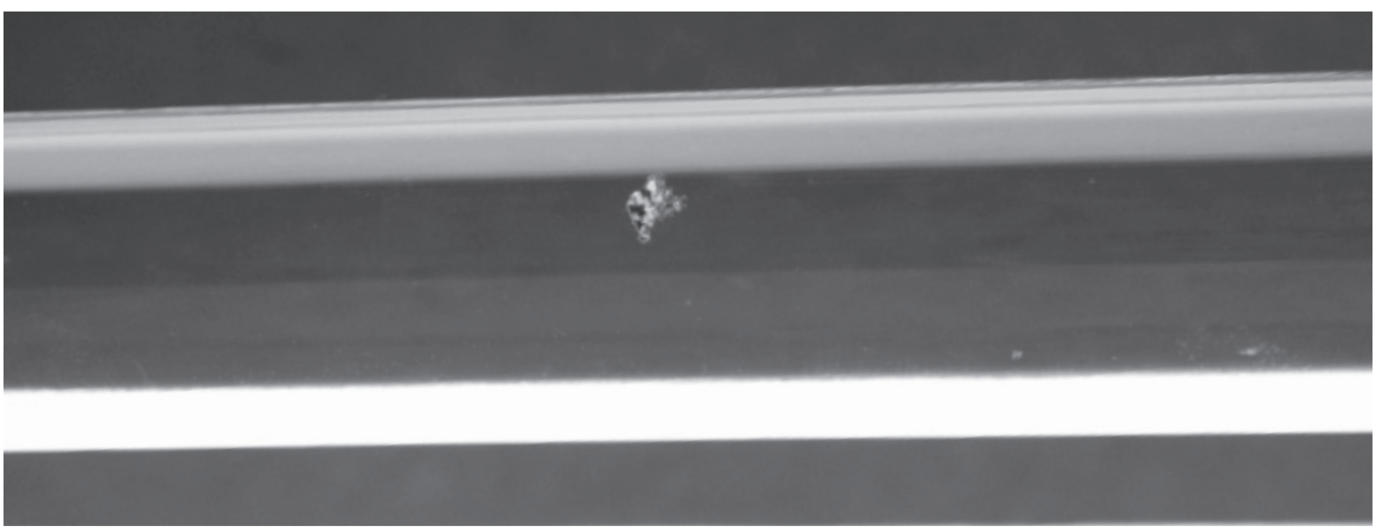
Surface Crack

Surface Impurities / Foreign Material

Definitions	Surface Impurity/ Foreign Material	This is any material adherent to the glass surface, that is foreign to the glass composition, such as dust, grease, oil, and other organic or inorganic material, which can be seen without magnification under normal lighting. Surface Impurities can be divided into different categories, such as Inner or Outer, removable or non-removable Surface Impurities (this is clarified on individual specifications).
	Size (S)	The diameter (or longest dimension) of the piece of the stain or spot as visually apparent from outside the tube.

Surface impurities / Foreign Material

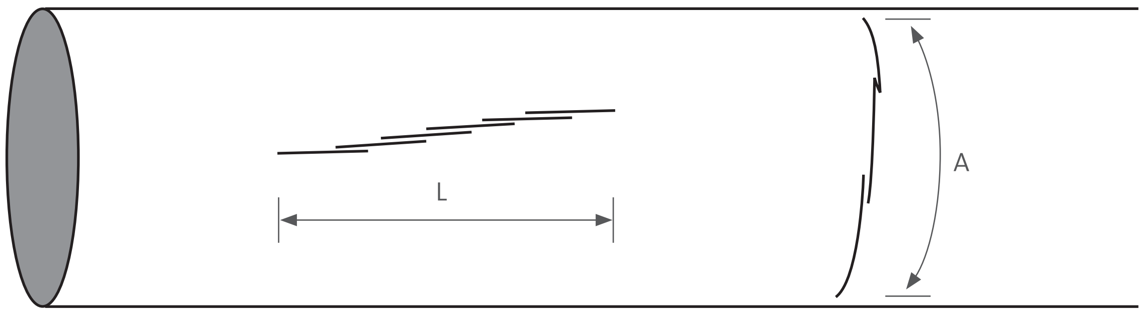




Scratches

Definitions

Scratches
The slight surface abrasions that do not penetrate the tubing wall.



Diagrams not to scale

Size
The size is measured with respect to the longitudinal and circular dimensions of the area occupied by the scratch.

Length (L) for longitudinal scratches

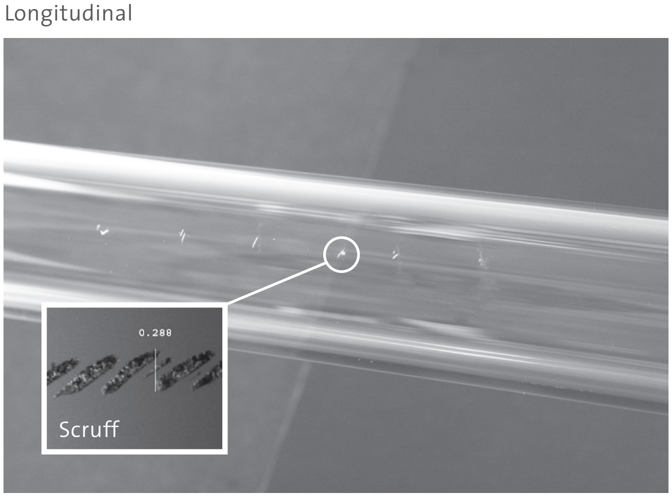
Arc (A) for circular ones (fraction of circumference)

Width
The width of the single Scratch. Can be better measured by means of a 10 x microscope.

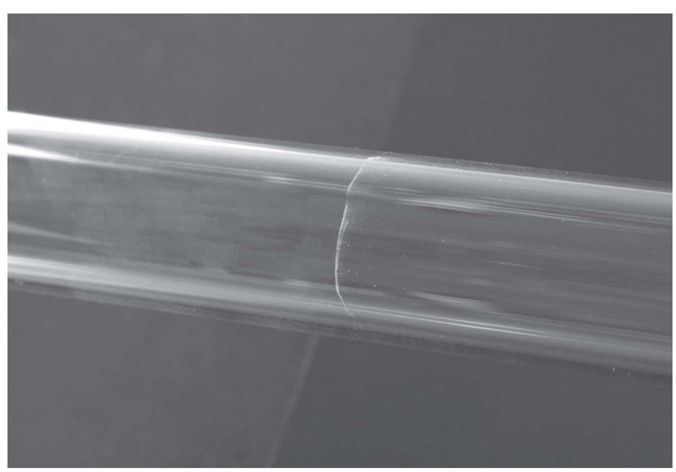
Aggregate Length
In case of multiple Scratches, the overall length (AL) shall be obtained by summing up the axial projection lengths of all Scratches wider than the specified minimum.

Scratches

Longitudinal

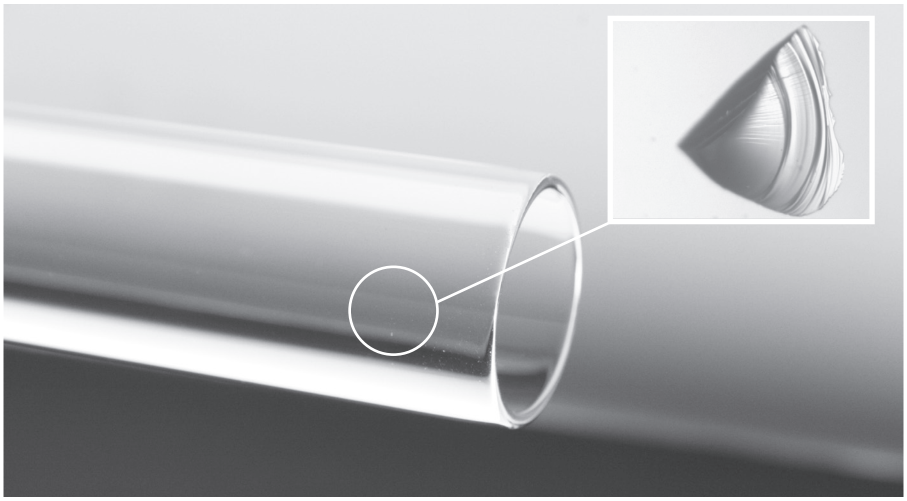


Circular



Glass Particles

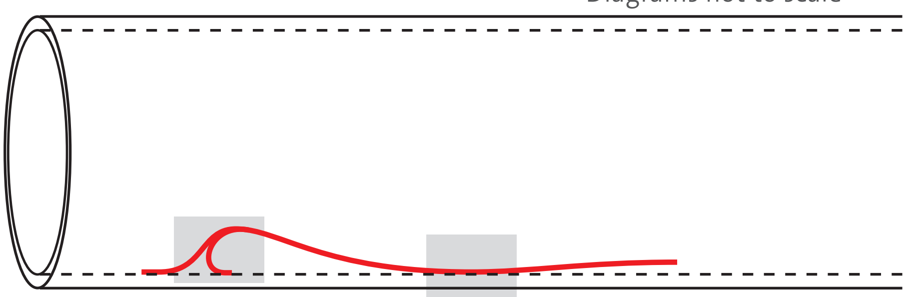
Definitions	Glass Particles	The fragments of glass inside the tube
	Particle Size (S)	The diameter (or longest dimension) of the fragment as visually apparent from outside the tube.

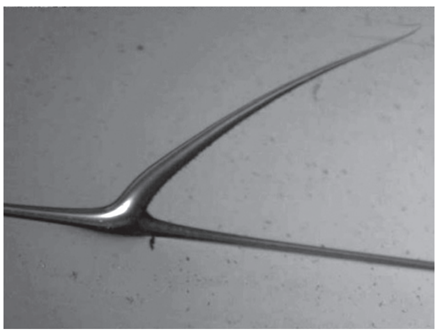


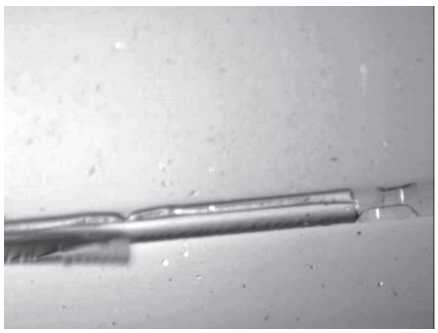
Glass Thread

Definitions	"Thread"	The elongated mass of glass, completely or partially sticking to the inner or outer surface of the tube.

Diagrams not to scale

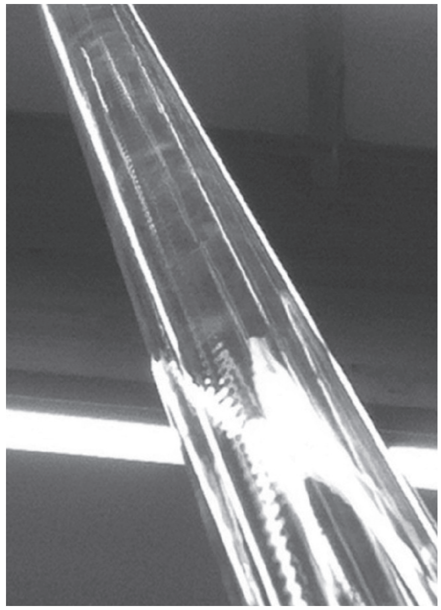


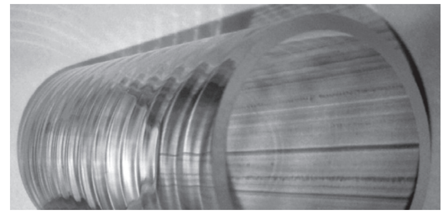




Pit Trail / Roller Marks

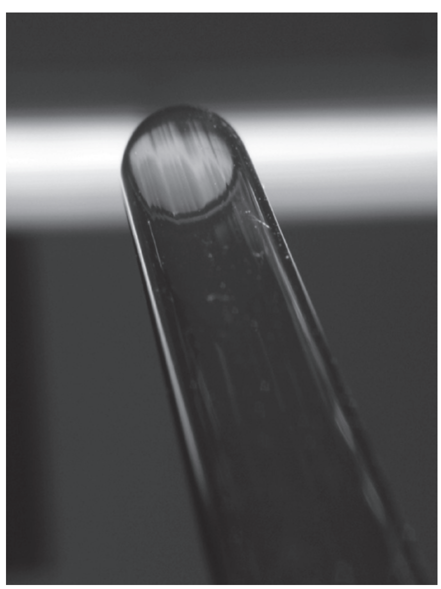
Definitions	Pit Trail / Roller Marks	Dimples in the glass that are positioned in a straight line, spaced a certain distance apart.





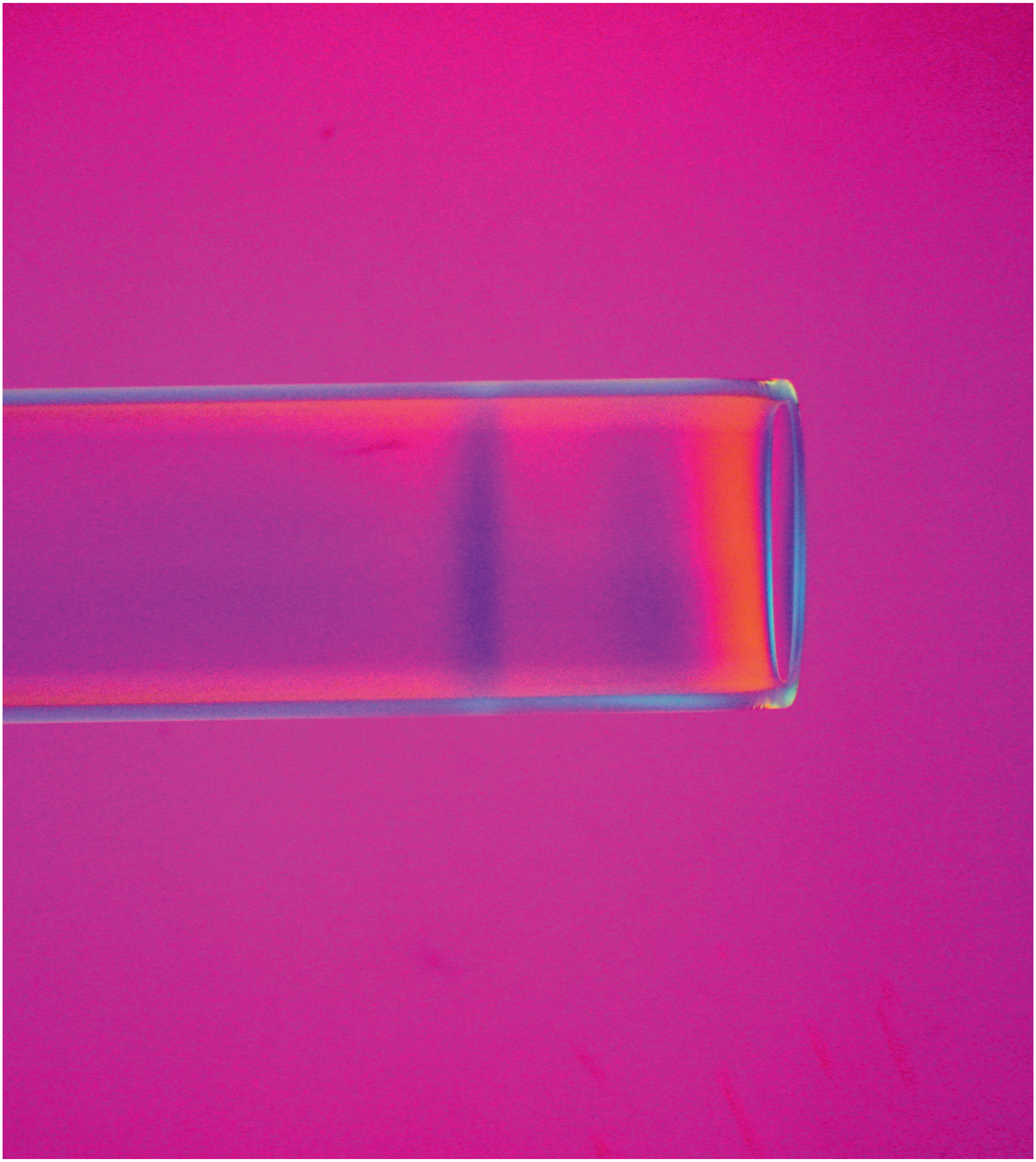
Paneling (Waving)

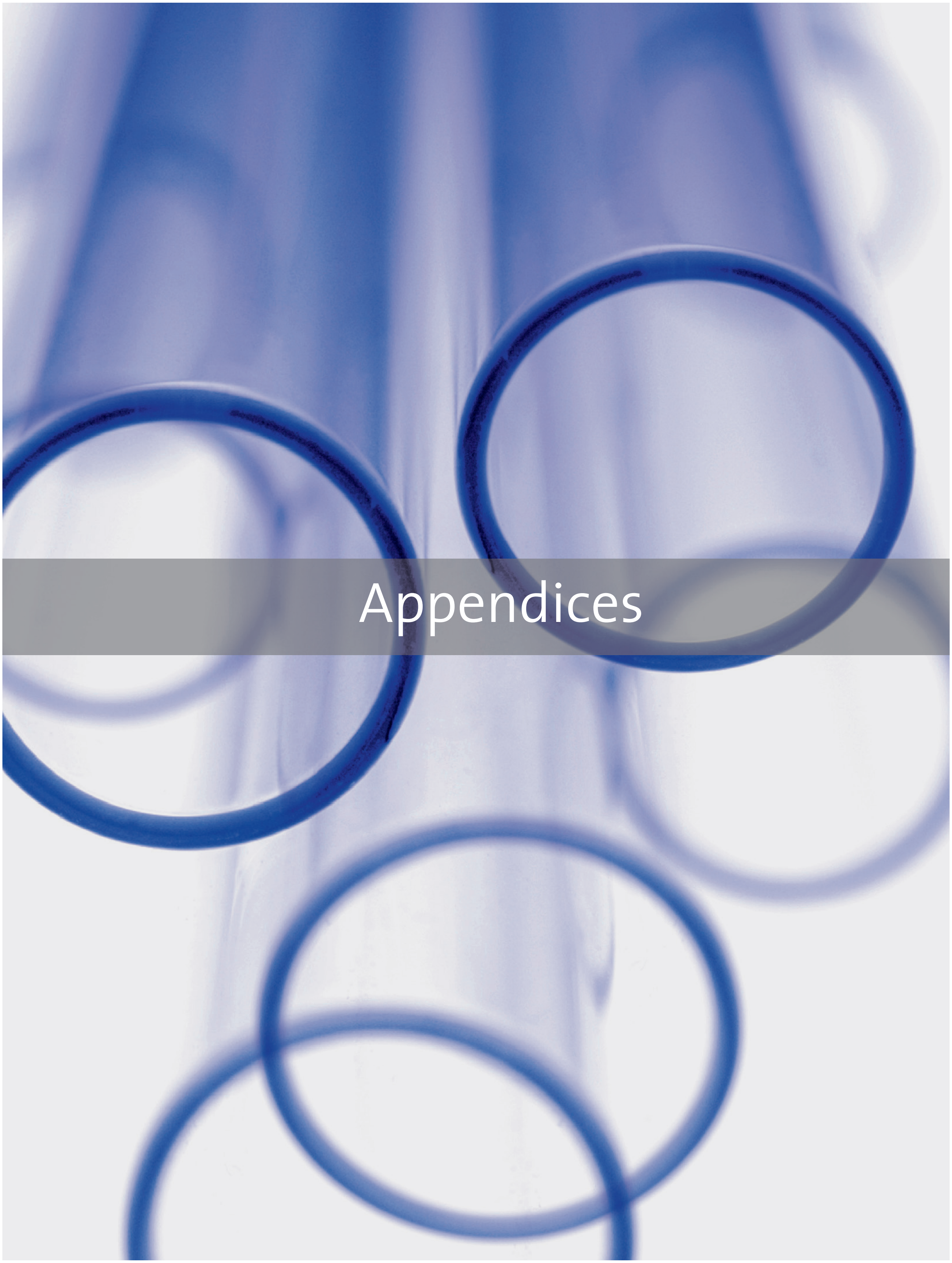
Definitions	Paneling (Waving)	The deviation of the transverse optical properties from the ideal case of "uniform glass and annular cross section", consistent along the tubing. The typical effect is the appearance of "wavy" patterns, when looking at a banded pattern in the background, across the tube, while same is being rotated.



Strain

Definitions	Strain	An elastic deformation caused by tensile and/or compressive forces existing within the glass.




Appendices

A. Sampling Methods and Tables

Generally the Single Sampling Plan, Normal Inspection (Level II) as described in ISO 2859 is used. For the sampling plan definition, and subsequent delivery acceptance or rejection, one batch is always defined to be one pallet, while the Test Unit is defined for each defect type according to the following guidelines.

Any local deviation of same in correspondence with knots or stones or other dimensionally relevant defects, shall not be considered defect with respect to the dimensional specification.

Sampling Table

Single Sampling Plans | Normal Inspection – Level II (from ISO 2859)

Batch Size N	AQL 0.025	AQL 0.10	AQL 0.25	AQL 0.40	AQL 0.65	AQL 1.0	AQL 1.5	AQL 2.5	AQL 4.0	AQL 6.5
from – to	n / AC	n / AC	n / AC	n / AC	n / AC	n / AC	n / AC	n / AC	n / AC	n / AC
1201 – 3200	500 / 0	125 / 0	200 / 1	125 / 1	125 / 2	125 / 3	125 / 5	125 / 7	125 / 10	125 / 14
3201 – 10000	500 / 0	125 / 0	200 / 1	200 / 2	200 / 3	200 / 5	20 / 7	200 / 10	200 / 14	200 / 21
10001 – 35000	500 / 0	500 / 1	315 / 2	315 / 3	315 / 5	315 / 7	315 / 10	315 / 14	315 / 21	200 / 21
35001 – 150000	500 / 0	500 / 1	500 / 3	500 / 5	500 / 7	500 / 10	500 / 14	500 / 21	315 / 21	200 / 21
150001 – 500000	500 / 0	800 / 2	800 / 5	800 / 7	800 / 10	800 / 14	800 / 21	500 / 21	315 / 21	200 / 21
▸ 500000	2000 / 1	1250 / 3	1250 / 7	1250 / 10	1250 / 14	1250 / 21	800 / 21	500 / 21	315 / 21	200 / 21

Batch — 1 pallet
n — Random sample size (number of testing units evaluated).
c — Acceptance figure (lot is accepted if number of defects in random sample is less than or equal to the acceptance figure).

BTU

The Basic Testing Unit (BTU or audit sample size) is a one tubing length. 5 kg random sample (500 TU of 10 grams each) should be used when Basic Testing Unit is not acknowledged under sample size.

Test Unit

1 tube. The sample must be extracted randomly as per same ISO 2859, Normal Inspection – Level II, sampling plan, from a minimum of three non-consecutive bundles. The batch size is the number of tubes in a pallet.

Test Unit

1 bundle. For evaluating packaging defects (e.g. labelling, plastic wrap), the sample will be as per same sampling plan of ISO 2859, randomly extracted from different rows of the pallet.

B. Chemical and Physical Characteristics

Glass Composition (approximate oxide weight [%])

Oxide Component	Symbol	Corning® 51-V	Corning® 51-D (*)	Corning® 51-L (Amber)	Corning® 33
Silicon Dioxide	SiO_2	72.0	73.0	69.0	80.0
Boron Oxide	B_2O_3	11.5	11.2	10.0	12.7
Aluminium Oxide	Al_2O_3	6.8	6.8	6.0	2.6
Calcium & Magnesium Oxide	CaO + MgO	0.7	1.0	1.0	< 0.1
Sodium Oxide	Na_2O	6.5	6.8	6.0	4.3
Potassium Oxide	K_2O	2.4	1.2	2.0	0.1
Iron Oxide	Fe_2O_3	< 600 ppm (**)	< 400 ppm (**)	1.0	< 500 ppm (**)
Barium Oxide	BaO	< 400 ppm (**)	< 400 ppm (**)	1.5	< 400 ppm (**)
Titanium Dioxide	TiO_2	< 400 ppm (**)	< 300 ppm (**)	3.0	< 400 ppm (**)

(*) Formulated for closed ampoules / (**) Not introduced in the batch composition

Chemical Resistance Classifications

Resistance Class	Specification	Gx®51-V	Gx®51-D	Gx®51-L	Gx®33
Hydrolytic Resistance (Glass Grain)	EP (3.2.1B) / USP <660>	Type I	Type I	Type I	Type I
Hydrolytic Resistance (Glass Grain)	ISO 720	HGA1	HGA1	HGA1	HGA1
Soluble Alkali Test	JP 7.01	Complies	Complies	Complies	Complies
Acid Resistance Class	DIN 12116	Class S1	Class S1	Class S1	Class S1
Alkali Resistance Class	ISO 695	Class A2	Class A2	Class A2	Class A2
ASTM Laboratory Glass Class	ASTM E 438	Class B	–	–	Class A

Physical Properties

Name	Unit	Corning® 51-V	Corning® 51-D	Corning® 51-L	Corning® 33
Average Linear T.E.C.	$10^{-7}\ K^{-1}$	54	51	53	32.5
Density	$g\ cm^{-3}$	2.33	2.34	2.37	2.23
Relative Refractive Index	(number) *	1.49	1.49	1.50	1.47

* λ at 587,6nm

Viscosity Curve — Characteristic Temperatures

Name	Viscosity [Poise]	Corning® 51-V	Corning® 51-D	Corning® 51-L	Corning® 33
Working Point	$10^{4.0}$	1130 °C	1155 °C	1140 °C	1240 °C
Softening Point	$10^{7.6}$	785 °C	777 °C	765 °C	825 °C
Annealing Point	$10^{13.0}$	570 °C	555 °C	550 °C	565 °C
Strain Point	$10^{14.5}$	525 °C	515 °C	515 °C	515 °C

Heavy Metals / Arsenic / Antimony

Heavy Metals

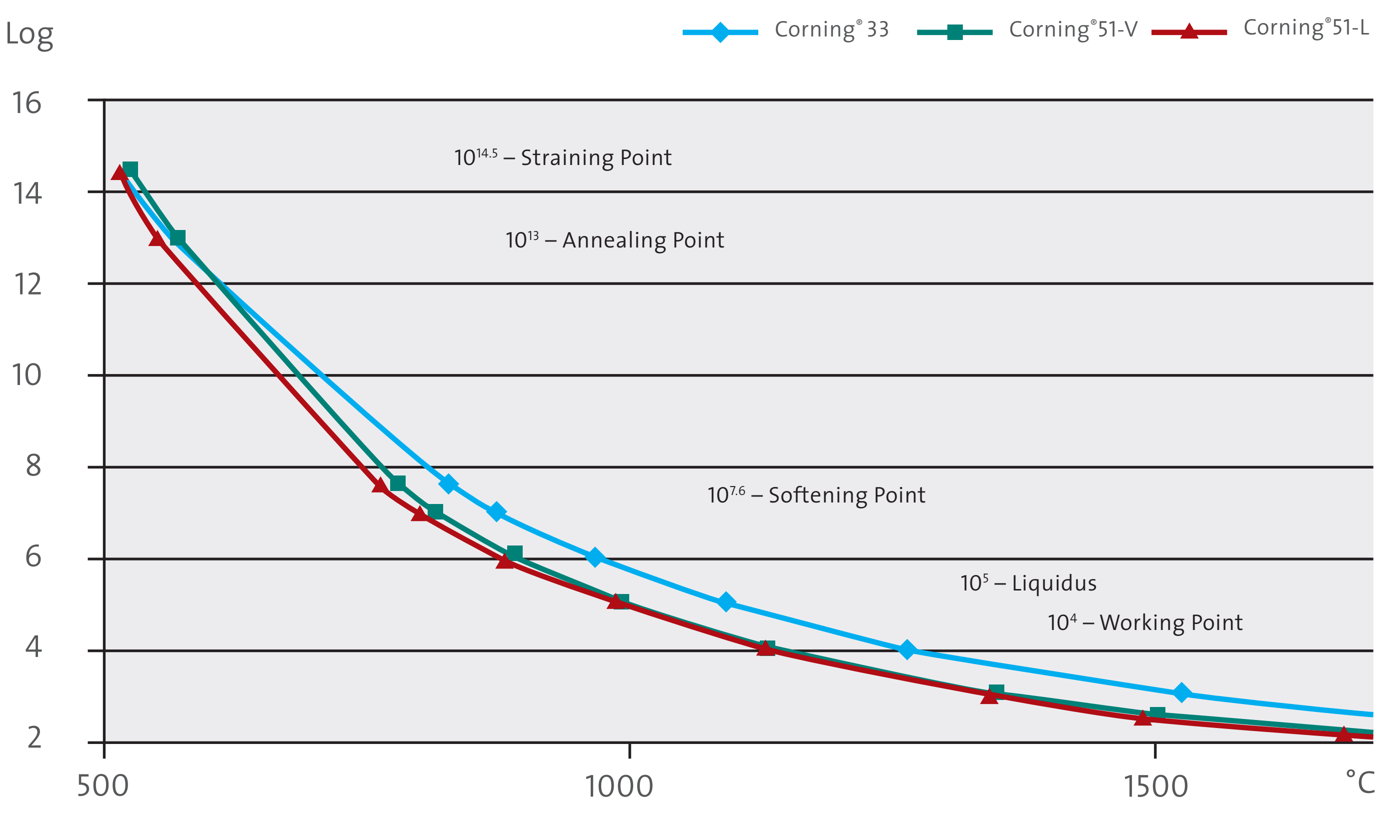
Contents of Pb, Cd, Hg, Cr^{VI} is below the 100 ppm limit value stated by the US Toxics in Packaging Clearing House (TPCH) and European Parliament and Council Directive Article 11 of 94/62/EC of 10. Dec. 1994 on packaging and packaging waste with updates 2001/171/EC and 2006/340/EC.

Arsenic and Antimony

Corning Pharmaceutical Glass does not introduce any arsenic nor antimony in the batch composition of its glasses. Tests performed as per U.S. and European Pharmacopoeia prescriptions on containers made from Corning Pharmaceutical Glass clear glass tubes give the following results:
As = Not detectable; Sb = Not detectable

B. Chemical and Physical Characteristics

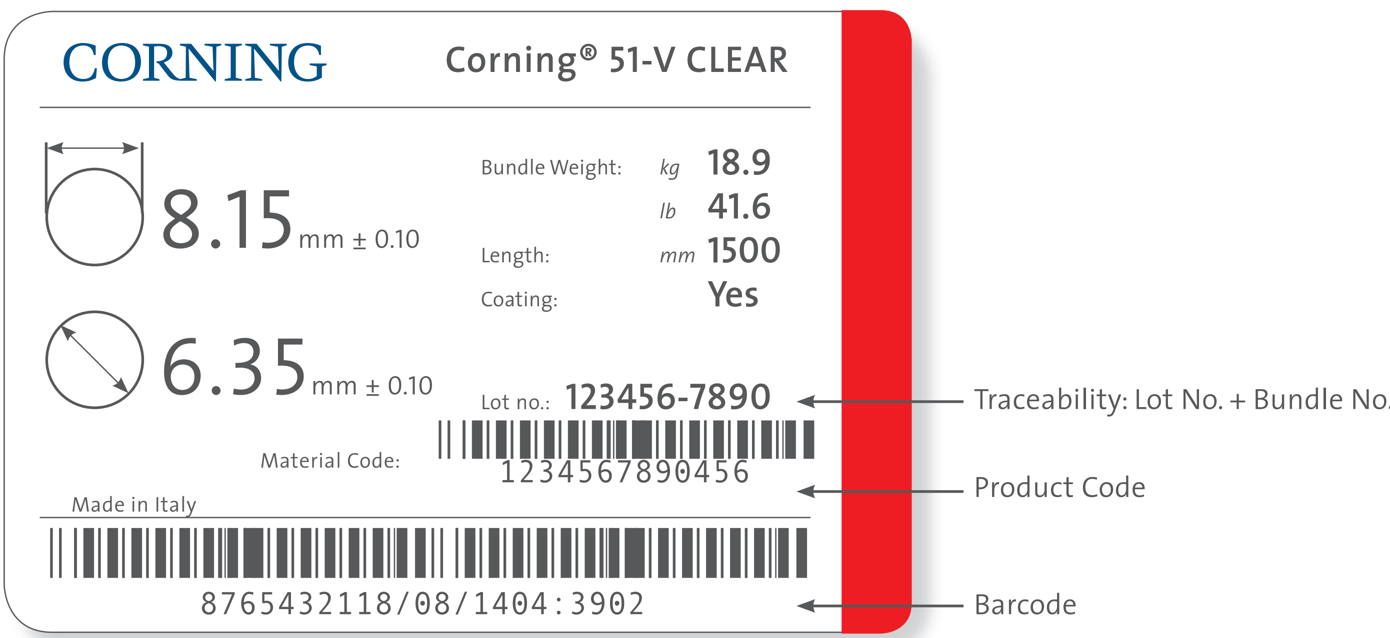
Definitions	Viscosity Curve	The temperature at which the glass reaches some defined levels of Viscosity. Those levels are conventionally defined, and their names refer to specific steps of the transforming process (ASTM Standard Method of Test C336-71). All values are given in °C.
	Working Point	The temperature at which the glass is sufficiently soft to be worked (formed, blowed, pressed, drawn). Log 4.
	Softening Point	The temperature that the glass deforms under its own weight. Log 7.6.
	Annealing Point	The temperature at which internal stresses, such as those caused by a rapid cooling process can be substantially eliminated in minutes. Log 13.
	Strain Point	The temperature where the internal stress of the glass is substantially relieved only after a matter of hours. Log 14.5.
	Average Linear Expansion Coefficient (T.E.C.)	The average length increase per unit length when the temperature varies from 0 to 300 °C. As the expansion coefficient is slightly affected by the annealing, reported values refer to annealed glass. Values are in K^{-1}.
	Density	The mass per unit volume. Values are in g cm^{-3}.
	Hydrolytic Resistance	The resistance index of the glass to Hydrolytic attack measured on a powdered or glass grain sample. The testing methods and limits for Type 1 glass are established by international pharmacopoeias (USP, EP, JP, and those related to same).



C. Traceability and Labelling — Corning Pharmaceutical Glass S.p.A. (Pisa)

Definitions	Finished Product Lot	A sequence of pallets consecutively manufactured on the same line with unchanged production specifications.
	Traceability	The unique six digit code Y A WW NN telling the production lot along with the bundle number. **Y** = Year Code **A** = Alley Code **WW** = Week Code **NN** =P rogressive Number
	Bundle Number	The progressive BBBB bundle number within the production lot. Complete bundle identification is therefore YAWWNN – BBBB.

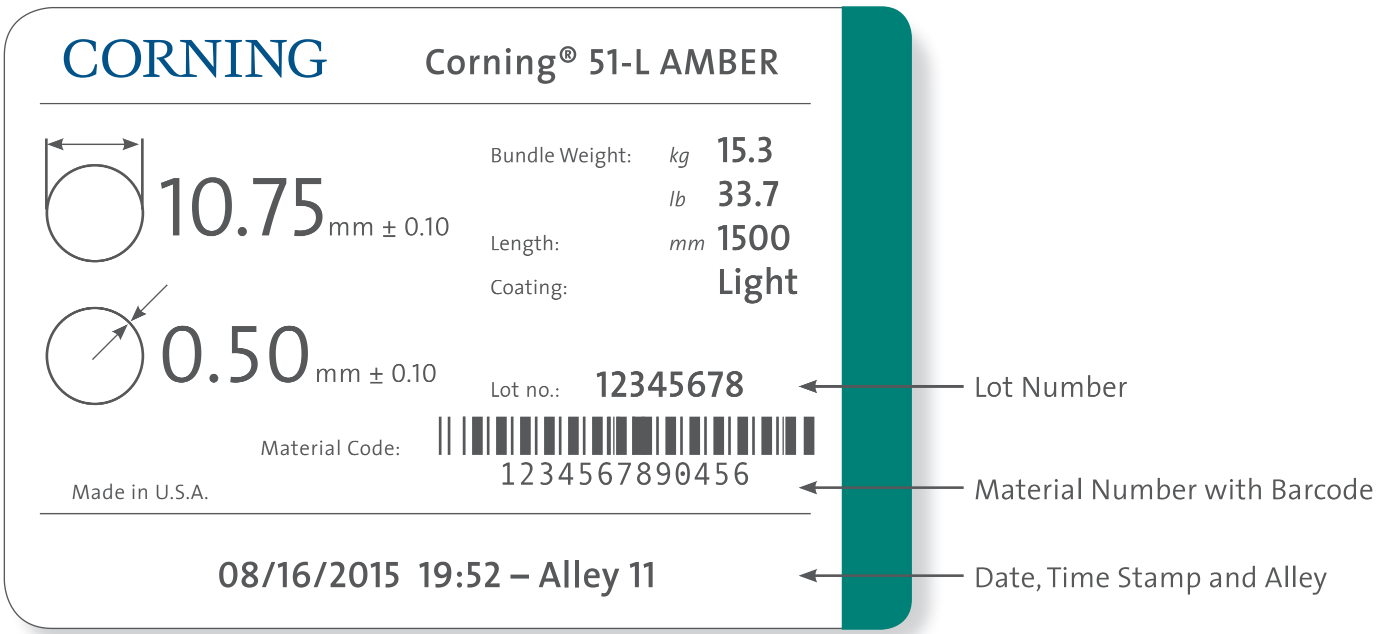
Bundle Label Sample



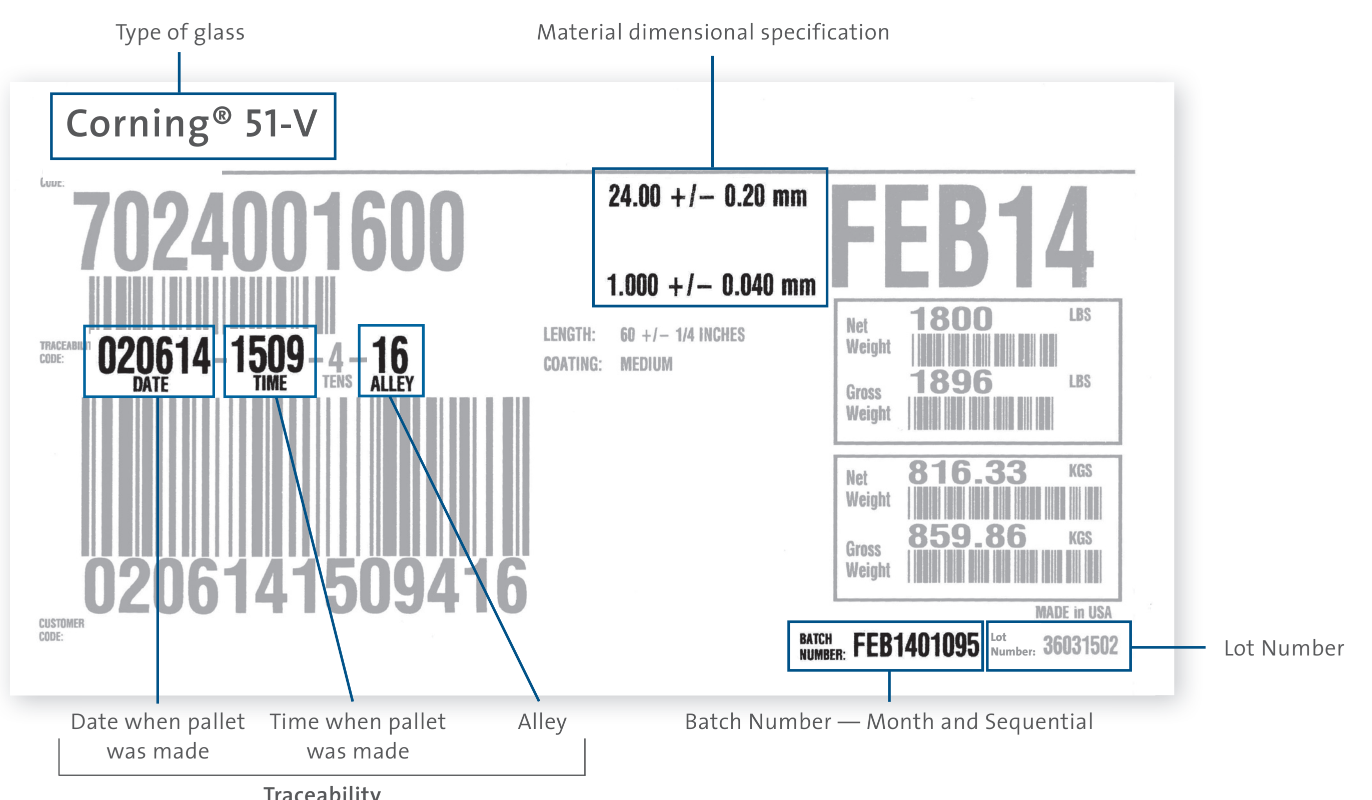
D. Traceability and Labelling — Corning Pharmaceutical Glass, LLC (Vineland)

Definitions	Finished Product Lot	A sequence of pallets consecutively manufactured on the same line with unchanged production specifications.
	Traceability	The big label contains unique thirteen digit code MMDDYY-HHMM-S-Alley.

Bundle Label Sample



U.S. Pallet Label Sample



Contacting Corning Pharmaceutical Glass

Do not hesitate to contact our local Sales and Quality departments:

Your Needs	Corning Pharmaceutical Glass S.p.A.	Corning Pharmaceutical Glass, LLC
Sales and Delivery Information	Tel. +39 050 566614 Fax +39 050 566334 E-mail: cpginfoeu@corning.com	Tel. +1 856 794 5592 Fax +1 856 494 1629 E-mail: cpginfousa@corning.com
Quality and Technical Inquiries	Tel. +39 050 566631 Fax +39 050 566334 Address Via Montelungo, 4 56122 Pisa, ITALY	Tel. +1 856 692 5981 Fax +1 856 691 1307 Address 563 Crystal Avenue Vineland, NJ 08360-3257, USA
	E-mail: cpgquality@corning.com	

Complaint Procedure

In case of complaints, please follow the steps below:

Identify the material by attaching the tray label or by specifying:

- Traceability Number
- Nominal Dimensions

Describe the issue:

- Kind of defect
- Describe how it was found (incoming inspection, in production, on the field)
- Quantify the frequency (pieces worked, pieces inspected, pieces defective)
- Quantify the issue: values and measurements should be obtained applying, whenever possible the definitions of this specification
- Localize the issue (in the pallet and/or in the tube) at your best

Document your findings:

- If possible, attach documents or pictures about the measured samples
- If possible, ship measured samples of suitable dimension and proper identification (including, if relevant, the position of them in the original whole tubing)

Please address the whole communication to our Quality Management Department preferably by e-mail with attachments, and ship the samples with reference to same e-mail (see the address above).

The forms found on pages 28 and 29 can be used to document any quality issues.

Complaint Procedure

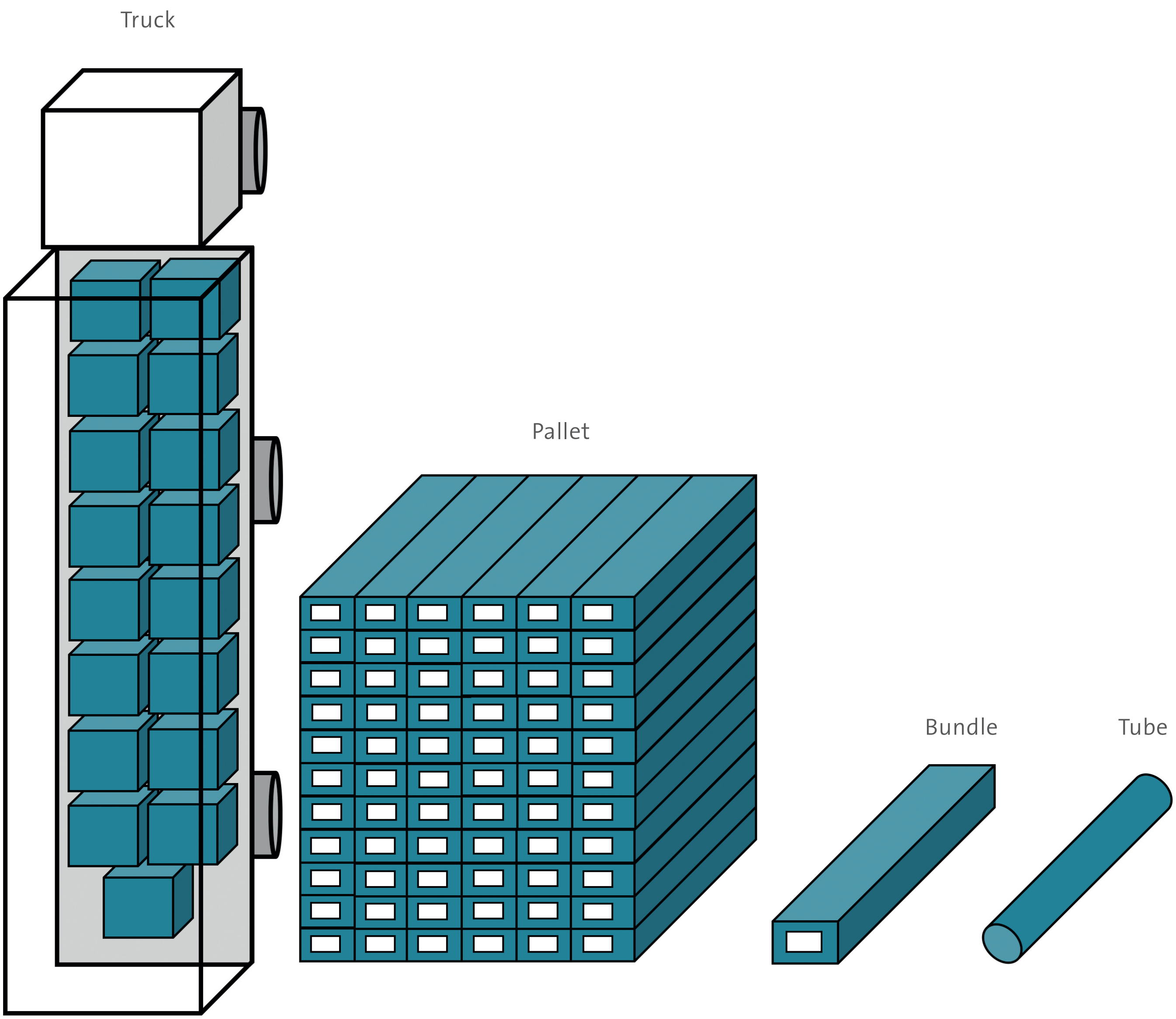
Tape	Data				
Traceability					
Nominal Dimensions	+/-	+/-	+/-		
Kind of defect					
Describe how it was found	Incoming inspection	Yes	No		
	In production	Yes	No		
	On the field	Yes	No		
Quantify the frequency	Pieces worked	N°			
	Pieces inspected	N°			
	Pieces defective	N°			
Quantify the issue	Kg	Lbs			
Localize the issue	Mark with “X“ the defect position (Page 29)				
Attach documents or pictures about the measured samples					
Ship measured samples of suitable dimension and proper identification (including, if relevant, the position of them in the original whole tubing)					

Please address the whole communication to our Quality Management Department preferably by email with attachments, and ship the samples with reference to same e-mail.

Corning Pharmaceutical Glass S.p.A.	Corning Pharmaceutical Glass, LLC
Via Montelungo, 4 56122 Pisa, ITALY	563 Crystal Avenue Vineland, NJ 08360-3257, USA
cpgquality@corning.com	cpgquality@corning.com

Localize the Complaint Issue

Please Mark with “X“ the Defect Position.



Notes

CORNING

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