

Generic Attributes Requirements Glass Vials

Refer to PDA TR43 Glass defect Lexicon for definitions.

AQL range criteria as listed in the tables below should be aligned with in-house finished product AQL expectations.

Critical AQL=0.025%-0.065%

Major AQL=0.40%-0.65%

minor AQL=1.50%-2.5%

<u>Category</u>	<u>Non-conformity</u>	<u>Location</u>	<u>Detection Method</u>
Critical (if seal is compromised)	Broken Finish	Finish	Visual
Critical (if seal integrity compromised)	Chipped Sealing Surface	Seal Surface	Visual
Critical (if internal & non-removable)	Contamination/ Foreign Material	General	Visual
Critical	Crack	General	Visual
Critical (if seal integrity is compromised)	Line Over Finish	Finish	Visual
Critical (if trapped)	Loose Glass	General	Visual
Critical (if seal is compromised)	Malformed	Finish	Visual
Critical (if seal integrity is compromised)	Ridge	Seal Surface	Visual
Critical	Spiticule	General	Visual
Critical (if not annealed)	Strain	General	Visual only in polarized light
Critical (if seal integrity is compromised)	Unfilled	Finish	Visual
Critical (if seal integrity is compromised)	Wavy Top	Seal Surface	Visual
Major if Seal is intact	Chipped Sealing Surface	Seal Surface	Visual
Major if Seal is intact	Line Over Finish	Finish	Visual
Major	Ring Off	Body	Visual
Major	Bent	Finish	Visual
Major if seal is intact	Broken Finish	Finish	Visual
Major	Check	General	Visual

Category	Non-conformity	Location	Detection Method
Major	Chipped	General	Visual
Major	Crizzle	Finish/Neck	Visual
Major	Flared	Bottom	Visual
Major if out of diameter	Flared Shoulder	Shoulder	Visual
Major if it causes handling concerns	Fused	General	Visual
Major	Heel Sticker	Heel	Visual
Major	Leaner	Bottom	Visual
Major	Lensing	Bottom	Visual
Major if seal is intact	Malformed	Finish	Visual
Major	Offset	Finish	Visual
Major if seal is intact	Ridge	Seal Surface	Visual
Major	Rocker	Bottom	Visual
Major	Sunken Neck	Neck	Visual
Major if seal is intact	Unfilled	Finish	Visual
Major if seal is intact	Wavy Top	Seal Surface	Visual
Major	Splits (OD to ID)	Finish	Visual
Major	Score Lines	Neck	Visual
Major	Stuck Glass	General	Visual
Minor, if > 0.25 mm wide and full length	Airline	Body	Visual
Minor	Belt Marks	General	Visual
Minor or N/A	Bruise	General	Visual
Minor	Bubble	General	Visual
Minor or N/A	Bulls-Eye	Bottom	Visual
Minor > 0.5mm	Bump Check	General	Visual
Minor if external (non-removable)	Contamination	General	Visual
Minor	Fire Check	Finish	Visual
Minor	Frost	Finish	Visual
Minor if removable	Fused	General	Visual
Minor and > 1mm	Knot	General	Visual
Minor	Lap	Finish	Visual
Minor	Lehr Sticker	Body	Visual
Minor if removable	Loose Glass	General	Visual
Minor	Malformed Shoulder	Shoulder	Visual
Minor or N/A	Orange Peel	General	Visual
Minor or N/A	Pressure Mark	Finish	Visual
Minor or N/A	Re-Boil	General	Visual
Minor or N/A	Rippled Shoulder	Shoulder	Visual
Minor if > 0.2mm wide, full body length or exceeds 360 degrees	Scratch	Body, Edge, or Side	Visual
Minor or N/A	Scuff	Body	Visual

<u>Category</u>	<u>Non-conformity</u>	<u>Location</u>	<u>Detection Method</u>
Minor or N/A	Smoke	Body	Visual
Minor and > 1mm	Stone	General	Visual
Minor	Tooling Mark	Finish	Visual
Minor or N/A	Twisted	Finish	Visual
Minor	Uneven Shoulder	Shoulder	Visual
Minor or N/A	Wavy	Bottom	Visual
Major	ID-Min Thru-Choke	Finish	Dimensional
Major	I.D. (0.093")	Finish	Dimensional
Major	O.D. or "T" Dimension	Finish	Dimensional
Major	Lip Thickness	Neck	Dimensional
Major	Length	Body	Dimensional
Major	Core	Finish	Dimensional
Major	Sulfur Treatment	Body	Dimensional /Visual
Major	"H" Dimension	Neck	Dimensional
Major	Heel Radius	Between Body & Bottom	Dimensional
Major	Shoulder Angle Radius	Shoulder	Dimensional
Minor	Bottom Thickness	Bottom	Dimensional
Major	Bottom Concavity	Bottom	Dimensional
Major	Body O.D.	Body	Dimensional

Additional Dimensional Requirements which may be critical

<u>Category</u>	<u>Non-conformity</u>	<u>Location</u>	<u>Detection Method</u>
Critical	Overall Vial Length (L)	Finish	Dimensional
Critical	Body OD (D)	Finish	Dimensional
Critical	Finish ID (I)	Finish	Dimensional
Critical	Neck aperture	Finish	Dimensional
Critical	Finish OD Top	Finish	Dimensional
Critical	Finish to Shoulder (H)	Finish	Dimensional
Critical	Lip Thickness	Finish	Dimensional