



1640 South West Boulevard Vineland NJ 08360

Tel(856)691-1697, Fax (856)691-4525

Internet: <http://www.richlandglass.com>

Email: Sales@richlandglass.com

Glass Vial:

Quality Assurance Acceptance Criteria

Issue Date: 05/18/2011

Revision No: 1.0

Replaces Revision No: none

This program defines the procedures for sampling and inspection and criteria for acceptance applicable to glass vials supplied by the Richland Glass Company. Where applicable, this program has been tailored to the specific requirements of the Customer's end use products and is consistent with industry standards.

I. Sampling Criteria

- A. Unless otherwise as agreed upon between Richland Glass and our customer, product shall be sampled in accordance with the current ANSI/ASQ Z1.4 sampling plan.
- B. A "lot" or unit for inspection is a given quantity of glass vials of the same item delivered as one shipment. This shipment lot may be all or part of a purchase order or production run.
- C. Normal Level II Inspection Level base on shipment lot will be applied.
- D. Other sampling levels or lot definitions may be employed by the customer for their own purposes and inspection economics; however, Richland Glass recognizes the above plan as criteria for rejection or acceptance which is consistent with industry standards.

II. Inspection Criteria

Inspection covers three basic areas for conformity to specification, i.e. Physical (dimensional), Functional (test) and Visual criteria.

1. Physical (dimensional) characteristics include color, shape and dimensions for each glass vial.
 - a. An approved Richland Glass drawing with dimensional tolerances is part of the purchase agreement.
 - b. Applicable physical characteristics will be verified with appropriate gauges, instruments, and measuring techniques.

- c. Richland Glass will work with the customer to determine characteristics that are considered Critical to Quality and if necessary, assure that customer and Richland Glass gage reproducibility and repeatability (R&R) values are within acceptable ranges.
2. Functional (test) characteristics include certain tests for glass types such as those listed in the U.S. Pharmacopeia (USP) Chemical Assays.
3. Visual Characteristics include flaws and imperfections inherent with glass vials.
 - a. Many visual conditions are not necessarily nonconforming and are subject to human judgment. Appropriate limit samples are established, where required, to assist in that judgment.
 - b. Limit samples are defined as the maximum conditions allowable for acceptance. Items not exceeding the limit are classified as acceptable.

III. Acceptance Criteria Definitions

NOTE: Richland Glass takes into consideration customer product needs and Richland's process capabilities.

A. Classification of Non-Conformities:

1. Critical – A non-conformity that judgment and experience indicate may result in a hazardous or unsafe condition during its manufacturing cycle or its end use.
2. Major A – A non-conformity that may result in a functional failure of the vial or render it unusable for its intended purpose.
3. Major B – A non-conformity that may affect the usability of the vial but is more easily detected through visual observation, or is self-eliminating.
4. Minor – A non-conformity that is usually aesthetic in nature and may detract from overall appearance, but doesn't affect usability of the item or process capability.

B. Non-Conforming Product(s) are those products outside the Acceptable Quality Limit (AQL). The Acceptable Quality Limit (AQL) is the maximum percent of non-conforming product that can be considered acceptable as a process average.

C. The designation of an AQL shall not imply that Richland Glass knowingly supplies any defective items. The nature of our processes is such that non-conformities are produced; however, the processes and inspections are designed to maintain the defect rates below AQL levels.

D. Using the AQL as an incoming sampling plan, the method of sampling will be based on the general inspection level II, single sampling plan table (Table II-A) for normal inspection as presented in the ANSI/ASQ Z1.4-2003 Sampling Procedures and Tables for Inspections by Attributes.

IV. A.Q.L Classification of Defect for Glass Vials

- A. Critical – 0.0% AQL
 1. Annealing – Strain
 2. Mixed or incorrect item
 3. Wrong glass or color
 4. Incorrect pack or label

- B. Major A – 0.4% AQL
 1. Body – Ring Off
 2. Trapped glass
 3. Fused or loose inside glass particulate (other than obvious transit damage)
 4. Split finish
 5. Fire cracks
 6. Contamination – Interior – Non-removable

- C. Dimensions – 0.65% AQL
 1. All out of tolerance drawing dimensions that would impair the use of vial.

- D. Major B – 0.65% AQL
 1. Line over finish (forms a channel completely across the sealing surface breaking both radii).
 2. Chipped sealing surface
 3. Checked finishes
 4. Convex or rocky bottoms – limit sample
 5. Unfilled/warped finish – limit sample
 6. Bottom thickness
 7. Leaner or bent necks > 1.5 degrees
 8. Slack Finish – malformed or subject to leak test
 9. Malformed vials
 10. Lehr marks
 11. Contamination – exterior – non-removable
 12. Frost – limit sample
 13. Bump checks > 0.5mm

- E. Minor – 2.5%
 1. Airlines > 0.010" (0.25mm)
 2. Stones > 0.030" (0.76mm)
 3. Knots > 0,060" (1.52mm)
 4. Scratches – limit samples
 5. Twisted necks
 6. Malformed shoulder
 7. Out of round > 10% of target dimension

Acceptance Criteria Notes:

1. The acceptance criteria are based on the incoming inspection process and as per agreed AQL limits above.
2. If nonconforming product is found subsequent to the incoming inspection process, it will be determined again if the product meets the intended AQL. If the product meets the intended AQL, the product will be considered acceptable material.
3. Under minimum or over maximum "T" dimension at some point on the circumference is not unusual in the glass vial forming process. This particular condition will usually not affect function and is considered acceptable. The "T" dimension is calculated by taking the average of two "T" dimensional measurements on a vial. The first measurement is taken and the second measurement is to be taken 90 degrees from the first measurement location. The recorded result will be the average of the two measurements.
4. Under minimum or over maximum "ID" dimension at some point on the circumference is not unusual in the glass vial forming process. This particular condition will usually not affect function and is considered acceptable. The "ID" dimension is calculated by taking the average of two "ID" dimensional measurements on a vial. The first measurement is taken and the second measurement is to be taken 90 degrees from the first measurement location. The recorded result will be the average of the two measurements.
5. Visual defects that do not have proper mutually agreed upon limit samples are subject to functionality evaluation and mutually agreed upon future limit samples establishment.
6. Statements that appear on drawings with no associated control levels are for reference only.

History of Revisions:

Revision	Section	Description of Change
1	--	New Document

Customer:

Signed: _____ Date: _____

Print Name: _____

Title: _____

Company Name: _____