

Technical Report No. 43 (Revised 2013)

Identification and Classification of
Nonconformities in Molded and Tubular Glass
Containers for Pharmaceutical Manufacturing:
Covering Ampoules, Bottles, Cartridges,
Syringes and Vials

2013



PDA Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing: Covering Ampoules, Bottles, Cartridges, Syringes and Vials

Technical Report Team

Authors

Nicholas R. DeBello , Wheaton Industries Inc. (Co-Chair)	Linda Lesh , Nipro Glass Americas
Michael N. Eakins, PhD , Eakins & Associates (Co-Chair)	Kevin McLean , SGD North America
Roger Asselta , Genesis Packaging Technologies (Syringe Subteam Chair)	Michael McMaster , Gerresheimer Glass Inc.
Luis Baez, PhD , Amgen Inc.	Sarvang Mishra , Biogen Idec Inc.
Kevin Bailey , Assem-Pak, Inc.	Thomas Pamukcoglu , Medimmune LLC
Anthony Bantug , Baxter Healthcare Corp.	Anthony Perry , Schott North America, Inc. (Vial Subteam Chair)
John Berggren , Reokace with SiO ₂ Medical Products	Wesley Prais , BD Medical-Pharmaceutical Systems
Alfred B. Breunig , Nipro Glass Germany AG	Scott Ramseyer , CLS Behring
Juan Cerdan-Diaz, PhD , Nipro Glass Americas	Markus Riffel , Vetter Pharma-Fertigung GmbH & Co. KG
Stuart Chambers , GE Healthcare	Kishan Rijal, PhD , Sanofi Pasteur
Jack Cheeseman , Gerresheimer Glass Inc.	Tilman Roedle , Vetter Pharma-Fertigung GmbH & Co. KG
David Davidow , Davidow and Associates	Suzanne Seeley , Merck & Company, Inc.
Mads Espersen , Novo Nordisk A/S	Chris A. Sellards , Schott North America, Inc.
Peter Gassmann, PhD , Cilag AG	Barbara H. Sneade , Grifols Therapeutics Inc.
Stanley B. Hall , Pfizer Inc. (retired)	Rob Swift , Amgen Inc.
Rick Heckaman , Heckaman & Associates	Li-Chun Tsou, PhD , Merck & Company, Inc.
Hans Thomas Hemrich , Sanofi-Aventis	David Walker, PhD , Merck & Company, Inc.
Raj Jani , Baxter Healthcare Corporation	David Weiser , Schott North America, Inc.
Alessandro Landi , Stevanato Group	Hans Woerder , Hawe Packing Consulting
Mark Leney, PhD , MassBiologics	Kirk Wolff , Eli Lilly and Company

Disclaimer: The content and views expressed in this Technical Report are the result of a consensus achieved by the authorizing technical report team members and are not necessarily views of the organizations they represent.

Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing: Covering Ampoules, Bottles, Cartridges, Syringes and Vials

Technical Report No. 43 (Revised 2013)

ISBN: 978-0-939459-59-9

© 2013 Parenteral Drug Association, Inc.

All rights reserved.



Table of Contents

<p>1.0 INTRODUCTION 1</p> <p style="padding-left: 20px;">1.1 Purpose and Scope..... 1</p> <p>2.0 GLOSSARY OF TERMS 2</p> <p>3.0 GLASS CONTAINER CONFORMANCE SPECIFICATION DEVELOPMENT PROCESS 4</p> <p style="padding-left: 20px;">3.1 Glass Container Dimensional Development 4</p> <p style="padding-left: 20px;">3.2 Glass Container Sampling..... 4</p> <p style="padding-left: 40px;">3.2.1 Definition of Lots..... 5</p> <p style="padding-left: 40px;">3.2.2 Sampling Plans..... 5</p> <p style="padding-left: 60px;">3.2.2.1 Continuous Sampling..... 6</p> <p style="padding-left: 60px;">3.2.2.2 Lot-to-Lot Sampling 6</p> <p style="padding-left: 60px;">3.2.2.3 Defective Parts Per Million 7</p> <p style="padding-left: 40px;">3.2.3 AQLs..... 7</p> <p>4.0 GLASS NONCONFORMITIES LEXICONS 10</p> <p style="padding-left: 20px;">4.1 Molded Glass Container Lexicon 10</p> <p style="padding-left: 20px;">4.2 Tubular Glass Container Lexicons 16</p>	<p style="padding-left: 20px;">4.2.1 Vials..... 16</p> <p style="padding-left: 20px;">4.2.2 Ampoules 21</p> <p style="padding-left: 20px;">4.2.3 Cartridges..... 25</p> <p style="padding-left: 20px;">4.2.4 Syringes 30</p> <p>4.3 Reinspection of Glass Containers 34</p> <p>4.4 Documentation and Training..... 34</p> <p>5.0 CONCLUSION..... 35</p> <p>6.0 APPENDICES 36</p> <p style="padding-left: 20px;">6.1 Molded Glass Container Lexicon..... 36</p> <p style="padding-left: 20px;">6.2 Tubular Glass Container Lexicon: Vials..... 70</p> <p style="padding-left: 20px;">6.3 Tubular Glass Container Lexicon: Ampoules 98</p> <p style="padding-left: 20px;">6.4 Tubular Glass Container Lexicon: Cartridges.. 129</p> <p style="padding-left: 20px;">6.5 Tubular Glass Container Lexicon: Syringes 155</p> <p>7.0 REFERENCES 182</p> <p>8.0 ADDITIONAL READING 183</p>
---	--

FIGURES AND TABLES INDEX

<p>Table 3.2.3-1 Examples of True AQL Values for Accept on Zero, Reject on One. $P_a = 95\%$..... 8</p> <p>Table 4.1-1 Molded Glass Container Lexicon: Bottles and Vials..... 11</p> <p>Figure 4.1-1 Molded Bottle Lexicon Example A..... 15</p> <p>Figure 4.1-2 Molded Bottle Lexicon Example B..... 15</p> <p>Table 4.2.1-1 Tubular Glass Container Lexicon: Vials 16</p> <p>Figure 4.2.1-1 Tubular Vials Lexicon Example A 20</p> <p>Figure 4.2.1-2 Tubular Vials Lexicon Example B 20</p> <p>Table 4.2.2-1 Tubular Glass Container Lexicon: Ampoules 21</p> <p>Figure 4.2.2-1 Tubular Glass Ampoules Lexicon Example A 25</p>	<p>Figure 4.2.2-2 Tubular Glass Ampoules Lexicon: Example B 25</p> <p>Table 4.2.3-1 Tubular Glass Container Lexicon: Cartridges..... 26</p> <p>Figure 4.2.3-1 Tubular Glass Cartridge Lexicon: Example A 29</p> <p>Figure 4.2.3-2 Tubular Glass Cartridge Lexicon: Example B 29</p> <p>Table 4.2.4-1 Tubular Glass Container Lexicon: Syringes 30</p> <p>Figure 4.2.4-1 Tubular Glass Syringe Lexicon: Example A 33</p> <p>Figure 4.2.4-2 Tubular Glass Syringe Lexicon: Example B 33</p>
---	--

1.0 Introduction

Pharmaceutical and biopharmaceutical companies and glass manufacturers have made quality decisions based on visual inspections of glass containers without the aid of universal guidelines or standards. Inconsistency in defining glass-container nonconformities has resulted in a lack of clarity within the pharmaceutical/biopharmaceutical industry. This inconsistency has also resulted in a non-uniform approach in meeting regulatory expectations to deliver high-quality pharmaceutical products.

PDA members recognized the need to provide guidance for the identification and classification of glass-container nonconformities in the form of a consensus-based technical report. A Technical Report Team was formed to represent a broad cross-section of glass and pharmaceutical manufacturing professionals and to create a consensus document.

This document provides an approach to a quality decision-making process and represents best practices for identification and classification of visual nonconformities for glass containers.

1.1 Purpose and Scope

The standardized quality criteria in this document are intended as guidance for component manufacturers and for incoming inspection at pharmaceutical companies. While the defect identification will remain the same, the quality criteria used for filled containers will likely differ. Five detailed lexicons (**Appendices 6.1-6.5**) that visually illustrate glass nonconformities have been developed: one for molded glass bottles and vials and four for tubular glass vials, ampoules, cartridges, and syringes. The photographs and drawings for the molded and tubular glass containers in this technical report and the lexicons were collected by the glass task force subteams.

The identification and classification of glass imperfections represent only a part of the overall criteria, which include, but are not limited to, adherence to dimensional standards, an incoming lot sampling program, acceptable quality limits, and reinspection. This technical report provides the building blocks for developing an overall supplier quality agreement for these glass containers.

These guidelines are not intended to establish mandatory standards for classification and identification of glass nonconformities; they are intended to be a single-source overview that complements existing guidelines and standards or documents listed in the reference section. For greater detail on various topics throughout this technical report, additional reading has been provided. It is always advisable to consult with the appropriate regulatory authorities for agreement on the strategies employed for identification and classification of visual nonconformities of glass containers.