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

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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.