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Identification and Classification of Nonconformities in Moulded and Tubular Glass Containers for Pharmaceutical Manufacturing

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1.0 Introduction

PDA *Technical Report No. 43 (Revised 2023): Identification and Classification of Nonconformities in Moulded and Tubular Glass Containers for Pharmaceutical Manufacturing* provides an updated approach to a quality decision-making process and represents best practices for the identification and classification of visual nonconformities for glass containers.

This technical report was originally published in 2007 and applied only to moulded bottles and tubular vials. The document was revised in 2013 to address industry feedback; that revision expanded to include other tubular container types and increased the focus on container quality by the industry as a whole. The 2023 revision is issued to address evolving standards and container types, including:

- Reduced reliance on limit samples that require visual consensus and are difficult to maintain in a manufacturing environment. Instead, additional guidance is provided on minimum sizes identified for nonconformities.
- Harmonized risk levels assigned to defects associated with glass particles based on contemporary risk assessment information that address the use of containers by the majority of drug manufacturers.
- Broader concepts on ready-to-use (RTU) vials and cartridges covering steps previously completed by pharmaceutical manufacturers that some glass suppliers are now performing. Due to their introduction directly into the pharmaceutical filling environment, RTU formats require different standards for particular types of defect.
- Minor changes in descriptions throughout the lexicons to help improve the precise identification of nonconformities.
- Additional information in the lexicons to include locations and possible sources of defects.
- Standardized terminology for defect classifications, replacing the term "N/A" with "acceptable imperfection."
- Condensed lexicons that removed some defects or combined similar defects; for example, "Residual Stress" defects were eliminated as they were considered out of scope for this visual defect reference.

1.1 Purpose

The standardized quality criteria in TR-43 are intended as guidance for container manufacturers and for incoming container acceptance inspection at pharmaceutical companies. The attributes identified in this lexicon are not intended to represent the defect after a theoretical extrapolation of further damage during processing, rather just the defect when discovered. While defect identification remains the same, the quality criteria used for filled containers will likely differ. Five detailed lexicons have been updated which visually illustrate glass nonconformities—one for moulded glass bottles and vials, and four for tubular glass vials, ampoules, cartridges, and syringes (see **Section 8.0** (Appendix)). Additionally, defects specific to RTU containers and their categorization are included for use as applicable. Consulting with the appropriate regulatory authorities for agreement on the strategies employed for identification and classification of visual nonconformities of glass containers is always advisable.

The identification and classification of glass imperfections represents only a part of the overall acceptance criteria for glass utilized for pharmaceutical products. Other aspects include adherence to dimensional standards, visual nonconformance inspection programs, acceptable quality limits, and reinspection. This technical report provides some of the building blocks for developing overall specifications for glass containers.

1.2 Scope

These guidelines are not intended to establish mandatory standards for the classification and identification of glass nonconformities but, instead, are intended to provide an overview that complements existing guidelines, standards, and referenced materials. Additional reading (See **Section 7.0**) has been suggested that can provide greater detail on the various topics discussed in this technical report.