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⟨790⟩ VISIBLE PARTICULATES IN INJECTIONS

INTRODUCTION

All products intended for parenteral administration must be visually inspected for the presence of particulate matter as specified in *Injections and Implanted Drug Products* ⟨1⟩. Dry solids, from which constituted solutions are prepared for injection, meet the requirements for *Completeness and clarity of solutions* in *Injections and Implanted Drug Products* ⟨1⟩ when they are prepared just before use. Where used in this chapter, the term *essentially free* means that when injectable drug products are inspected as described herein, no more than the specified number of units may be observed to contain visible particulates. Particulate matter is defined in *Particulate Matter in Injections* ⟨788⟩ as extraneous mobile undissolved particles, other than gas bubbles, unintentionally present in solutions. See *Subvisible Particulate Matter in Therapeutic Protein Injections* ⟨787⟩ for additional information on inherent, intrinsic, and extrinsic particulates. Examples of such particulate matter include, but are not limited to, fibers, glass, metal, elastomeric materials, and precipitates. However, some products may contain inherent particles or agglomerates; in such cases, requirements for these particular visible particulates are specified in the individual monograph or in the approved regulatory application but the control and acceptance criteria for extraneous particles described in this chapter apply.

Where the nature of the contents or the container–closure system permits only limited capability for inspection of the total contents, the 100% inspection of a batch shall be supplemented with the inspection of constituted (e.g., dried) or withdrawn (e.g., dark amber container, suspensions, highly colored liquids) contents of a sample of containers from the batch. The destructive nature of these tests requires the use of a sample smaller[1] than those traditionally used for non-destructive acceptance sampling after 100% inspection. Although the tests described in this chapter may be useful during studies to examine product stability, this chapter is not intended to establish any new testing requirements for stability studies.

INSPECTION PROCEDURE

Used along with 100% inspection during the manufacturing process, this procedure is sufficient to demonstrate that the batch is essentially free of visible particulates. A complete program for the control and monitoring of particulate matter remains an essential prerequisite.

Inspected units must be free of visible particulates when examined without magnification (except for optical correction as may be required to establish normal vision) against a black background and against a white background. Illumination at the inspection point is maintained at a minimum intensity between 2000 and 3750 lux. This can be achieved through the use of two 13-W or 15-W fluorescent lamps (e.g., F13/T5 or F15/T8). The use of a high-frequency ballast to reduce flicker from the fluorescent lamps is recommended. Alternative light sources (e.g., incandescent, LED) that provide illumination at the point of inspection within the specified minimum intensity range are acceptable. Higher illumination intensity is recommended for examination of colored solutions or product in containers other than clear glass.

Before performing the inspection, remove any adherent labels from the container, and wash and dry the outside. The unit under inspection should be gently swirled and/or inverted, ensuring that no air bubbles are produced, and inspected for approximately 5 s against each of the backgrounds. The presence of any particles should be recorded.

Sampling at Batch Release (After 100% Manufacturing Inspection)

Sample and inspect the batch using ANSI/ASQ Z1.4 (or ISO 2859-1). General Inspection Level II, single sampling plans for normal inspection with an AQL of 0.65%. Alternative sampling plans with equivalent or better protection are acceptable. NMT the specified number of units contains visible particulates.

Product in Distribution[2]

If it becomes necessary to evaluate product that has been shipped to customers (e.g., because of a complaint or regulatory concern), sample and inspect 20 units. If no particles are observed in the sample, the batch is considered essentially free of visible particulates. If available, additional units may be inspected to gain further information on the risk of particulates in the batch.

[1] The special level sampling plans described in ANSI/ASQ Z1.4–2008 or ISO 2859 are appropriate to guide the selection of sample size and acceptance criteria for this purpose.

[2] Testing outlined in *Product in Distribution* is permissible only if *Sampling at Batch Release (after 100% Manufacturing Inspection)* has been successfully completed.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
<790> VISIBLE PARTICULATES IN INJECTIONS	Desmond G. Hunt Principal Scientific Liaison	GCDF2020 General Chapters - Dosage Forms 2020

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