

Visual Inspection Guide

Our sterile filtration products are used in critical applications such as the sterilization of injectable drugs. We strive to deliver products that meet our customers' performance expectations and manufacture our sterilizing grade products in ISO 8 / ISO 7 certified controlled rooms to maximize particle control. Before release, every cartridge filter is subject to visual inspection as a standard component of quality testing. The procedures for inspecting cartridge filters are summarized below:

- All inspectors must pass the visual acuity test per our Visual Acuity policy.
- Lighting in the inspection area should be 150–200 foot candles.
- Inspection is performed by holding the cartridge approximately 12–16 inches away so that the line of sight is perpendicular to the cartridge and free of shadows and glare.
- Inspection time is based on the size of the cartridge (**Table 1**).
- Any cartridge that is dropped or subjected to physical impact must be rejected.
- Our Jaffrey, New Hampshire facility uses calibrated TAPPI charts* (**Figure 1**) to measure perceived loose, trapped, and embedded foreign matter.

*Jaffrey Manufacturing purchase TAPPI charts from Choyokai®

Table 1. Inspection Time by Cartridge Size

Cartridge Size (inches)	Inspection Time (sec)
5 or smaller	5–20
10	10–30
20, 30, and 40	20–90

Figure 1. TAPPI Chart Example



Key Inspection Definitions

Particle Type	Definition
Loose Particles / Foreign Matter	Foreign material that can be wiped off or moves easily
Embedded Foreign Matter	Specks that are embedded or encapsulated in a cartridge molded plastic component
Bubbles	Air pockets in the molded material

Inspection Criteria

Perceived Defect	Accept / Reject	Example
Hair	REJECT ALL	
Loose Particles / Foreign Material	ACCEPT if $\leq 0.2 \text{ mm}^2$ REJECT if $> 0.2 \text{ mm}^2$	
Embedded Particles	ACCEPT if $\leq 0.5 \text{ mm}^2$ on the TAPPI scale REJECT if $> 0.5 \text{ mm}^2$ on the TAPPI scale	
Clustered Embedded Foreign Matter	REJECT if a cluster of four (4) or more embedded particles $\leq 0.5 \text{ mm}^2$ in size within a 1" diameter	
Surface Material	REJECT visible foreign surface material (e.g., grease, rust, ink, or dirt).	
Bubbles in Adapter Bonds	ACCEPT fully encapsulated "hard" bubbles upstream or downstream of the adapter bond.	
	REJECT soft "airy" bubbles upstream or downstream of the adapter bond.	

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