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Dye Migration Tests - Medistri

Dye Migration Tests

Medical device manufacturers need to ensure the integrity of packaging seals. One of the key methods employed to verify seal integrity is the Dye Migration Test. This test, governed by standards such as ASTM F1929 and F3039, utilizes a brightly colored dye to visually detect any channels or leaks in the package seal. The process involves filling the package with a dye solution, subjecting it to conditions that might cause the dye to migrate through potential leaks, and then inspecting the package for any evidence of seal failure. The Dye Migration Test is an essential part of quality control processes, helping manufacturers ensure that their packaging is secure and reliable, thereby maintaining the sterility of the medical device until use.

Dye migration is a test in which liquid dye is introduced inside the package. The package is then rotated until all seals have been exposed to the dye. If a channel of dye is visible through the seal, it indicates an open channel in the seal of the package and a breach of integrity. The dye used in the Dye Migration Test is typically a strong color that can easily be seen if it leaks.

👉 The Dye Migration Test is a method used to determine the integrity of the package seal. It helps manufacturers identify if there are any leak channels in the pouch seal.

Dye Migration Testing is crucial for several reasons:

- Package Integrity.
- Quality Control.
- Safety.
- Compliance.
- Consumer Confidence.

Here's a brief overview of the process:

- 1. Preparation:** The package is filled with a dye solution. The type of dye used can vary, but it's typically a strong color that can easily be seen if it leaks.
- 2. Testing:** The package is then subjected to conditions that might cause the dye to migrate or move through any potential leaks in the seal. This could involve placing weight on the solution against the seal for less than 5 seconds.
- 3. Inspection:** After the test, the package is examined for evidence of seal failure. If dye is found outside of the intended area, it indicates that there is a leak in the seal.

The absence of dye penetration suggests that the package maintains its integrity under the tested conditions. This means that the package is likely to keep its contents secure and uncontaminated, which is especially important for medical packaging. However, it's important to note that this test is qualitative and does not measure the size of the leak.

ASTM F1929 is a standard test method for detecting seal leaks in porous medical packaging by dye penetration. It defines materials and procedures that will detect and locate a leak equal to or greater than a channel formed by a 50 µm (0.002 in.) wire in package edge seals formed between a transparent material and a porous sheet material. A dye penetrant solution is applied locally to the seal edge to be tested for leaks. After contact with the dye penetrant for a specified time, the package is visually inspected for dye penetration. This test method is intended for use on packages with edge seals formed between a transparent material and a porous sheet material.

On the other hand, ASTM F3039 is a standard test method for detecting leaks in nonporous packaging or flexible barrier materials by dye penetration. It defines a procedure that will detect and locate a leak equal to or greater than a channel formed by a 50 µm (0.002 in.) wire in the edge seals of a nonporous package. A dye penetrant solution is applied locally to the seal edge to be tested for leaks. After contact with the dye penetrant for a minimum specified time, the package is visually inspected for dye penetration or, preferably, the seal edge is placed against an absorbent surface and the surface inspected for staining from the dye.

Should you fully validate your packaging system or should you simply test one particular characteristic of your packaging, Medistri laboratory is accredited and highly experienced to work with the ASTM Standards, helping your company avoiding risks.

🌐 To learn more about Medistri's Dye Migration Test, visit on our website [here](#) or directly contact our team at contact@medistri.swiss.

- The Medistri Team

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