

Reference : CHANGE NOTICE No. MB/13/04

Subject : Change in Certificate of Quality for mdi M-Funnel

Scope : This change notification will affect the following Clauses of the Certificate of Quality:

- Sterility Test : Re-structured and updated
- Microbial Recovery Test : Added
- Inhibitory Effect of Ink Grid : Added
- Package Integrity Test : Added
- EO Residual Level : Added
- Biosafety : Removed

Background:

In our efforts to inform the user about more relevant and properly structured information regarding the products they use, it has been decided to make certain changes in the contents of the Certificate of Quality for mdi M-Funnel.

Need for Change:

As above.

How Does It Affect the User:

From a practical point of view this change notification will provide more relevant and properly structured information regarding the products. All performance specifications and product attributes remain unchanged.

- **Sterility Test:** This test is being done on each and every lot produced. The test has been re-structured as per United States Pharmacopoeia (USP) and updated in Certificate of Quality.
- **Microbial Recovery Test:** The product has been validated for Microbial Recovery as per ISO 7704: Water Quality – Evaluation of membrane filter used for microbiological analysis. To provide the user relevant information regarding the product, this test has been added in Certificate of Quality.
- **Inhibitory Effect of Ink Grid:** The product has been validated for Inhibitory Effect of Ink Grid as per ASTM D4200-82: Standard test method for evaluating inhibitory effect of ink grids on membrane filters. To provide the user relevant information regarding the product, this test has been added in Certificate of Quality.

- **Package Integrity:** Each and every produced lot has been tested for Package Integrity as per ASTM F1929-98: Standard test method for detecting seal leaks in porous medical packaging by Dye Penetration Test. To provide the user relevant information regarding the product, this test has been added in Certificate of Quality.
- **EO Residual Level:** The product has been validated for EO Residual Level. To provide the user relevant information regarding the product, this test has been added in Certificate of Quality.
- **Biosafety:** This test has been removed from Certificate of Quality as this test is not relevant to the product.

Effective Date:

mdi M-Funnel shipped after 12th December, 2013 will have Certificate of Quality with said changes.

In case you have any queries, please feel free to contact our Technical Support Team at 'mdi@vsnl.com'.



Quality Assurance
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