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Summa quality in sterile pharmaceutical manufacturing
Qualité summa en fabrication stérile de médicaments

Rapport sur l'évaluation biologique des valves
unidirectionnelles de non-retour de type MedXL
VALV4FLLMLL à l'aide d'un bactériophage staphylococcique
(Traduction anglaise de l'introduction, objectif et conclusion)

NUMÉRO DE RAPPORT
RVL-004

Département
Laboratoire de Microbiologie

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INTRODUCTION

This report assesses the effectiveness of MedXL one-way valves of type VALV4FLLMLL to prevent contamination by a patient of sterile solutions or drugs in multiple doses injected upstream of this valve.

The internal protocol described below was followed for the most part. This protocol was designed to assess the ability of MedXL valves of type VALV4FLLMLL to prevent contamination of sterile solutions or drugs in multiple doses.

This protocol consists of filling the tubing set with a saline solution, to perform on the valve in question three pressure tests with a syringe containing bacteriophages and, finally, check for the presence of these bacteriophages upstream of the valve after each pressure test.

OBJECTIVE

Ensure MedXL valves of type VALV4FLLMLL are able to prevent backflow and contamination of sterile solutions or drugs in multiple doses injected into patients.

Verified by: Melissa Babin

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Approved by: Annie Aubé

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We certified that this document is the exact translation of the original document.

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CONCLUSION

To evaluate the MedXL one-way anti-reflux valves, several steps were necessary. First, the preparation of a strain of *Staphylococcus aureus* ATCC 27696 (host strain of the bacteriophage). Secondly, the preparation of the bacteriophage, where we inoculate several tubes of broth to obtain a large amount of bacteriophages, followed by its quantification enabling us to determine how many bacteriophages our initial suspension contained and thus ensure a sufficiently high concentration ($> 10^6$ PFU / mL) to see whether bacteriophages were able to cross the one-way valve. Then, the pressure resistance tests on the valves, where one subjects a series of 12 valves to three pressure tests of one minute each in order to ascertain whether they can resist to the pressure and prevent contamination upstream of the valve. Finally, the verification of samples taken during the pressure resistance tests on the valves that indicate whether bacteriophages are able to cross the one-way valve.

Table 3 shows all results for the MedXL valves of type VALV4FLLMLL. We can see that the positive control samples before each of the valve tests, all show lysis plaques (growth of the bacteriophage). This shows that the bacteriophages were viable before proceeding to the three pressure resistance tests of each valve. In the negative control column (sample taken upstream of the valve before the three pressure tests), we can see that no lysis plaques were observed for each of the valves, thus demonstrating the absence of contamination before the pressure tests. The table also shows the results of samples collected upstream of the one-way valve after each of the three pressure tests. No lysis plaques were observed in these samples, demonstrating that the bacteriophages have not traversed the valve. In the same table, we can also see the positive control results after the pressure tests. These samples indicate the validity of the analysis. In fact, the presence of growth (lysis plaques) in these samples demonstrates the viability of bacteriophages after the series of pressure tests. This means that if the bacteriophages were able to move upstream of the valves as a result of pressure tests, we could see their presence as they were viable after the three tests.

Since all the samples collected upstream of the valves did not show the presence of lysis plaques and all the positive and negative controls are conforming, thus confirming the validity of this analysis, we conclude that the MedXL unidirectional valves of type VALV4FLLMLL are effective to prevent backflow and the contamination of sterile solutions or drugs injected in multiple doses to patients.

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