

## CLEANING and SANITIZATION of FURON® UPM 1000 VALVES

The equipment used in many analytical applications must be periodically cleaned and sanitized to control contamination by bacteria and their residues, especially pyrogens. Each component in the analytical equipment must be able to withstand the cleaning and sanitization procedures. A major OEM manufacturer of high performance liquid chromatography systems has demonstrated that Furon® UPM 1000 valves can be cleaned, disinfected, and depyrogenated using standard procedures.

### TEST METHOD

A chromatography system containing a UPM valve was inoculated with a 24-hour suspension of *Streptococcus pyogenes* (ATCC No. 19615) in saline. After the system was cleaned and sanitized, its effluent was tested for the presence of bacteria. The system was depyrogenated and tested for endotoxin using a BioWhittaker Kinetic-QCL endotoxin assay kit and controls. The tests were performed in duplicate.

**Cleaning procedure:** A chromatography system containing a UPM 1000 valve was cleaned for 30 minutes with recirculating 0.2 M NaOH at 45-50°C. Cleaning was followed by a rinse with sterile deionized water until pH returned to neutral. The system then was sanitized with 200 ppm NaOCl at 25 °C and rinsed with sterile neutralizing buffer until no residual chlorine could be detected.

**Depyrogenation procedure:** A chromatography system was rinsed three times with pyrogen-free water (PFW). A clean-in-place (CIP) step using recirculated 0.2M NaOH at 45 °C for 30 minutes was followed by a second triplicate PFW rinse. Samples were taken for pyrogen analysis after the first PFW rinse and after the CIP/PFW rinse.

### RESULTS

The *Streptococcus pyogenes* count was reduced by more than 99.9999% (greater than 6 logs removal) by the cleaning and sanitization procedure (Table 1).

| Sample           | Bacterial Count (CFU/ml) |
|------------------|--------------------------|
| Initial inoculum | 1.07 x 10 <sup>3</sup>   |
| Test 1           | 25                       |
| Test 2           | 17                       |

**Table 1:** Bacterial reduction due to cleaning and sanitization procedure

After inoculation, endotoxin concentrations were greater than 80 EU/ml in the system effluent. The triplicate PFW rinse reduced the endotoxin levels to 0.015-0.024 EU/ml. The CIP/PFW rinse reduced the endotoxin levels further to less than 0.005 EU/ml.

| Sample                  | Endotoxin level (EU/ml) |        |
|-------------------------|-------------------------|--------|
|                         | Test 1                  | Test 2 |
| Initial endotoxin level | 80.24                   | 86.176 |
| After PFW rinse         | 0.017-0.024             | 0.015  |
| After CIP/PFW rinse     | <0.005                  | <0.005 |

**Table 2:** Endotoxin levels measured before and after depyrogenation procedure

## SUMMARY

Furon® UPM 1000 valves can be successfully cleaned and sanitized using standard laboratory procedures. Tests performed by a major manufacturer of chromatography equipment resulted in a 6-log reduction in the concentration of *Streptococcus pyogenes*. Similarly, a standard depyrogenation procedure reduced endotoxin concentration to less than 0.005 EU/ml.

## REFERENCES

ASTM F 838-83, pp. 982-986, 1988.

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