ClorDiSys

Application Note #9

ß-Lactam Inactivation Utilizing Chlorine Dioxide Gas

Abstract:

Chlorine dioxide gas is proven effective against ß-lactams(beta-lactams), and can inactive them on equipment or in rooms so that there is no risk of allergic exposure. Chlorine dioxide, as a true gas, will reach all areas of your room and equipment surfaces. After inactivation, equipment can be used for non-beta-lactam pharmaceutical products with no risk of contamination.

Background:

There is no official approved method for decontamination of beta-lactams from the FDA. The method used must stand up based on analytical testing and quality controls (QC's) under controlled experiments and in field test samples. The decontamination process that ClorDiSys utilizes was originally validated as described in the attached ABSA article. This was performed with a pharmaceutical customer, a consultant (Dr. Voyksner[1]) that specializes in beta-lactams, and an outside laboratory. The validation consisted of a series of cycles with varying chlorine dioxide dosages that were tested to achieve a 3-log inactivation of 8 different beta-lactams. The 8 beta-lactams were mixed together and inoculated into grooves on coupons made of stainless steel, Lexan, and aluminum. These materials were considered to be commonplace and cover the range of materials in most pharmaceutical facilities. The grooves were machined in and were considered to represent hard-to-reach crevices.

Process:

The on-site decontamination process consists of setting up the generation and humidification equipment and sealing the area with tape and plastic. This preparation typically takes from a few hours to two days dependent on the facility volume and the degree of sealing required. The actual decontamination event will take approximately 12 hours. A report is issued upon completion documenting the event including all process parameters.

Results:

ClorDiSys does not perform post exposure testing nor do we guarantee inactivation since we are not knowledgeable of the actual make-up of a customer's proprietary beta-lactam. In-house or outside testing labs should be utilized to verify the post exposure inactivation. Because of the proprietary nature of beta-lactams, ClorDiSys' guarantee is that the process parameters used for the validated cycle will be achieved. Numerous beta-lactam decontamination projects have been performed and all customer post-treatment analyses have been satisfactory. Dr. Voyksner has performed experiments with ClO_2 gas on different surfaces and for different facilities and has submitted the reports to the FDA with approval of the results. All of the decontaminations performed were with large pharmaceutical companies with confidentiality agreements in place so individual results cannot be shared. ClorDiSys does guarantee that the ppm-hour dosage that customers have verified to be effective will be achieved. ClorDiSys can work with your consulting and lab team or the designer of the original validation studies to perform both pre-exposure and post-exposure testing if requested.

Reference: [1]Robert D. Voyksner Ph.D., LCMS Limited, PO Box 27228, Raleigh, NC 27611-7228, 919-403-7711 Office, 919-201-0047 Cell, robert.voyksner@reliont.com, www.lcmslimited.com