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Contents and abstracts

Update on TSEs

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The July issue of the Journal1 contained a review of the then current situation with regard to transmissible spongiform encephalopathies (TSEs). Since that time, there has been much activity, both within the UK and throughout the European Union (EU), to seek a sensible resolution of the

problems which legislative proposals in relation to TSE pose for the European pharmaceutical industry.

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Bacillus cereus PHG 5/11 in the microbiological process control of sterilisation methods

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The pharmaceutical industry employs a wide range of biological indicators for microbiological process control. These include streptococci, staphylococci and Bacillus subtilis, used for checking the effectiveness of thermal and chemical disinfection; microbial populations found in the actual working environment, for testing the efficiency of disinfectants and disinfection procedures, and Bacillus pumilus for checking the radiation sterilisation of substances, such as starting materials used in the aseptic manufacture of a drug product.1

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Clean steam

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There are no uniform official definitions of different steam qualities for use in the pharmaceutical industry. Some properties for the steam and feed water to be used for sterilisers in the healthcare sector are defined in the European Standard EN 2851 (Table 1). As well as this, the UK National Health Service (NHS) Estates Health Technical Memorandum, HTM 2031 (in draft) suggests certain characteristics for production of pharmaceutical products2 (Table 2).

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The measurement of total organic carbon (TOC) and conductivity in USP 23 grade pharmaceutical water

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Some 10 years ago now, questions concerning water quality and product recalls caused the water quality committee (WQC) of the then US Pharmaceutical Manufacturers' Association (PMA) to consider updating the testing of its Purified Water and Water for Injection. For although water is the most widely used excipient in the pharmaceutical industry, most of the methods used to confirm its quality were over 100 years old, and one or two had been in the United States Pharmacopeia (the USP) since 1840.1 This paper charts the developments which led to the appearance in November 1996 of new recommendations on water, contained in the Fifth Supplement of USP 23, and discusses some modern testing techniques.

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Contents and abstracts

Commentary: validation of novel methods of sterilisation

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Recent changes in occupational safety and health legislation — along with the development of smaller and more complex medical devices and instruments, the toxicity of residuals and the resistance of micro-organisms to traditional methods of sterilisation — have led to the emergence of alternative technologies for sterilisation in the healthcare setting. These include ion plasma sterilisation, electron beam sterilisation and pure bright pulsed light sterilisation. To be recognised as viable methods of sterilisation, these new technologies should be monitored easily and reproducibly by either physical, chemical or biological indicators.

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Development and practical application of high-frequency wave (microwave) continuous steriliser

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The development of electronics technology has led to 'mechatronics' in mechanical equipment of all kinds in recent years. In particular, many machines with automatic control now contain an embedded processor, and machinery for manufacturing pharmaceuticals similarly features higher speed and improved performance. Meanwhile, Good Manufacturing Practice (GMP) requires that manufacturing systems, machinery and equipment be properly validated, to guarantee the quality of pharmaceuticals at manufacturing stage.

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Active Sampling of Airborne Viable Particles in Controlled Environments: a comparative study of common instruments

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Microbial monitoring of controlled environments can be performed in several ways, and by using a variety of different sampling instruments. Knowing the limitations of the chosen system is of vital importance for the correct evaluation and interpretation of the results, since the number of colony-forming units (CFUs) detected by one method cannot be directly compared with results from another method.

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Case study: the validation of an isolator for aseptic filling

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This paper discusses the design and validation of an isolator system used for the sterile filling of a small-scale parenteral product into stoppered vials. It examines problems and difficulties encountered during the validation project, and specific validation requirements which apply to the validation of isolation systems. The results show that use of isolation technology for such a small-scale aseptic filling operation offers a cost-effective solution, which can be demonstrated to meet industry standards and regulatory requirements.

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Application of High-frequency Wave (Microwave) Sterilisation to Pharmaceutical Preparations

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High-frequency waves (microwaves) are now being used for a wide variety of industrial applications, including food sterilisation, lumber and textile drying, and rubber curing. They have also come into popular domestic use as microwave ovens for heating and thawing foods. This report provides a brief account of how high-frequency waves (microwaves) could be used for pharmaceutical industry applications, describes the state of development of ampoule sterilising devices, and introduces a continuous microwave steriliser recently developed by Iijima et al of Eisai Co.

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The application of UV technology to pharmaceutical water treatment

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Ultraviolet (UV) light represents a powerful technology that has been successfully deployed for disinfection in several diverse industries such as pharmaceutical, semi-conductor, power generation, food and beverage, cosmetics, aquaculture, healthcare, and so forth, for several decades. This paper will focus particularly on its application in the pharmaceutical and biotechnology industries to assist in the production of high-purity water. While the most common application of UV radiation in water treatment is disinfection, its powerful energy can also be harnessed for other applications

such as total oxidisable carbon (TOC) reduction, ozone destruction, and chlorine/chloramine elimination.

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PureBright pulsed light processing and sterilisation

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**While Principal Scientist (and, respectively) Vice President, Engineering, Development and Testing, Technical Group Leader, Application Engineer, PurePulse Technologies, Inc.; **Vice President of New Products, Automatic Liquid Packaging, Inc.*

PureBright pulsed light uses short, intense flashes of broad-spectrum white light to kill all exposed micro-organisms, including bacterial and fungal spores, viruses, and protozoan oocysts. Each high-power flash, or pulse of light, lasts only a few hundred millionths of a second but is very intense, being about 20,000 times more intense than sunlight. Flashes are typically applied at rates of one to 10 flashes per second. This paper discusses the PureBright method and results for particular applications, including the terminal sterilisation of blow-fill-seal (BFS) containers, sterilisation of packaging, devices, pharmaceuticals or parenterals, and water and air treatment.

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Effect of nitric acid passivation on the surface composition of a mechanically polished type 316l sanitary tube

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Passivation has a profound effect on the chromium-to-iron ratios in mechanically polished Type 316L tubing. Pieces of the same tube were subjected to hot nitric acid for various passivation times and the passive layer was analysed using XPS (X-ray photoelectron spectroscopy). The

changes in surface chemistry, especially with regard to the amount of elemental iron in the passive layer, were very measurable. There were significant differences in the Cr:Fe ratio and in the ratio of elemental chromium to chromium oxide. Other elements that exhibited anomalous behaviour were silicon and molybdenum. More elemental iron and chromium exist in the passive layer of the mechanically polished tubing than the equivalent electropolished tube, suggesting a more easily corroded surface for the mechanically polished tubing.

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