



Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. This report was prepared by Health Technology Wales on behalf of the Bevan Commission. It summarises the existing evidence on the technology of interest to support a Bevan health technology exemplar application.

Topic:	Rapid microbial quality assurance (QA) of aseptically prepared products
Topic exploration report number:	TER023
Referrer:	Sarah Hiom
Topic exploration undertaken by:	Health Technology Wales

Aim of Search

Health Technology Wales researchers searched for evidence on the use of Milliflex Quantum (or other rapid microbial QA technique) of aseptically prepared products.

Summary of Findings

There is limited evidence on microbial QA of aseptically prepared products. We identified two studies that investigated the use of Milliflex Quantum system, one of which compared Milliflex Quantum to traditional bioburden methods, but further high-quality research is needed.

Key sources of evidence

- Gordon O et al. Validation of Milliflex Quantum for Bioburden Testing of Pharmaceutical Products. PDA J Pharm Sci Technol [Internet]. 2017 [cited 2017 May-Jun];71(3):206-224. <https://www.ncbi.nlm.nih.gov/pubmed/28196917>
- Osono E et al. Rapid detection of microbes in the dialysis solution by the microcolony fluorescence staining method (Milliflex quantum). Biocontrol Sci [Internet]. 2014 [cited 2014];19(1):57-60. <https://www.ncbi.nlm.nih.gov/pubmed/24670620>

Areas of Uncertainty

Existing evidence on the use of Milliflex Quantum is limited. Further high-quality research is needed to validate this technique in the QA of aseptically prepared products.

Brief literature search results

Resource	Results
Guidelines and guidance	
NICE <i>We searched for guidelines, technology appraisals, diagnostics, interventional procedures, and medical technologies guidance.</i>	No guidance was identified on the use of Milliflex Quantum or other methods of quality assurance for aseptic products.
Healthcare Improvement Scotland: <i>We searched the HIS website for any relevant advice and hand-searched Scottish Health Technologies Group and Scottish Intercollegiate Guidelines Network publications.</i>	No guidance was identified on the use of Milliflex Quantum or other methods of quality assurance for aseptic products.
Guidelines International Network	No guidance was identified on the use of Milliflex Quantum or other methods of quality assurance for aseptic products.
Secondary literature and economic evaluations	
ECRI	No assessments were identified on the use of Milliflex Quantum or other methods of quality assurance for aseptic products.
Cochrane library <i>We searched for relevant Cochrane Reviews.</i>	No studies were identified on the use of Milliflex Quantum or other methods of quality assurance for aseptic products.
Medline <i>We searched the Medline database for systematic reviews, meta-analyses, economic evaluations only.</i>	No studies were identified on the use of Milliflex Quantum or other methods of quality assurance for aseptic products.
Primary studies	
Medline <i>We searched the Medline database for studies of any design.</i>	<p>Gordon O et al. Validation of Milliflex Quantum for Bioburden Testing of Pharmaceutical Products. PDA J Pharm Sci Technol [Internet]. 2017 [cited 2017 May-Jun];71(3):206-224. In: Ovid MEDLINE(R) [Internet]. https://www.ncbi.nlm.nih.gov/pubmed/28196917</p> <p>Osono E et al. Rapid detection of microbes in the dialysis solution by the microcolony fluorescence staining method (Milliflex quantum). Biocontrol Sci [Internet]. 2014 [cited 2014];19(1):57-60. In: Ovid MEDLINE(R) [Internet]. https://www.ncbi.nlm.nih.gov/pubmed/24670620</p> <p>Parveen S, Kaur S, David SA, Kenney JL, McCormick WM, Gupta RK. Evaluation of growth based rapid microbiological methods for sterility testing of vaccines and other biological products. Vaccine [Internet]. 2011</p>

	<p>[cited 2011 Oct 19];29(45):8012-23. In: Ovid MEDLINE(R) [Internet]. https://www.ncbi.nlm.nih.gov/pubmed/21871516</p> <p>Gray JC et al. Identification of micro-organisms after milliflex rapid detection--a possibility to identify nonsterile findings in the milliflex rapid sterility test. PDA J Pharm Sci Technol [Internet]. 2011 [cited 2011 Jan-Feb];65(1):42-54. In: Ovid MEDLINE(R) [Internet]. https://www.ncbi.nlm.nih.gov/pubmed/21414939</p>
<p>Cochrane library</p> <p><i>We searched the Cochrane Trials database for studies of any design.</i></p>	No studies were identified on the use of Milliflex Quantum or other methods of quality assurance for aseptic products.
Ongoing research	
Clinicaltrials.gov	No ongoing studies were identified on the use of Milliflex Quantum or other methods of quality assurance for aseptic products.

Date of search:	September 2018
Concepts used:	aseptic, intravenous (IV), infection control, quality assurance