



USP <60> Microbiological examination of non-sterile products – Test for *Burkholderia cepacia* complex (Bcc)

Non-sterile, aqueous drug products contain a potential risk of *Burkholderia cepacia* complex (Bcc) contamination. Bcc strains are opportunistic water-borne pathogens often resistant to selective preservatives and antimicrobial agents. Pharmaceutical water systems are especially susceptible to contamination by these organisms.

USP <60> provides the methodology and testing parameters for detecting Bcc. The general USP chapter was published in June 2019 and effective as of December 1, 2019. Contamination of finished drug products by *B. cepacia* complex will continue to be an area of increased scrutiny by regulators.

Eurofins BPT Toronto can help determine Bcc contamination risks

- Testing in GMP compliant facility for suitability and product testing to specifications by USP <60>
- Assist with establishing a scientifically sound and appropriate acceptance criteria and test to assure compliance to quality standards
- Offer knowledgeable consultation to assist with audits, inspections and guidance to investigate any need to implement appropriate corrective actions and avoid violations and recalls

Test highly recommended for aqueous products (ie. oral, oromucosal, cutaneous, nasal) and products for high risk populations.