

A new general chapter, USP<60>, will include *Burkholderia cepacia* and will become official December 1st, 2019.

Burkholderia cepacia is an objectionable microorganism that often caused many microbiological problems in the pharmaceutical, OTC and cosmetic industries in recent years. It was also found as a frequent recall issue based on CDER data. The new general chapter, USP <60>, Microbiological Examination of Nonsterile Products, specifies tests to determine the presence or absence of *Burkholderia cepacia* in the manufacturing process.

What is *Burkholderia cepacia*?

Burkholderia cepacia (Bcc) a group of 17 closely related bacteria species. Bcc are gram negative aerobic bacteria found in soil and water. The method of transmission through direct contact with other individuals includes the shaking of hands and even body perspiration. Although *B. cepacia* does not appear to survive on completely dry surfaces for more than one week, it can survive for many months in water. *B. cepacia* can use other routes of transmission including contact with hard surfaces. Importantly, these bacteria can stay viable under harsh conditions (e.g., organic solvents, antiseptics, low nutrients, etc.) for many months and are resistant to many antibiotics.

Most importantly, this microorganism may be present in manufacturing equipment, components, or the process water used in manufacturing of the pharmaceutical products and could contaminate the final product causing a risk for the patient.

Proper disinfection of surfaces.

Besides the isolation and identification of *B. cepacia* in your process, it is important to make sure Bcc is eliminated from your surfaces. The correct use of an appropriate disinfectant will ensure your surfaces stay clean and do not cause any risk for your final product.

TexQ[®] Disinfectant is an **EPA-registered**, one-step disinfectant and cleaner proved to be effective against *Burkholderia cepacia* **within a 10 minutes contact time**. It is fragrance-free, dye-free, and available in **sterile ready-to-use or non-sterile concentrate** formulations, in a spray bottle or 1-gallon bottle. TexQ[®] Disinfectant is **compatible with stainless steel** and other sensitive surfaces such as polycarbonate, polyvinylchloride, chrome and vinyl, Plexiglas[®] and enameled surfaces.

Find more information about **[TexQ[®] Disinfectant here.](#)**