Is it possible to apply for CEPs for sterile substances?

Answer:

An applicant can apply for a CEP that will carry the subtitle ‘sterile’. In this case, the dossier must include a detailed description of the sterilisation process as well as validation data. The specifications must of course include the sterility test as described in the general monograph *Substances for pharmaceutical use (2034)*. The CEP will also specify the sterilisation method used and will refer to the test for sterility. The manufacturing site will be inspected before or after granting of the CEP (at the latest 18 months after the CEP is granted).

If both sterile and non-sterile substances are produced, separate dossiers must be submitted and separate certificates will be granted.

Please note that validation data can be requested by licensing authorities for the purpose of assessing a marketing authorisation application.