



Edition: BP 2025 (Ph. Eur. 11.6 update)

Intramammary Infusions of the British Pharmacopoeia (Veterinary)

[General Notices](#)

In addition to the above requirements of the European Pharmacopoeia, the following statements apply to those intramammary infusions that are the subject of an individual monograph in the British Pharmacopoeia (Veterinary).

DEFINITION

Intramammary Infusions intended for administration to lactating animals are described as Intramammary Infusions (Lactating Cow) and those intended for administration to animals at the end of lactation or during the non-lactating period for the prevention or treatment of infections during the dry period are described as Intramammary Infusions (Dry Cow).

PRODUCTION

Intramammary Infusions are prepared by dissolving or suspending the sterile medicaments in the sterilised vehicle using aseptic technique, unless a process of terminal sterilisation is employed.

When Intramammary Infusions are supplied in single-dose containers, these are sealed so as to exclude micro-organisms and are fitted with a smooth, tapered nozzle to facilitate the introduction of the infusion into the teat canal. The containers are sterilised before being filled aseptically unless the intramammary infusion is to be subjected to a process of terminal sterilisation.

[Sterility](#)

Guidance to manufacturers on the number of containers to be tested is provided in the Annex to this monograph.

ANNEX

Guidance to manufacturers in performing the test for [sterility](#)

In determining the number of containers to be tested, the manufacturer should have regard to the environmental conditions of manufacture, the quantity (volume) of preparation per container and any other special considerations applying to the preparation concerned. With respect to intramammary infusions, 1% of the containers in a batch, with a minimum of three and a maximum of ten is considered a suitable number assuming that the preparation has been manufactured under appropriately validated conditions designed to exclude contamination.