

Certificate of Quality

REF

188161

LOT

26040132

Product description: TUBE, 15 ML, PS, 17/120 MM, CONICAL BOTTOM,
BLUE SCREW CAP, CLEAR, GRADUATED,
WRITING AREA, STERILE, 50 PCS./BOX

Following inspections were carried out and passed:

raw material	<input checked="" type="checkbox"/>	passed
visual	<input checked="" type="checkbox"/>	passed
physical	<input checked="" type="checkbox"/>	passed

Free of detectable DNase/RNase/human DNA
Representative product was tested by Real-Time-PCR.

Detection limits:

DNase 4.54 × 10⁻⁹ Kunitz units
RNase 1.0 × 10⁻⁹ Kunitz units
hDNA 2.7 pg

Free of detectable endotoxins (pyrogens)

Representative product was tested according to the United States Pharmacopoeia (USP) Chapter <85>
Detection limit: 0.03 EU/ml

Non-cytotoxic

Representative product was tested according to ISO 10993-5 and has been shown to be non-cytotoxic.

BSE/TSE

Our raw materials used for this product fulfil the requirements laid down in the regulation of Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products (EMA/410/01 rev 3).

Substances of animal origin are either not intentionally used in this product or tallow-derived substances are processed according to conditions of section 6.4 of EMA/410/01 rev 3.

We do not analyse for the above-mentioned substances or compounds.

We hereby certify that our products were manufactured and tested in accordance with the following



2031-01-01

STERILESAL 10⁻³

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international standards and meet the required specifications:

ISO 10993-5 "Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity"

ISO 11137 "Sterilization of health care products - Radiation"

We are certified according to the Quality System Standard ISO 9001 and ISO 13485.



2031-01-01

STERILE

SAL 10^{-3}

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