

Certificate of Quality



542070



M190397

Product description: EASYSTRAINE FOR TUBES 22

EASYSTRAINER 70 µM, FOR 50 ML TUBES, FOR TUBES 227XXX/210XXX, BLUE, STERILE, SINGLE PACKED

Following inspections were carried out and passed:

raw material	X	passed
visual	\mathbf{X}	passed
physical	\mathbf{X}	passed

Free of detectable DNase/RNase/human DNA Representative product was tested by Real-Time-PCR. Detection limits: DNase 1.3×10^{-8} Kunitz units

RNase 5.0 × 10⁻¹¹ Kunitz units hDNA 5 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.

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



2024-04-01 STERILE

SAL 10⁻³

This certificate is valid for the above mentioned lot and has no validity if no lot number is provided.



Certificate creation date: 2019-04-02

www.gbo.com

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