

Certificate of Quality

REF

762077

LOT

E19093E7

Product description: STRIP PLATE, 12xF8, PS, F-BOTTOM,
BLACK, FLUOTRAC, HIGH BINDING, 10 PCS./BAG

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 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

Binding Property

MICROLON® coefficient of variation < 5% (IgG ELISA / transmission measurement)
FLUOTRAC# coefficient of variation < 10% (IgG ELISA / fluorescence measurement)
LUMITRAC# coefficient of variation < 10% (IgG ELISA / luminescence measurement)

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



2023-09-12

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



Certificate creation date: 2021-01-20

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