Thermo Fisher Scientific Baltics UAB
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Company data are stored at the Register of Legal Entities of the Republic of Lithuania

CERTIFICATE OF ANALYSIS

TherePure™ GMP Eam1104I (EarI)

Catalog number:	**ER023SKB004**
Sample catalog number:	**ER023BSMP2**
Lot number:	**XX-XXXXXXX**
Manufacturing Date:	**YYYY-MM-DD**
Retest Date:	**YYYY-MM-DD**
CoA Issue No.:	**XXXX**

Concentration:	20 U/µL
Storage:	at -20 ± 5 °C
Composition:	Protein in formulation buffer: 0.2 mg/mL rBSA, 10 mM Tris-HCl, pH 7.4, 1 mM EDTA, 100 mM KCl, 1 mM DTT, 50 % glycerol

Compliance statement

This product has been manufactured, tested, and released in compliance with applicable regulations and current quality standards, as well as locally imposed requirements as per written agreements.

This product has been manufactured, packed, and tested in compliance with the defined manufacturing processes.

The relevant records for this lot have been reviewed for accuracy, completeness, and compliance with established standard operating procedures. Completeness includes confirmation that all quality events associated with the lot have been closed and accepted by QA of Manufacturer.

Intended use (regulatory) statement and disclaimer

For research use or further manufacturing. Not for diagnostic use or direct administration into humans or animals.

“TheraPure™ GMP” refers to the quality level of the raw, ancillary, or starting materials to be used for further manufacturing. TheraPure GMP products are manufactured in facilities with ISO 9001–certified quality management systems operating in accordance with relevant good manufacturing practice (GMP) principles as outlined in ICH Q7 or equivalent guidance documents or standards.

QUALITY CONTROL

Parameter	Method	Requirement	Result
Color	Ph. Eur. 2.2.2	Not more intense than B9 (B palette)	Conforms
Clarity	Ph. Eur. 2.2.1	< 6 NTU	Conforms
pH	Potentiometric determination of pH, Ph. Eur. 2.2.3, USP <791>	7.0 - 7.8	0.0
Activity	Restriction digestion, in-house method	18 - 24 U/µL	0 U/µL
Star activity	Restriction digestion, in-house method	Not detected	Conforms
[1]Protein concentration	SDS-PAGE, in-house method	Reported value	0.00 mg/mL
[1]Identity	SDS-PAGE, in-house method	Main band of the test sample corresponds to position of the	Conforms

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CERTIFICATE OF ANALYSIS

TherePure™ GMP Eam1104l (Earl)

Catalog number: **ER023SKB004**
Sample catalog number: **ER023BSMP2**
Lot number: **XX-XXXXXXX**
Manufacturing Date: **YYYY-MM-DD**
Retest Date: **YYYY-MM-DD**
CoA Issue No.: **XXXX**

Parameter	Method	Requirement	Result
		main band of IRS	
[1]Purity	SDS-PAGE, in-house method	≥ 95.0 %	0.0 %
Host cell gDNA	qPCR, in-house method	< 100.0 pg/mL protein (LOQ - 5 pg/mL)	0.0 pg/mL protein
Residual RNA	qPCR, in-house method	< 100.0 pg/mL protein (LOQ – 0.1 pg/mL)	0.0 pg/mL protein
Ribonucleases	Fluorimetric assay, in-house method	< LOQ (LOQ – 0.06 ng/mL)	Conforms
Deoxyribonucleases	Fluorimetric assay, in-house method	< LOQ (LOQ- 2.04 ng/mL)	Conforms
Endotoxins	Chromogenic kinetic method; USP <85> Bacterial endotoxin test; Ph. Eur. 2.6.14, Bacterial endotoxin test, Method D	< 5.0 EU/mL protein	0.0 EU/mL protein
Residual host cell proteins	ELISA, in-house method	< 100.0 ng/mL protein (LOQ - 5.28 ng/mL)	0.0 ng/mL protein
Microbial contamination	Membrane filtration method, Ph. Eur. 2.6.12; USP <61>	Total Aerobic Microbial Count (TAMC): < 5 CFU/10 mL	Conforms
		Total Yeast and Mold Count (TYMC): < 5 CFU/10 mL	Conforms
[1] Test is performed for concentrate sample			

ISO CERTIFICATION
Manufactured by Thermo Fisher Scientific Baltics UAB, in compliance with ISO 9001 and ISO 13485 certified quality management system.

CoA is issued by

Quality Assurance Department Signature Date

CoA is verified and approved by

Quality Assurance Manager Signature Date