CUSTOMBIOTECH

Roche

mRNA raw materials: a clear path to market

Quality that comes from experience.
Scale that drives innovation.

Focus on possibilities, not hurdles.

Increasing quality and regulatory requirements are indicative of a maturing market for mRNA therapeutics. We believe they should improve your product, not delay it. Focus on the development of your drug and your manufacturing process. Let us focus on providing your critical raw materials in the quality and scale you need for *in vitro* transcription during commercial production.

Where experience matters: GMP Grade and fit-for-purpose reagents

Design your mRNA manufacturing process with the certainty of fit-for-purpose standards for raw materials. Developed in response to customer requests, CustomBiotech mRNA raw materials align to industry specifications and are produced in the state-of-the-art facilities and quality infrastructure of Roche Pharmaceuticals and Diagnostics.

GMP Grade and fit-for-purpose mRNA raw materials

GMP Grade & ISO 13485

To rely on validated methods and processes as well as appropriate documentation

Animal-origin-free (AOF)

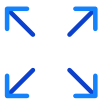
To minimize risk of viral contamination

Antibiotic-free (β-lactam-free)

To minimize risk of potential allergic reactions

Extended impurity testing

To limit introduction of e.g. host cell impurities, heavy metals, endotoxins etc. into the drug manufacturing process



Scalability & Consistency

To be able to use the same raw materials from R&D to commercialization of the mRNA drug; rely on our lot to lot consistency

Manufactured in Germany

Enzymes developed and produced in one of the largest biotech centers in Europe – at Roche's center of excellence in Penzberg, Germany

Limit risks in your end product

A core commitment to quality

CustomBiotech raw materials that are labeled GMP Grade and used in Pharmaceutical and Diagnostics manufacturing process are manufactured under a Quality Management (QM) System according to ISO 13485:2016.

GMP Grade reagents include:

Manufacturing
- Validated manufacturing process
- Validated cleaning procedures
- Adequate hygiene environment
- Continuous monitoring

Quality control
- Stability program
- Validated release methods

QM-System
- Change control system incl. notification
- Deviation management

Animal-origin-free (AOF) & (β-Lactam) antibiotics-free raw materials

Using raw materials that are antibiotics-free and animal-origin-free is a crucial biopharmaceutical requirement to limit the risk of allergic reactions and viral contamination. As a biopharma supplier of mRNA raw materials, we enforce AOF and completely antibiotics-free production for our enzymes from our master cell banks to the release of our materials.

CustomBiotech mRNA raw materials portfolio

Proteins	Catalog Number	Pack size	GMP Grade	AOF[1]	Anti-biotic-free	RNase/ DNAse activity tested	Extended impurity testing[4]
T7 RNA Polymerase, rec.	08 140 669 103	10 ml (ca. 10 mg)	Yes	Yes	Yes	Yes	Yes
Pyrophosphatase, rec.	08 140 677 103	20 ml (ca. 40 mg)	Yes	Yes	Yes	Yes	Yes
RNase Inhibitor, rec.	09 537 643 103 09 537 589 103	100 kU 2 MU	Yes	Yes	Yes	Yes	Yes
DNase I, rec., RNase-free	09 852 093 103 09 873 562 001	320 mL 200 kU	Yes	Yes	Yes	Yes	Yes
Proteinase K, rec.	03 654 672 103	850 mL	Yes (except for Hb assay)	Planned	Yes	Yes	Planned
SP6 RNA Polymerase	09 959 513 103	25 mL (ca. 50 mg)	Yes	Yes	Yes	Yes	Yes
Xba I rec.	09 520 848 101 09 520 848 103	5 ml (50 kU) 25 m (250 kU)	No	Yes	Yes	No	Partially

Nucleotides	Catalog Number	Pack size	GMP Grade	AOF[1]	β-lactam-anti-biotic-free	RNase/ DNAse activity tested	Extended impurity testing[4]
ATP	04 980 824 103	100 mL	Yes	No[2, 3]	Yes	Yes	No
CTP	04 980 875 103	100 mL	Yes	No[2, 3]	Yes	Yes	No
GTP	04 980 859 103	100 mL	Yes	No[2, 3]	Yes	Yes	No
UTP	04 979 818 103	100 mL	Yes	No[2, 3]	Yes	Yes	No
N1-Methyl-Pseudo-UTP	09 744 878 103 09 744 762 103	100 mL 1.0 mL	Yes	Yes	Yes	Yes	Yes
Pseudo-UTP	09 754 334 103 09 538 798 103	100 mL 1.0 mL	No	Yes	Yes	Yes	Yes

[1] For details see Certificates of Origin.
[2] TSE/BSE certificate available.
[3] Orthogonal virus depletion steps included in manufacturing process (e.g. virus retentive filter). Further information on virus depletion study is available.
[4] Includes e.g. testing for bioburden, endotoxin, heavy metals, host-cell DNA, host-cell protein, if applicable = subject to change in on-going project.

Regulatory disclaimer
For further processing only.

SP6 RNA Polymerase/DNase I
For further processing into medical devices, IVD and pharmaceutical products only.

Warranty limitation applies:
It is the sole responsibility of the customer to determine the suitability of all raw materials, products and components in order to ensure that the final end-use product is safe for its end use; performs or functions as intended; and complies with all applicable legal and regulatory requirements. Roche makes no representations or warranties of any kind regarding the Product, express or implied, other than those expressly set forth in the terms and conditions of sale (if any), and disclaims all implied or statutory warranties including warranty of merchantability and fitness for a particular purpose.

Scan for ordering information for product portfolio of mRNA therapeutics raw materials

Published by
Roche Diagnostics GmbH
Sandhofer Str. 116
68305 Mannheim
Germany

custombiotech.roche.com

Please contact your local CustomBiotech representative

Europe, Middle East, Africa, Latin America
mannheim.custombiotech@roche.com

United States
custombiotech.ussales@roche.com

Canada
custombiotech.can@roche.com

Asia Pacific
apac.custombiotech@roche.com