

mRNA raw materials: a clear path to market

Quality that comes from experience.
Scale that drives innovation.







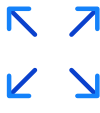

Focus on possibilities, not hurdles.

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 | Animal-origin-free (AOF) | Antibiotic-free (β-lactam-free) | Extended impurity testing | Scalability & Consistency | Manufactured in Germany |
| To rely on validated methods and processes as well as appropriate documentation | To minimize risk of viral contamination | To minimize risk of potential allergic reactions | To limit introduction of e.g. host cell impurities, heavy metals, endotoxins etc. into the drug manufacturing process | 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 | Enzymes and nucleotides developed and produced 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 and NTPs 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 ² |
|----------------------------------|----------------------------------|-------------------------------|------------------------------|------------------|------------------|-----------------------------|--|
| 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, rec. | 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 ² |
|-----------------------------|----------------------------------|---------------------|-----------|------------------|---------------------------|-----------------------------|--|
| ATP, 100 mM, pH 8.3 | 09 744 363 103 | 100 mL ³ | Yes | Yes | Yes | Yes | Yes |
| CTP, 100 mM, pH 8.3 | 09 745 092 103 | 100 mL ³ | Yes | Yes | Yes | Yes | Yes |
| GTP, 100 mM, pH 8.3 | 09 745 173 103 | 100 mL ³ | Yes | Yes | Yes | Yes | Yes |
| UTP, 100 mM, pH 8.3 | 09 745 343 103 | 100 mL ³ | Yes | Yes | Yes | Yes | Yes |
| ATP, 325 mM, pH 8.3 | 09 744 410 103 | 100 mL | Yes | Yes | Yes | Yes | Yes |
| CTP, 325 mM, pH 8.3 | 09 745 122 103 | 100 mL | Yes | Yes | Yes | Yes | Yes |
| GTP, 325 mM, pH 8.3 | 09 745 220 103 | 100 mL | Yes | Yes | Yes | Yes | Yes |
| UTP, 325 mM, pH 8.3 | 09 962 689 103 | 100 mL | Yes | Yes | Yes | Yes | Yes |
| 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 Includes e.g. testing for bioburden, endotoxin, heavy metals, host-cell DNA, host-cell protein, if applicable

³ For larger pack size please inquire

Regulatory disclaimer

For further processing only.

SP6 RNA Polymerase/DNase/Nucleotides

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.



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materials**

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