

Quality and security that empower breakthroughs
Raw materials for mRNA therapeutics





Our pledge at CustomBiotech

To reduce uncertainties

mRNA therapeutics – from development to manufacturing

Though discovered over 50 years ago, mRNA has only recently entered the limelight as a therapeutic agent. *In vitro* transcribed mRNAs are engineered to elicit protein expression either in immune cells as a new front to treat cancer and combat infections, or in other tissues to improve replacement therapies.

Critical decisions in drug development

Not all causes for setbacks or deviations during technical development of a new drug can be anticipated. We believe, however, that variations in raw materials or limitations in scale up should not be a reason for delays of development or commercialization of your mRNA drug.

Therefore, selecting fit-for-purpose critical raw materials from the beginning with the foresight to smoothly transition into a routine manufacturing process is a pivotal decision.

Fit-for-purpose raw materials comply with the following standards

- Manufactured under Good Manufacturing Practice (GMP) quality standards
- Highly consistent from lot to lot
- Available in scale and quality for commercial production
- Produced free of animal-derived components and beta-lactam antibiotics
- Tested for critical impurities, e.g. endotoxin, bioburden, residual metals, as well as host cell DNA and host cell protein

Reliable partner for industrial production

We merge the experiences, knowledge and lessons learned over 30 years of industry leadership to offer a partnership that goes far beyond supplying raw materials. Our experts understand the industry and thus can anticipate and resolve issues before they become a problem. Count on our products to support your scale-up and regulatory approval.

Gain peace of mind

Let our raw materials and their traceable quality control, change and deviation management contribute to your standardized, robust manufacturing processes. Make the right sourcing decisions early in your development to minimize risk of project delays and to drive the fast market launch of your drug.

Foresight

The effective path to market

We are growing with you

The CustomBiotech portfolio of raw materials evolves alongside the therapeutic mRNA market. Even with increasing requirements you can focus on the development of your drug. Let us focus on providing critical raw materials in quality and scale needed for your commercial mRNA production.

In ongoing projects CustomBiotech optimizes the entire portfolio to meet fit-for-purpose standards. The specifications are determined by the intended use of manufacturing therapeutic mRNA.

Product portfolio

| Product | Catalog number | Pack size | GMP Grade | Animal-origin-free ¹ (AOF) | Antibiotic-free | Tested for RNase / DNase activity | Extended impurity testing ⁴ |
|------------------------------------|----------------------------------|--------------------------------|---------------------------|---------------------------------------|-----------------|-----------------------------------|--|
| Proteins | | | | | | | |
| T7 RNA Polymerase, rec., GMP Grade | 08 140 669 103 | 10 ml (ca. 10 mg) | Yes | Yes | Yes | Yes | Yes |
| Pyrophosphatase, rec., GMP Grade | 08 140 677 103 | 20 ml (ca. 40 mg) | Yes | Yes | Yes | Yes | Yes |
| RNase Inhibitor, rec., GMP Grade | 09 537 643 103 09 537 589 103 | 100 kU 2 MU | Yes | Yes | Yes | Yes | Yes |
| DNase I, rec., RNase-free | Inquire 03 539 121 103 | 20 kU 200 kU | Yes | No ² | Yes | Yes | Yes |
| Proteinase K, rec. | 03 654 672 103 | 850 mL | Yes (except for Hb assay) | No ² | Yes | Yes | Partially |
| SP6 RNA Polymerase, rec. | 09 788 131 103 | 25 mL | Planned | Yes | Yes | Yes | Yes |
| Xba I rec. | 09 520 848 101 09 520 848 103 | 5 ml (50 kU) 25 ml (250 kU) | No | Yes | Yes | No | Partially |

| Product | Catalog number | Pack size | GMP Grade | Animal-origin-free ¹ (AOF) | β-Lactam-antibiotic-free | Tested for RNase / DNase activity | Extended impurity testing ⁴ |
|---------------------------------|----------------------------------|------------------|-----------|---------------------------------------|--------------------------|-----------------------------------|--|
| Ribo-Nucleotides | | | | | | | |
| 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, GMP Grade | 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.

Use GMP Grade reagents to reduce process risks.

Our reagents are manufactured under ISO 13485.

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
- Periodic reviews

Regulatory disclaimer

For further processing only.

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