

9.6 Certificates of Analysis BNT162a1

BioNTech RNA Pharmaceuticals GmbH

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Report of Results *In vitro* transcribed mRNA

Product:	<i>In vitro</i> transcribed mRNA RBL063.3 (ATM batch uRNAv05)
Lot/Batch No.:	RNA-SK200305-01
RNA length:	1261 nt
Media and additives:	10 mM HEPES/0.10 mM EDTA (pH 7.0)
Production date:	06 Mar 2020 (produced by BioNTech RNA Pharmaceuticals GmbH)
Storage:	-30 °C to -15 °C

Test	Result
Content (RNA concentration) Ultraviolet Absorption Spectrophotometry; A ₂₆₀	(b) (4)
Identity (RNA length) Agarose Gel Electrophoresis	
RNA Integrity Capillary Electrophoresis (Fragment Analyzer, Advanced Analytical)	
Potency <i>In vitro</i> translation followed by gel electrophoresis	
pH Potentiometric Determination of pH	
Bacterial Endotoxins LAL-test (Ph. Eur. 2.6.14)	
Residual DNA template Quantitative PCR	
Osmolality Measurement of depression of freezing point	
Bioburden Microbial examination of non sterile products (Ph. Eur. 2.6.12)	

Remarks:

None.

(b) (6)

(b) (6)

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Non-GMP CoA
 Material not for human use
 Version 3

Product: CoVVAC
Batch: RBL063.3 LNP
Lot: CoVVAC/090320

Test	Method	Result
Appearance	Visual Inspection (224/SOP/011)	(b) (4)
RNA identity	CE (223/SOP/016)	
RNA Integrity	CE (223/SOP/016)	
RNA content	Ribogreen Assay (221/SOP/018)	
RNA encapsulation	Ribogreen assay +/- LNP disruption (221/SOP/018)	
ALC-0315 content	HPLC-CAD (222/SOP/044)	
ALC-0159 content	HPLC-CAD (222/SOP/044)	
DSPC content	HPLC-CAD (222/SOP/044)	
Cholesterol content	HPLC-CAD (222/SOP/044)	
Particle size (Z _{avg})	Dynamic light scattering (224/SOP/002)	
Polydispersity index (PDI)	Dynamic light scattering (224/SOP/002)	
pH	pH (224/SOP/016)	
Osmolality	Freezing point depression (224/SOP/009)	
Endotoxins/Pyrogens	Turbidimetric, kinetic LAL assay (Ph.Eur. 2.6.14/ USP<85>)	
Bioburden	Membrane filtration method 225/SOP/001	

Store at: -70°C

Date: 26.03.2020

Date: 26.03.20

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9.7 Certificates of Analysis BNT162b1

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Report of Results *In vitro* transcribed mRNA

Product:	<i>In vitro</i> transcribed mRNA RBP020.3 (ATM batch modRNAv05)
Lot/Batch No.:	RNA-RF200304-03
RNA length:	1262 nt
Media and additives:	10 mM HEPES/0.10 mM EDTA (pH 7.0)
Production date:	05 Mar 2020 (produced by BioNTech RNA Pharmaceuticals GmbH)
Storage:	-30 °C to -15 °C

Test	Result
Content (RNA concentration) Ultraviolet Absorption Spectrophotometry; A ₂₆₀	(b) (4)
Identity (RNA length) Agarose Gel Electrophoresis	
RNA integrity Capillary Electrophoresis (Fragment Analyzer, Advanced Analytical)	
Potency <i>In vitro</i> translation followed by gel electrophoresis	
pH Potentiometric Determination of pH	
Bacterial Endotoxins LAL-test (Ph. Eur. 2.6.14)	
Residual DNA template Quantitative PCR	
Residual dsRNA Antibody-based limit test	
Osmolality Measurement of depression of freezing point	
Bioburden Microbial examination of non sterile products (Ph. Eur. 2.6.12)	

Remarks:

None.

(b) (6)

(b) (6)

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Non-GMP CoA

Material not for human use
 Version 3

Product: CoVVAC
Batch: RBP020.3 LNP
Lot: CoVVAC/100320

Test	Method	Result
Appearance	Visual Inspection (224/SOP/011)	(b) (4)
RNA identity	CE (223/SOP/016)	
RNA integrity	CE (223/SOP/016)	
RNA content	Ribogreen Assay (221/SOP/018)	
RNA encapsulation	Ribogreen assay +/- LNP disruption (221/SOP/018)	
ALC-0315 content	HPLC-CAD (222/SOP/044)	
ALC-0159 content	HPLC-CAD (222/SOP/044)	
DSPC content	HPLC-CAD (222/SOP/044)	
Cholesterol content	HPLC-CAD (222/SOP/044)	
Particle size (Z _{avg})	Dynamic light scattering (224/SOP/002)	
Polydispersity index (PDI)	Dynamic light scattering (224/SOP/002)	
pH	pH (224/SOP/016)	
Osmolality	Freezing point depression (224/SOP/009)	
Endotoxins/Pyrogens	Turbidimetric, kinetic LAL assay (Ph.Eur. 2.6.14/ USP<85>)	
Bioburden	Membrane filtration method 225/SOP/001	

Store at: -70°C

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Date: 26.03.2020

Date: 26.03.2020

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9.8 Certificates of Analysis BNT162b2

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Report of Results *In vitro* transcribed mRNA

Product:	<i>In vitro</i> transcribed mRNA RBP020.2 (ATM batch modRNAv09)
Lot/Batch No.:	RNA-RF200321-06
RNA length:	4283 nt
Media and additives:	10 mM HEPES/0.10 mM EDTA (pH 7.0)
Production date:	19 Mar 2020 (produced by BioNTech RNA Pharmaceuticals GmbH)
Storage:	-30 °C to -15 °C

Test	Result
Content (RNA concentration) Ultraviolet Absorption Spectrophotometry; A ₂₆₀	(b) (4)
Identity (RNA length) Denaturing Agarose Gel Electrophoresis	
RNA integrity Capillary Electrophoresis (Fragment Analyzer, Advanced Analytical)	
Potency <i>In vitro</i> translation followed by gel electrophoresis	
pH Potentiometric Determination of pH	
Bacterial Endotoxins LAL-test (Ph. Eur. 2.6.14)	
Residual DNA template Quantitative PCR	
Residual dsRNA Antibody-based limit test	
Osmolality Measurement of depression of freezing point	
Bioburden Microbial examination of non sterile products (Ph. Eur. 2.6.12)	

Remarks:

None.

(b) (6)

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Non-GMP CoA
 Material not for human use
 Version 3

Product: CoVVAC
Batch: RBP020.2LNP
Lot: CoVVAC/270320

Test	Method	Result
Appearance	Visual Inspection (224/SOP/011)	(b) (4)
RNA identity	CE (223/SOP/016)	
RNA integrity	CE (223/SOP/016)	
RNA content	Ribogreen Assay (221/SOP/018)	
RNA encapsulation	Ribogreen assay +/- LNP disruption (221/SOP/018)	
ALC-0315 content	HPLC-CAD (222/SOP/044)	
ALC-0159 content	HPLC-CAD (222/SOP/044)	
DSPC content	HPLC-CAD (222/SOP/044)	
Cholesterol content	HPLC-CAD (222/SOP/044)	
Particle size (Z _{avg})	Dynamic light scattering (224/SOP/002)	
Polydispersity index (PDI)	Dynamic light scattering (224/SOP/002)	
pH	pH (224/SOP/016)	
Osmolality	Freezing point depression (224/SOP/009)	
Endotoxins/Pyrogens	Turbidimetric, kinetic LAL assay (Ph.Eur. 2.6.14/ USP<85>)	
Bioburden	Membrane filtration method 225/SOP/001	

Store at: -70°C

Date: 09.04.20

Date: 09.04.20

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9.9 Certificates of Analysis BNT162c2

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Report of Results *In vitro* transcribed mRNA

Product:	<i>In vitro</i> transcribed mRNA RBS004.2 (ATM batch saRNAv09)
Lot/Batch No.:	RNA-RF200310-01
RNA length:	11917 nt
Media and additives:	10 mM HEPES/0.10 mM EDTA (pH 7.0)
Production date:	09 Mar 2020 (produced by BioNTech RNA Pharmaceuticals GmbH)
Storage:	-30 °C to -15 °C

Test	Result
Content (RNA concentration) Ultraviolet Absorption Spectrophotometry; A_{260}	(b) (4)
Identity (RNA length) Agarose Gel Electrophoresis	
RNA integrity Capillary Electrophoresis (Fragment Analyzer, Advanced Analytical)	
pH Potentiometric Determination of pH	
Bacterial Endotoxins LAL-test (Ph. Eur. 2.6.14)	
Residual DNA template Quantitative PCR	
Osmolality Measurement of depression of freezing point	
Bio burden Microbial examination of non sterile products (Ph. Eur. 2.6.12)	

Remarks:

None.

(b) (6)

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Non-GMP CoA
 Material not for human use
 Version 3

Product: CoVVAC
Batch: RBS004.2 LNP
Lot: CoVVAC/170320

Test	Method	Result
Appearance	Visual Inspection (224/SOP/011)	(b) (4)
RNA identity	CE (223/SOP/015)	
RNA integrity	CE (223/SOP/015)	
RNA content	Ribogreen Assay (221/SOP/018)	
RNA encapsulation	Ribogreen assay +/- LNP disruption (221/SOP/018)	
ALC-0315 identification and content	HPLC-CAD (222/SOP/044)	
ALC-0159 identification and content	HPLC-CAD (222/SOP/044)	
DSPC identification and content	HPLC-CAD (222/SOP/044)	
Cholesterol identification and content	HPLC-CAD (222/SOP/044)	
Particle size (Z_{avg})	Dynamic light scattering (224/SOP/002)	
Polydispersity index (PDI)	Dynamic light scattering (224/SOP/002)	
pH	pH (224/SOP/016)	
Osmolality	Freezing point depression (224/SOP/009)	
Endotoxins/Pyrogens	Turbidimetric, kinetic LAL assay (Ph.Eur. 2.6.14/ USP<85>)	
Bioburden	Membrane filtration method 225/SOP/001	

Store at: -70°C

(b) (6)

Date: 26.03.2020

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