OPUS® Column Certificate of Analysis

Product Identification

Criteria	Description
GMP Level:	GMP Run Ready
Catalog Number:	XX-XXX-XXXX-XXX-G
Lot Number:	XXXXXXXX
Serial Number:	XXXXXXXX-XXX
Column Diameter:	XX cm (for 45cm=45.7cm for 60cm=59.9cm)
Bed Height:	XX.X cm
Resin Type:	<insert resin name>
Resin Lot Number:	<insert resin lot #>
Shipping Solution:	<insert shipping solution>
Storage Temperature:	XXXXXX (Ambient or 2-8°C)
Date of Manufacture:	DD MMM YYYY
Customer Property #:	CPXXXXXX (or "N/A" for "BC" part numbers)

Quality Control Release Data

Criteria	Specification	Result
Column Efficiency: (Plates/meter)	≥ XXXX	XXXX
Column Asymmetry:	X.XX – X.XX	X.XX
Microbial Bioburden: (CFU/mL)	<10	pass/fail
Endotoxin Level: (EU/mL)	<0.25	pass/fail
Max. Column Hardware Pressure	X bar (3 bar ≥45cm or 4 bar ≤30cm)	
Max. Packing Pressure (bar):	Report	X.X
Max. Packing Flow Rate (cm/hr):	Report	XXXX

Reviewed and approved for accuracy and completeness

QA Representative Signature

Date

Document Number: QA-FM-10164-18

<Insert Resin Name> is a <registered> trademark of <Insert Company name>

REPLIGEN

OPUS® Column Certificate of Analysis

Column Information:

Catalog Number:	XX-XXX-XXXX-XXX-G
Lot Number:	XXXXXXXX
Serial Number:	XXXXXXXX-XXX

Test Conditions:

Injection Solution:	<insert injection solution description>
Injection Volume (mL):	XXX
Mobile Phase:	<insert mobile phase description>
Flow Rate (cm/hr):	XXX

[Insert Chromatogram here – Shape Height = 4.5]

Reviewed and approved for accuracy and completeness

QA Representative Signature

Date

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Quality Assurance Statements

Quality Standard
Manufactured in the U.S.A under an ISO 9001 Quality Management System

Material Compatibility
All materials in direct fluid contact meet USP class VI <88> requirements for In Vivo B Biological Reactivity

Animal Origin Free
All materials in direct fluid contact comply to EMA/410/01 Rev.3

Environment
Columns are packed in a controlled, classified clean room that meets ISO Class 7 NVP standards

Chromatography Resin Control
All resins are subject to incoming material controls including resin identity testing. Traceability is achieved using controlled documents and records according to good documentation practices.

Reviewed and approved for accuracy and completeness

QA Representative Signature

Date

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