OPUS® Column Certificate of Analysis

Product Identification

Criteria	Description
GMP Level:	GMP Run Ready
Catalog Number:	XX-XXX-XXXX-XXX-G
Lot Number:	OCXXXXXX
Serial Number:	XXXX
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>
Date of Manufacture:	DD MMM YYYY
Customer Property #:	CPXXXXXX (or "N/A" for "BC" part numbers)

Reviewed and approved for accuracy and completeness

Quality Control Release Data

Criteria	Specification	Result
Column Efficiency: (Plates/meter)	≥ XXXX	XXXX
Column Asymmetry:	X.XX – X.XX	X.XX
Pressure vs. Flow: (XX mL/min at XX psi)	XXXX	XXXX
Microbial Bioburden: (CFU/mL)	<10	pass/fail
Endotoxin Level: (EU/mL)	<0.25	pass/fail

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

QA Representative Signature

Date

Document Number: QA-FM-10164-15

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Chromatography Resin Control

All resins are subject to incoming material controls including lot number identification. Traceability is achieved using controlled documents and records according to good documentation practices.

Column Information:

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

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

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