

# OPUS® Column Certificate of Analysis

## Product Identification

<u>Criteria</u>	<u>Description</u>
GMP Level:	Pre GMP
Catalog Number:	XX-XXX-XXXX-XXX-P
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)

*Reviewed and approved for accuracy and completeness*

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QA Representative Signature

Document Number: QA-FM-10162-16

## Quality Control Release Data

<u>Criteria</u>	<u>Specification</u>	<u>Result</u>
Column Efficiency: (Plates/meter)	≥ XXXX	XXXX
Column Asymmetry:	X.XX – X.XX	X.XX
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

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Date

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

# OPUS<sup>®</sup> Column Certificate of Analysis

## **Column Information:**

Catalog Number: XX-XXX-XXXX-XXX-P  
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]

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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.

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