

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

Forms with a Lot Number will expire in 30 days. Forms without a Lot Number will expire 2 days after print date. Printed on 2019-09-04T17:20:23

## Product Identification

## Quality Control Release Data

<u>Criteria</u>	<u>Description</u>
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>
Storage Temperature:	XXXXXX (Ambient or 2-8°C)
Date of Manufacture:	DD MMM YYYY
Customer Property #:	CPXXXXXX (or "N/A" for "BC" part numbers)

<u>Criteria</u>	<u>Specification</u>	<u>Result</u>
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-10164-17

<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-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]

Forms with a Lot Number will expire in 30 days. Forms without a Lot Number will expire 2 days after print date.

Printed on 2019-09-04T17:20:25

*Reviewed and approved for accuracy and completeness*

\_\_\_\_\_  
QA Representative Signature

\_\_\_\_\_  
Date

Document Number: QA-FM-10164-17

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



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

Forms with a Lot Number will expire in 30 days. Forms without a Lot Number will expire 2 days after print date.

## 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

Document Number: QA-FM-10164-17

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

