

OPUS[®] Column Certificate of Analysis

Product Identification

<u>Criteria</u>	<u>Description</u>
GMP Level:	GMP Run Ready
Catalog Number:	XX-081-XXXX-XXX-G
Lot Number:	XXXXXXXX
Serial Number:	XXXXXXXX-XXX
Column Diameter:	8.1 cm
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

Reviewed and approved for accuracy and completeness

QA Representative Signature

Document Number: QA-FM-10570-03

Product Identification (continued)

<u>Criteria</u>	<u>Description</u>
Customer Property #:	CPXXXXXX (if applicable)
Column Hardware Maximum Pressure:	4 bar

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
Maximum Packing Pressure (bar):	Report	XXXX
Maximum Packing Flow Rate (cm/hr):	Report	XXXX
Microbial Bioburden: (CFU/mL)	<10	pass/fail
Endotoxin Level: (EU/mL)	<0.25	pass/fail

Date

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

OPUS[®] Column Certificate of Analysis

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 with 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 lot number identification. Traceability is achieved using controlled documents and records according to good documentation practices.

Reviewed and approved for accuracy and completeness

QA Representative Signature

Document Number: QA-FM-10570-03

Date

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

OPUS[®] Column Certificate of Analysis

Column Information:

Catalog Number: XX-081-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

Document Number: QA-FM-10570-03

Date

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