

OPUS[®] Column Certificate of Analysis

Product Identification

<u>Criteria</u>	<u>Description</u>
GMP Level:	Pre GMP
Catalog Number:	XX-081-XXXX-XXX-P
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

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

Reviewed and approved for accuracy and completeness

QA Representative Signature

Document Number: QA-FM-10571-03

Date

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

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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

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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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