

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:	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)

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
Pressure vs. Flow: (XX mL/min at XX psi)	XXXX	XXXX

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

Reviewed and approved for accuracy and completeness

QA Representative Signature

Document Number: QA-FM-10162-13

Date

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

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Column Information:

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

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