

OPUS® Column (Gamma) Certificate of Analysis

Product Identification

<u>Criteria</u>	<u>Description</u>
GMP Level:	GMP Run Ready
Catalog Number:	XX-XXX-XXXX -XXX-XX
Lot Number:	XXXXXXXX
Serial Number:	XXXX
Column Diameter:	XX.X cm
Bed Height:	XX.X cm
Resin Type:	<insert description>
Resin Lot Number:	<insert resin lot #>
Shipping Solution:	<insert description>
Storage Temperature	(Ambient or 2-8C)
Date of Manufacture:	DD MMM YYYY

Reviewed and approved for accuracy and completeness.

QA Representative (Name & Signature)

Document Number: QA-FM-10609-05

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	
Max. Packing Pressure (bar)	Report	X.X
Max. Packing Flow Rate (cm/hr)	Report	XXXX
Pre-gamma Irradiation Testing: Microbial Bioburden (CFU/mL):	<10	Pass / Fail
Endotoxin level (EU/mL):	<0.25	Pass / Fail
Date of Gamma Irradiation:	DD MMM YYYY	
Gamma Irradiation Dose: (Kilogray)	25-40 kGy	Pass / Fail
Gamma sticker color:	Red	Pass / Fail
Appearance:	Visually integral	Pass / Fail
FTIR Analysis (Correlation Coefficient):	≥95%	Pass/Fail or N/A

Date

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Column Information:

Catalog Number: XX-XXX-XXXX-XXX-XX
Lot Number: XXXXXXXX
Serial Number: XXXX

Test Conditions:

Injection Solution: <insert description>
Injection Volume (mL): XXX
Mobile Phase: <insert 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.

OPUS Column Gamma Service Liability Statement

Gamma irradiation is a custom service Repligen offers at the request of our customers. Copies of the Certificate of Processing from the third-party gamma irradiation vendor are attached as part of this Certificate of Analysis. Repligen does not have data demonstrating sterility post-gamma irradiation or how the OPUS column shelf-life is affected by gamma irradiation. Prior to gamma irradiation, the OPUS column/s must pass the Bioburden and Endotoxin specifications as stated on Page 1 of this Certificate of Analysis.

Note: Gamma irradiation may void the chromatography resin warranty. Repligen will not guarantee resin binding capacity or performance post-gamma irradiation, as each resin and ligand type will be affected differently.

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