

Leader of the Pack from process validation

to GMP manufacturing

OPUS® Pre-packed Chromatography Columns enable linear scale-up from process validation to commercial and GMP manufacturing. Select from the broadest portfolio of pre-packed columns, including large scale OPUS® 45R, 60R, and 80R Columns. Pre-packed columns enhance facility efficiency overall by converting column packing resources into productive chromatography and accelerating campaign turnaround time.



OPUS®: Open Platform, User Specified

- 12 internal diameters: 2.5 cm - 80 cm
- Bed height (OPUS® 2.5 - 30): 5 cm - 30 cm
- Bed height (OPUS® 45R - 80R): 10 cm - 30 cm
- Column volume: 25 mL - 150 L
- Pre-packed with user-specified resin

Innovation in purification

- Configure bed height to nearest mm
- Pack nearly any resin from nearly any supplier
- Customize plate count, asymmetry, and test method
- Unpack resin using recovery port featured on OPUS® 45R, 60R, and 80R Columns

Unparalleled scalability from 2.5 cm - 80 cm

- Consistent materials of construction
- Class VI, EMA 410/01 compliant materials
- GMP and non-GMP quality support packages
- ISO documentation (CoA, RSF)
- Select from > 150 resins
- Individual column release testing



OPUS® 2.5

OPUS® 80R

Repligen 2024



Scale to manufacturing with no self-packing

OPUS® Pre-packed Chromatography Columns constitute an open platform technology in which the column diameter, bed height, and resin type are user-specified. Configure column parameters to meet application-specific needs. Select from the largest range of column diameters and bed heights and pack the column with nearly any resin from nearly any supplier. Scale from process development to GMP manufacturing on a single platform with no column packing equipment and no column packing steps.



Leader of the Pack: Any size, any resin, ultimate flexibility

OPUS® Pre-Packed Chromatography Columns, from OPUS® RoboColumn® Columns to OPUS® 80R Columns, lead the way with unparalleled flexibility in resin choice, application, and size.

Partial list of available resins		
Affinity	IEX/Mixed Mode Resins	
Captiva®	Praesto® (Q, SP)	POROS® (50 HQ, XQ)
NGL COIVD-19 Spike Protein Affinity Resin	Capto™ (Adhere, MMC, Phenyl)	POROS® (50 HS, XS)
Praesto® (AC, AP, Jetted A50)	Capto™ (DEAE, Q, S)	POROS® (Benzyl, Ethyl)
Amsphere™ A3	Capto™ Core 700	Sephadex™ G-25
AVB Sepharose™ HP	Capto™ ImpRes (Adhere, Butyl, MMC)	Sepharose™ FF (Butyl, Phenyl)
Capto™ Plasmid Select	Capto™ ImpRes (Q, SP)	Sepharose™ FF (DEAE, Q, SP)
Eshmuno® A	CHT™ Types I and II: 40 µm, 80 µm ¹	Sepharose™ HP (Butyl, Phenyl)
KANEKA KanCapA™	Eshmuno® (CPX, HXC, Q, S)	Sepharose™ HP (Q, SP)
MabSelect™ Family	Fractogel® EMD (COO ⁻ , SO ₃ ⁻)	SOURCE™ 30 (Q, S)
POROS® CaptureSelect™ AAV8, AAV9, AAVX	Fractogel® EMD (DEAE, DMAE, TMAE)	Superdex™ (75, 200)
POROS® CaptureSelect™ Affinity Matrix	Fractogel® EMD SE HiCap	TOYOPEARL® 600M (Butyl, Phenyl, PPG)
POROS® Heparin	Fractogel® EMD TMAE HiCap	TOYOPEARL® 650M (DEAE, HIC, Super Q)
POROS® Oligo (dT)	HyperCel™ (CMM, HEA, MEP, PPA)	TOYOPEARL® GigaCap 650M (Q, S)
TOYOPEARL® AF-rProten A HC-650F	Nuvia™ (cPrime, HRS, S)	UNOsphere™ (Q, S)

1. ≤ 60 cm ID Columns

Initiate GMP manufacturing at 25 mL

OPUS® 2.5, 5 and 8 Pre-packed Chromatography Columns enable process validation and small-scale GMP manufacturing with column volumes ranging from 25 mL - 1.5 L. Manufacturing standards established for the OPUS® family, including bioprocess compliant product contact materials and ISO documentation, are maintained for scaled-down OPUS® 2.5, 5, and 8 Columns. Individual column testing facilitates product specific certificate of analysis that includes asymmetry, theoretical plates, and maximum packing pressure.

- Define bed height within 1 mm
- Select from > 150 resins
- Receive pre-packed and ready to use
- Connect to any chromatography system
- Rely on consistent performance batch-to-batch

The only 2.5 cm pre-packed column for GMP manufacturing

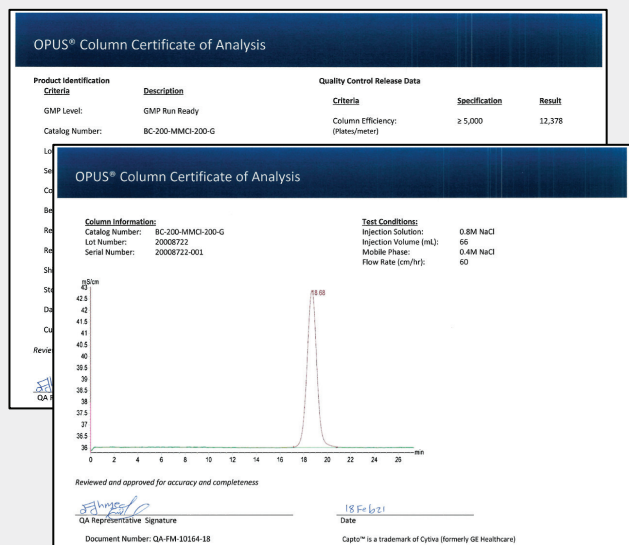


Comprehensive documentation supports new product implementation and incoming quality acceptance

Regulatory Support File (RSF) includes:

- Product overview and sample CoA
- Materials of construction
- Manufacturing overview, controls, SOPs
- Shipping qualification
- Extractables: test protocol and results
- Leachables: OPUS® column parameters and testing considerations
- OPUS® column and packaging drawings
- Warranty information
- International Shipping Transit Association (ISTA) Study, summary of tests and results

Example CoA for GMP quality package



Revised 02/04/2021

Proven column design for OPUS® 45R, 60R and 80R



Part

1. Inlet port
2. Outlet port
3. Unpacking port
4. Flow distributor
5. O-rings
6. Return line
7. Side guard
8. Tube
9. Integral casters

Materials of Construction

- Polypropylene
- Polypropylene
- Silicone and Polypropylene composite
- Polypropylene
- Silicone
- Silicone and Polypropylene
- Composite
- Polypropylene glass composite
- Composite

Expert Engineering

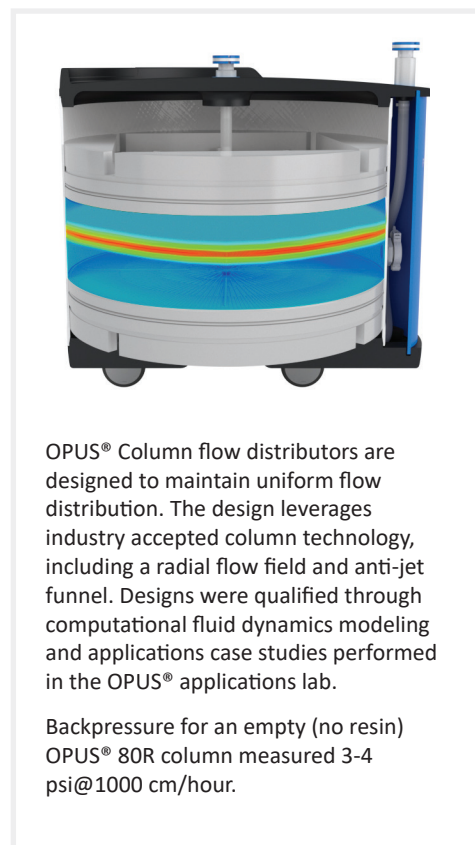
OPUS® Columns are the result of expert engineering combined with deep industry knowledge and experience in downstream chromatography.

- **Unique design** features
- **Reliable** multi-cycle performance
- **Robust** GMP-compliant construction
- **Easy** cleaning and sanitization
- **Scalable** performance consistent across different sizes
- **Performance** maintained after shipping

GMP Manufacturing

OPUS® Columns are designed for use in GMP environments for the manufacturing of clinical and commercial biologic drugs.

- Packed in ISO Class 7 clean rooms
- Complete Regulatory Support File
- Certificate of Analysis for each column configuration



OPUS® Column flow distributors are designed to maintain uniform flow distribution. The design leverages industry accepted column technology, including a radial flow field and anti-jet funnel. Designs were qualified through computational fluid dynamics modeling and applications case studies performed in the OPUS® applications lab.

Backpressure for an empty (no resin) OPUS® 80R column measured 3-4 psi@1000 cm/hour.

