Data file 29-0432-59 AA BioProcess™ columns

VERSAchrom

VERSAchrom is an efficient, dependable, and robust BioProcess chromatography column (Fig 1). Simple to operate and maintain, the column is designed to help users achieve reliable throughput across a wide range of chromatographic applications, while helping to ensure compliance with regulatory requirements.

Based on the familiar, proven, and established BPG column platform, VERSAchrom is backed by an intelligently designed adaptor handling unit that reduces the effort users need for packing and unpacking operations, without any compromise on chromatographic performance.

VERSAchrom offers a combination of performance and quality to its users.

- Proven chromatographic performance
- Reduced effort for packing and unpacking operations for maximum up-time
- Robust configurations for reliable outcomes
- End-to-end application support and service

Proven chromatographic performance

VERSAchrom column is incorporated with a proven distribution system that efficiently distributes the sample to generate a reproducible chromatographic performance that is on par with the established BPG column.

Reduced effort for packing and unpacking operations for maximum up-time

With an optimal design that does away with the need for complex assembly or heavy manual lifting, the high-quality VERSAchrom BioProcess column reduces the effort and tools needed for packing operations and reduces unproductive processing time from production schedules, thus promoting faster product or process change-over.



Fig 1. VERSAchrom column.

Robust configurations for reliable outcomes

VERSAchrom comprises of high-quality components, which are carefully chosen to help ensure consistent chromatographic performance. In addition to the column materials, its robust design and optimized distribution system contribute to predictable and reliable purification outcomes.

VERSAchrom columns are individually tested under strict quality control guidelines to ensure that they fulfill critical performance specifications. Functional test records and a certificate of conformance are provided with every column.



End-to-end application support and service

In addition to offering high-quality products and consumables of proven performance, GE Healthcare Life Sciences supports users with practical help and dedicated service. Thus, our end-to-end services cover the entire life sciences value chain and assist you in quickly ramping up your operations for increased productivity.

Column description General

VERSAchrom is available in one size with a column diameter of 450 mm and in three different tube lengths: 500 mm, 750 mm, and 1000 mm.

The column can be packed by using a constant flow or pressure methodology wherein the media slurry inside the column is first settled and then packed using the flow of a packing buffer, which is delivered by a pump, from the top of the column to the bottom. However, the preferred packing method is a two-step method where the media is first settled at a low flow rate to create a homogenous bed, and then compressed to the correct compression factor by using a higher flow rate. Column specifications and materials of construction are listed in Table 1 and 2, respectively.

Table 2. Materials of construction

Description	Material
Adaptor plate	Duplex
Flange	316L
Column tube	Acrylic
End piece	Duplex
Support net end piece/adaptor	Polypropylene
Filter end piece/adaptor	Polypropylene
Flange O-ring	EPDM
Adaptor O-ring	EPDM
Gasket	EPDM

Use of adaptor handling unit

The adaptor handling unit enables effortless handling of the adaptor during packing, unpacking and maintenance operations, thereby facilitating these operations. In order to use the adaptor handling unit, the VERSAchrom column adaptor first needs to be secured to the handling unit before the adaptor can be lifted out of/in to the column by rotating the lifting nut in an anti-clockwise or clockwise manner, whichever the case maybe. The adaptor handling unit is made of SS 304 structural material, and has a maximum lift capacity of 200 kg, and a maximum lift height of 1840 mm.

Table 1. Column specifications

Tube length (mm)	500	750	1000
Inner diameter (mm)	446	446	446
Minimum bed height (cm)	0	25	50
Maximum bed height (cm)	20	36	52
Minimum bed volume (L)	0	39.1	78.1
Maximum bed volume (L)	31.2	56.2	81.2
Maximum operating pressure (bar)	2.5	2.5	2.5
Maximum design pressure (bar)	2.5	2.5	2.5
Total weight (kg)	192	203	214
Foot-print, $max D \times W$ (cm)	82 × 82	82 × 82	82 × 82
Minimum space required for maintenance $W \times D \times H$ (cm)	$85 \times 110 \times 180$	85 × 110 × 205	$85 \times 110 \times 230$
Operating temperature (°C)	4 to 40	4 to 40	4 to 40
Adaptor movement	Manual	Manual	Manual

Regulatory considerations

All wetted polymeric materials and elastomers meet the requirements of USP Class VI as described in *USP Biological Reactivity Tests In Vivo* <88> and FDA *21 CFR Part 177*. Additionally, two levels of documentation are available with the column to help fulfill the requirements set by the regulatory authorities:

- Basic: including general specification, assembly drawing, functional test record, installation test record, spare part list, user manual, and certificate of conformity. These documents come standard with the purchase of the system.
- Extended: including material certificates, surface finish measurement records, and preventive maintenance document. These documents can be purchased at an additional cost.

Validation documentation, such as Installation and Operational Qualification (IQ/OQ) documents, as well as a service to perform actual qualification of the column on-site upon installation, can be ordered separately. These services help towards satisfying the increasingly strict demands posed by regulatory authorities who expect manufacturers of pharmaceuticals to qualify equipment before using in production.

Chemical resistance

Chemical compatibility data for VERSAchrom is listed in Table 3. The information has been collected from several published sources and not from individual tests of column components and should only be used as a guide. The effect of chemicals will generally be more severe at higher temperatures. Note also that the combined effects of agents have not been taken into account. The applicable chemical resistance depends on the configuration of the column and the associated materials of construction.

Table 3. Chemical compatibility

Chemical	Conc.	Time/cycle restrictions	Comments
Acetic acid	25% (v/v)	3 h	Clean-in-place (CIP)
Acetone	2% (v/v)	1 h	Function test
Ammonium sulphate	2 M	5 h	Adsorption
Benzyl alcohol	2% (v/v)	12 months	Storage
Ethanol	20% (v/v)	12 months and max 0.5 bar	Storage
Ethanol	70% (v/v)	1 h	Fume, wiping external surfaces
Ethanol/acetic acid	20% / 10% (v/v)	3 h	CIP
Guanidine hydrochloride	6 M	5 h	CIP
Hydrochloric acid	0.1 M (pH 1)	1 h	CIP
Hydrogen peroxide	10% (v/v)	1 h	Fume, wiping external surfaces
Isopropanol	10% / 30% (v/v)	1 h	CIP
Phosphoric acid	5% (v/v)	16 h	For passivation of SS parts
Per-acetic acid	4% (v/v)	1 h	Fume, wiping external surfaces
Sodium chloride	0 to 3 M	3 h	Purification, CIP
Sodium hydroxide	1 M (pH 14)	24 h	CIP
Sodium hydroxide	0,01 M (pH 12)	12 months	Storage
Sodium sulphate	1 M	3 h	Adsorption
Sodium hydroxide / Ethanol	1 M / 20% (v/v)	3 h	CIP
Urea	8 M	5 h	Purification, CIP
Commonly used aqueous buffers for chromatographic use	10 to 250 mM pH 3 to 10	24 h	Equilibration, adsorption, elution

Spare parts

Recommended spare parts for VERSAchrom and VERSAchrom adaptor handling unit are listed in Table 4 and 5.

Table 4. Recommended spare parts for VERSAchrom

Tag no	Description	Material	Units/ pack	Units installed	Incl. in PM	Recommended no of packs	Wetted part	Code number
1	Support net adaptor	PP	1	1	1	1	Yes	29-0401-05
2	Support net end piece	PP	1	1	1	1	Yes	29-0401-06
3	Net 23 µM adaptor	PP	1	1	1	1	Yes	29-0401-11
4	Net 23 µM end piece	PP	1	1	1	1	Yes	29-0401-12
5	U-Shaped seal	EPDM	1	1	1	1	Yes	29-0401-16
6	U-Shaped seal	FPM/FKM	1	-	-	-	Yes	29-0401-17
7	Flange O-ring 446 x 6	EPDM	2	1	1	1	Yes	29-0401-18
8	Flange O-ring 446 x 6	FEP	1	-	-	-	Yes	29-0401-19
9	Adaptor O-ring 419 x 10	EPDM	1	1	1	1	Yes	29-0401-20
10	Adaptor O-ring 419 x 10	FEP	1	-	-	-	Yes	29-0401-21
11	O-ring 12.3 x 2.4	EPDM	2	2	1	1	Yes	29-0401-22
12	O-ring 12.3 x 2.4	FEP	1	-	-	-	Yes	29-0401-23
13	Distribution plate	PP	2	2	1	1	Yes	29-0401-24
14	Snap plug	PP	2	2	1	_	Yes	29-0401-25

Table 5. Recommended spare parts for VERSAchrom adaptor handling unit

Tag no	Description	Material	Units/ pack	Units installed	Recommended no of packs	Wetted part	Code number
1	Nut Assembly for VERSAchrom 450	SS 304 / PEEK	1	1	1	No	29-0385-38
2	Bushing ring	PP	2	1	1	No	29-0401-26
3	Friction reduction washer	PP	2	1	1	No	29-0385-43

Accessories

Accessories for VERSAchrom are listed in Table 6.

Table 6. Recommended accessories for VERSAchrom

Tag no	Accessory	Material	Qty/pack	Code number
1	Air trap complete ¹	304/316/glass/EPDM	1	18-1103-00
2	Top valve ¹	316/EPDM	1	18-1121-44
3	Torque wrench	304	1	18-0251-37
4	12-point opening socket	304	1	18-1105-31
5	Allen key	304	1	18-1030-98
6	T-junction i.d. 10 mm ²	316	1	28-4057-75
7	Valve sealing washer³	PTFE	2	18-1128-69
8	Manometer kit (0 to 6 bar)	316L	1	28-9944-72
9	Wheel with brake			28-9226-77
10	Media stirrer (150 mm plate diameter)	PP	1	28-9191-04
11	Grounding kit		1	18-1157-87
Tubing	with sanitary fitting¹ length i.d.			
12	30 cm 10 mm	PVC	1	18-1012-85
13	40 cm 10 mm	PVC	1	18-1012-86
14	75 cm 14 mm	PVC	1	18-1027-28
15	90 cm 10 mm	PVC	1	18-1012-62
16	140 cm 10 mm	PVC	1	18-1012-63
17	170 cm 10 mm	PVC	1	18-1012-64
18	180 cm 14 mm	PVC	1	18-1027-29
19	200 cm 10 mm	PVC	1	18-1012-87
Connec	ctors ⁴			
20	TC 25 mm clamp-10mm 1/2in threaded	PP	2	18-1012-68
21	TC 25 ID10/TC51 ID14	PP	2	18-1027-25
22	Connector TC50 ID14 / TC50 ID22	PP	2	18-1027-26
Clamps	s, gaskets			
23	Clamp 25 mm	304	1	28-4043-38
24	Clamp 25 mm	316	12	44-0568-01
25	Clamp 51 mm	304	1	44-7134-01
26	Gasket 25 mm i.d. 10 mm	EPDM	2	18-1035-79
27	Gasket 25 mm i.d. 10 mm	FPM/FKM	2	28-9914-44
28	Gasket 25 mm i.d. 12 mm	EPDM	2	18-0200-00
29	Gasket 25 mm i.d. 12 mm	FPM/FKM	2	28-9914-47
30	Blind flange 25 mm incl. gasket	304/EPDM	1	18-1001-25
31	Gasket 51 mm i.d. 10 mm	EPDM	5	18-1012-88
32	Gasket 51 mm i.d. 14 mm	EPDM	5	18-1017-57
33	Gasket 51 mm i.d. 22 mm	EPDM	5	44-7133-01
34	Gasket 51 mm i.d. 22 mm	FPM/FKM	2	28-9914-54
35	Blind flange 51 mm incl. gasket	304/EPDM	1	44-7135-01
Valves				
36	4port, 2way i.d. 10 mm ¹	316L/PTFE	1	18-1012-56
37	4port, 4way i.d. 10 mm ¹	316L/PTFE	1	18-1012-57
38	3port, 2way i.d. 15 mm ¹	316L/PTFE	1	44-5499-90
39	Pressure relief valve i.d. 10 mm ¹	316L/FPM	1	18-1106-97
40	Safety valve ⁴	316/EPDM	1	18-1103-65

 $^{^2}$ 2 × 25 mm, 1 × 51 mm TC

 $^{^{\}rm 3}{\rm Fits}$ 6 and 10 mm, 2- and 4-way valves

⁴2.5 bar

Summary

Developed by GE Healthcare Life Sciences, a company with a long and proven history in column manufacturing, VERSAchrom offers superior performance across a range of chromatography applications, while helping to ensure compliance with regulatory requirements.

Ordering information

To order VERSAchrom, please contact your regional sales representative.

For local office contact information, visit www.gelifesciences.com/contact

www.gelifesciences.com

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