



Available Extractables Reports

Version Number:	12.0
Version Date:	October 16, 2023
Author:	Chien-Ju Shih

List of Extractables Reports for Pall Life Sciences Manufactured Components

Cytiva[®] (now including Pall Life Sciences) recognizes the need for standardized extractables data, such as those proposed by the BioPhorum Operations Group (BioPhorum) and United States Pharmacopeia (USP) <665>, which support risk assessment requirements and facilitate qualification of single-use systems (SUS).

This includes data aligned with BioPhorum, USP <665> as well as existing legacy compound-specific extractables reports.

Detailed legacy Pall Life Sciences product extractables reports may be accessed with an account via the [AcceleratorSM Regulatory Dossier](#). Additional Cytiva product extractables reports may be found via the [Cytiva Regulatory Support page](#).

Extractables reports for non-Cytiva/Pall Life Sciences manufactured components integrated in legacy Pall Life Sciences SUS may be available via the [Accelerator Regulatory Dossier](#) or the [BioPhorum Extractables Portal](#).

For further information as to how these reports relate to your specific process, or for support with simulation and leachables studies, please contact our [Accelerator Validation Services](#) team in [Europe](#), [Americas](#), [China](#), and [Greater Asia](#).

Table 1

The list of currently available BioPhorum, USP <665>, and legacy compound-specific extractables reports for Cytiva (legacy Pall Life Sciences)-manufactured components

Product Type	Product Description	Representative Part Number	Report Type	Primary MOC ¹	Pre-Treatment ² (Radiation, Autoclave)	Report ID	Solvent List ³
Biocontainer & Mixers	Allegro® 2D and 3D biocontainer chambers (film, port)	LGR0010L7700 (619-31A)	Comprehensive summary ⁴	ULDPE, HDPE	Radiation	USTR 3941	pH 3, pH 10, 50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl
	Magnetic mixer impeller	4100654	BioPhorum & USP <665>	HDPE, PVDF, ceramic	Radiation	VAL-AS-006929-ER1	50% EtOH, pH 1.6, pH 13.5, water, NaCl, pH 10
Mixers	Allegro single-use mixers	Various	Legacy	Various	Radiation	USTR 2777a	Water, EtOH
Bioreactor & Mixers	Large-scale drain valve (O-ring)	SC00817 (O-ring)	BioPhorum	Si	Radiation	VAL-AS-005734-ER	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl
	Broadley James® single-use pH sensor	SU-800-1100-N	USP <665>	PEEK, EPDM, Si	Radiation	VAL-AS-010802-ER	50% EtOH, pH 3, pH 10
	Broadley James® single-use bioprocessing container (BPC) gas well (sensor)	SU-100	USP <665>	PEEK, PPSU, Si	Radiation	VAL-AS-013144-ER	50% EtOH
	Large-scale drain valve (spigot)	SC00816, SC00817	BioPhorum	PBT	Radiation	VAL-AS-007006-ER1	50% EtOH, pH 1.6, pH 13.5, water, NaCl

Table 1 Continued

The list of currently available BioPhorum, USP <665>, and legacy compound-specific extractables reports for Cytiva (legacy Pall Life Sciences)-manufactured components

Product Type	Product Description	Representative Part Number	Report Type	Primary MOC ¹	Pre-Treatment ² (Radiation, Autoclave)	Report ID	Solvent List ³
Sterile Connectors	Kleenpak® sterile connector	KPCHT02F11, KPCHT02M11	Comprehensive summary	PC	Radiation and autoclave	USTR 3946	50% EtOH, pH 1.6, water, 1% PS80, NaCl, pH 10
	Kleenpak Presto sterile connector	PSC1G8	Comprehensive summary	PES	Radiation and autoclave	USTR 3947	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl
					Autoclave	VAL-AS-004126-ER1	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl
			BioPhorum	PSU	Radiation	VAL-AS-004126-ER2	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl
					Autoclave	VAL-AS-004126-ER3	pH 3, pH 10
	Kleenpak II sterile connector and disconnecter	KPD01HB6	USP <665>	PSU	Radiation	VAL-AS-004126-ER4	pH 3, pH 10

Table 1 Continued

The list of currently available BioPhorum, USP <665>, and legacy compound-specific extractables reports for Cytiva (legacy Pall Life Sciences)-manufactured components

Product Type	Product Description	Representative Part Number	Report Type	Primary MOC ¹	Pre-Treatment ² (Radiation, Autoclave)	Report ID	Solvent List ³
	Kleenpak capsules with Supor® EKV membrane	KA3EKVP1G	Comprehensive summary	PES, PP	Radiation and autoclave	USTR 3948	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl
					Autoclave	VAL-AS-005068-ER1	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl
	Kleenpak Nova capsules with Supor EKV membrane	NT6EKVP1G	BioPhorum	PES, PP	Radiation	VAL-AS-005068-ER2	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl
					Autoclave	VAL-AS-006888-ER1	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl, pH 10
	Kleenpak capsules with Supor EAV membrane	KA3EAVP1G	BioPhorum & USP <665>	PES, PP, Si	Radiation	VAL-AS-006888-ER2	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl, pH 10
	Kleenpak Nova capsules with Supor EX grade ECV membrane	NP6UECV1G	Comprehensive summary	PES, PP, Si	Radiation and autoclave	USTR 3949	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl, pH 10
	Kleenpak Nova capsules with Fluorodyne® EX grade EDF membrane	NT6UEDFP1G	Comprehensive summary	PES, PVDF, PP, Si	Radiation and autoclave	USTR 3950	50% EtOH, pH 1.6, water, pH 10
	Kleenpak Nova capsules with Fluorodyne EX grade EDT membrane	NT6UEDTP1G	Comprehensive summary	PES, PVDF, PP, Si	Radiation and autoclave	USTR 3951	50% EtOH, pH 1.6, water, 1% PS80, NaCl, pH 10
					Autoclave	VAL-AS-006449-ER1	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl, pH 10
Sterilizing Filters	Kleenpak Nova capsules with Supor EAV membrane	NT6UEAVP1G	BioPhorum & USP <665>	PES, PP, Si	Radiation	VAL-AS-006449-ER2	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl, pH 10

Table 1 Continued

The list of currently available BioPhorum, USP <665>, and legacy compound-specific extractables reports for Cytiva (legacy Pall Life Sciences)-manufactured components

Product Type	Product Description	Representative Part Number	Report Type	Primary MOC ¹	Pre-Treatment ² (Radiation, Autoclave)	Report ID	Solvent List ³
Sterilizing Filters	Supor Prime Filter	FC6ASFP1	BioPhorum & USP <665>	PES, PP	Autoclave	VAL-AS-012571-ER1	50% EtOH, pH 3, Water, pH 10, pH 13.5
	Supor Prime Filter	FC6ASFP1	BioPhorum & USP <665>	PES, PP	Radiation	VAL-AS-012571-ER2	50% EtOH, pH 3, Water, pH 10, pH 13.5
	Kleenpak Nova capsules with Fluorodyne II DFL membrane	NT6DFLP1G	BioPhorum & USP <665>	PVDF, PP, Si	Autoclave	VAL-AS-005884-ER1	50% EtOH, pH 1.6, water, 1% PS80, NaCl, pH 10
					Radiation	VAL-AS-005884-ER2	50% EtOH, pH 1.6, water, pH 10
			BioPhorum	PVDF, PP, Si	Radiation	VAL-AS-005884-ER3	1% PS80
					Autoclave	VAL-AS-002700-ER1 (01)	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl
					Radiation	VAL-AS-002700-ER2 (01)	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl
	Kleenpak capsules with Fluorodyne II DFL membrane	KA3DFLP1G	USP <665>	PVDF, PP	Autoclave	VAL-AS-009149-ER1	pH 10
					Radiation	VAL-AS-009149-ER2	pH 10
					Autoclave	VAL-AS-009305-ER1	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, pH 10
	Polypropylene filter hardware used in NP5L Kleenpak Nova capsules and AB05 filter cartridges	FY00630	BioPhorum & USP <665>	PP	Radiation	VAL-AS-009305-ER2	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, pH 10
		FY00111					

Table 1 Continued

The list of currently available BioPhorum, USP <665>, and legacy compound-specific extractables reports for Cytiva (legacy Pall Life Sciences)-manufactured components

Product Type	Product Description	Representative Part Number	Report Type	Primary MOC ¹	Pre-Treatment ² (Radiation, Autoclave)	Report ID	Solvent List ³
Sterilizing Filters	Kleenpak Nova capsules with Posidyne® membrane	NT6NFZP1G	BioPhorum & USP <665>	Nylon, PP, PE, Si	Autoclave	VAL-AS-008626-ER1	50% EtOH, pH 3, Water, 1% PS80, pH 10
	Ultipor® N66 filter cartridges	AB1NF7P	BioPhorum	PP, nylon	Autoclave	PHA-AM-009775-1	50% EtOH, water, 1% PS80, NaCl, pH 2.7, pH 11.8
						PHA-EU-000990-1	Water
	Emflon® II filter cartridges	AB1V0027PV	Legacy	PVDF, PP	Autoclave	PHA-EU-000990-4	50% EtOH
	Kleenpak capsules with Emflon II membrane	KA3V002PVIG	Legacy	PVDF, PP, EPDM	Radiation	PHA-EU-013161-ER	50% EtOH, water
Virus Filter	Kleenpak Nova capsules with Pegasus™ Prime virus removal filter membrane	NP6LUPRMP1S	BioPhorum	PES, PP	Autoclave	VAL-AS-004360-ER1	Water, pH 4, pH 9
	Kleenpak Nova capsules with Pegasus SV4 virus removal filter membrane	NT6USV4P1	BioPhorum	PVDF, PE, PP, Si	Autoclave	VAL-AS-008472-ER1	pH 1.6, water, pH 9
	Kleenpak Nova capsules with Pegasus Protect virus prefilter membrane	NP6PRTPI	BioPhorum & USP <665>	Nylon, PP, PE	Autoclave	VAL-AS-005331-ER1	Water, 50% EtOH, 1% PS80, NaCl, pH 4, pH 9
	Kleenpak Nova capsules with Pegasus Protect virus prefilter membrane	NP6LPRTPIG	BioPhorum & USP <665>	Nylon, PP, PE	Radiation	VAL-AS-005331-ER2	Water, 50% EtOH, pH 4, pH 9
					Autoclave	VAL-AS-009605-ER10	50% EtOH
Process Filter	Profile® II filter cartridges	AB1Y0057PH4	USP <665>	PP, PE, Si	Radiation	VAL-AS-009605-ER11	50% EtOH
	Duo-Fine® II series filter	DFNT04510USM7	USP <665>	Fiberglass, PP, PE, Si	Autoclave	PHA-AM-014106-ER3	50% EtOH

Table 1 Continued

The list of currently available BioPhorum, USP <665>, and legacy compound-specific extractables reports for Cytiva (legacy Pall Life Sciences)-manufactured components

Product Type	Product Description	Representative Part Number	Report Type	Primary MOC ¹	Pre-Treatment ² (Radiation, Autoclave)	Report ID	Solvent List ³
Fittings	Polypropylene fittings	FY02311	BioPhorum & USP <665>	PP	Radiation	VAL-AS-011234-ER	50% EtOH
TFF	Cadence® single-use TFF modules with Omega™ PES membrane	CSUM010T050, CSUM010T010	Legacy	PES, PSU, PP	N/A	USTR 2906	Water
	T-Series TFF cassettes with Omega membrane	OS030T06	Legacy	PES, urethane, PP	N/A	USTR 2928	25% EtOH
	T-Series TFF cassettes with Omega membrane	OS030T06	Legacy	PES, urethane, PP	N/A	TR451402732	Water
	Cadence inline diafiltration module with Omega PES membrane	DFOS030T120612	BioPhorum	PES, PP, Si, PSU	N/A	PHA-AM-013313-ER1	pH 1.6, pH 13.5, water
	Cadence inline diafiltration module with Delta regenerated cellulose membrane	DFDC030T120612	BioPhorum	Reg. cellulose, PP, Si	N/A	PHA-AM-013313-ER3	pH 1.6, pH 13.5, water
Filling Needles	Allegro single-use filling needle	DFNST1201160	BioPhorum & USP <665>	PEEK	Autoclave	VAL-AS-008892-ER1	Water, 50% EtOH, pH 3, pH 10
		DFNST1201160	BioPhorum & USP <665>	PEEK	Radiation	VAL-AS-008892-ER2	Water, 50% EtOH, pH 3, pH 10
		DFNLR1208632	Legacy	PEEK, PP	Radiation, Autoclave	USTR 2837a	Water, EtOH

¹ Materials of construction: ULDPE = Ultra-low density polyethylene; HDPE = High-density polyethylene; PC = Polycarbonate; PSU = Polysulfone; PES = Polyethersulfone; PP = Polypropylene; PVDF = Polyvinylidene fluoride; PEEK = Polyether ether ketone; Si = Silicone elastomer; PBT = Polybutylene terephthalate, EPDM = Ethylene propylene diene monomer.

² Extractions performed on post-Radiation irradiated or post-autoclaved test articles.

³ Solvents: 50% EtOH = 50% ethanol in water, 25% EtOH = 25% ethanol in water, pH 1.6 = 0.1 M H₃PO₄, pH 13.5 = 0.5 N NaOH, 1% PS80 = 1% polysorbate 80, pH 3 = USP <665> Solution C1, pH 10 = USP <665> Solution C2, NaCl = 5 M NaCl.

⁴ Summary of extractable studies and other relevant information supporting risk assessment with all report files embedded

**Corporate Headquarters**

Port Washington, NY, USA
+1-800-717-7255 toll free (USA)
+1-516-484-5400 phone

European Headquarters

Fribourg, Switzerland
+41 (0)26 350 53 00 phone

Asia-Pacific Headquarters

Singapore
+65 6389 6500 phone

Visit us on the Web at www.pall.com/biotech
Contact us at www.pall.com/contact

Pall Corporation has offices and plants throughout the world. To locate the Pall office or distributor nearest you, visit www.pall.com/contact.

The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

© Copyright 2023, Pall Corporation. Pall, , Allegro, Cadence, Duo-Fine, Emflon, Fluorodyne, Kleenpak, Omega, Pegasus, Posidyne, Profile, Supor, and Ultipor are trademarks of Pall Corporation. ® Indicates a trademark registered in the USA. Accelerator is a service mark of Pall Corporation.

*Cytiva is a trademark of Life Sciences IP Holdings Corporation (USA). Broadley James is a trademark of Broadley-James Corporation.