



Available Extractables Reports

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List of Available Extractables Reports for Pall-Manufactured Components

Pall Corporation 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.

Please find a list of our currently available extractables reports for components manufactured by Pall and integrated into Pall single-use systems (SUS) (Table 1). This includes data aligned with BioPhorum, USP <665>, as well as existing legacy compound-specific extractables reports.

The detailed extractables reports may be accessed with an account via the [AcceleratorSM Regulatory Dossier](#).

Additional extractables reports for non-Pall manufactured components integrated in Pall SUS may be found 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 Pall-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™ 1 L system - film	619-31A (film)	BioPhorum	ULDPE	Radiation	VAL-AS-003176-ER	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl
			USP <665>	ULDPE	Radiation	VAL-AS-003176-ER	pH 3, pH 10
	Allegro 1 L system - HDPE ports	619-31A (port)	BioPhorum	HDPE	Radiation	VAL-AS-003177-ER	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl
			USP <665>	HDPE	Radiation	VAL-AS-003177-ER	pH 3, pH 10
Mixers	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
	Allegro single-use mixers	Various	Legacy	Various	Radiation	USTR2777a	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

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; PPSU = Polyphenylsulfone.

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

³ Solvents: 50% EtOH = 50% 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.

Table 1 Continued

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

Product Type	Product Description	Representative Part Number	Report Type	Primary MOC ¹	Pre-Treatment ² (Radiation, Autoclave)	Report ID	Solvent List ³
					Autoclave	VAL-AS-006265-ER1	50% EtOH, pH 1.6, water, 1% PS80, NaCl, pH 10
	Kleenpak® sterile connector	KPCHT02F11, KPCHT02M11	BioPhorum & USP <665>	PC	Radiation	VAL-AS-006265-ER2	50% EtOH, pH 1.6, water, 1% PS80, NaCl, pH 10
					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
	Kleenpak II sterile connector and disconnecter	KPD01HB6	USP <665>	PSU	Autoclave	VAL-AS-004126-ER3	pH 3, pH 10
					Radiation	VAL-AS-004126-ER4	pH 3, pH 10
					Autoclave	VAL-AS-002951-ER1	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl
Sterile Connectors	Kleenpak Presto sterile connector	PSC1G8	BioPhorum	PES	Radiation	VAL-AS-002951-ER2	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl

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³ Solvents: 50% EtOH = 50% 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.

Table 1 Continued

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

Product Type	Product Description	Representative Part Number	Report Type	Primary MOC ¹	Pre-Treatment ² (Radiation, Autoclave)	Report ID	Solvent List ³
					Autoclave	VAL-AS-02790-ER1 (01)	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl
			BioPhorum	PES, PP	Radiation	VAL-AS-02790-ER2 (01)	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl
					Autoclave	VAL-AS-012299-ER1	pH 10
	Kleenpak capsules with Supor® EKV membrane	KA3EKVP1G	USP <665>	PES, PP	Radiation	VAL-AS-012299-ER2	pH 10
					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
					Autoclave	VAL-AS-007314-ER1	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl, pH 10
Sterilizing Filters	Kleenpak Nova capsules with Supor EX grade ECV membrane	NP6UECVPIG	BioPhorum & USP <665>	PES, PP, Si	Radiation	VAL-AS-007314-ER2	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl, pH 10

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.

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Table 1 Continued

The list of currently available BioPhorum, USP <665>, and legacy compound-specific extractables reports for Pall-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 Nova capsules with Fluorodyne® EX grade EDF membrane	NT6UEDFP1G	BioPhorum & USP <665>	PES, PVDF, PP, Si	Autoclave	VAL-AS-004780-ER1	50% EtOH, pH 1.6, water, pH 10	
					Radiation	VAL-AS-004780-ER2	50% EtOH, pH 1.6, water, pH 10	
	Kleenpak Nova capsules with Fluorodyne EX grade EDT membrane	NT6UEDTP1G	BioPhorum & USP <665>	PES, PVDF, PP, Si	Autoclave	VAL-AS-007888-ER1	50% EtOH, pH 1.6, water, 1% PS80, NaCl, pH 10	
					Radiation	VAL-AS-007888-ER2	50% EtOH, pH 1.6, water, 1% PS80, NaCl, pH 10	
	Sterilizing Filters	Kleenpak capsules with Fluorodyne II DFL membrane	KA3DFLP1G	USP <665>	PVDF, PP	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
						Autoclave	VAL-AS-009149-ER1	pH 10
						Radiation	VAL-AS-009149-ER2	pH 10

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Table 1 Continued

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

Product Type	Product Description	Representative Part Number	Report Type	Primary MOC ¹	Pre-Treatment ² (Radiation, Autoclave)	Report ID	Solvent List ³
					Autoclave	VAL-AS-005884-ER1	50% EtOH, pH 1.6, water, 1% PS80, NaCl, pH 10
	Kleenpak Nova capsules with Fluorodyne II DFL membrane	NT6DFLP1G	BioPhorum & USP <665>	PVDF, PP, Si	Radiation	VAL-AS-005884-ER2	50% EtOH, pH 1.6, water, pH 10
			BioPhorum	PVDF, PP, Si	Radiation	VAL-AS-005884-ER3	1% PS80
	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
					Autoclave	VAL-AS-006449-ER1	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, NaCl, pH 10
	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
					Autoclave	VAL-AS-009305-ER1	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, pH 10
	Polypropylene filter hardware used in Pall NP5L Kleenpak Nova capsules and AB05 filter cartridges	FY00631 FY00630 FY00111	BioPhorum & USP <665>	PP	Radiation	VAL-AS-009305-ER2	50% EtOH, pH 1.6, pH 13.5, water, 1% PS80, pH 10
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

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Table 1 Continued

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Sterilizing Filters						PHA-EU-000990-1	Water
	Emflon® II filter cartridges	AB1V0027PV	Legacy	PVDF, PP	Autoclaved	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	NP6LUPRMPIS	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

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Fittings	Polypropylene fittings	FY02311	BioPhorum & USP <665>	PP	Radiation	VAL-AS-011234-ER	50% EtOH
	Cadence® single-use TFF modules with Omega™ PES membrane	CSUM010T050, CSUM010T010	Legacy	PES, PSU, PP	N/A	USTR2906	Water
	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
TFF	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
		DFNST1201160	BioPhorum & USP <665>	PEEK	Autoclave	VAL-AS-008892-ER1	Water, 50% EtOH, pH 3, pH 10
Filling Needles	Allegro single-use filling needle	DFNLR1208632	Legacy	PEEK, PP	Radiation, Autoclave	USTR 2837a	Water, EtOH

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