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Product Type	Product description	Representative part number	Primary fluid contacting material of construction[1]	Pretreatment[2]	Extractables study design			Comment	Applicable extractables reports	Report portal[5]
					USP<665>[3]	BioPhorum	Legacy[4]			
Aseptic connector	ReadyMate™ DAC	28936688	PC	Irradiation & Autoclave	H	Yes	—	Cytiva manufactured component	Component family file: ReadyMate DAC. Extractables study: 17-002	Reg. Sup.
	Kleenpak® sterile connector	KPCHT02F11 KPCHT02M11	PC	Irradiation & Autoclave	H	Yes	—	Cytiva manufactured component	USTR 3946 (Comprehensive summary)	ADC
	Kleenpak® Presto sterile connector	PSC1G8	PES	Irradiation & Autoclave	M	Yes	—	Cytiva manufactured component	USTR 3947 (Comprehensive summary)	ADC
	Kleenpak® II sterile connector and disconnector	KPD01HB6	PSU	Irradiation & Autoclave	H	Yes	—	Cytiva manufactured component	USTR 4100	ADC
Biocontainers, mixers and bags	HyClone™ liquid media and buffer bags with CX5-14 film	N/A	Polyolefin	Irradiation	M	Yes	—	Information is provided per component in alignment with BioPhorum guide	Extractables study 15-004 CX5-14 film	Reg. Sup.
	HyClone™ liquid media and buffer bags with Cytiva Film Cell Culture 1	N/A	Polyolefin	Irradiation	H	Yes	—	Information is provided per component in alignment with BioPhorum guide	Extractables study 22-031 Cytiva™ Film Cell Culture 1	Reg. Sup.
	HyClone™ liquid media and buffer bags with Aegis 5-14 film	N/A	Polyolefin	Irradiation	M	Yes	—	Information is provided per component in alignment with BioPhorum guide	Extractables study: 15-005 Aegis5-14 film	Reg. Sup.
	HyClone™ liquid media and buffer bags - Tubing	N/A	PVC	Irradiation	H	—	—	Information is provided per component in alignment with BioPhorum guide	Extractables study 24-020 SV21413 – Tubing Medical Grade PVC	Reg. Sup.
	HyClone™ liquid media and buffer bags - Ports	N/A	Polyolefin Elastomer	Irradiation	H	Yes	—	Information is provided per component in alignment with BioPhorum guide	Extractables study 24-019 - POE Ports	Reg. Sup.
	ReadyToProcess™ bags with Fortem™ film	29381886	Polyolefin	Irradiation	H	Yes	—	Information is provided per component in alignment with BioPhorum guide	Assembly Family File: Assembly family ReadyToProcess bags with Fortem film - guide to extractables studies of components	Reg. Sup.
	ReadyCircuit™ bags with Fortem™ film China	29315051	Polyolefin	Irradiation	H	Yes	—	Information is provided per component in alignment with BioPhorum guide	Assembly Family File: Assembly family ReadyCircuit bags with Fortem film Extractables study: 15-003 Fortem film. Extractables study: 20-002 Fortem film in 2% Benzyl alcohol and Phosphate buffer pH 10	Reg. Sup.
	ReadyCircuit™ bags with ReadyKleer™ film	12410225	Polyolefin	Irradiation	M	Yes	Yes	1) Information is provided per component in alignment with BioPhorum guide. 2) In addition, a study was performed on assembled bags.	1) Extractables study: 15-002 ReadyKleer film 2) Validation guide: VG ReadyCircuit - extractables study on Hanging bag assembly	Reg. Sup.
	WAVE Cellbag™ bioreactor and M*bag Mixing bags with Fortem™ film	CB0002L722-11-01PK	Polyolefin	Irradiation	H	Yes	—	Information is provided per component in alignment with BioPhorum guide	Extractables study: 15-003 Fortem film. Extractables study: 20-002 Fortem film in 2% Benzyl alcohol and Phosphate buffer pH 10. Validation guide: VG Cellbag Bioreactor bags with Fortem film	Reg. Sup.
	WAVE Cellbag™ bioreactor and mixer bags with Fortem™ film China	CB0001L722-01-08PK-CN	Polyolefin	Irradiation	H	Yes	—	Information is provided per component in alignment with BioPhorum guide	Extractables study: 15-003 Fortem film Extractables study: 20-002 Fortem film Validation guide: VG Cellbag Bioreactor bags with Fortem film China - presents data from Extractables study 15-003 plus studies on extractable antioxidant (TBPP) and its degradation products	Reg. Sup.
	WAVE Cellbag™ bioreactor and M*bag Mixing bag with Bioclear™ 11 film	CB0002L11-01	EVA	Irradiation	M	Yes	Yes	1) Information is provided per component in alignment with BioPhorum guide. 2) In addition, a study was performed on assembled bags.	1) Extractables study: 15-006 Bioclear 11 film 2) Validation guide: VG Cellbag bioreactor and M*bag mixing bag with Bioclear 11 film - presents study on Cellbag assembly	Reg. Sup.

Product Type	Product description	Representative part number	Primary fluid contacting material of construction[1]	Pretreatment[2]	USP<665>[3]	BioPhorum	Legacy[4]	Comment	Applicable extractables reports	Report portal[5]
Biocontainers, mixers and bags	WAVE Cellbag™ bioreactor and M*bag mixing bags with Bioclear™ 10 film	CB0002L10-01	EVA	Irradiation	—	—	Yes	Testing in line with former industry best practice performed on complete assemblies. No further testing is planned.	Validation guide: VG Cellbag bioreactor and M*bag mixing bag with Bioclear 10 film - presents studies on Cellbag assemblies	Reg. Sup.
	Xcellerex™ XDM bags with Fortem™ film	29300460	Polyolefin	Irradiation	H	Yes	—	Information is provided per component in alignment with BioPhorum guide	Assembly Family File: Assembly family XDM bags with Fortem film - guide to extractables studies of components	Reg. Sup.
	Xcellerex™ XDM bags with ASI 26/77 film	888-0086-N	Polyolefin	Irradiation	M	Yes	Yes	1) Information is provided per component in alignment with BioPhorum guide. 2) In addition, a study was performed on PEEK impeller in line with former best practice testing.	1) Extractables study: 15-001 ASI 26/77 film 2) Validation guide: VG Xcellerex XDA disposable assemblies - extractables study on PEEK impeller and listing of surface areas of bag film and impellers	Reg. Sup.
	Xcellerex™ XDR bags with ASI 26/77 film	888-0070-C	Polyolefin	Irradiation	M	Yes	Yes	1) Information is provided per component in alignment with BioPhorum guide. 2) In addition, a study was performed on PEEK impeller and polycarbonate material of XDR 500MO impeller in line with former best practice testing.	1) Extractables study: 15-001 ASI 26/77 film 2) Validation guide: VG Xcellerex XDA disposable assemblies - extractables studies on PEEK impeller and polycarbonate material, with surface areas of bag film and impellers	Reg. Sup.
	Xcellerex™ XDR perfusion bags with ASI 26/77 film	29605397	Polyolefin	Irradiation	M	Yes	—	Information is provided per component in alignment with BioPhorum guide	Assembly Family File: Assembly family Bioreactor bags for Xcellerex APS - guide to extractables studies of components.	Reg. Sup.
	Xcellerex™ XDR- bags with ReadyKleer™ film	29398286	Polyolefin	Irradiation	M	Yes	—	1) Information is provided per component in alignment with BioPhorum guide. 2) In addition, a study was performed on PEEK impeller in line with former best practice testing.	Asselby Family File: Assembly family XDR bags with ReadyKleer film 2) Validation guide: VG XDA disposable assemblies - extractables study on PEEK impeller and listing of surface areas of bag film and impellers	Reg. Sup.
	Xcellerex™ X-platform bioceactor bags	29696534	Polyolefin	Irradiation	M	Yes	—	Information is provided per component in alignment with BioPhorum guide.	Assembly Family File: Assembly family Xcellerex X-platform bioreactor bags	Reg. Sup.
	Assembly family XDR-2000L Pro Max Bag	29724937	Polyolefin	Irradiation	M	Yes	—	Information is provided per component in alignment with BioPhorum guide.	Assembly Family File: Assembly family XDR-2000L Pro Max Bag - guide to extractables studies of components.	Reg. Sup.
	Allegro Film	(619-31A)	ULDPE	Irradiation	—	—	Yes	100% Ethanol, 8 hours	VSI-SH-04053-ER1	ADC
	HDPE Biocontainer Ports	AX000077	HDPE	Irradiation	—	—	Yes	100% Ethanol, 8 hours	VSI-SH-04053-ER2	ADC
	Allegro™ 2D and 3D biocontainer chambers (film, port)	LGR0010L7700 (619-31A)	ULDPE, HDPE	Irradiation	H	Yes	—	Version 3	USTR 3941 (Comprehensive summary)	ADC
	Allegro™ 2D and 3D mixers	LGRMX200L	ULDPE, HDPE, PSU, LDPE, Si	N/A	H	Yes	—		USTR 4119 (Materials, Surface Areas, and Applicable Extractables Reports)	ADC
	Magnetic mixer impeller	4100654	HDPE, PVDF, ceramic	Irradiation	H	Yes	—		VAL-AS-006929-ER1	ADC
	Allegro™ single-use mixers	Various	Various	Irradiation	—	—	Yes		USTR 2777a	ADC
	LevMixer & Magnetic Mixers	LGRLMC0050L0001	ULDPE, HDPE	N/A	H	Yes	—	Version 2	USTR 3983 (Materials, Surface Areas, and Applicable Extractables Reports)	ADC
	Allegro™ Cubical Magnetic Mixer	LGRLMC0050L0001	ULDPE, HDPE, Si, PC	Irradiation	—	—	Yes	30% DMSO, 30% DMA, 50% Ethanol	ADC solvent evaluation report	ADC
	Wandmixers	LGRWM10L01	ULDPE, HDPE, PSU, LDPE, Si	N/A	M	Yes	Yes		USTR 4128 (Materials, Surface Areas, and Applicable Extractables Reports)	ADC
	PadMixers	LGRPM0025LC03185	ULDPE, HDPE, PSU, LDPE, Si	N/A	H	Yes	—		USTR 4145 (Materials, Surface Areas, and Applicable Extractables Reports)	ADC

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Column housing	AxiChrom™ 50 to 200 columns	29016534	Glass	Cleaning in place (CIP)	—	—	Yes		Extractables study: 15-015 AxiChrom 50 to 200 columns	Reg. Sup.
	AxiChrom™ 300 to 1600 columns	29457805	Polymethyl methacrylate (PMMA)	CIP	—	—	Yes		Extractables study: 15-014 AxiChrom 300 to 1600 columns	Reg. Sup.
	BPG columns	18110301	Glass	CIP	—	—	Yes		Extractables study: 15-017 BPG columns	Reg. Sup.
	Chromaflow™ columns	18116141	PMMA	CIP	—	—	Yes		Extractables study: 15-016 Chromaflow columns	Reg. Sup.
	ReadyToProcess™ column housings ≤359 mm	N/A	Polyolefin	N/A	M	Yes	—		Validation guide: VG ReadyToProcess columns	Reg. Sup.
	ReadyToProcess™ column housings ≥450 mm	N/A	PMMA	N/A	M	Yes	—		Validation guide: VG ReadyToProcess columns	Reg. Sup.
Chromatographic resins (plastic containing)	Sephacryl	17061201	Allyl dextran and N,N-methylene bisacrylamide	N/A	H	Yes	—		Extractables study 25-005 Sephacryl S-100 HR	Reg. Sup.
	Source	17512003	Polystyrene/divinyl benzene	N/A	H	Yes	—		Extractables study 25-006 SOURCE 30RPC	Reg. Sup.
Filling needles	Allegro™ single-use filling needle	DFNST1208632	PEEK	Irradiation and autoclave	H	Yes	—		VAL-AS-008892-ER1 (Autoclave) VAL-AS-008892-ER2 (Irradiation)	ADC
	Allegro™ single-use filling needle	DFNLR1208632	PEEK, PP	Irradiation and autoclave	—	—	Yes		USTR 3568 (TOC, NVR, Elemental impurity)	ADC
Fittings	Polypropylene fittings	FY02311	PP	Irradiation	M	—	—		VAL-AS-011234-ER	ADC
	Allegro™ Fittings (Poplypropylene Blanking Cap)	SC02278	PP	Irradiation	M	—			VAL-AS-014599-ER	ADC
	Cytiva powder port	700223	HDPE	Irradiation	H	—	—		VSI-SH-01146-ER	ADC
	Large-scale drain valve (O-ring)	SC00817 (O-ring)	Si	Irradiation	M	Yes	—		VAL-AS-005734-ER	ADC
	Silicone gasket	FY01712	Si	Irradiation	M	—	—		VAL-AS-013292-ER	ADC
	Large-scale drain valve (spigot)	SC00816, SC00817	PBT	Irradiation	M	Yes	—		VAL-AS-007006-ER1	ADC
Hardware system	ÄKTA™ Pilot 600	29274328	Fluorinated Ethylene Propylene (FEP)	CIP	M	Yes	—		Extractables study: 17-001 ÄKTA pilot 600	Reg. Sup.
	ÄKTA process™	N/A	Polyolefin	CIP	H	Yes	Yes		1) Extractables study: 15-019 ÄKTAprocess PP system 2) Extractables study: 22-001 ÄKTA process	Reg. Sup.
	UniFlux™ 30	29001375	Stainless steel	CIP	—	—	Yes	Testing in line with former industry best practice performed on complete UniFlux 30 SS system. No further testing is planned.	Extractables study: 15-020 UniFlux 30	Reg. Sup.
Process filters	ULTA™ Prime GF	28908433	Glass microfiber	Autoclave	—	—	Yes	Testing in line with former industry best practice performed on complete assemblies. No further testing is planned.	Extractables study: 15-023 ULTA Prime GF	Reg. Sup.
	ULTA™ Prime PP	28908477	Polyolefin	Autoclave	—	—	Yes	Testing in line with former industry best practice performed on complete assemblies. No further testing is planned.	Extractables study: 15-024 ULTA Prime PP	Reg. Sup.
	ReadyToProcess™ ULTA™ filter capsules	29410059	Polyethersulfone	Irradiation	—	—	Yes	Testing in line with former industry best practice performed on complete assemblies. No further testing is planned.	Validation guide: VG ReadyCircuit - extractables studies on ReadyToProcess ULTA HC; ULTA SG; ULTA CG; ULTA GF assemblies	Reg. Sup.
Process filters	Profile® II KleenpaK™ Nova Filter	NP6Y005P1G	PP, Si	Autoclave	M	—	—		Extractables study: 25-020	Reg. Sup.
	Preflow™ KleenpaK™ Nova Capsules	NP6UUAP1G	Glass fiber, PP, PET	Irradiation	M	—	—		Extractables study: 25-021	Reg. Sup.
	Preflow™ KleenpaK™ Nova Capsules	NP6UUAP1G	Glass fiber, PP, PET	Autoclave	M	—	—		Extractables study: 25-022	ADC
	KleenpaK™ Nova Capsule with Ultipleat Profile™ filter	NP6UUAP1G	Glass fiber, PP, PET	Autoclave	M	—	—		VAL-AS-04183-ER1 (Autoclave) VAL-AS-04183-ER2 (Irradiation)	ADC
	KleenpaK™ Nova Capsules with HDC II® membrane	NP6UY045P1G	PP, Si	Irradiation and autoclave	M	—	—		VSI-SH-03151-ER1 (Autoclave) VSI-SH-03151-ER2 (Irradiation)	ADC
	KleenpaK™ Nova Profile™ Star Filter Capsules	NP6A030P1G	PP, Si	Irradiation and autoclave	M	—	—		VSI-SH-04184-ER1 (Autoclave) VSI-SH-04184-ER2 (Irradiation)	ADC
	Starclear™ KleenpaK™ Nova Filter Capsules	NP6HAZP1G	Hydrophilic PES, PP, Si	Autoclave	M	—	—		VSI-SH-04289-ER1	ADC
	Kleenpak® capsules with Supor EAV membrane	KA3EAVP1G	PES, PP, Si	Irradiation and autoclave	H	Yes	—		VAL-AS-006888-ER1 (Autoclave) VAL-AS-006888-ER2 (Irradiation)	ADC
	Kleenpak® Nova capsules with Supor EAV membrane	NT6UEAVP1G	PES, PP	Irradiation and autoclave	H	Yes	—		VAL-AS-006449-ER1 (Autoclave) VAL-AS-006449-ER2 (Irradiation)	ADC
	Duo-Fine® II series filter	DFNT04510USM7	Fiberglass, PP, PE, Si	Autoclave	M	—	—		PHA-AM-014106-ER3	ADC
	Emflon™ FM Filter Cartridge	AB1FM7PH4	PTFE, PP, Si	Autoclave	M	—	—		VSI-SH-03730-ER1	ADC

Product Type	Product description	Representative part number	Primary fluid contacting material of construction[1]	Pretreatment[2]	USP<665>[3]	BioPhorum	Legacy[4]	Comment	Applicable extractables reports	Report portal[5]
Sterilizing grade filters	Kleenpak® capsules with Supor® EKV membrane	KA3EKVP1G	PES, PP	Irradiation and autoclave	H	Yes	—		USTR 3948 (Comprehensive summary)	ADC
	Supor® EKV membrane filter cartridges and Kleenpak® Nova capsules (including 5-inch, Mini Kleenpak 20, and Novasip capsule)	NT6EKVP1G	PES, PP	Irradiation and autoclave	M	Yes	—	Version 2 Now includes pH10 data	USTR 4090 (Comprehensive summary)	ADC
	Kleenpak® Nova capsules with Supor® EX grade ECV membrane	NP6UECVP1G	PES, PP, Si	Irradiation and autoclave	H	Yes	—		USTR 3949 (Comprehensive summary)	ADC
	Kleenpak® Nova capsules with Fluorodyne® EX grade EDF membrane	NT6UEDFP1G	PES, PVDF, PP, Si	Irradiation and autoclave	H	Yes	—	Version 2	USTR 3950 (Comprehensive summary)	ADC
	Kleenpak® Nova capsules with Fluorodyne® EX grade EDT membrane	NT6UEDTP1G	PES, PVDF, PP, Si	Irradiation and autoclave	H	Yes	—		USTR 3951 (Comprehensive summary)	ADC
	Supor Prime Filter in Kleenpak® Spectrum Capsule and Cartridge Format	FC6ASFP1	PES, PP	Irradiation and autoclave	H	Yes	—		VAL-AS-012571-ER1 (Autoclave) VAL-AS-012571-ER2 (Irradiation)	ADC
	Fluorodyne® II membrane filter capsules and cartridges	NT6DFLP1G	PVDF, PP, Si	Irradiation and autoclave	H	Yes	—	DFL/DBL/DJL	USTR 4093 (Comprehensive summary)	ADC
	Kleenpak® capsules with Fluorodyne® II membrane	KA3DFLP1G	PVDF, PP	Irradiation and autoclave	H	Yes	—	DFL/DBL/DJL	USTR 4092 (Comprehensive summary)	ADC
	5-inch Kleenpak® Nova filter capsules and cartriges with Fluorodyne® II membrane	NP5LDFLP1G	PVDF, PP	Irradiation and autoclave	H	Yes	—		USTR 4094 (Comprehensive summary)	ADC
	Polypropylene filter hardware used in Pall NP5L Kleenpak® Nova capsules and AB05 filter cartridges	FY00631, FY00630, FY00111	PP	Irradiation and autoclave	H	Yes	—		VAL-AS-009305-ER1 (Autoclave) VAL-AS-009305-ER2 (Irradiation)	ADC
	Kleenpak® Nova capsules with Posidyne® membrane	NT6NFZP1G	Nylon, PP, PE, Si	Autoclave	H	Yes	—		VAL-AS-008626-ER1	ADC
	Kleenpak™ Capsules with Ultipor® N66 Membrane	KA3NFP1G	Nylon, PP, PE, EPDM	Irradiation and autoclave	H	Yes	—		VAL-AS-013006-ER1 (Autoclave) VAL-AS-013006-ER2 (Irradiation)	ADC
	Ultipor® N66 filter cartridges	AB1NF7P	PP, Nylon	Autoclave	M	Yes	—		PHA-AM-009775-1	ADC
	Emflon® II filter cartridges	AB1V0027PV	PVDF, PP	Autoclave	M	—	Yes	Bracleted by NP6V002P1G reports (VSI-SH-01993-ER1 and -ER2)	PHA-EU-000990-1 (Water) PHA-EU-000990-4 (50% Ethanol)	ADC
	Kleenpak® Nova capsules with Emflon II membrane	NP6V002P1G	PVDF, PP, Si	Irradiation and autoclave	M	—	—		VSI-SH-01993-ER1 (Autoclave) VSI-SH-01993-ER2 (Irradiation)	ADC
	Kleenpak® capsules with Emflon II membrane	KA3V002PV1G	PVDF, PP, EPDM	Irradiation	M	—	Yes		PHA-EU-013161-ER	ADC
Virus filters	Kleenpak Nova capsules with Pegasus™ Prime virus removal filter membrane	NP6LUPRMP1S	PES, PP	IrIrradiation and autoclave	H	Yes	—		VAL-AS-004360-ER (00) (IrIrradiation) VAL-AS-004360-ER1(01) (Autoclave)	ADC
	Kleenpak Nova capsules with Pegasus™ SV4 virus removal filter membrane	NT6USV4P1	PVDF, PE, PP, Si	Autoclave	H	Yes	—		VAL-AS-008472-ER1	ADC
	Kleenpak Nova capsules with Pegasus™ Protect virus prefilter membrane	NP6PRTP1	Nylon, PP, PE	Autoclave	H	Yes	—		VAL-AS-005331-ER1	ADC
	Kleenpak Nova capsules with Pegasus™ Protect virus prefilter membrane	NP6LPRTP1G	Nylon, PP, PE	Irradiation	H	Yes	—		VAL-AS-005331-ER2	ADC
	Kleenpak Nova capsules with Ultipor™ VF DVD membrane	NT6DVDP1G	PVDF, PP	Autoclave	H	—	—		VSI-SH-04010-ER1	ADC
	Kleenpak Nova capsules with Ultipor™ VF UDV50 membrane	NP6LUDV50P1	PVDF, PP, PET	Autoclave	H	—	—		VSI-SH-03765-ER1	ADC
	Kleenpak Nova capsules with Ultipor™ VF UDV20 membrane	NP6LUDV20P1	PVDF, PP, PET	Autoclave	H	—	—		VSI-SH-03690-ER1	ADC
Tangential flow filters (TFF)	Cadence® single-use TFF modules with Omega™ PES membrane	CSUM010T050, CSUM010T010	PES, PSU, PP	N/A	—	—	Yes		USTR 2906 (Water) USTR 2928 (25% Ethanol)	ADC
	T-Series TFF cassettes with Omega membrane	OS030T06	PES, urethane, PP	N/A	—	—	Yes		TR451402732	ADC
	Cadence inline diafiltration module with Omega PES membrane	DFOS030T120612	PES, PP, Si, PSU	N/A	—	Yes			PHA-AM-013313-ER1	ADC
	Cadence inline diafiltration module with Delta regenerated cellulose membrane	DFDC030T120612	Reg. cellulose, PP, Si	N/A	—	Yes	—		PHA-AM-013313-ER3	ADC
	ReadyToProcess Microfiltration hollow fiber filter	RTPCFP-2-E-6S RTPCFP-2-E-8S	Polysulfone	Irradiation	H	Yes	Yes	1) Testing performed in line with former industry best practice performed on complete assemblies. 2) Tested in alignment with BioPhorum guide and USP <665>.	1) Extractables study: 15-021 Hollow fiber cartridges 2) Extractables study 21-014 HF CFP RTP	Reg. Sup.
	ReadyToProcess Ultrafiltration hollow fiber filter	RTPUFP-30-C-6S RTPUFP-750-E-6S RTPUFP-500-C-35	Polysulfone	Irradiation	H	Yes	Yes	1) Testing performed in line with former industry best practice performed on complete assemblies. 2) Tested in alignment with BioPhorum guide and USP <665>.	1) Extractables study: 15-021 Hollow fiber cartridges 2) Extractables study 21-013 HF UFP RTP	Reg. Sup.
	Microfiltration hollow fiber filter	CFP-2-E-6A CFP-2-E-35STM CFP-1-D-5A	Polysulfone	CIP / Steam in place (SIP)	H	Yes	Yes	1) Testing performed in line with former industry best practice performed on complete assemblies. 2) Tested in alignment with BioPhorum guide and USP <665>.	1) Extractables study: 15-021 Hollow fiber cartridges 2) Extractables study 21-012 HF CFP Autoclave	Reg. Sup.
	Ultrafiltration hollow fiber filter	UFP-10-C-6A UFP-100-E-6A UFP-10-E-35 UFP-10-C-55STM UFP-10-E-55STM	Polysulfone	CIP / SIP	H	Yes	Yes	1) Testing performed in line with former industry best practice performed on complete assemblies. 2) Tested in alignment with BioPhorum guide and USP <665>.	1) Extractables study: 15-021 Hollow fiber cartridges 2) Extractables study: 18-019 Hollow fiber ultrafiltration cartridges	Reg. Sup.

Product Type	Product description	Representative part number	Primary fluid contacting material of construction[1]	Pretreatment[2]	USP<665>[3]	BioPhorum	Legacy[4]	Comment	Applicable extractables reports	Report portal[5]
Sensors	Broadley James® single-use pH sensor	SU-800-1100-N	PEEK, EPDM, Si	Irradiation	H	—	—		VAL-AS-010802-ER	ADC
	Broadley James® single-use bioprocessing container (BPC) gas wells	SU-100	PEEK, PPSU, Si	Irradiation	M	—	—		VAL-AS-013144-ER	ADC
Flow kits	Single-Use Needle and Flow Path with DAC	610477 604877 610478 610479 600460 604975	Si	Irradiation	M	Yes	Yes	Information is provided per component in alignment with BioPhorum guide	Assembly Family File: Assembly family information Single-Use Needle (SUN) and Flow Path with DAC	Reg. Sup.
	Allegro™ Connect Bulk Fill system	ACBFSCEPLC ACBFSCEIO ACBFSULIO ACBFSULPLC	Slicone, PP, PSE, PES	Irradiation	H	Yes	—	Representative assembly tested for scaling to user's system	VAL-AS-014453-ER	ADC
	ÄKTA ready™ Flow Kit	28930182	Si	Irradiation	H	Yes	—	Additional extractables studies were performed in DMSO and DMA.	Validation guide: VG ÄKTA ready Flow Kit	Reg. Sup.
	ÄKTA ready™ XL Flow Kit	29264593	Si	Irradiation	M	Yes	—		Validation guide: VG ÄKTA ready XL Flow Kit	Reg. Sup.
	ÄKTA readyflux™ Flow Kit	29187383	Thermoplastic elastomer (TPE)	Irradiation	H	Yes	—	Additional extractables studies were performed in DMSO and DMA.	Assembly family ÄKTA readyflux flow kit Validation guide: VG ÄKTA readyflux Flow Kit	Reg. Sup.
	ÄKTA readyflux™ XL Flow Kit	29403132	Si	Irradiation	M	Yes	—		Assembly Family File: Assembly family ÄKTA readyflux XL flow kit - guide to extractables studies of components	Reg. Sup.
	ÄKTA ready™ 450 Flow Kit	29631244	Si	Irradiation	M	Yes	—		Assembly Family File: Assembly family ÄKTA ready 450 flow kit - guide to extractables studies of components	Reg. Sup.
	NFF pump Flow kits	29707092	Si	Irradiation	M	Yes	—		Assembly family NFF Pump Flow kit	Reg. Sup.
	Tubing kit for AxiChrom™ 200	28943020	Si	N/A	—	—	Yes	Testing in line with former industry best practice performed on complete assemblies. No further testing is planned.	Extractables study: 15-027 Silicone Tubing Kit for AxiChrom 200	Reg. Sup.
	Tubing kit for chromatography hardware	28938126	Polytetrafluoroethylene (PTFE)	N/A	—	—	Yes	Testing in line with former industry best practice performed on complete assemblies. No further testing is planned.	Extractables study: 15-028 Tubing PTFE	Reg. Sup.
	Xcellerex™ APS flow kit	29377111	TPE	Irradiation	H	Yes	—	Information is provided per component in alignment with BioPhorum guide	1) Assembly family file: Xcellerex APS flow kit - guide to extractables studies of components. 2) Extractables study: 19-002 Xcellerex APS flow kit.	Reg. Sup.
	NxGen scale-ready cartridge 12L/h	29803653	Cyclic olefin polymer	Irradiation	H	—	—	100% Ethanol included	Extractable study PHA-AM-016099	Reg. Sup.
	NxGen commercial flow kit for use with NanoAssemblr commercial formulation system	1002279	N/A	Irradiation	H	Yes	—		Extractable study 24-017 (VAL-AS-015755)	Reg. Sup.

Note 1: Materials of construction: ULDPE = Ultra-low density polyethylene; HDPE = High-density polyethylene; EVA= Ethylenevinylacetate; 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.
Note 2: Irradiation refers to X-ray and/or Gamma irIrradiation.
Note 3: USP<665> is divided into High (H) or Moderate (M) risk level study design. Only fully satisfied USP <665> high risk dataset would be marked H, otherwise M.
Note 4: Dataset available using different study design than USP<665> or BPOG.
Note 5: See description on top how to access the portal.
Note 6: Summary of extractable studies and other relevant information supporting risk assessment with all report files embedded.