

This information was updated in December 2022

How to obtain extractables information

1. Navigate to cytiva.com/rsf
2. Create an account if necessary and log in to the Regulatory support portal. A confidentiality agreement will need to be accepted and approved before access to reports is provided.
3. Under Search & Subscribe, click on the Extractables information tab.
4. For products identified with an Assembly Family File below, locate and subscribe to this file first as it lists all extractables reports available for the assembly family.
5. Go to My Subscriptions and click on Extractables Information to view the Assembly Family File you have subscribed to.
6. Go back to Search & Subscribe/Extractables information. Locate and subscribe to the applicable Extractables Reports for the assembly of interest.
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8. For products identified with extractables data in Validation Guide, return to Search & Subscribe, click on the Validation guides tab and subscribe to the desired validation guide.
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Product Type	Product description	Representative part number	Main fluid contacting material of construction	Pretreatment	Extractables study design	Applicable extractables reports	BioPhorum protocol test status	Target date
Aseptic connector	ReadyMate™ DAC	28936688	Polycarbonate	Gamma & Autoclave	Tested in alignment with BioPhorum guide and USP <665>	Component family file: ReadyMate DAC. Extractables study: 17-002	Completed	N/A
Bag	HyClone™ liquid media and buffer bags with CX5-14 film	N/A	Polyolefin	Gamma	Information is provided per component in alignment with BioPhorum guide	Extractables study: 15-004 CX5-14 film	Completed	N/A
	HyClone liquid media and buffer bags with Aegis 5-14 film	N/A	Polyolefin	Gamma	Information is provided per component in alignment with BioPhorum guide	Extractables study: 15-005 Aegis5-14 film	Completed	N/A
	ReadyToProcess™ bags with Fortem film	29381886	Polyolefin	Gamma	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	Completed	N/A
	ReadyCircuit bags with Fortem film China	29260177	Polyolefin	Gamma	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	Completed	N/A
	ReadyCircuit bags with ReadyKleer film	12410225	Polyolefin	Gamma	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	Completed	N/A
	WAVE Cellbag™ bioreactor and M*bag Mixing bags with Fortem film	CB0002L722-11-01PK	Polyolefin	Gamma	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 - presents studies on extractable antioxidant (TBPP) and its degradation products	Completed	N/A
	WAVE Cellbag bioreactor and mixer bags with Fortem film China	CB0001L722-01-08PK-CN	Polyolefin	Gamma	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	Completed	N/A
WAVE Cellbag bioreactor and M*bag Mixing bag with Bioclear™ 11 film	CB0002L11-01	Ethylenevinylacetate (EVA)	Gamma	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 Mbag mixing bag with Bioclear 11 film - presents study on Cellbag assembly	Completed	N/A	

Product Type	Product description	Representative part number	Main fluid contacting material of construction	Pretreatment	Extractables study design	Applicable extractables reports	BioPhorum protocol test status	Target date
Bag (cont.)	WAVE Cellbag bioreactor and M*bag mixing bags with Bioclear 10 film	CB0002L10-01	EVA	Gamma	Testing in line with former industry best practice performed on complete assemblies. No further testing is planned.	<i>Validation guide:</i> VG Cellbag bioreactor and Mbag mixing bag with Bioclear 10 film - presents studies on Cellbag assemblies	N/A	N/A
	Xcellerex™ XDM bags with Fortem film	29300460	Polyolefin	Gamma	Information is provided per component in alignment with BioPhorum guide	<i>Assembly Family File:</i> Assembly family XDM bags with Fortem film - guide to extractables studies of components	Completed	N/A
	Xcellerex XDM bags with ASI 26/77 film	888-0086-N	Polyolefin	Gamma	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) <i>Extractables study:</i> 15-001 ASI 26/77 film 2) <i>Validation guide:</i> VG Xcellerex XDA disposable assemblies - extractables study on PEEK impeller and listing of surface areas of bag film and impellers	Completed	N/A
	Xcellerex XDR bags with ASI 26/77 film	888-0070-C	Polyolefin	Gamma	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) <i>Extractables study:</i> 15-001 ASI 26/77 film 2) <i>Validation guide:</i> VG Xcellerex XDA disposable assemblies - extractables studies on PEEK impeller and polycarbonate material, with surface areas of bag film and impellers	Completed	N/A
	Xcellerex XDR perfusion bags with ASI 26/77 film	29605397	Polyolefin	Gamma	Information is provided per component in alignment with BioPhorum guide	<i>Assembly Family File:</i> Assembly family Bioreactor bags for Xcellerex APS - guide to extractables studies of components.	Completed	N/A
	Xcellerex XDR-10 bags with ReadyKleer film	29398286	Polyolefin	Gamma	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) <i>Extractables study:</i> 15-002 ReadyKleer film 2) <i>Validation guide:</i> VG XDA disposable assemblies - extractables study on PEEK impeller and listing of surface areas of bag film and impellers	Completed	N/A
Column housing	AxiChrom™ 50 to 200 columns	29016534	Glass	Cleaning in place (CIP)	Testing in line with former industry best practice performed on assembled column. No further testing is planned.	<i>Extractables study:</i> 15-015 AxiChrom 50 to 200 columns	N/A	N/A
	AxiChrom 300 to 1600 columns	29457805	Polymethyl methacrylate (PMMA)	CIP	Testing in line with former industry best practice performed on assembled column. No further testing is planned.	<i>Extractables study:</i> 15-014 AxiChrom 300 to 1600 columns	N/A	N/A
	BPG columns	18110301	Glass	CIP	Testing in line with former industry best practice performed on assembled column. No further testing is planned.	<i>Extractables study:</i> 15-017 BPG columns	N/A	N/A
	Chromaflo™ columns	18116141	PMMA	CIP	Testing in line with former industry best practice performed on assembled column. No further testing is planned.	<i>Extractables study:</i> 15-016 Chromaflo columns	N/A	N/A
	ReadyToProcess column housings ≤359 mm	N/A	Polyolefin	N/A	Assembled column housings were tested at conditions in alignment with BioPhorum guide.	<i>Validation guide:</i> VG ReadyToProcess columns	Completed	N/A
	ReadyToProcess column housings ≥450 mm	N/A	PMMA	N/A	Assembled column housings were tested at conditions in alignment with BioPhorum guide.	<i>Validation guide:</i> VG ReadyToProcess columns	Completed	N/A

Product Type (cont.)	Product description	Representative part number	Main fluid contacting material of construction	Pretreatment	Extractables study design	Applicable extractables reports	BioPhorum protocol test status	Target date
Hardware system	ÅKTA™ Pilot 600	29274328	Fluorinated Ethylene Propylene (FEP)	CIP	Complete system was tested in alignment with BioPhorum guide.	<i>Extractables study:</i> 17-001 ÅKTA pilot 600	Completed	N/A
	ÅKTA process™	N/A	Polyolefin	CIP	1) Testing in line with former industry best practice performed on complete system. 2) Tested in alignment with USP <665> performed on complete system	1) <i>Extractables study:</i> 15-019 ÅKTAprocess PP system 2) <i>Extractables study:</i> 22-001 ÅKTA process	N/A	N/A
	UniFlux™ 30	29001375	Stainless steel	CIP	Testing in line with former industry best practice performed on complete UniFlux 30 SS system. No further testing is planned.	<i>Extractables study:</i> 15-020 UniFlux 30	N/A	N/A
Process filter	ULTA™ Prime GF	28908433	Glass microfiber	Autoclave	Testing in line with former industry best practice performed on complete assemblies. No further testing is planned.	<i>Extractables study:</i> 15-023 ULTA Prime GF	N/A	N/A
	ULTA Prime PP	28908477	Polyolefin	Autoclave	Testing in line with former industry best practice performed on complete assemblies. No further testing is planned.	<i>Extractables study:</i> 15-024 ULTA Prime PP	N/A	N/A
	ReadyToProcess ULTA filter capsules	29410059	Polyethersulfone	Gamma	Testing in line with former industry best practice performed on complete assemblies. No further testing is planned.	<i>Validation guide:</i> VG ReadyCircuit - extractables studies on ReadyToProcess ULTA HC; ULTA SG; ULTA CG; ULTA GF assemblies	N/A	N/A
Tangential-flow filter (TFF)	ReadyToProcess Microfiltration hollow fiber filter	RTPCFP-2-E-6S	Polysulfone	Gamma	1) Testing performed in line with former industry best practice performed on complete assemblies. 2) Testing on-going in alignment with BioPhorum guide and USP <665>.	1) <i>Validation guide:</i> VG ReadyToProcess hollow fiber cartridges. 2) <i>Extractables study:</i> ReadyToProcess Microfiltration hollow fiber filters (on-going)	Started	Q3 2023
	ReadyToProcess Ultrafiltration hollow fiber filter	RTPUFP-30-C-6S RTPUFP-750-E-6S	Polysulfone	Gamma	1) Testing performed in line with former industry best practice performed on complete assemblies. 2) Testing on-going in alignment with BioPhorum guide and USP <665> guide.	1) <i>Validation guide:</i> VG ReadyToProcess hollow fiber cartridges 2) <i>Extractables study:</i> ReadyToProcess Ultrafiltration hollow fiber filters (on-going)	Started	Q3 2023
	Microfiltration hollow fiber filter	CFP-2-E-6A CFP-2-E-35STM	Polysulfone	CIP / Steam in place (SIP)	1) Testing performed in line with former industry best practice performed on complete assemblies. 2) Testing on-going in alignment with BioPhorum guide and USP <665>.	1) <i>Extractables study:</i> 15-021 Hollow fiber cartridges 2) <i>Extractables study:</i> Microfiltration hollow fiber filters (on-going)	Started	Q3 2023
	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	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) <i>Extractables study:</i> 15-021 Hollow fiber cartridges 2) <i>Extractables study:</i> 18-019 Hollow fiber ultrafiltration cartridges	Completed	N/A

Product Type (cont.)	Product description	Representative part number	Main fluid contacting material of construction	Pretreatment	Extractables study design	Applicable extractables reports	BioPhorum protocol test status	Target date
Tubing kit	ÅKTA ready™ Flow Kit	28930182	Silicone	Gamma	Assembled kits were tested at conditions aligning with BioPhorum guide and USP <665>. In addition, extractables studies were performed in DMSO and DMA.	<i>Validation guide:</i> VG ÅKTA ready Flow Kit	Completed	N/A
	ÅKTA ready XL Flow Kit	29264593	Silicone	Gamma	Assembled kits were tested at conditions aligning with BioPhorum guide.	<i>Validation guide:</i> VG ÅKTA ready XL Flow Kit	Completed	N/A
	ÅKTA readyflux™ Flow Kit	29187383	Thermoplastic elastomer (TPE)	Gamma	Assembled kits were tested at conditions aligning with BioPhorum guide.	<i>Validation guide:</i> VG ÅKTA readyflux Flow Kit	Completed	N/A
	ÅKTA readyflux XL Flow Kit	29403132	Silicone	Gamma	Information is provided per component in alignment with BioPhorum guide.	<i>Assembly Family File:</i> Assembly family ÅKTA readyflux XL flow kit - guide to extractables studies of components	Completed	N/A
	ÅKTA ready 450 Flow Kit	29631244	Silicone	Gamma	Information is provided per component in alignment with BioPhorum guide.	<i>Assembly Family File:</i> Assembly family ÅKTA ready 450 flow kit - guide to extractables studies of components	Completed	N/A
	Tubing kit for AxiChrom 200	28943020	Silicone	N/A	Testing in line with former industry best practice performed on complete assemblies. No further testing is planned.	<i>Extractables study:</i> 15-027 Silicone Tubing Kit for AxiChrom 200	N/A	N/A
	Tubing kit for chromatography hardware	28938126	Polytetrafluoroethylene (PTFE)	N/A	Testing in line with former industry best practice performed on complete assemblies. No further testing is planned.	<i>Extractables study:</i> 15-028 Tubing PTFE	N/A	N/A
	Xcellerex APS flow kit	29377111	TPE	Gamma	1) Information is provided per component in alignment with BioPhorum guide. 2) In addition, assembled flow kits were tested aligned with USP <665>.	1) <i>Assembly family file:</i> Xcellerex APS flow kit - guide to extractables studies of components. 2) <i>Extractables study:</i> 19-002 Xcellerex APS flow kit.	Completed	N/A

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