



Biotech

Technical Regulatory Topic

Extractables Reports Information

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List of Available Extractables Reports for Pall-Manufactured Components

Pall Biotech recognizes the need for standardized extractables data, such as those proposed by the BioPhorum Operations Group (BPOG) 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. They are for components manufactured by Pall Biotech and integrated into Pall single-use systems (Table 1). We have data compliant with BPOG and USP as well as existing legacy compound-specific data.

Please email requests for specific reports (indicated in Table 1) to Catherine_hohil@pall.com (Americas), Virginie_brochier@europe.pall.com (EU/UK), Christina_bruntner@europe.pall.com (EU/UK), Zhaodi_Zhang@Pall.com (China), or Anand_ibrahimpur@ap.pall.com (rest of Asia-Pacific).

For extractables reports on components manufactured by third-party suppliers that are integrated into Pall single-use systems, please contact Pall.

Table 1.

The list of currently available BPOG, 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 (Gamma, Autoclave) | Report ID | Solvent List ³ |
|-----------------------|---|----------------------------|------------------|--------------------------|--|-------------------|---|
| Biocontainer & mixers | Allegro™ 1 L system - film | 619-31A (film) | BPOG | ULDPE | Gamma | VAL-AS-003176-ER | 50% EtOH, pH 1.6, pH 13.5, water, PS80, NaCl |
| | | | USP <665> | ULDPE | Gamma | VAL-AS-003176-ER | pH 3, pH 10 |
| | Allegro 1 L system - HDPE ports | 619-31A (port) | BPOG | HDPE | Gamma | VAL-AS-003177-ER | 50% EtOH, pH 1.6, pH 13.5, water, PS80, NaCl |
| | | | USP <665> | HDPE | Gamma | VAL-AS-003177-ER | pH 3, pH 10 |
| Mixers | Magnetic Mixer | 4100654 | BPOG & USP <665> | HDPE, PVDF, ceramic | Gamma | VAL-AS-006929-ER1 | 50% EtOH, pH 1.6, pH 13.5, water, NaCl, pH 10 |
| | Allegro™ single-use mixers | Various | Legacy | Various | Gamma | USTR2777a | Water, EtOH |
| Bioreactor & mixers | Large drain valve (O-ring) | SC00817 (O-ring) | BPOG | Si | Gamma | VAL-AS-005734-ER | 50% EtOH, pH 1.6, pH 13.5, water, PS80, NaCl |
| | Spigot component of the large-scale drain valve | SC00816, SC00817 | BPOG | PBT | Gamma | VAL-AS-007006-ER1 | 50% EtOH, pH 1.6, pH 13.5, water, NaCl |

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

| Product Type | Product Description | Representative Part Number | Report Type | Primary MOC ¹ | Pre-Treatment ² (Gamma, Autoclave) | Report ID | Solvent List ³ |
|--------------------|---|----------------------------|------------------|--------------------------|--|-----------------------|---|
| Sterilizing filter | Kleenpak™ capsules with Supor® EKV membrane | KA3EKVP1G | BPOG | PES, PP | Autoclave | VAL-AS-02790-ER1 (01) | 50% EtOH, pH 1.6, pH 13.5, water, PS80, NaCl |
| | | | BPOG | PES, PP | Gamma | VAL-AS-02790-ER2 (01) | 50% EtOH, pH 1.6, pH 13.5, water, PS80, NaCl |
| | Kleenpak™ Nova capsules with Supor® EKV membrane | NT6EKVP1G | BPOG | PES, PP | Autoclave | VAL-AS-005068-ER1 | 50% EtOH, pH 1.6, pH 13.5, water, PS80, NaCl |
| | | | BPOG | PES, PP | Gamma | VAL-AS-005068-ER2 | 50% EtOH, pH 1.6, pH 13.5, water, PS80, NaCl |
| | Kleenpak™ capsules with Supor® EAV membrane | KA3EAVP1G | BPOG & USP <665> | PES, PP, Si | Autoclave | VAL-AS-006888-ER1 | 50% EtOH, pH 1.6, pH 13.5, water, PS80, NaCl, pH 10 |
| | | | BPOG & USP <665> | PES, PP, Si | Gamma | VAL-AS-006888-ER2 | 50% EtOH, pH 1.6, pH 13.5, water, PS80, NaCl, pH 10 |
| | Kleenpak™ Nova capsules with Supor® EX grade ECV membrane | NP6UECVP1G | BPOG & USP <665> | PES, PP, Si | Autoclave | VAL-AS-007314-ER1 | 50% EtOH, pH 1.6, pH 13.5, water, PS80, NaCl, pH 10 |
| | | | BPOG & USP <665> | PES, PP, Si | Gamma | VAL-AS-007314-ER2 | 50% EtOH, pH 1.6, pH 13.5, water, PS80, NaCl, pH 10 |

| Product Type | Product Description | Representative Part Number | Report Type | Primary MOC ¹ | Pre-Treatment ² (Gamma, Autoclave) | Report ID | Solvent List ³ |
|--------------------|--|----------------------------|------------------|--------------------------|--|------------------------|--|
| Sterilizing filter | Kleenpak™ Nova capsules with Fluorodyne® EX grade EDF membrane | NT6UEDFP1G | BPOG & USP <665> | PES, PVDF, PP, Si | Autoclave | VAL-AS-004780-ER1 | 50% EtOH, pH 1.6, water, pH 10 |
| | | | BPOG & USP <665> | PES, PVDF, PP, Si | Gamma | VAL-AS-004780-ER2 | 50% EtOH, pH 1.6, water, pH 10 |
| | Kleenpak™ Nova capsules with Fluorodyne® EX grade EDT membrane | NT6UEDTP1G | BPOG & USP <665> | PES, PVDF, PP, Si | Autoclave | VAL-AS-007888-ER1 | 50% EtOH, pH 1.6, water, PS80, NaCl, pH 10 |
| | | | BPOG & USP <665> | PES, PVDF, PP, Si | Gamma | VAL-AS-007888-ER2 | 50% EtOH, pH 1.6, water, PS80, NaCl, pH 10 |
| | Kleenpak™ capsules with Fluorodyne® II DFL membrane | KA3DFLP1G | BPOG | PVDF, PP | Autoclave | VAL-AS-002700-ER1 (01) | 50% EtOH, pH 1.6, pH 13.5, water, PS80, NaCl |
| | | | BPOG | PVDF, PP | Gamma | VAL-AS-002700-ER2 (01) | 50% EtOH, pH 1.6, pH 13.5, water, PS80, NaCl |
| | | | USP <665> | PVDF, PP | Autoclave | VAL-AS-009149-ER1 | pH 10 |
| | | | USP <665> | PVDF, PP | Gamma | VAL-AS-009149-ER2 | pH 10 |

| Product Type | Product Description | Representative Part Number | Report Type | Primary MOC ¹ | Pre-Treatment ² (Gamma, Autoclave) | Report ID | Solvent List ³ |
|--------------------|--|-------------------------------|------------------|--------------------------|--|-------------------|---|
| Sterilizing filter | Kleenpak™ Nova capsules with Fluorodyne® II DFL membrane | NT6DFLP1G | BPOG & USP <665> | PVDF, PP, Si | Autoclave | VAL-AS-005884-ER1 | 50% EtOH, pH 1.6, water, PS80, NaCl, pH 10 |
| | Ultipor® N66 filter cartridges | AB1NF7P | BPOG | PP, nylon | Autoclave | PHA-AM-009775-1 | 50% EtOH, water, PS80, NaCl, pH 2.7, pH 11.8 |
| | Kleenpak™ Nova capsules with Supor® EAV membrane | NT6UEAVP1G | BPOG & USP <665> | PES, PP, Si | Autoclave | VAL-AS-006449-ER1 | 50% EtOH, pH 1.6, pH 13.5, water, PS80, NaCl, pH 10 |
| | | | BPOG & USP <665> | PES, PP, Si | Gamma | VAL-AS-006449-ER2 | 50% EtOH, pH 1.6, pH 13.5, water, PS80, NaCl, pH 10 |
| | Polypropylene filter hardware used in Pall NP5L Kleenpak™ Nova capsules and AB05 filter cartridges | FY00631 FY00630 FY00111 | BPOG & USP <665> | PP | Autoclave | VAL-AS-009305-ER1 | 50% EtOH, pH 1.6, pH 13.5, water, PS80, pH 10 |
| | Kleenpak™ Nova capsules with Posidyne® membrane | NT6NFZP1G | BPOG & USP <665> | Nylon, PP, PE, Si | Autoclave | VAL-AS-008626-ER1 | 50% EtOH, pH 3, Water, PS80, pH 10 |
| | Emflon® II filter cartridges | AB1V0027PV | Legacy | PVDF, PP | Autoclaved | PHA-EU-000990-1 | Water |
| | | | Legacy | PVDF, PP | Autoclaved | PHA-EU-000990-4 | 50% EtOH |
| | Kleenpak™ capsules with Emflon® II membrane | KA3V002PV1G | Legacy | PVDF, PP, EPDM | Gamma | PHA-EU-013161-ER | 50% EtOH, water |

| Product Type | Product Description | Representative Part Number | Report Type | Primary MOC ¹ | Pre-Treatment ² (Gamma, Autoclave) | Report ID | Solvent List ³ |
|----------------|---|----------------------------|------------------|--------------------------|--|--------------------|-------------------------------|
| Virus filter | Kleenpak™ Nova capsules with Pegasus™ Prime virus removal filter membrane | NP6LUPRMP1S | BPOG | PES, PP | Gamma | VAL-AS-004360-ER | Water, PS80, NaCl, pH 4, pH 9 |
| | | | BPOG & USP <665> | PES, PP | Autoclave | VAL-AS-004360-ER1 | Water, pH 4, pH 9 |
| | Kleenpak™ Nova capsules with Pegasus™ SV4 virus removal filter membrane | NT6USV4P1 | BPOG | PVDF, PE, PP, Si | Autoclave | VAL-AS-008472-ER1 | pH 1.6, water, pH 9 |
| Process filter | Kleenpak™ Nova capsules with Pegasus™ Protect virus prefilter membrane | NP6PRTP1 | BPOG | Nylon, PP | Autoclave | VAL-AS-005331-ER1 | Water, PS80, NaCl, pH 4, pH 9 |
| | Profile® II Filter cartridges | AB1Y0057PH4 | USP <665> | PP, PE, Si | Autoclave | VAL-AS-009605-ER10 | 50% EtOH |
| | | | USP <665> | PP, PE, Si | Gamma | 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 |

| Product Type | Product Description | Representative Part Number | Report Type | Primary MOC ¹ | Pre-Treatment ² (Gamma, Autoclave) | Report ID | Solvent List ³ |
|---|--|----------------------------|------------------|--------------------------|--|-------------------|---------------------------|
| Fittings | Polypropylene fittings | FY02311 | BPOG & USP <665> | PP | Gamma | VAL-AS-011234-ER | 50% EtOH |
| TFF | Cadence [®] single-use TFF modules with Omega [™] PES membrane | CSUM010T050, CSUM010T010 | Legacy | PES, PSU, PP | N/A | USTR2906 | Water |
| | | | Legacy | PES, PSU, PP | N/A | USTR2906 | 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 | BPOG | 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 | BPOG | Reg. cellulose, PP, Si | N/A | PHA-AM-013313-ER3 | pH 1.6, pH 13.5, water |
| Filling needle | Allegro [™] single-use filling needle | DFNLR1208632 | Legacy | PEEK, PP | Gamma, Autoclave | USTR 2837a | Water, EtOH |
| <ol style="list-style-type: none"> 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. Extractions performed on post-gamma irradiated or post-autoclaved test articles. Solvents: 50% EtOH = 50% ethanol in water, pH 1.6 = 0.1 M H₃PO₄, pH 13.5 = 0.5 N NaOH, PS80 = 1% polysorbate 80, pH 3 = USP <665> Solution C1, pH 10 = USP <665> Solution C2, NaCl = 5 M NaCl | | | | | | | |



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