wmarchitect
single-use solutions

Validation full guide

Single-use fluid transfer standard assemblies

WATSON MARLOW Fluid Technology Solutions

This is the full validation guide for WMArchitect™ standard assemblies. This guide contains hyperlinks to the full validation guides for the individual components where the reader can find the full reports which provide the detailed test procedures and actual test results (section 7, page 14).

Contents

1. Introduction

WMArchitect™ single-use solutions deliver a variety standard configurations for basic bioprocessing fluid transfer applications. WMArchitect manages a range of standard components and assemblies that can be used in combination with a Watson-Marlow Pump to deliver a total fluid transfer solution. All fluid-contacting components have been validated to fulfil requirements for biopharmaceutical processing. This validation guide covers the components, materials, and the manufacturing processes of the whole assembly, including sterilisation by gamma irradiation which is available on request.

For a detailed list and data sheets of our standard fluid transfer configurations, please visit : Single-use fluid transfer assemblies | WMFTS. Detailed drawings are available from your local Watson-Marlow representative.

Custom configurations are available upon request. Depending on the extent of customisation, this validation guide may not apply. Please check with your local Watson-Marlow representative where necessary.

Standard WMArchitect fluid transfer assemblies will be from now known as *assemblies*.

2. Conditions of Use

Standard assemblies are suitable for use using the conditions in Table 1.

Table 1. Conditions for manufacturing, sterilisation, working and storage of assemblies.

Manufacturing	Sterilisation	Maximum	Storage
ISO 14644-1 class 7 cleanrooms	All configurations of standard assemblies are sold non-irradiated.	For information on the use of higher pressures for your standard assembly, please contact your local WMFTS representative.	Ambient Temperature
ISO 9001 quality management system, following ISO 13485 principles.	Suitable for gamma irradiation up to 50 kGy		Dry environment, away from direct sunlight
ISO 14001 environmental management			No exposure to chemicals or stress

Original packaging must be retained and stock rotated on a first in, first out (FIFO) basis. The performance of components cannot be assured beyond use by date or when not stored according to recommendations above.

3. Chemical Compatibility

Based on the material of construction, our standard assemblies are compatible with a variety of fluids including weak and strong acids and bases. For specific applications, it is advisable for these standard assemblies to be tested under actual process conditions (see section 5 validation testing services).

4. Validation Testing

Each assembly has a unique lot number that enables each component to be fully traced to its constituent materials. Reference is also made to the quality processes employed at every stage in the manufacture of the assemblies.

Please note that compliance stated in Table 2 may come from the suppliers of the various components and not be based on in-house testing.

4a. Summary Table

Table 2. Testing Summary of evaluated standards.

Product	Biocompatibility									
	USP <85> Endotoxin	USP <87> Biological Reactivity, *in vitro*	USP <88> Biological Reactivity, *in vivo*	USP <788> Particulate	ISO 10993-4 Interactions with blood	ISO 10993-5 Cytotoxicity	ISO 10993-6 Implantation	ISO 10993-10 Sensitisation	ISO 10993-11 Systemic Toxicity	ADCF or EMA/410/01
Bioprene Tubing	✓*	✓	✓	✓*	✓	✓	✓	✓	✓	✓
Pumpsil Tubing	✓*	✓	✓	✓*	✓	✓	✓	✓	✓	✓
PureWeld XL Tubing	✓*	✓	✓	✓*	✓	✓	✓	✓	✓	✓
Silicone Braided Hose	✓*	✓	✓	✓*	✓	✓	✓	✓	✓	✓
STA-PURE PCS Tubing		✓	✓							✓
Silicone Gasket	✓*	✓	✓	✓*	✓	✓	✓	✓	✓	✓
BioBarb	✓*	✓	✓	✓*	✓	✓	✓	✓	✓	✓
Y-Connector *(Eldon James Corp.)*	✓*		✓	✓*	✓	✓				✓
Y-Connector *(Nordson Medical)*	✓*			✓*	✓	✓				✓

Aseptiquik Connectors	✓*	✓	✓	✓*		✓		✓	✓	✓
MPC Connector	✓*	✓	✓	✓*		✓		✓	✓	✓
MPU Connector	✓*	✓	✓	✓*		✓		✓	✓	✓
MPX Connector	✓*	✓	✓	✓*		✓		✓	✓	✓
BioClamp	✓*	✓	✓	✓*		✓	✓	✓	✓	✓

✓* - This material is evaluated for endotoxin (USP <85>) and sub-visible particulate (USP <788>) during internal periodic testing by WMFTS.

4b. Components in the fluid path

Bioprene Tubing

Bioprene tubing is entirely manufactured from virgin raw material: no rework material is used. Full traceability is assured through the lot number of the tubing, enabling identification of the raw material throughout manufacture, and in the quality control and production records.

Table 3. Testing summary of Bioprene tubing.

Test	Description	Result
USP <85>	Bacterial endotoxin test	PASS
USP <87>	Biological reactivity tests, *in vitro*	PASS
USP <88>	Biological reactivity tests, *in vivo*	PASS
USP <788>	Particulate matter in injections	PASS
ISO 10993-4	Biological evaluation of medical devices, Tests for interactions with blood	PASS
ISO 10993-5	Biological evaluation of medical devices, Tests for *in vitro* cytotoxicity	PASS
ISO 10993-6	Biological evaluation of medical devices, Tests for local effects after implantation	PASS
ISO 10993-10	Biological evaluation of medical devices, Kligman Maximisation test	PASS
ISO 10993-10	Biological evaluation of medical devices, Sensitisation	PASS
ISO 10993-11	Biological evaluation of medical devices, Tests for systemic toxicity	PASS
USP <381>	Elastomeric closures for injections	PASS
Extractables	Analysis of material extracts for organic extractables and extractables metals	REPORT

Pumpsil Tubing

Pumpsil tubing is entirely manufactured from virgin raw material: no rework material is used. Full traceability is assured through the lot number of the tubing, enabling identification of the raw material throughout manufacture, and in the quality control and production records.

Table 4. Testing summary of Pumpsil tubing.

Test	Description	Result
USP <85>	Bacterial endotoxin test	PASS
USP <87>	Biological reactivity tests, *in vitro*	PASS
USP <88>	Biological reactivity tests, *in vivo*	PASS
USP <788>	Particulate matter in injections	PASS
ISO 10993-4	Biological evaluation of medical devices, Tests for interactions with blood	PASS
ISO 10993-5	Biological evaluation of medical devices, Tests for *in vitro* cytotoxicity	PASS
ISO 10993-6	Biological evaluation of medical devices, Tests for local effects after implantation	PASS
ISO 10993-10	Biological evaluation of medical devices, Sensitisation	PASS
ISO 10993-10	Biological evaluation of medical devices, Kligman Maximisation test	PASS
ISO 10993-11	Biological evaluation of medical devices, Tests for systemic toxicity	PASS
USP <381>	Elastomeric closures for injections	PASS
EP 3.1.9	Silicone elastomer for closures and tubing	PASS
Extractables	Analysis of material extracts for organic extractables and extractables metals	REPORT

PureWeld XL Tubing

PureWeld XL tubing is entirely manufactured from virgin raw material: no rework material is used. Full traceability is assured through the lot number of the tubing, enabling identification of the raw material throughout manufacture, and in the quality control and production records.

Table 5. Testing summary of PureWeld XL tubing.

Test	Description	Result
USP <87>	Biological reactivity tests, *in vitro*	PASS
USP <88>	Biological reactivity tests, *in vivo*	PASS
USP <788>	Particulate matter in injections	PASS
ISO 10993-4	Biological evaluation of medical devices, Tests for interactions with blood	PASS
ISO 10993-5	Biological evaluation of medical devices, Tests for *in vitro* cytotoxicity	PASS
ISO 10993-6	Biological evaluation of medical devices, Tests for local effects after implantation	PASS
ISO 10993-10	Biological evaluation of medical devices, Kligman Maximisation test	PASS
ISO 10993-10	Biological evaluation of medical devices, Sensitisation	PASS
ISO 10993-11	Biological evaluation of medical devices, Tests for systemic toxicity	PASS
Extractables	Analysis of material extracts for organic extractables and extractables metals	REPORT

Silicone Braided Hose

Silicone Braided Hose is manufactured at Watson-Marlow Manufacturing Inc., Devens, MA, USA and is a high-pressure flexible hose with continuously extruded platinum cured silicone core.

Table 6. Testing summary of Silicone Braided hose.

Test	Description	Result
USP <85>	Bacterial endotoxin test	PASS
USP <87>	Biological reactivity tests, *in vitro*	PASS
USP <88>	Biological reactivity tests, *in vivo*	PASS
USP <788>	Particulate matter in injections	PASS
ISO 10993-4	Biological evaluation of medical devices, Tests for interactions with blood	PASS
ISO 10993-5	Biological evaluation of medical devices, Tests for *in vitro* cytotoxicity	PASS
ISO 10993-6	Biological evaluation of medical devices, Tests for local effects after implantation	PASS
ISO 10993-10	Biological evaluation of medical devices, Kligman Maximisation test	PASS
ISO 10993-10	Biological evaluation of medical devices, Sensitisation	PASS
ISO 10993-11	Biological evaluation of medical devices, Tests for systemic toxicity	PASS
European Pharmacopeia 3.1.9	Silicone Elastomer for Closures and Tubing	PASS
Extractables	Analysis of material extracts for organic extractables and extractables metals	REPORT

STA-PURE PCS Tubing

STA-PURE PCS pump tubing is a durable, resilient peristaltic pump tubing manufactured by GORE.

Table 7. Testing summary of STA-PURE PCS tubing

Test	Description	Result
USP <87>	Biological reactivity tests, *in vitro*	PASS
USP <88>	Biological reactivity tests, *in vivo*	PASS
Extractables	Analysis of material extracts for organic extractables and extractables metals	REPORT

Silicone Gasket

5000 series platinum-cured silicone gasket are precision engineered for a smooth bore, contamination free, fluid path under clamping compression with laser-etched lot numbering for full traceability.

Table 8. Testing summary of Silicone Gasket.

Test	Description	Result
USP <85>	Bacterial endotoxin test	PASS
USP <87>	Biological reactivity tests, *in vitro*	PASS
USP <88>	Biological reactivity tests, *in vivo*	PASS
USP <788>	Particulate matter in injections	PASS
ISO 10993-4	Biological evaluation of medical devices, Tests for interactions with blood	PASS
ISO 10993-5	Biological evaluation of medical devices, Tests for *in vitro* cytotoxicity	PASS
ISO 10993-6	Biological evaluation of medical devices, Tests for local effects after implantation	PASS
ISO 10993-10	Biological evaluation of medical devices, Kligman Maximisation test	PASS
ISO 10993-11	Biological evaluation of medical devices, Tests for systemic toxicity	PASS
European Pharmacopeia 3.1.9	Silicone elastomer for closures and tubing	PASS
Extractables	Analysis of material extracts for organic extractables and extractables metals	REPORT

BioBarb

BioBarb is a hose tail to tri-clamp adaptor manufactured from polypropylene with moulded size identification and lot numbering for full traceability.

Table 9. Testing summary of BioBarb.

Test	Description	Result
USP <85>	Bacterial endotoxin test	PASS
USP <87>	Biological reactivity tests, *in vitro*	PASS
USP <88>	Biological reactivity tests, *in vivo*	PASS
ISO 10993-4	Biological evaluation of medical devices, Tests for interactions with blood	PASS
ISO 10993-5	Biological evaluation of medical devices, Tests for *in vitro* cytotoxicity	PASS
ISO 10993-6	Biological evaluation of medical devices, Tests for local effects after implantation	PASS
ISO 10993-10	Biological evaluation of medical devices, Kligman Maximisation test	PASS
ISO 10993-10	Biological evaluation of medical devices, Sensitisation	PASS
ISO 10993-11	Biological evaluation of medical devices, Tests for systemic toxicity	PASS
Extractables	Analysis of material extracts for organic extractables and extractables metals	REPORT

Y-Connector

Y-connectors are made from PVDF and are manufactured by Eldon James Corp. or Nordson Medical.

Table 10. Testing summary of Y-Connector manufactured by Eldon James Corp.

Test	Description	Result
USP <88>	Biological reactivity tests, *in vivo*	PASS
ISO 10993-4	Biological evaluation of medical devices, Tests for interactions with blood	PASS
ISO 10993-5	Biological evaluation of medical devices, Tests for *in vitro* cytotoxicity	PASS
Extractables	Analysis of material extracts for organic extractables and extractables metals	REPORT

The testing was conducted on the material pellets, not the product itself, however, Eldon James does not use any additional additives or compounds when manufacturing the product.

Table 11. Testing summary of Y-Connector manufactured by Nordson Medical.

Test	Description	Result
ISO 10993-4	Biological evaluation of medical devices, Tests for interactions with blood	PASS
ISO 10993-5	Biological evaluation of medical devices, Tests for *in vitro* cytotoxicity	PASS

Aseptiquik Connector

Aseptiquik G, L and S polycarbonate connectors are manufactured by CPC. Extractables information available from CPC upon request.

Table 12. Testing summary of Aseptiquik G/L/S Connector, polycarbonate.

Test	Description	Result
USP <87>	Biological reactivity tests, *in vitro*	PASS
USP <88>	Biological reactivity tests, *in vivo*	PASS
ISO 10993-5	Biological evaluation of medical devices, Tests for *in vitro* cytotoxicity	PASS
ISO 10993-10	Biological evaluation of medical devices, Sensitisation	PASS
ISO 10993-11	Biological evaluation of medical devices, Tests for systemic toxicity	PASS

Table 13. Testing summary of Aseptiquik G/L/S Connector, silicone membrane.

Test	Description	Result
USP <87>	Biological reactivity tests, *in vitro*	PASS
USP <88>	Biological reactivity tests, *in vivo*	PASS
ISO 10993-5	Biological evaluation of medical devices, Tests for *in vitro* cytotoxicity	PASS

ISO 10993-10	Biological evaluation of medical devices, Sensitisation	PASS
ISO 10993-11	Biological evaluation of medical devices, Tests for systemic toxicity	PASS
USP <381>	Elastomeric closures for injections	PASS

MPC Connector

MPC polycarbonate connectors are manufactured by CPC. Extractables information available from CPC upon request.

Table 14. Testing summary of MPC Connector, polycarbonate.

Test	Description	Result
USP <87>	Biological reactivity tests, *in vitro*	PASS
USP <88>	Biological reactivity tests, *in vivo*	PASS
ISO 10993-5	Biological evaluation of medical devices, Tests for *in vitro* cytotoxicity	PASS
ISO 10993-10	Biological evaluation of medical devices, Sensitisation	PASS
ISO 10993-11	Biological evaluation of medical devices, Tests for systemic toxicity	PASS

Table 15. Testing summary of MPC Connector, silicone membrane.

Test	Description	Result
USP <87>	Biological reactivity tests, *in vitro*	PASS
USP <88>	Biological reactivity tests, *in vivo*	PASS
ISO 10993-5	Biological evaluation of medical devices, Tests for *in vitro* cytotoxicity	PASS
ISO 10993-10	Biological evaluation of medical devices, Sensitisation	PASS
ISO 10993-11	Biological evaluation of medical devices, Tests for systemic toxicity	PASS
USP <381>	Elastomeric closures for injections	PASS

MPU Connector

MPU polysulfone connectors are manufactured by CPC. Extractables information available from CPC upon request.

Table 16. Testing summary of MPU Connector, polysulfone.

Test	Description	Result
USP <87>	Biological reactivity tests, *in vitro*	PASS
USP <88>	Biological reactivity tests, *in vivo*	PASS
ISO 10993-5	Biological evaluation of medical devices, Tests for *in vitro* cytotoxicity	PASS
ISO 10993-10	Biological evaluation of medical devices, Sensitisation	PASS

ISO 10993-11	Biological evaluation of medical devices, Tests for systemic toxicity	PASS

Table 17. Testing summary of MPU Connector, silicone membrane.

Test	Description	Result
USP <87>	Biological reactivity tests, *in vitro*	PASS
USP <88>	Biological reactivity tests, *in vivo*	PASS
ISO 10993-5	Biological evaluation of medical devices, Tests for *in vitro* cytotoxicity	PASS
ISO 10993-10	Biological evaluation of medical devices, Sensitisation	PASS
ISO 10993-11	Biological evaluation of medical devices, Tests for systemic toxicity	PASS
USP <381>	Elastomeric closures for injections	PASS

MPX Connector

MPX polycarbonate connectors are manufactured by CPC. Extractables information available from CPC upon request.

Table 18. Testing summary of MPX Connector, polycarbonate.

Test	Description	Result
USP <87>	Biological reactivity tests, *in vitro*	PASS
USP <88>	Biological reactivity tests, *in vivo*	PASS
ISO 10993-5	Biological evaluation of medical devices, Tests for *in vitro* cytotoxicity	PASS
ISO 10993-10	Biological evaluation of medical devices, Sensitisation	PASS
ISO 10993-11	Biological evaluation of medical devices, Tests for systemic toxicity	PASS

Table 19. Testing summary of MPX Connector, silicone membrane.

Test	Description	Result
USP <87>	Biological reactivity tests, *in vitro*	PASS
USP <88>	Biological reactivity tests, *in vivo*	PASS
ISO 10993-5	Biological evaluation of medical devices, Tests for *in vitro* cytotoxicity	PASS
ISO 10993-10	Biological evaluation of medical devices, Sensitisation	PASS
ISO 10993-11	Biological evaluation of medical devices, Tests for systemic toxicity	PASS
USP <381>	Elastomeric closures for injections	PASS

4c. Components with no direct fluid contact

BioClamp

The BioClamp is designed for the biopharmaceutical industry to provide a secure sanitary connection.

Table 20. Testing summary of BioClamp.

Test	Description	Result
USP <87>	Biological reactivity tests, *in vitro*	PASS
USP <88>	Biological reactivity tests, *in vivo*	PASS
ISO 10993-5	Biological evaluation of medical devices, Tests for *in vitro* cytotoxicity	PASS
ISO 10993-6	Biological evaluation of medical devices, Tests for local effects after implantation	PASS
ISO 10993-10	Biological evaluation of medical devices, Sensitisation	PASS
ISO 10993-11	Biological evaluation of medical devices, Tests for systemic toxicity	PASS
Extractables	Analysis of material extracts for organic extractables and extractables metals	REPORT

Cable ties

Nylon cables ties are used in the assembly to secure the tubing to connectors, to product bags, filling nozzles and filters.

Packaging

Filling assemblies are double pouched, and heat sealed within transparent polyamide/ polyethylene (PA/PE) pouches.

5. Validation Testing

Our Validation Testing team will design your validation studies using the most up to date industry recognised standards alongside fully qualified testing partners. We will provide a bespoke results assessment to ensure you meet your specific quality assurance requirements.

Testing protocols cover a wide range of industry recognised validation tests for one-off or lot-release testing. These include but are not limited to:

- Bioburden
- Particulates
- Endotoxin
- Leak testing

- Extractables and Leachables
- Sterility assurance
- Nitrosamines
- Chemical compatibility
- Pressure testing

Contact Validation.WMArchitect@wmfts.com or your WMFTS representative for more information.

6. Conclusions

WMArchitect™ standard single-use assemblies have passed testing standards as summarised in this guide.

For more information on quality and compliance information not stated in this guide, please contact your WMFTS representative or BioPureQuality@wmfts.com.

7. Hyperlinks to Component Validation Guides

Section	Hyperlink to Validation Guides
Bioprene Tubing	Request full validation guides | WMFTS
Pumpsil Tubing	
PureWeld XL Tubing	
Silicone Braided Hose	
STA-PURE Tubing	
Silicone Gasket	
BioBarb	
BioClamp	
Y-Connector (Nordson Medical)	Material Information | Nordson MEDICAL
Y-Connector (Eldon James)	Material Regulatory Information - Eldon James
Aseptiquik Connectors	Validation Reports - Colder Products Company : CPC
MPC Connector	
MPU Connector	
MPX Connector	

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