

To whom it may concern

Ringsted, 15 February 2011

Dear customer and user of Watson-Marlow Flexicon filling equipment

ACCUSIL™ silicone tubing for accurate dispensing

From the 1st of February 2011 Watson-Marlow Flexicon A/S will begin supplying ACCUSIL™, a platinum-cured silicone tubing manufactured at our production facility in Cornwall, UK.

ACCUSIL™ has been developed for accurate dispensing with Watson-Marlow Flexicon peristaltic pumps and will regularly be validated to ensure compliance with the current Ph. Eur. 6.8 chapter 3.1.9, ISO10993, USP Class VI and FDA 21CFR 177.2600 standards.

A detailed validation guide is available to our customers upon request.

Each tubing size is supplied double-bagged and boxed in 10meter lengths together with a certificate of conformance.

Dispensing volume in ml*	Part number	Bore mm (inch)	Wall mm (inch)	Length m (ft)
< 0.5	84-103-005	0.5 ($\frac{1}{50}$)	1.6 ($\frac{1}{16}$)	10 (32.8)
0.5 - 1.0	84-103-008	0.8 ($\frac{1}{32}$)	1.6 ($\frac{1}{16}$)	10 (32.8)
1.0 - 1.7	84-103-012	1.2 ($\frac{3}{64}$)	1.6 ($\frac{1}{16}$)	10 (32.8)
1.7 - 7.0	84-103-016	1.6 ($\frac{1}{16}$)	1.6 ($\frac{1}{16}$)	10 (32.8)
7.0 - 12.0	84-103-032	3.2 ($\frac{1}{8}$)	1.8 ($\frac{1}{14}$)	10 (32.8)
12.0 - 22.0	84-103-048	4.8 ($\frac{3}{16}$)	2.0 ($\frac{19}{127}$)	10 (32.8)
22.0 - 35.0	84-103-060	6.0 ($\frac{6}{25}$)	2.1 ($\frac{19}{127}$)	10 (32.8)
> 35.0	84-103-080	8.0 ($\frac{5}{16}$)	2.2 ($\frac{2}{23}$)	10 (32.8)

Figure 1: This table is applicable for selecting ACCUSIL™ tubing for a specific fill volume. A filling accuracy of ± 0.5% is achievable with fluids having a viscosity similar to water.



All ACCUSIL™ tubing features LaserTraceability™. All tubes are laser etched with the part number, lot number and use-by date along the full length of the tube.

Full traceability is assured even when the tubing is removed from the packaging.

ACCUSIL™ is double-bagged in two heat-sealed polyethylene bags in 10m lengths as standard - other lengths are available by special request. A corrugated cardboard box provides optimum protection against contamination and UV light.



Filling tests have been performed on a QC12 pump head, which is an integrated part of PF6, PD12, FP50, FPC50 and FMB210 filling equipment from Watson-Marlow Flexicon.

The tests show that ACCUSIL™ meets our high standards for dispensing accuracy. That is, a filling accuracy of $\pm 0.5\%$ is achievable for liquids with a viscosity similar to water.

In brief - ACCUSIL™ platinum-cured silicone tubing will give you

- Excellent dispensing accuracy of $\pm 0.5\%$ from your Watson-Marlow Flexicon pump
- 100% traceability with laser-etched part number, lot number and use-by date. This data is also recorded on the box label, bag label and certificate
- Full biopharmaceutical compliance according to Ph. Eur. 6.8 Chapter 3.1.9, ISO 10993, USP Class VI, and FDA 21CFR 177.2600
- Is manufactured in an ISO14644-1 Class 7 cleanroom operating within an ISO9001:2008 quality system, and according to cGMP
- Superior purity achieved by a post-curing process after extrusion
- A comprehensive validation pack, giving full validation support
- An ADCF, Animal Derived Content Free fluid path

The ACCUSIL™ platinum-cured silicone tubing has undergone the following tests to ensure that it meets the requirements of the biopharmaceutical industry:

- European Pharmacopoeia Testing for 6.8 Chapter 3.1.9
- Cytotoxicity Test - L929 MEM Elution ISO 10993-5 & USP Class VI <87>
- Intracutaneous injection ISO 10993-10
- Sensitization Test - Kligman Maximization ISO 10993-10
- Acute Systemic Toxicity Test - Systemic Injection Test ISO 10993-11 Hemolysis testing (Human Blood) ISO 10993- 4
- Implantation Tests - Short Term Muscle Implant 2 weeks ISO 10993-6
- Food Migration Testing - Rubber Articles for repeated use (Total Extractable) FDA 21 CFR 177.2600
- USP Containers: Physicochemical Test - Plastics USP661
- USP Elastomeric Closures for Injection (Aqueous Only) USP381
- Biological Reactivity Testing in Vivo USP ClassVI <88>
- TOC - Total Organic Carbon in Water for Injection USP643
- USP LAL Test - Limulus Amebocyte Lysate Test for Endotoxins USP 32-NF27 <85>
- Microscopic Particle Count Test USP 32-NF27 <788>
- Filling accuracy tests and tests for durability

We trust that you will find ACCUSIL™ the natural choice, when peristaltic filling with a high filling accuracy and easy validation of your filling process really matters.

For any further information please contact Watson-Marlow Flexicon A/S or your local distributor.

We look forward to learning about your filling applications and to presenting to you with an optimum solution.

Yours sincerely,
Watson-Marlow Flexicon

Lone M. Nielsen
QA - Manager

Attachment: Accusil™ Data Sheet

ACCUSIL™ Data Sheet

Platinum-cured silicone tubing

Physical properties	
Name	ACCUSIL™
Colour	Transparent
Shore hardness	60 ±5 Shore A
Elongation at break (%)	300-650
Tear strength, (N/mm)	15-30
Tensile strength, N/mm ²	6.5-13.0
Compression set (%)	8.0-12.0
Sterilisation	
Gamma irradiation (maximum 50kGy)	Comply
Autoclave 1 bar / 14.5psi, 121 °C / 250 °F, 20 minutes	Comply
EtO (ethylene oxide)	Comply
Working temperature range	
Range	-20°C to +80°C
Test	
Physicochemical Tests USP 32NF27 <661>	Report
Physicochemical Tests USP 33NF28 <381> including Total organic carbon	Report
European Pharmacopeia 6.8 Chapter 3.1.9	Pass
Intramuscular Implantation - ISO 10993-6	Pass
Class VI – injections – USP32NF27 <88>	Pass
Hemolysis testing (Human Blood) – ISO 10993- 4	Pass
Systemic Injection Test - ISO 10993-11&12	Pass
Intracutaneous Injection Test – ISO 10993-10&12	Pass
Kligman Maximization Test – ISO 10993-10	Pass
L929 Elution Test – ISO 10993-5/USP 32NF27 <87> – T1/T2, γ/non-γ	Pass
Total extractables – 21CFR 177.2600 – T1/T2, γ/non-γ	Pass
Particulate Matter In Injections – USP 33NF28 <788>	Report
Bacterial Endotoxins Test – USP 32NF27 <85>	Report
Shelf life	
Use-by after production date	5 years
Warehouse storage	-10°C to +40°C

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Lone M. Nielsen
QA -Manager

Fill tests of ACCUSIL™ with Watson-Marlow Flexicon QC12 pump head

All tests have been performed on a QC12 pump head that is an integrated part of PF6, PD12, FP50, FPC50 and FMB210 from Watson-Marlow Flexicon.

The tests show that ACCUSIL™ achieves our high standards for dispensing accuracy. That is, a filling accuracy of $\pm 0.5\%$ is achievable for liquids with a viscosity similar to water.



Tubing	Inner diameter	Min. fill volume with fill accuracy better than $\pm 0.5\%$	Tubing can do > 100.000 fills
84-103-005	0.5	0.2 ml - Pass	Pass
84-103-008	0.8	0.5 ml - Pass	Pass
84-103-012	1.2	1.4 ml - Pass	Pass
84-103-016	1.6	1.8 ml - Pass	Pass
84-103-032	3.2	6.5 ml - Pass	Pass
84-103-048	4.8	12 ml - Pass	Pass
84-103-060	6.0	24 ml - Pass	Pass
84-103-080	8.0	50 ml - Pass	Pass

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