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Extractables Testing Complete for PharmaFocus® Premium Tubing

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BPOG and USP 665 tested for single-use biopharmaceutical tubing

Freudenberg Medical, a global contract manufacturer of medical device components and pharmaceutical tubing, announces the completion of extractables testing on PharmaFocus® Premium silicone tubing used in biopharma fluid processing and single-use applications. Freudenberg contracted with Eurofins Lancaster Laboratories to conduct independent extractables testing according to BPOG and USP 665 protocols. The two protocols include a total of 8 solvents and they were tested to the 21 day exposure timeframe.

“We understand that identifying extractable and leachable substances is extremely important for our biopharma customers,“ said Jeff Mohror, VP & General Manager of Freudenberg Medical Carpinteria. “When specifying tubing into a process, this data will save customers valuable time and cost when bringing a new process into production.“

Tubing that has undergone extractables testing includes PharmaFocus® Premium Silicone Tubing (ASTC), PharmaFocus® Premium Reinforced Tubing (ASTR), and PharmaFocus® Premium Peristaltic Pump Tubing (ASTP).

PharmaFocus® Premium tubing has also undergone additional physical, chemical and biological tests. All studies were conducted by outside laboratories licensed to perform testing and meet all requirements of CGLP, FDA, CFR, Part 58, European Pharmacopoeia, ISO and other special test requirements. Select testing has been performed on the finished products in addition to the silicone material.