USP GammaVI BioPharmaSil®

HIGH PURITY PLATINUM SILICONE

For Peristaltic Pump Applications

BioPharmaSil Gamma VI platinum cured silicone tubing is available from Lennox Single Use Systems and Fluid Technologies. BioPharmasil Gamma VI is the only silicone tubing, in Europe, tested post gamma irradiation. BioPharmaSil meets ISO 10993 standard and fully meets USP Class VI, FDA 21CFR, NSF and European Pharmacopoeia classifications.

Key Benefits

- USP Class VI tested pre and post gamma irradiation
- Certificate of Conformity
- Post-cured to ensure low leachables and stable flow
- Lot Traceable
- Free from cross linked by-products
- Free from PCBs
- Low spallation
- Predictable pump life

Applications

Lennox BioPharmaSil is designed for a wide range of Single Use Biopharmaceutical Applications including:

- Media Processing and Transfer
- Filtration and Fermentation
- Cell Harvest Collection Systems

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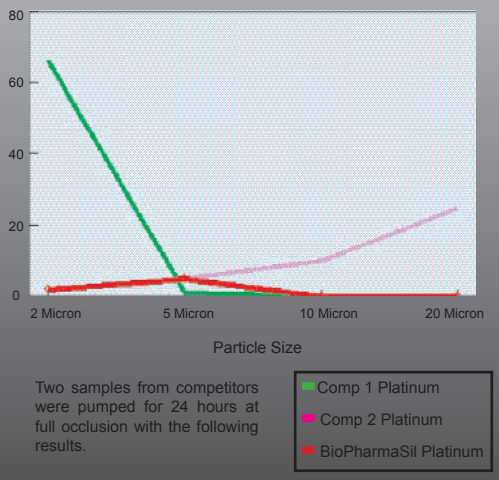
Physical Properties

Test	Range	Unit	Test Standard
Hardness	55 - 65	Shore A	ASTMD2240
Specific Gravity	1.15 - 1.21	g/cm3	Electronic Analysis
Tensile Strength	8.0 Minimum	N/mm2	BS ISO 37:2005
Elongation	400 Minimum	%	BS ISO 37:2005
Tear Strength	30 Minimum	Kn/m	BS ISO 34-1:2004
Temperature Range	-50 up to 200	°C	
Compression Set	TBA	%	BS 903/A6
Colour	Translucent		

Curing

Cured at 200ºC for a minimum of 4 hours, up to 24 hours depending on the wall thickness of the tubing which ensures low leachables and enables stable flow.

Particle Count Analysis



Two samples from competitors were pumped for 24 hours at full occlusion with the following results.

Ensure USP Class VI Conformance

USP Class VI <88>
"These tests are designed for application to plastics and other polymers in the condition in which they are used. If the material is to be exposed to any cleansing or sterilization process prior to its end-use, then the tests are to be conducted on a Sample prepared from a specimen preconditioned by the same processing."

Our team of Specialist Engineers and Area Business Managers are on hand to support and ensure your FDA and USP requirements are met.

How can **BioPharmaSil®** help you?

- Simplify your Production Operations
- Lower Cost of GMP Pharma Manufacturing
- Reduce Process Validation
- Increase your Manufacturing Efficiencies
- Satisfy Regulatory Agency Requirements
- Reduce the Risk of Bioburden Contamination
- Increase Sustainability

Get In Touch

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