AllPure Technologies, Inc.

Technical Memo

Memo Number: TMB-221
Date: Feb 4, 2010

RE: TAKEONE™ Aseptic Sampling System Material Component Summary

AllPure Technologies TAKEONE™ Aseptic Sampling System includes a number of components from different suppliers. AllPure's Quality Manual includes procedures designed to exercise control and traceability over all materials and components used in our cGMP approved products. The AllPure Quality Policy includes change notification procedures ensuring that impacted customers are alerted of any impending change. All suppliers must meet supplier qualification criteria as defined by AllPure's Quality Manual. Once qualified, the supplier's components may be used on a cGMP approved product.

The table below provides detail summarizing product contact surface materials and components for the TAKEONE™ Aseptic Sampling System. Custom designs may differ from the table – consult factory for details

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Component Name	Component Description	Raw Material(s)	Raw Material (Generic)	Specifications/Test Standards
TAKEONE™ Mount	Sanitary fitting to connect TAKEONE™ to vessel, etc	316L Stainless Steel	316L Stainless Steel	Electropolish, 15rA or better
TAKEONE™ Septa	Self-sealing septa overmolded to and hermetically sealed to TAKEONE™ Mount	Elastosil LR3003/50 A.B (or equivalent)	Platinum-cured Silicone	USP VI (87 & 88) Animal Derivative Free
TAKEONE™ Body	Sampling mechanism housing secured to TAKEONE™ mount	Valox HX420HP-1H1001 (or equivalent)	High Temperature Glass Reinforced Polyester	USP VI (87 & 88) Animal Derivative Free
Cannula Diaphragm	Flexible aseptic seal molded to cannula and hermetically sealed between the upper and lower halves of TAKEONE™ body	Momemntive Platinum-cured silicone 6030 (or equivalent)	Platinum-cured Silicone	USP VI (87 & 88) Animal Derivative Free
Cannula	2 mm needle that punctures TAKEONE™ Septa during actuation and acts as fluid conduit for transferring fluid through tubing assembly.	316L Stainless Steel	316L Stainless Steel	Electropolish, 15rA or better
Fluid Tubing	Acts as conduit for fluid transfer.	Watson-Marlow 913.D Platinum-Cured Silicone (or equivalent)	Platinum-cured Silicone	USP VI (87 & 88) Animal Derivative Free
		C-Flex® R70-374-000 (or equivalent)	SEBS	USP VI (87 & 88) Animal Derivative Free
Hose Barbed Y	Barbed connectors that connect three tubes in Y orientation	P5080-X/P5M6K-080X (or equivalent)	Polypropylene	USP VI (87 & 88) Animal Derivative Free
		Kynar® 1000HD (or equivalent)	Kynar® PVDF	USP VI (87 & 88) Animal Derivative Free
Hose Barbed Fittings	Barbed connectors that connect two tubes or more tubes together	P5080-X/P5M6K-080X (or equivalent)	Polypropylene	USP VI (87 & 88) Animal Derivative Free
		Kynar® 1000HD (or equivalent)	Kynar® PVDF	USP VI (87 & 88) Animal Derivative Free
Hose Barbed by Luer	Barbed connectors that connect that adapts to luer fitting	P5080-X/P5M6K-080X (or equivalent)	Polypropylene	USP VI (87 & 88) Animal Derivative Free
		Kynar® 1000HD (or equivalent)	Kynar® PVDF	USP VI (87 & 88) Animal Derivative Free
Luer by Luer	Adaptor fitting between two luers	Kynar® 1000HD (or equivalent)	Kynar® PVDF	USP VI (87 & 88) Animal Derivative Free
PE Sampling Bag	Multi-layer sample collection vessel. Contact surface is ultra low density polyethylene	HyQ® CX5-14 (or equivalent)	Ultra Low Density Polyethylene	USP VI (87 & 88) Animal Derivative Free
EVA Sampling Bag	Multi-layer sample collection vessel. Contact surface is ethyl vinyl acetate	S71 Film (or equivalent)	Ethyl Vinyl Acetate	USP VI (87 & 88) Animal Derivative Free
Septum Site	Self-sealing elastomer septa allows for needle withdrawl of liquids	Makrolon 2658	Polycarbonate	USP VI (87 & 88)
		cis-1.4-polyisoprene	Polyisoprene	USP VI (87 & 88) Animal Derivative Free
Needleless Access Site	Swabbable, needless access site with luer fittings	Makrolon Rx 1805 451118 (or equivalent)	Polycarbonate	USP VI (87 & 88) Animal Derivative Free
		Wacker LR3003/40, DT Color K57238 (or equivalent)	Platinum-cured silicone	USP VI (87 & 88) Animal Derivative Free
Stopcock Manifolds	Multi-path stopcock manifold diverts flow to selected pathways	Makrolon 2658	Polycarbonate	USP VI (87 & 88)
		Purell GC 7260	High Density Polyethylene	USP VI (87 & 88) TSE/BSE Statement
		Lexan HPS 71125	Polycarbonate	USP VI (87 & 88)

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About AllPure

AllPure Technologies, Inc. designs, manufactures and markets cutting-edge products for biopharmaceutical and pharmaceutical drug developers and manufacturers. AllPure operates in compliance with cGMP guidelines, where applicable. **You've Been Heard** is the company philosophy and is elemental to our products and services. You've Been Heard means engaging with our customers and partners to understand their challenges and helping them realize practical solutions. From enhancing operating efficiencies and perfecting process reliability to improving operator safety, AllPure launches sensible products.

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