

TEST RESULT CERTIFICATE

Sponsor	Malema Sensors	Technical Initiation	5/17/2017
Address	1060 S Rogers Circle Boca Raton, Florida 33487	Technical Completion	5/17/2017
Contact	Kalash Jhamb	Report Date	5/22/2017
P.O. Number	027019-00	Final Non-GLP Report	17-01361-N1

Test Article	PEEK (polyetheretherketone (PEEK))- Solvay KT-880NT	Ratio	Fluid Path
Lot/Batch #	5.5 mm Lot - gamma irradiated	Vehicle	Purified Water
Study	Particulate Matter by Light Obscuration of extract from a Solid Test Article	Extraction Conditions	Ambient temperature for 1 hour $\pm$ 2 minutes
Comments	None		

REFERENCES: The study was conducted based upon the following references: United States Pharmacopeia 40, National Formulary 35, 2017. <788> Particulate Matter In Injections. Particle Measuring System. Operations Manual for "SLS-FAMILY Syringe Liquid Sampler" publication no. 1000014034, Rev G. Particle Measuring System. Operations Manual for "LiQuilaz® -E20 Particle Counter" publication no. M10179, Rev G. Sponsor specifications.

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: The test article (4 units) was extracted by filling the fluid path of the device with purified water (40 mL) at ambient temperature for 1 hour $\pm$ 2 minutes. The resulting extract was analyzed using a Particle Measuring System Automated Parenteral Syringe Sampler (APSS)-2000. Particles were analyzed using channel settings of 10 and 25 μ m. The differential count results were recorded directly from the instrument. Control sample (purified water) was also analyzed and reported.

RESULTS: The results are presented in Table 1.

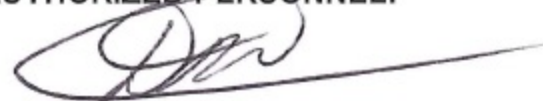
TABLE 1
Results of Particle Size Analysis

Sample ID	Replicate	(Particles per mL)	
		$\geq 10 \mu\text{m}$	$\geq 25 \mu\text{m}$
Control (Purified Water)	1	Discarded Sample	
	2	0.0000	0.0000
	3	0.2000	0.0000
	4	0.2000	0.0000
	5	0.4000	0.0000
	Average	0.2000	0.0000
Test Article: PEEK (polyetheretherketone (PEEK))- Solvay KT-880NT	1	Discarded Sample	
	2	27.6000	1.2000
	3	30.6000	1.2000
	4	30.6000	0.8000
	5	35.2000	2.0000
	Average	31.0000	1.3000

Each replicate was a 5 mL aliquot of the sample.

CONCLUSION: The test article contained the amounts of each particle size as presented in the table above, when tested based on the methods employed.

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