

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 ± 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 ± 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 µm. 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.

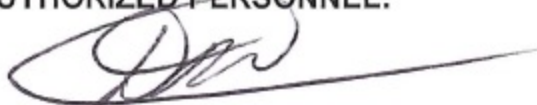
TABLE 1
Results of Particle Size Analysis

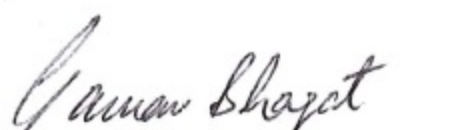
Sample ID	Replicate	(Particles per mL)	
		≥ 10 µm	≥ 25 µm
Control (Purified Water)	1	Discarded Sample	
	2	0.0000	0.0000
	3	0.2000	0.0000
	4	0.2000	0.0000
	5	0.4000	0.0000
	Average	0.2000	0.0000
Test Article: PEEK (polyetheretherketone (PEEK))- Solvay KT-880NT	1	Discarded Sample	
	2	27.6000	1.2000
	3	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.

AUTHORIZED PERSONNEL:


Douglas Mercadante, B.S.
Quality Assurance


Gaurav Bhagat, M.S.
Study Director