

TEST RESULT CERTIFICATE

Sponsor	Malema Sensors	Technical Initiation	5/3/2021
Address	1060 S Rogers Circle Boca Raton, Florida 33487	Technical Completion	5/3/2021
Contact	Kalash Jhamb	Report Date	5/7/2021
P.O. Number	38365	Final Non-GLP Report	21-01449-N2

Test Article	Thermoplastic Polyurethane – TPU (Texin RxT76D and Texin RxT90A) Pulsation Dampener (DMP-7000-08H0-001, Manufacturing date. April 7th 2021)	Ratio	Fluid path
Lot/Batch #	N/S	Vehicle	Purified Water
Study	Particulate Matter by Light Obscuration of extract from a Solid Test Article	Extraction Conditions	Room temperature, 3 hours ± 10 minutes
Comments	N/A		

REFERENCES: The study was conducted based upon the following references: United States Pharmacopeia 43, National Formulary 38, 2020. <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, 2017, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: The test article was filled with extraction solution (purified water) and extracted for 3 hours at room temperature). The test article together with a similarly prepared control solution of purified water were analyzed using the 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.

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	59.0000	3.0000
	3	76.0000	1.0000
	4	49.0000	3.0000
	5	50.0000	0.0000
	Average	58.5000	1.7500
Test Article	1	Discarded Sample	
	2	95.0000	2.0000
	3	109.0000	1.0000
	4	73.0000	2.0000
	5	80.0000	3.0000
	Average	89.2500	2.0000

Each replicate was a 5 mL aliquot of the sample.

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and Texin RxT90A) Pulsation Dampener-DMP-7000-08H0-001, Manufacturing date. April 7th 2021

CONCLUSION: The test article contained the amounts of each particle size as presented in Table 1, when tested based on the methods employed.

AUTHORIZED PERSONNEL:



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