EVALUATION OF ENVIRONMENTAL CONDITIONS ON ELECTRONIC CIGARETTES' NICOTINE AND AEROSOL GENERATION

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ABSTRACT #80

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With increasing interest in electronic cigarette testing, understanding the impact of environmental conditions on e cigarette aerosol generation and collection is an area of importance. Due to inherent differences of electronic versus traditional cigarettes, testing of traditional cigarettes in a conditioned environment has been shown to be necessary due to temperature, pressure, and humidity variables, while the effect of these variables is still undetermined for electronic cigarettes. A comparison study was completed on electronic cigarettes between a non-conditioned environment and an environment controlled to meet ISO-3402 requirements for atmospheric conditioning and testing of tobacco and tobacco products. Additionally, a comparison study was conducted between a Cerulean Linear SM450 and a Cerulean Electronic Cigarette Testing Instrument (CETI8) to ensure comparable aerosol generation between aerosol collection instruments. From these studies it is apparent that testing electronic cigarettes in a non-conditioned environment has no statistically significant impact on aerosol generation nor nicotine delivery. In addition, the CETI8 aerosol collection instrument offers several capabilities necessary to match the advancement and development of the electronic cigarette industry, including push button battery actuators. Through the comparison and validation of the Cerulean CETI8 aerosol collection instrument, this poster summarizes the indiscernible effect of environmental conditions on testing electronic cigarettes as well as the advancement in testing capabilities of current instrumentation.

INTRODUCTION

The effects of relative humidity, temperature, and atmospheric pressure and their impacts on aerosol generation and nicotine delivery in electronic cigarettes are important factors to understand. Relative humidity is important due to the fact that the base components of e-liquids, propylene glycol and glycerin, are both hygroscopic materials. Experimentation is required to comprehend if changing the moisture content of the atmosphere in which electronic cigarette aerosol is generated will change the amount of aerosol generated. Temperature is important as the viscosity of liquids, thus e-liquids, is greatly dependent on temperature. While the temperature of the atomizer is significantly greater than the atmospheric conditions in which electronic cigarettes are normally operated¹, investigation can shed light on the effects of short-term environmental conditions on device performance. Atmospheric pressure is not relevant for electronic cigarettes due to the operating principles of electronic cigarettes. There is no free-burn with electronic cigarettes, simply electronic circuitry that heats a filament which is in contact with e-liquid aerosolizing the liquid².

Electronic cigarette liquids selected for this study vary in nicotine concentration as well as water content in order to encompass the variety of commercially available e-liquids on the market.

A comparison study between the Cerulean Electronic Cigarette Testing Instrument (CETI8) and the industry standard Cerulean Linear Smoke Machine 450 (SM450) was conducted to establish similar aerosol generation and nicotine delivery for both e-liquid samples.

MATERIALS & METHODS

Aerosol Collection:

Disposable blu devices and pads were conditioned, in each respective environment, at least 18 hours prior to aerosol collection. Aerosol was collected using either a Linear SM450 or a CETI8 (Molins PLC, Milton Keynes, United Kingdom) under the CORESTA recommended puff regime: 55 mL puff volume, 3 sec draw, 30 sec puff interval, Square wave puff profile; collecting 99 puffs per device. ACM (Aerosol Collected Matter) from electronic cigarettes was collected on Cambridge filter pads.

Nicotine Quantification:

Cambridge filter pads were extracted in MeOH with 0.1% Anethole (ISTD) and analyzed by GC-FID according to a validated and controlled internal test method, TM – 0024.

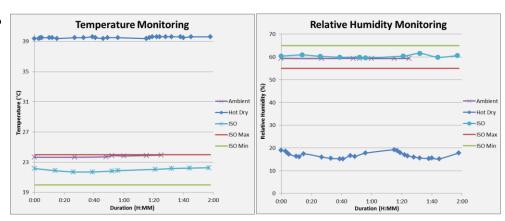
<u>Devices:</u>

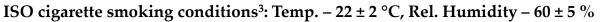
Disposable 'cig-a-like' devices were filled in-house prior to conditioning.

- Sample A: Lower Nicotine, Water Saturated Formulation
- Sample B: Higher Nicotine, Water Unsaturated Formulation

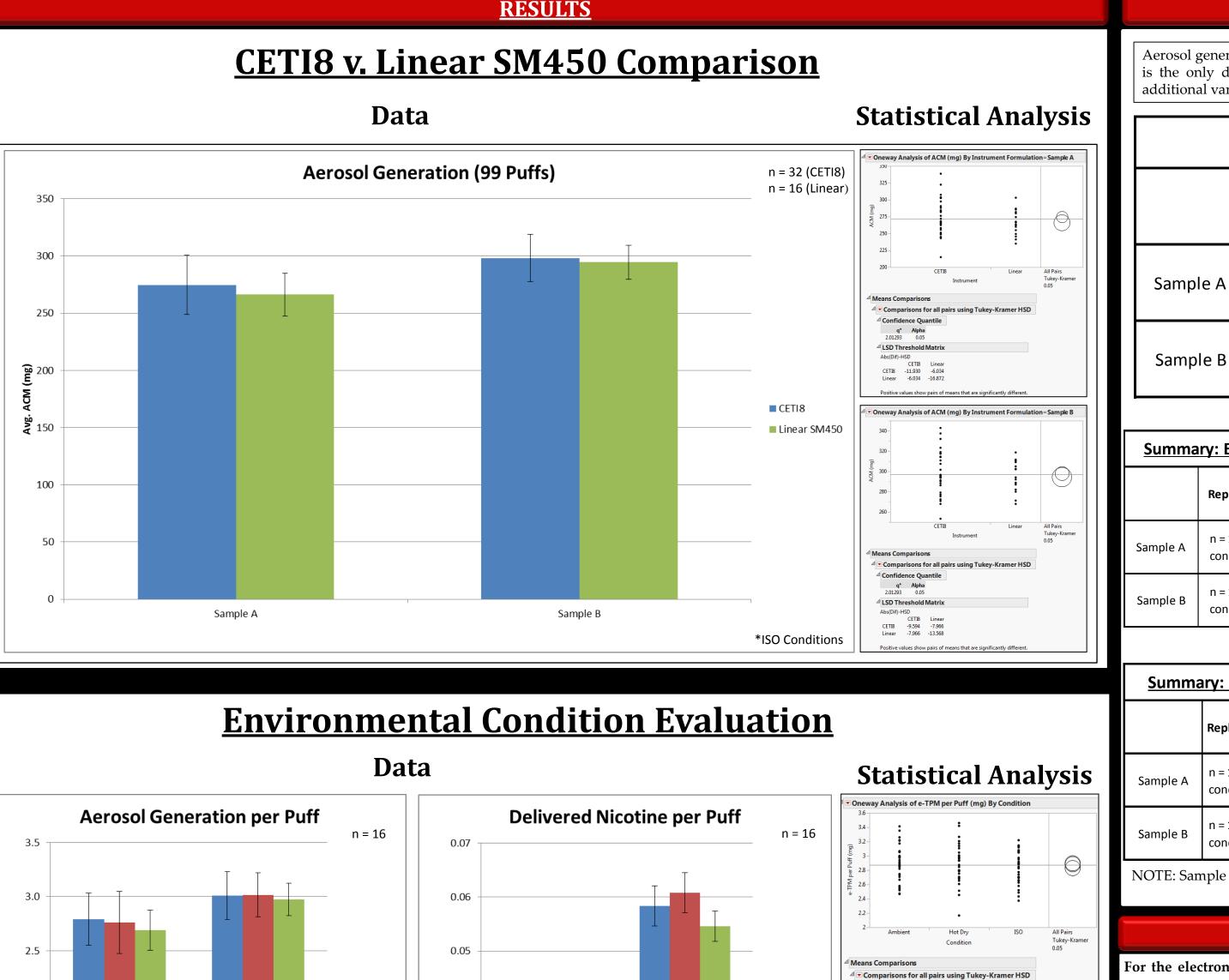
Experimental Environmental Conditions:

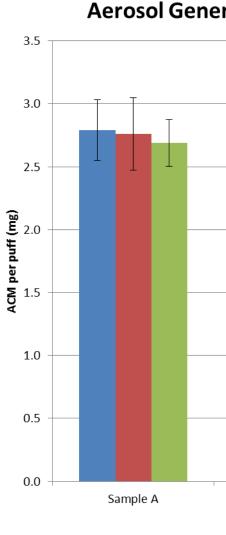
- Ambient: Temp. 23.8 °C, Rel. Humidity 59.3%
- <u>Hot Dry</u>: Temp. 39.6 °C, Rel. Humidity 16.7%
- <u>ISO</u>: Temp. 22.0 °C, Rel. Humidity 59.4%





CORESTA recommended aerosol collection conditions⁴: Temp. – $X \pm 2$ °C, Rel. Humidity – $Y \pm 5$ %

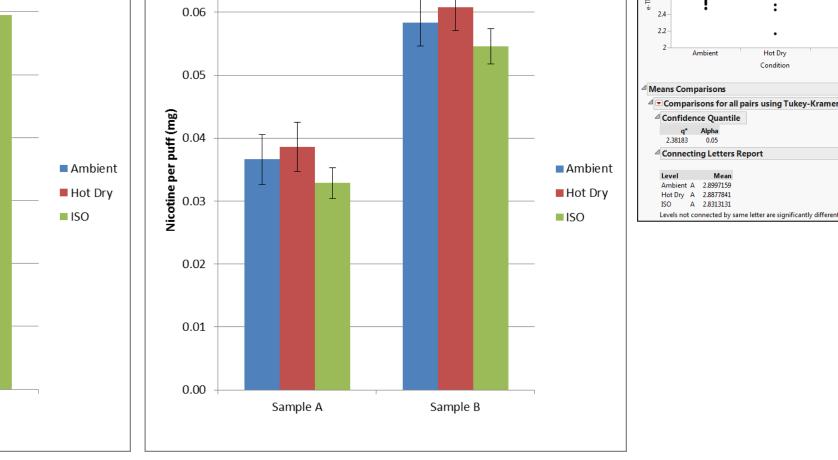




Sample B

ITG Brands, Greensboro, NC 27405, USA

RESULTS



NOTE: Sample B at higher nicotine strength than Sample A.

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SUMMARY

Aerosol generation is the only data point that results directly from the aerosol collection instrument; as such, it s the only data that should be statistically compared between the two instruments without introducing additional variability. Nicotine delivery did pass internal acceptance criteria of percent difference < 15%.

Summary: CETI8 v Linear SM450

		Stats	CETI8 Linear		Deveent	
Re	Replicates		Aerosol Generation	Aerosol Generation	Percent	
			(mg)	(mg)	Difference	
	n = 32	Avg.	274.7	266.1		
A		St. Dev.	25.8	18.6	3.2%	
		% RSD	9.4%	7.0%		
	n = 16	Avg.	298.3	294.5		
В		St. Dev.	20.8	14.9	1.3%	
		% RSD	7.0%	5.1%		

Summary: Environmental Conditions' Effect on Aerosol Generation

	Ambient	Hot Dry	ISO			
Stats	Aerosol Generation	Aerosol Generation	Aerosol Generation			
	(mg)	(mg)	(mg)			
Avg.	276.2	273.2	266.1	1	Percent Di	fference
St. Dev.	24.0	28.3	18.6			Sample
% RSD	8.7%	10.3%	7.0%		A	В
Avg.	298.0	298.6	294.5	Ambient v Hot Dry	1.1%	0.2%
St. Dev.	22.0	20.3	14.9	Ambient v ISO	3.6%	1.2%
% RSD	7.4%	6.8%	5.1%	Hot Dry v ISO	4.8%	1.4%
	Avg. St. Dev. % RSD Avg. St. Dev.	Stats Aerosol Generation (mg) Avg. 276.2 St. Dev. 24.0 % RSD 8.7% Avg. 298.0 St. Dev. 22.0	Stats Aerosol Generation (mg) Aerosol Generation (mg) Avg. 276.2 273.2 St. Dev. 24.0 28.3 % RSD 8.7% 10.3% Avg. 298.0 298.6 St. Dev. 22.0 20.3	Stats Aerosol Generation (mg) Aerosol Generation (mg) Aerosol Generation (mg) Avg. 276.2 273.2 266.1 St. Dev. 24.0 28.3 18.6 % RSD 8.7% 10.3% 7.0% Avg. 298.0 298.6 294.5 St. Dev. 22.0 20.3 14.9	Stats Aerosol Generation (mg) Aerosol Generation (mg) Aerosol Generation (mg) Avg. 276.2 273.2 266.1 St. Dev. 24.0 28.3 18.6 % RSD 8.7% 10.3% 7.0% Avg. 298.0 298.6 294.5 St. Dev. 22.0 20.3 14.9	Stats Aerosol Generation (mg) Percent Di St. Dev. 24.0 28.3 18.6 Anbient v Hot Dry Aa % RSD 8.7% 10.3% 7.0% A A Avg. 298.0 298.6 294.5 Ambient v Hot Dry 1.1% St. Dev. 22.0 20.3 14.9 Ambient v ISO 3.6%

NOTE: Percent difference without regard for statistical significance.

: Environmental Conditions' Effect on Nicotine Delivery								
eplicates		Ambient	Hot Dry	ISO				
	Stats	Delivered Nicotine	Delivered Nicotine	Delivered Nicotine				
		(mg/puff)	(mg/puff)	(mg/puff)	_			
- 10	Avg.	0.037	0.039	0.033	Raw		oifference	
= 16 per ondition	St. Dev.	0.003	0.004	0.002		Sample	Sample	
Dificition	% RSD	9.5%	10.2%	7.5%		А	В	
- 16 por	Avg.	0.058	0.061	0.055	Ambient v Hot Dry	0.002	0.002	
= 16 per	St. Dev.	0.005	0.004	0.003	Ambient v ISO	0.004	0.004	
ondition	% RSD	8.2%	6.1%	5.1%	Hot Dry v ISO	0.006	0.006	
D at h	: - le	ation a stream attaction					0)	

NOTE: Sample B at higher nicotine strength than Sample A.

CONCLUSION

For the electronic cigarettes tested, it was demonstrated that differing environmental conditions of the aerosol collection environment had no significant effect on aerosol generation or nicotine delivery. This data suggests that, under the conditions in this study, electronic cigarettes are capable of delivering consistent levels of nico and aerosol in varying conditions.

NEXT STEPS

Going forward, future studies to include in the Evaluation of Environmental Conditions on Electronic **Cigarettes' Nicotine and Aerosol Generation are:**

Single Variable Manipulation

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High Humidity Environmental Condition

Percent Water Content of devices and e-liquids before/after conditioning in additional environments Test additional device designs and e-liquids

REFERENCES

Polosa, R., B. Rodu, P. Caponnetto, M. Maglia, C. Raciti; A fresh look at tobacco harm reduction: the case for the electronic cigarette; Harm Reduction Journal 2013; 😡 doi:10.1186/1477-7517-10-19 Brown, C.J., J. M. Cheng; Electronic cigarettes: product characterisation and design considerations; Tob Control 2014;23: suppl 2 ii4-ii10 doi:10.1136/tobaccocontrol 2013-

ISO 3402:1999(E), Tobacco and tobacco products - Atmosphere for conditioning and testing.

CRM 81: 2015, Routine analytical machine for e-cigarette aerosol generation and collection - definitions and standard conditions