1. Introduction

- Demonstrating the consistency of nicotine delivery from an e-cigarette is a requirement of EUTPD2, Article 20, 3(f) (The European Council and the Council of the European Union, 2014) [1]. The Directive states that e-cigarettes placed on the European Union (EU) market should “…deliver the nicotine doses at consistent levels under normal conditions of use.”
- This means that the dose of nicotine should be within a specified acceptable range around a predefined target value (this can either be the mean average of the nicotine levels, or the labelled claim for nicotine delivery per puff). However, the EUTPD2 does not provide definitions of a “consistent level”, “dose” or “normal conditions of use”. Therefore defining consistency of nicotine delivery is open to interpretation.
- In 2016, the French national organization for standardization (AFNOR) published the experimental standard “Electronic cigarettes and e-liquids — Part 3” [2] which may form the basis of future European standards. This experimental standard requires the nicotine concentration for the first, third and fifth series of 20 puffs to be within ±25% of the mean value.
- The objective of this study was to assess whether the AFNOR acceptance criteria was achievable using blu™ e-cigarettes marketed in the EU.

2. Experimental Set Up

- Products tested were blu GO, PLUS, FILL and PRO (Table 1) with two e-liquids (Table 2).
- All device-liquid combinations were vaped on a linear smoking machine (SM450R, Cerulean) under CRM81 vaping regime described in Table 3.
- Aerosol was collected for the first 100 puffs in five blocks of 20 puffs (n = 3).
- For each smoking run (each block of 20 puffs), aerosol was trapped on a 44 mm CFP (Cambridge Filter Pad). Nicotine was analysed using a GC/FID method (ISO 17025 accredited).
- All tests were performed using a square shaped puff profile. During vaping, the blu PRO (push button device) was automatically activated using an electronic thumb (customized in-house system).

3. Assessing consistent nicotine delivery

According to the AFNOR experimental standard, the consistent delivery of nicotine is assessed by measuring the quantity of nicotine emitted during the first, third and fifth series of 20 puffs. The nicotine concentration measured for each of the three puff series should be within a range of ± 25% of the mean value of the three series. Figure 1 represents the relative differences from the mean of the puff series for each combinations (Product * E-Liquid * Puff block * Replicate). All product-liquid combinations were found to be within the limits of ± 25% defined by the AFNOR thereby complying with the standard for consistent nicotine delivery.

4. Conclusions

- Under the conditions of the test, the blu e-cigarette devices assessed deliver nicotine at consistent levels as defined by the AFNOR experimental standard XP D90-300-3.

5. References


Disclosure

The work presented here was supported by Fontem Ventures B.V., a fully owned subsidiary of Imperial Brands plc. Fontem Ventures B.V. is the manufacturer of the e-cigarette products used in this study.

Acknowledgments

We would like to thank Laboratories at Imperial Brands PLC for their assistance with sample analyses.

Table 1: e-cigarettes tested in this study

<table>
<thead>
<tr>
<th>Device</th>
<th>Types</th>
<th>PG (w/w)</th>
<th>VG (w/w)</th>
<th>Nicotine (w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GO</td>
<td>Closed-system</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PLUS+</td>
<td>Closed-system</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FILL</td>
<td>Open-system</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRO</td>
<td>Open-system</td>
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</table>

Table 2: e-liquids tested in this study

<table>
<thead>
<tr>
<th>Liquid 1 (L1)</th>
<th>PG (w/w)</th>
<th>VG (w/w)</th>
<th>Nicotine (w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquid 2 (L2)</td>
<td>48.8 %</td>
<td>50 %</td>
<td>1.2%</td>
</tr>
</tbody>
</table>

Table 3: Vaping regimes used for this study: CRM 81 [3]

Puff duration (s) | Puff Volume (mL) | Puff Interval (s) | Puff Block 1 | Puff Block 2 | Puff Block 3 | Puff Block 4 | Puff Block 5 |
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>3</td>
<td>15</td>
<td>1-20</td>
<td>21-40</td>
<td>41-60</td>
<td>61-80</td>
<td>81-100</td>
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</tbody>
</table>

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