

**Certificate of analyses/Quality statement****E-cigarette: Starter Kit IJOY Solo Mini Kit****E-liquid: Z01016008**

## Testprocedures/References

## Sampling

- Machine for e-cigarettes for aerosol generation and recording for routine analysis terms and standard conditions (draft DIN Standards Committee for Food and Agricultural Products NA057-04-01-05 AK)
- Preparations for inhalation, aerodynamic assessment (PharmEur 2.9.18)

## Analytics

- Determination of aldehydes and ketones in air via reaction with 2,4-dinitrophenylhydrazine, separation and detection of the derivative method by Waters, testing by BioChem Laboratory for Biological and Chemical Analysis GmbH
- Determination of nicotine content by HPLC / UV method , testing / method by BioChem Laboratory for biological and Chemische Analytik
- Determination of metals by AAS/GTT, testing/method by Techpharm GmbH

In accordance with DIN-EN-ISO 9001: 2015 and 17025: 2005 samples were taken and tested by qualified laboratories under GMP condition.

**Results correspond with expected values**

Date Signature

04.11.2016

Head of Quality Control

Test item	Expected value	result	evaluation
Setting e-cigarette	Specification		
1. resistance (Ohm)	0,6	0,63-0,66	corresponds
2. wattage (W)	35	35	
Setting sampler			
1. Puff duration	2 sec +/- 0,1	2	corresponds
2. Puff frequency	2/minute	2	
3. Number of puffs	60	60	
4. negative pressure	100-200mbar	100-200 mbar	
Nicotin content * <sup>1</sup>			
1. Volume e-liquid puffed/60 puffs	>0,2 ml	0,92	corresponds
2. mg nicotin/10ml puffed* <sup>2</sup>	Minimum 10% = 16 mg	97	
3. mg nicotin/60 puffs* <sup>3</sup>		10,8	
Aldehyde + Keton-Emissions* <sup>4</sup>	(MAK (mcg/m3)) -> mcg/60 puffs		
1. Formaldehyde	(370) < 83 mcg	5,3 mcg	corresponds
2. Acetaldehyde	(91.000) < 20.475 mcg	7,2 mcg	
3. Acroleine	(250) -> < 56 mcg	1,0 mcg	
4. others (Acetone, Propionaldehyde, Crotonaldehyde, ..)	Single value < 50mcg	15,6 mcg	
Metal-Emissions* <sup>5</sup>	Mcg/60puffs* <sup>6</sup>		
1. Al (Aluminium)	No limit	8,3	corresponds
2. Cr (Chromium)	0,29	<0,05	
3. Fe (Iron)	No limit	0,1	
4. Ni (Nickel)	0,60	<0,2	
5. Sn (Tin)	6,40	<0,1	

\*1: E-Cigarette working group discussion paper on submission of notification under article 20 of Directive 2014/40/EU Chapter 4

\*2: Nicotine dose in total by inhalation content of 10ml e-liquid under standard conditions

\*3: Nicotine uptake of standard smoker smoking 6 cigarettes (10 puffs/cigarette)

\*4: E-Cigarette working group discussion paper on submission of notification under article 20 of Directive 2014/40/EU Chapter 6.

Calculation expected value: MAK-Wert (mcg/m3) \*0,225 (=breath volume puff duration 60 puffs= 30 minutes)

\*5: E-Cigarette working group discussion paper on submission of notification under article 20 of Directive 2014/40/EU Chapter 3 e-cigarettes

\*6: Inhalation maximum/day according Guideline for Elemental Impurities Draft 23.Juli.2013 Appendix 2, Table 2.1 x safety factor 10