

**Senator URQUHART:** Can you tell me what therapeutic vaping products you all have currently on the market?

Good afternoon,

The following email is sent on behalf of from the fields Pharmaceutical whose CEO appeared last week at the Committee for Inquiry into the Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 [Provisions].

We understand or believe that no detailed, further questions on notice have been provided to us.

However, one of the Senators – Senator Anne Urquhart – had requested some more detail from industry players around their product suite and our approach to quality, approved product, during her line of questioning on the day.

As such we have **attached two documents** which the Committee may find of relevance. These are in addition to our submission, comments and answers to Qs on the day.

The include our product suite of therapeutic vaping product and a background power point presentation which has more detail including ingredients and the approach to manufacture of these TGA approved products.

We hope this is of interest.





















If either document is not relevant, our apologies. But we felt it could inform the Committee further.

Any questions please don't hesitate to reach out to either myself or Mr. David.

With kind regards, Simon Westaway (on behalf of from the fields Pharmaceutical).

**SIMON WESTAWAY | STRATEGY DIRECTOR**

# Wild By Instinct price list

<p><b>Prefilled POD device</b></p>		<p><b>RRP: \$24.99</b></p>
<p><b>Precise dose 0mg prefilled POD (2 x 1ml)</b></p>		<p><b>RRP: \$15.99</b></p>
<p><b>Precise dose 18 mg/ml prefilled POD (2 x 1ml)</b></p>	  	<p><b>RRP: \$15.99</b></p>
<p><b>Precise dose 50 mg/ml prefilled POD (2 x 1ml)</b></p>	  	<p><b>RRP: \$15.99</b></p>
<p><b>Discontinued due to TGA legislation</b></p>		
<p><b>50mg/ml Disposable 2.4ml</b></p>	  	<p><b>RRP: \$19.99</b></p>
<p><b>Discontinued due to TGA legislation</b></p>		
<p><b>50mg/ml Open POD liquid 30ml</b></p>	    	<p><b>RRP: \$29.99</b></p>
<p><b>Discontinued due to TGA legislation</b></p>		
<p><b>6mg/ml Open POD liquid 60ml</b></p>	    	<p><b>RRP: \$29.99</b></p>



# Our Mission:

# Make Australia smoke free

Published: 03.04.2024





# **Designed for Smoker Cessation**





# Content

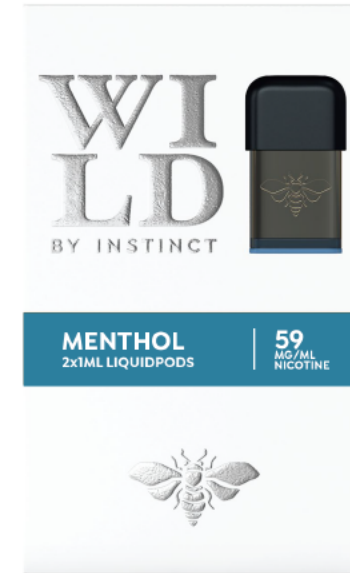
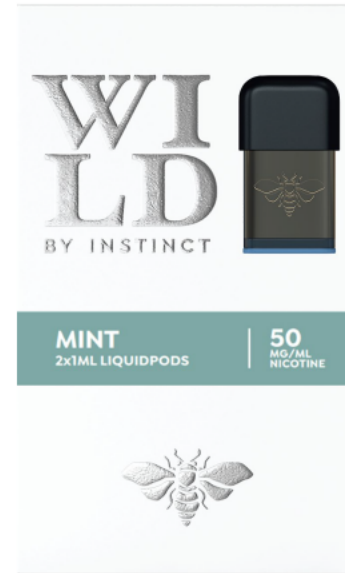
## ABOUT US

## OUR PRODUCTS

- Precise dose technology
- Nicotine consistency test results
- Standards to achieve lowest emissions
- Technology & testing
- Test results (liquids & emissions)
- Pathway for nicotine reduction
- Complete portfolio for treat smoking cessation
- Device & battery standards
- Device safety features
- Manufacturing standards
- Packaging standards
- Liquid bottle standards

## Prescribing Wild By Instinct

- Puff onset vs daily dosage
- 2 step prescribing process
- NVP's are better than NRT's for smoking cessation

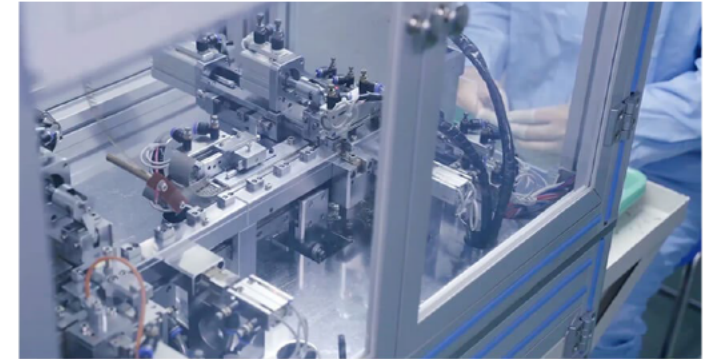


# About Us

Focused on using the best technology, fact-based science, and a passion for reimaging nicotine vaping products, We developed a unique aerosol vaporization system and a range of therapeutic liquids specifically designed to assist adult smokers to quit cigarettes.

Wild by Instinct, a Nicotine electronic inhalation system, with a prefilled, sealed, and precise dosage of Nicotine Pods is now available, to purchase in Australia through online pharmacies and selective chemist with a prescription.

Designed in California, U.S.A, our goal is to transition the world's adult smokers away from combustible cigarettes, eliminate their use and provide a credible electronic nicotine delivery alternative for smoker harm reduction and a journey towards full nicotine cessation.



# Our Products

Designed for only adult smokers. Australian TGO 110 standards compliant

WILD by instinct products deliver an exceptional nicotine experience designed for adult smokers looking for an alternative to quit cigarettes. The vaporizer that has no buttons or switches and uses a state-of-the-art technology to regulate temperature and vapour, combined with the USA made liquid, delivers a precise amount of nicotine in premeasured sealed liquid Pods.

Because every smoking harm reduction and cessation journey is unique and your needs for nicotine may evolve through your journey, we provide premeasured and precise amount of liquid pods that are available in nicotine strengths and non-nicotine in a range of flavours, putting you in control of what you want and how you want to manage your harm reduction and cessation objectives.





# Precision dose technology

Ensuring consistent nicotine delivery from puff to puff was a key goal when designing our system.

Unlike most other products in market which use coiled wire to heat liquids, WILD's coil is milled from a solid piece of medical grade stainless steel which provides a cleaner and larger heating surface which heats the liquid more evenly.

Pairing the coil with a PCB contained in the device, we are also able to accurately control the heating temperature.

By accurately controlling heating temperature combined with even heating we have achieved consistent nicotine dosage delivery which is evidenced through our emissions studies



# Precise dose

## Nicotine consistency test results

### MINT 18mg Closed POD

Test Condition: With reference to the CORESTA RECOMMENDED METHOD N° 81 method parameter and Afnor standardization XP D90-300-3, a smoke machine was used to collect the vapor.

Puff Duration	3.0s±0.1s
Puff Volume	55mL±0.3mL
Puff of Each Group	20
Maximum Flow	18.5mL/s±1.0mL/s
Pressure Drop	< 50hPa

The temperature and relative humidity of the test atmosphere during machine preparation and testing were kept within the following limits: temperature  $\pm 2^{\circ}\text{C}$ , relative humidity  $\pm 5\%$

Method: Wipe the clamp with isopropyl alcohol. Let stand for a minute. The aerosol generated by the e-cigarette is absorbed by the Cambridge filter. Remove the Cambridge filter and place it into a centrifuge tube, add 20 mL of Isopropyl alcohol and 0.2ml Internal standard stock solution. Shaken at 210 rpm for 30 min, and the solution was filtered and analyzed by GC-FID.

Sample No.	Nicotine(CAS No.:54-11-5) Contents(mg/20Puffs)						Total (mg/100puffs)
	Group 1*	Group 2	Group 3*	Group 4	Group 5*	AVG	
No.1	1.70	1.67	1.68	1.69	1.66	1.68	8.40
Deviation(%)	1.0	-	0.2	-	1.0	-	-

Source: Test report TCT210119C060, TCT200427C005

### MINT 50mg Closed POD

Test Condition: With reference to the CORESTA RECOMMENDED METHOD N° 81 method parameter and Afnor standardization XP D90-300-3, a smoke machine was used to collect the vapor.

Puff Duration	3.0s±0.1s
Puff Volume	55mL±0.3mL
Puff of Each Group	20
Maximum Flow	18.5mL/s±1.0mL/s
Pressure Drop	< 50hPa

The temperature and relative humidity of the test atmosphere during machine preparation and testing were kept within the following limits: temperature  $\pm 2^{\circ}\text{C}$ , relative humidity  $\pm 5\%$

Method: A reference liquid was prepared. A pharmaceutical nicotine inhaler was used as a comparator. Products were attached to a smoke machine, and the aerosol was collected in Cambridge filter pads. After trapping and solvent extraction, solution was analyzed by GC-MS and nicotine was dosed by comparing the areas obtained on the MS detector with those of standard solutions prepared in the laboratory under concentration conditions surrounding those of the samples.

Sample No.	Nicotine(CAS No.:54-11-5) Contents(mg/20Puffs)						Total (mg/100puffs)
	Group 1*	Group 2	Group 3*	Group 4	Group 5*	AVG	
No.1	4.16	4.15	4.17	4.14	4.19	4.16	20.8
Deviation(%)	0.0	-	0.2	-	0.6	-	-



# Standards to achieve lowest Emissions

Ensuring the lowest emissions was another primary objective when designing our products.

Delivering low emissions is achieved through Manufacturing Standards, Liquid Standards, proprietary Technology and testing at both a liquid & vapor level

## MANUFACTURING STANDARDS:

- ✓ Our products are manufactured in cGMP, ISO13485 and ISO 9001 certified facilities giving assurance of quality, consistency and purity whilst reducing the risk of errors and defects.



## LIQUID STANDARDS:

- ✓ Our flavours are defined at a molecular level effectively allowing us to control all ingredients used.
- ✓ To eliminating impurities and inconsistencies, we only use US / EU Pharmacopoeia grade Propylene Glycol, Vegetable Glycerin and Nicotine.
- ✓ To eliminate exposure to aldehydes, Volatile Organic Compounds and chemicals linked to cancer, we ensure no HPHC's (Harmful & Potential Harmful Constituents) or Prohibited or Contaminant ingredients





# Technology & testing to achieve lowest emissions

## TECHNOLOGY:

- ✓ Milled from a solid piece of medical grade stainless steel providing a cleaner and larger heating surface for consistent temperature control.
- ✓ Our smart device interacts with the POD to accurately control and effectively deliver a fuller flavour and consistent dosage.
- ✓ Sub-ohm resistance enables the notch coil to heat at 195 degrees, one of the lowest in category, delivering lower emissions.

## TESTING:

- ✓ Conducted in independent ISO 17025 certified labs, our liquids are batch tested to ensure no Prohibited Ingredients, Contaminants, Microbials and correct Nicotine concentration.
- ✓ Emissions testing is also performed for Carbonyl Compounds, Nitrosamines, Heavy Metals, VOC substances & Nicotine consistency
- ✓ Toxicity, carcinogenicity, and mutagenicity studies are conducted on ingredients to evaluate their potential adverse effects on human health.



# Our test results summary

	Test items conducted	Test results
Required under TGO 110	ACTIVE INGREDIENTS: Nicotine content, Taurine, Caffeine, THC, CBD	Not detected
	PROHIBITED INGREDIENTS: Formaldehyde, Acetaldehyde, Acrolein, Diacetyl, Pentane 2,3 dione, Acetoin, Vitamin E Acetate	Not detected
	CONTAMINANTS: Ethylene Glycol, Diethylene Glycol, Benzaldehyde, Cinnamaldehyde	Not detected
	MICROBIALS: Total Aerobic microbial Unit, Total combined Yeast/Mold count, Bile-tolerant gram-negative bacteria, Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia Coli, Salmonella, Aspergillus Flavus, Aspergillus Fumigatus, Aspergillus Niger, Aspergillus Terreus, E. Coli	Not detected
	Test items conducted	Test results
Additional to TGO 110	PESTICIDES: 57 pesticides analyzed	Not detected
	RESIDUAL SOLVENTS: 2-Propanol, Acetone, Acetonitrile, Butane, Ethyl Ether, Heptane, Hexane, Isobutane, M/P-Xylene, Methanol, O-Xylene, Pentane, propane, Toluene, Total Xylenes	Not detected
	HEAVY METALS: Arsenic, Cadmium, Lead, Mercury	Not detected
	MYCOTOXINS: Aflatoxin B1 & B2, Aflatoxin G1 & G2, Ochratoxin A+	Not detected
	TOXICOLOGY STUDIES: Toxicity, carcinogenicity, and mutagenicity studies conducted on ingredients	Compliant
	EMISSIONS: Carbonyl Compounds, Metals, Diacetyl and Pentane 2,3 dione, Nitrosamines, VOC substances	Not detected
	NICOTINE DOSE CONSISTENCY: to CORESTA RECOMMENDATION METHOD n 81 method parameter and AFNOR standardization XP D90-300-3	Within standards

**Testing to confirm compliance to TGO 110 and internal standards conducted at independent ISO17025 certified labs**

Source: Test report 072121UD0002, TCT210830C050-1, TCT210119C060



# Our liquid test result summary

Test items	TGO 110 regulations	Mint 0mg, 18mg & 50mg Closed POD	Menthol 20mg, 35mg & 59mg Closed POD	Tobacco 18mg & 50mg Closed POD	Menthol 50mg Open POD	Menthol 6mg Open MOD
<ul style="list-style-type: none"> <li>Formaldehyde</li> <li>Acetaldehyde</li> <li>Acrolein</li> </ul>	TGO 110 does not prohibit or set limits	<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> <li>Non-detect</li> </ul>
<ul style="list-style-type: none"> <li>Taurine</li> <li>Caffeine</li> </ul>	Nicotine is the only permitted active	<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> </ul>
<ul style="list-style-type: none"> <li>Diacetyl</li> <li>Pentane 2,3 dione</li> <li>Acetoin</li> <li>Vitamin E acetate</li> </ul>	Provided not been added to the product as an ingredient, these substances may be present in the product without breaching TGO 110	<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> <li>Non-detect</li> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> <li>Non-detect</li> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> <li>Non-detect</li> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> <li>Non-detect</li> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> <li>Non-detect</li> <li>Non-detect</li> </ul>
<ul style="list-style-type: none"> <li>Ethylene Glycol</li> <li>Diethylene Glycol</li> </ul>		<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> </ul>
<ul style="list-style-type: none"> <li>Benzaldehyde</li> <li>Cinnamaldehyde</li> </ul>		<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> <li>Non-detect</li> </ul>
<ul style="list-style-type: none"> <li>Microbials</li> </ul>	TGO 110	<ul style="list-style-type: none"> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> </ul>	<ul style="list-style-type: none"> <li>Non-detect</li> </ul>

## Testing to confirm compliance to TGO 110 and internal standards conducted at independent ISO17025 certified labs

Source: Test report TCT210830C051-1, TCT210830C055-1, TCT210830C050-1, TCT210830C054-1, TCT240220C001001, TCT240229C011002 (2), TCT240229C011002 (1), 37359-1, 37359-1.2, 35464-4, 37322-2, 35464-2, 35464-2 B, 37322-11





# Lowest Emissions in NVP

Test items		Test requested	Mint results	Tobacco results	EU TPD limits
1	CARBONYL COMPOUNDS; • Formaldehyde • Acetaldehyde • Acrolein • Crotonaldehyde	Emissions testing according to Article 20 of Tobacco Product Directive (2014/40/EU)	• 4.32 µg • 4.73 µg • Non-detect • Non-detect	• 9.2 µg • 8.49 µg • Non-detect • Non-detect	• 200 µg • 3200 µg • 16 µg • Not required
2	METALS: Aluminum, Chromium, Iron, Nickel, Tin, Lead, Cadmium, Arsenic, Antimony, Mercury, Copper		Non-detect	Non-detect	• 3 µg
3	Nicotine consistency		N/A	N/A	N/A
4	Diacetyl and Pentane 2,3 dione		Non-detect	Non-detect	Not required
5	Ethylene Glycol and Diethylene Glycol		Non-detect	Non-detect	Not required
6	SPECIFIC NITROSAMINES: N-nitrosornicotine(NNN), 4-(N-methylnitrosamino)-1-(3-pyridyl)-1-butanone(NNK)		Non-detect	Non-detect	Not required
7	VOC substances: Toluene, Benzene, 1,3-Butadiene, Isoprene		Non-detect	Non-detect	Not required

- Ug = one millionth (1×10<sup>-6</sup>) of a gram.

Source: Test report TCT200427C005, TCT210119C060



# 7-point emissions testing protocol

## Test items

Test Items		Test Requested
1	Carbonyl Compounds: Formaldehyde, Acetaldehyde, Acrolein, Crotonaldehyde	Emission testing according to Article 20 of Tobacco Product Directive (2014/40/EU)
2	Metals: Aluminum, Chromium, Iron, Nickel, Tin, Lead, Cadmium, Arsenic, Antimony, Mercury, Copper	
3	Nicotine consistency	
4	Diacetyl and Pentane 2,3 dione	
5	Ethylene Glycol and Diethylene Glycol	
6	Specific Nitrosamines: N-nitrosornicotine(NNN), 4-(N-methylnitrosamino)-1-(3-pyridyl)-1-butanone(NNK)	
7	VOC substances: Toluene, Benzene, 1,3-Butadiene, Isoprene	

## Test conditions

Test Condition for test items except Nicotine consistency test:

With reference to the CORESTA RECOMMENDED METHOD N° 81 method parameter, Afnor standardization XP D90-300-3, International Standard ISO 20768:2018 and PD CEN/TR 17236:2018, a smoke machine was used to collect the vapor.

Puff Duration	3.0s±0.1s
Puff Volume	55mL±0.3mL
Puff Frequency	30s±0.5s
Puff of Each Group	20
Group Interval Time	300s±120s
Maximum Flow	18.5mL/s±1.0mL/s
Pressure Drop	< 50hPa
Group	5
Total Number of Puff	100
Total Duration of Vaporization	300s

Source: Test report TCT210119C060



# Emissions testing results

## 1. Carbonyl Compounds Content(s)

Method: The aerosol generated by the e-cigarette is absorbed by the impactor containing 40mL acidified solution of 2,4-dinitrophenylhydrazine (DNPH) in acetonitrile. The solution was filtered and analyzed by reverse phase high - performance liquid chromatography and determined using a UV detector.

Test Item	CAS No.	Unit	LOD	LOQ	Content(s)
					No.1
Formaldehyde	50-00-0	ug/100puffs	0.667	2	4.32
Acetaldehyde	75-07-0	ug/100puffs	0.667	2	4.73
Acrolein	107-02-8	ug/100puffs	0.667	2	ND
Crotonaldehyde	4170-30-3	ug/100puffs	0.667	2	ND

Source: Test report TCT210119C060

## 2. Metals Content(s)

Method: Wipe the clamp with isopropyl alcohol. Let stand for a minute. 20 ml of nitric acid was added to the impactor and placed in series with the Cambridge filter to absorb the aerosol. The Cambridge filter was removed and placed in nitric acid, shaken at 210 rpm for 30 min, and the solution was filtered and analyzed by ICP-MS.

Test Item	CAS No.	Unit	LOD	LOQ	Content(s)
					No.1
Aluminum(Al)	7429-90-5	ug/100puffs	0.025	0.25	ND
Chromium(Cr)	7440-47-3	ug/100puffs	0.005	0.05	ND
Iron(Fe)	7439-89-6	ug/100puffs	0.005	0.05	ND
Nickel(Ni)	7440-02-0	ug/100puffs	0.025	0.25	ND
Tin(Sn)	7440-31-5	ug/100puffs	0.25	2.5	ND
Lead(Pb)	7439-92-1	ug/100puffs	0.025	0.25	ND
Cadmium(Cd)	7440-43-9	ug/100puffs	0.005	0.05	ND
Arsenic(As)	7440-38-2	ug/100puffs	0.025	0.25	ND
Antimony(Sb)	7440-36-0	ug/100puffs	0.025	0.25	ND
Mercury(Hg)	7439-97-6	ug/100puffs	0.025	0.25	ND
Copper(Cu)	7440-50-8	ug/100puffs	0.025	0.25	ND





# Emissions testing results

## 4. Diacetyl and Pentane 2,3 dione Content(s)

Method: The aerosol generated by the e-cigarette is absorbed by the impactor containing 20mL methanol. The solution was filtered and analyzed by GC-MS.

Test Item	CAS No.	Unit	LOD	LOQ	Content(s)
					No.1
Diacetyl	431-03-8	ug/100puffs	0.546	5.46	ND
Pentane 2,3 dione	600-14-6	ug/100puffs	0.546	5.46	ND

## 5. Ethylene Glycol and Diethylene Glycol Content(s)

Method: Wipe the clamp with isopropyl alcohol. Let stand for a minute. 20 ml of methanol was added to the impactor and placed in series with the Cambridge filter to absorb the aerosol. The Cambridge filter was removed and placed in methanol, shaken at 210 rpm for 30 min, and the solution was filtered and analyzed by GC-FID.

Test Item	CAS No.	Unit	LOD	LOQ	Content(s)
					No.1
Ethylene Glycol	107-21-1	ug/100puffs	0.667	2	ND
Diethylene Glycol	111-46-6	ug/100puffs	0.667	2	ND

Source: Test report TCT210119C060

## 6. Specific Nitrosamines Content(s)

Method: Wipe the clamp with isopropyl alcohol. Let stand for a minute. The aerosol generated by the e-cigarette is absorbed by Cambridge filter, and the Cambridge filter was removed and placed in an Erlenmeyer flask, added to 20 mL of 100 mM ammonium acetate solution, shaken at 210 rpm for 60 min, filtered and analyzed by LC-MS/MS.

Test Item	CAS No.	Unit	LOD	LOQ	Content(s)
					No.1
N-nitrosornicotine(NNN)	80508-23-2	ug/100puffs	0.004	0.04	ND
4-(N-methylnitrosamino)-1-(3-pyridyl)-1-butanone(NNK)	64091-91-4	ug/100puffs	0.004	0.04	ND

## 7. VOC substances content(s)

Method: Wipe the clamp with isopropyl alcohol. Let stand for a minute. 20 ml of methanol was added to the impactor and placed in series with the Cambridge filter to absorb the aerosol. The Cambridge filter was removed and placed in methanol, shaken at 210 rpm for 30 min, and the solution was filtered and analyzed by GC-MS.

Test Item	CAS No.	Unit	LOD	LOQ	Content(s)
					No.1
Toluene	108-88-3	ug/100puffs	0.667	2	ND
Benzene	71-43-2	ug/100puffs	0.667	2	ND
1,3-Butadiene	106-99-0	ug/100puffs	0.667	2	ND
Isoprene	78-79-5	ug/100puffs	0.667	2	ND



# Pathway for nicotine reduction

WILD e-liquids come in 3 strengths (50mg, 18mg and 0mg) in premeasured, precise dose pre-filled pods

This allows medical practitioners to prescribe the required dosage and, more importantly, allows adult consumers to transition off nicotine through the 0% nicotine flavour pods



COLOURED PODS FOR NICOTINE NAVIGATION



50mg/ml






18mg/ml



0mg/ml



# Complete Portfolio to treat smoking cessation including current vapers






Category	Closed POD	Open POD liquid	Open MOD liquid
Nicotine type	Nicotine Salt	Nicotine Salt	Freebase Nicotine
Patient type	Smoker looking to quit	Alternative Vapers	Alternative Vapers
Portfolio	 <p>The Closed POD section displays a variety of products. On the left is the 'BLACK DEVICE KIT' which includes a device, a USB charger, and pods sold separately. To the right is a grid of 8 individual pods, each in its own box. The pods are arranged in two rows of four. The top row features 'TOBACCO' (18 mg/ml nicotine) and 'MINT' (50 mg/ml and 18 mg/ml nicotine) flavors. The bottom row features 'TOBACCO' (50 mg/ml nicotine) and 'MENTHOL' (59 mg/ml, 35 mg/ml, and 20 mg/ml nicotine) flavors. Each pod box includes the 'WILD BY INSTINCT' logo and a bee icon.</p>	 <p>The Open POD liquid section shows a single bottle of 'MENTHOL' flavor. The bottle is clear with a white cap and a label that reads 'WILD BY INSTINCT MENTHOL 18mg/ml nicotine salt 30ml'.</p>	 <p>The Open MOD liquid section shows a single bottle of 'MENTHOL' flavor. The bottle is clear with a white cap and a label that reads 'WILD BY INSTINCT MENTHOL 6mg/ml nicotine 60ml'.</p>







# No device met our standards... so we designed our own



## DEVICE FEATURES

-  Magnetic POD retention & PCB board: : Ensuring device is always talking to the POD
-  Draw activated: No buttons or switches, convenient and easy to use
-  LED indicator: Notifying battery level, charging status, empty POD and POD / device short circuit
-  350 mAH battery: Will last a pod and a half
-  USB-C charger: delivering a full charge in 35 minutes

## SAFETY FEATURES

-  Anti burn protection
-  Short circuit detection
-  Continuous use shutdown
-  Crush proof construction





# Device and battery standards



- ✓ FCC certified: meets specific technical standards for Radio Frequency emissions, power levels, and other relevant parameters



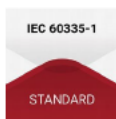
- ✓ CE certified: compliance with the health, safety, and environmental protection standards set by the European Union



- ✓ C-tick / RCM / PSE certified: compliant with the electromagnetic compatibility (EMC) and radio communications requirements set by the Australian Communications and Media Authority (ACMA)



- ✓ RoHS certified: Restriction of Hazardous Substances



- ✓ IEC 60335-1 certified: safety standard developed by the International Electrotechnical Commission (IEC) providing guidelines and criteria ensuring appliances are designed, constructed, and operated safely to minimize the risk of electrical shock, fire, and other hazards.



- ✓ UN 38.3 certified: international standard developed by the United Nations (UN) referring to a set of testing requirements and standards for the safe transport of lithium-ion batteries



- ✓ IEC 62133-2 certified : international safety standard developed by the International Electrotechnical Commission (IEC) that specifically addresses the safety requirements for rechargeable batteries used in portable electronic devices



# Manufacturing standards



- ✓ cGMP: regulations established by the pharmaceutical industry to ensure the quality, safety, and efficacy of products



- ✓ ISO 9001: internationally recognized standard for quality management systems



- ✓ ISO 13485: based on the ISO 9001 standard however includes additional specific requirements for medical devices



- ✓ HACCP: internationally recognized standard to food safety management that identifies and controls potential hazards



- ✓ ISO 14001: internationally recognized standard for environmental management systems helping organizations minimize negative environmental impacts and promote sustainability



- ✓ ISO 45001: international standard for occupational health and safety management systems (OH&S) providing a framework to establish and maintain systems and processes ensuring the health, safety, and well-being of employees and others affected by the organization's activities.



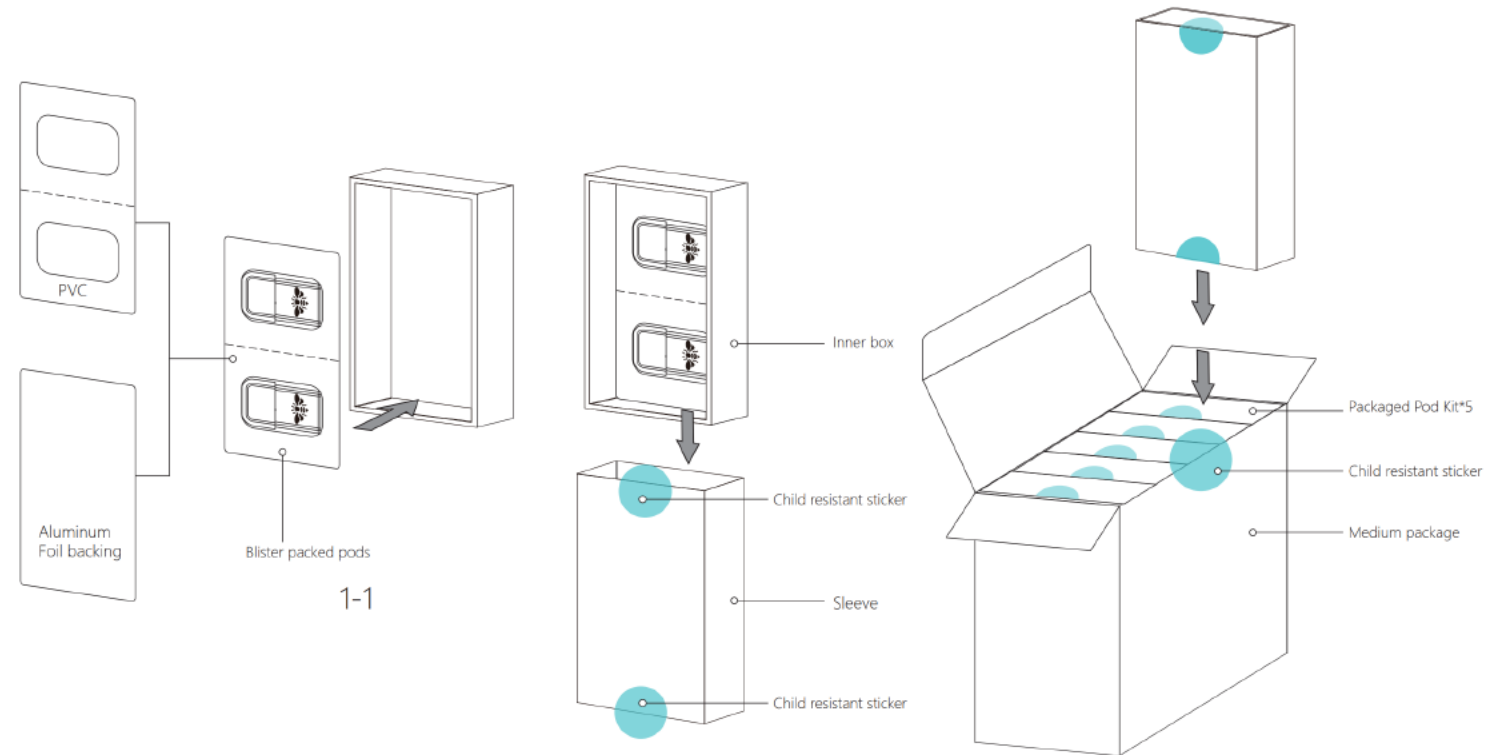
- ✓ SA 8000: international standard for social accountability in the workplace providing a framework for organizations to maintain socially responsible practices, focusing on labor rights, ethical working conditions, and fair treatment of workers



# Packaging compliant with TGO No. 95 – Child-resistant packaging requirements

From The Fields pharmaceuticals products are compliant with Therapeutic Goods Order No. 95 - Child-resistant packaging requirements for medicines 2017 as non-reclosable packages.

All closed pod products mentioned above, are packaged in a blister pack formed from plastic and aluminum foil. Child resistant stickers are used as a second barrier to entry



# Liquid bottle standards

## BOTTLE FEATURES

- ✓ Manufactured using food grade raw materials and are BPA free
- ✓ Child-Resistant Closure compliant
- ✓ Lock-On Tamper Evident Break-Off Band
- ✓ Refined Narrow Drip Tip with Easy-Flow Dispensing ensuring no spillage
- ✓ Soft Squeeze PET Bottle for Consistent and Natural Flow Rate





# Understanding nicotine dosage

## CURRENT DAILY USAGE

How much nicotine is being absorbed into the bloodstream per day

## QUANTITY SMOKED PER DAY

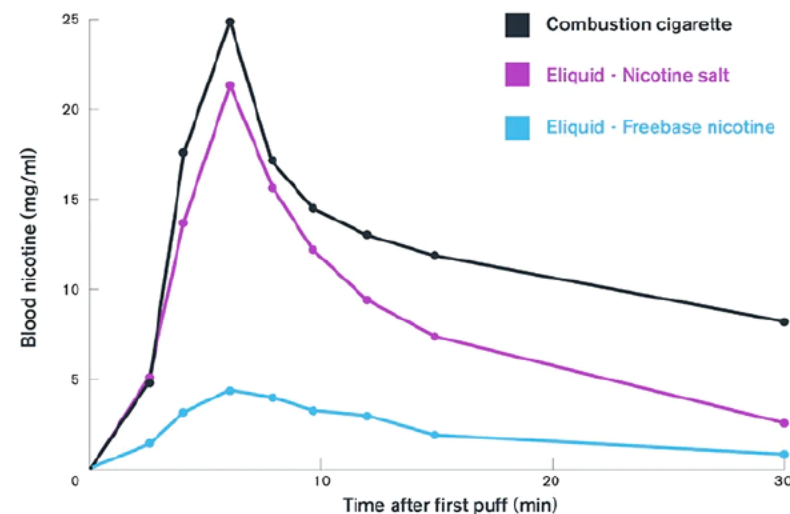
The first part of the formula, is the quantity of cigarettes smoked a day.

## STRENGTH OF THE CIGARETTE

Smokers absorb between 1.5 & 2mg of nicotine per cigarette into their bloodstream

## MATCHING THE RIGHT VAPE

This formula helps ensure you can best match nicotine absorption levels for a day.



## BLOOD ABSORPTION TABLE

Selecting the right type of nicotine vaping product, will ensure that it matches the current nicotine entering the blood stream.

Source: Paxlabs

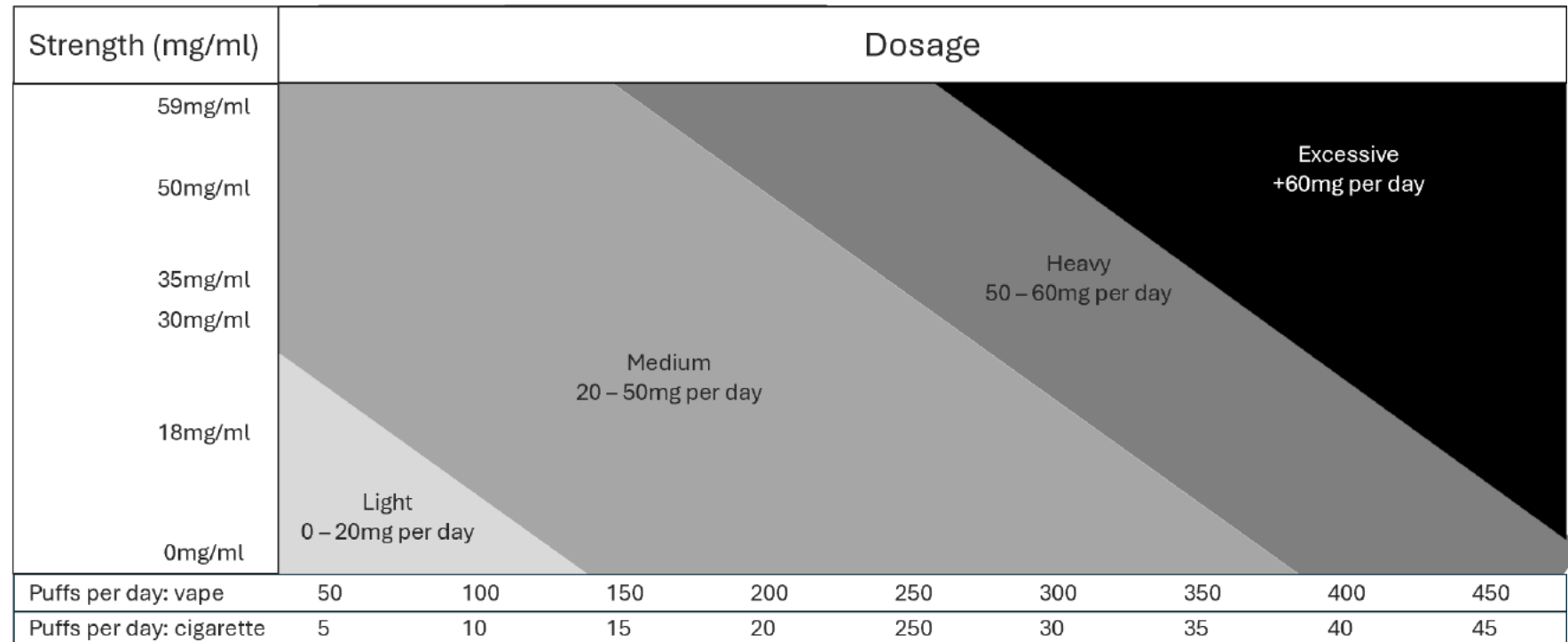


# Puff onset versus daily dosage

**“By inhaling tobacco smoke, the average smoker takes in 1–2 milligrams of nicotine per cigarette”**

Source – National Institute of Drug Abuse May '22

- TGA Hub notified products cover a dosage of 18mg to 100mg per Closed POD
- Average “pack” a day smoker takes in approx. 40 to 50 mg of nicotine per day



# 2 step process for prescribing Wild By Instinct NVP

1

## CIGARETTE DAILY CONSUMPTION

Is the simple math of cigarettes smoked per day times 2mg per cigarette.

We recommend using 2mg as the multiplier, as meeting nicotine cravings, in the first phase of cessation, is key to ensuring the patient is satisfied and not tempted back to smoking.

### SIMPLE CONVERSION TABLE

1. Cigarettes per day
2. 2mg of nicotine per cigarettes
3. Strength of vaping product needed

2

## WRITING A 3 MONTH SCRIPT

### CLOSED POD SYSTEMS:

Nicotine: Wild by Instinct nicotine vaping pod, 18mg/ml.  
Dosage: 10 puffs per session, up to 1 pod per day.  
Quantity: 15 Packs                      Repeats: 2

Wild by Instinct device  
Quantity: 1

### CLOSED POD SYSTEMS:

Nicotine: Wild by Instinct nicotine vaping pod, 50mg/ml.  
Dosage: 10 puffs per session, up to 1 pod per day.  
Quantity: 15 Packs                      Repeats: 2

Wild by Instinct device  
Quantity: 1

## WRITING A 3 MONTH SCRIPT

### DISPOSABLE SYSTEMS:

Nicotine: Wild by Instinct disposable, 50mg /ml.  
Dosage: 10 puffs per session, up to 1 disposable per 3 days. Quantity: 10 Repeats: 2  
No additional device  
Quantity: 0

### 30ML LIQUID:

Nicotine: Wild by Instinct 30ml nicotine vaping liquid, 50mg/ml.  
Dosage: 10 puffs per session, up to 1 x 30ml liquid bottle per 15 days.  
Quantity: 2 bottles                      Repeats: 2

2ml Open Pod Device required  
Quantity: 1

### 60ML LIQUID:

Nicotine: Wild by Instinct 60ml nicotine vaping liquid, 6mg/ml.  
Dosage: 10 puffs per session, up to 1 x 60ml liquid bottle per 15 days.  
Quantity: 2 bottles                      Repeats: 2

5ml Open Tank Device required  
Quantity: 1



# NVP's are better than NRT's for smoking cessation

“A Cochrane review has found the strongest evidence yet that e-cigarettes, also known as ‘vapes’, help people to quit smoking better than traditional nicotine replacement therapies, such as patches and chewing gums”

Source: Hartmann-Boyce J, Lindson N, Butler AR, McRobbie H, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Fanshawe TR, Hajek P. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2022, Issue 11. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub7. Accessed 03 April 2024

Electronic cigarettes for smoking cessation (Review)  
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## SUMMARY OF FINDINGS

### Summary of findings 1. Nicotine EC compared to NRT for smoking cessation

#### Nicotine EC compared to NRT for smoking cessation

**Patient or population:** People who smoke  
**Setting:** Various settings in New Zealand, UK, USA  
**Intervention:** Nicotine EC  
**Comparison:** NRT

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Events with NRT	Events with Nicotine EC				
Smoking cessation at 6 months to 1 year Assessed with biochemical validation	Study population 6 per 100	10 per 100 (8 to 12)	RR 1.59 (1.29 to 1.93)	2544 (7 RCTs)	⊕⊕⊕⊕ HIGH	-
Adverse events at 4 weeks to 6-9 months Assessed by self-report	Study population 23 per 100	24 per 100 (21 to 27)	RR 1.03 (0.91 to 1.17)	2052 (5 RCTs)	⊕⊕⊕⊖ MODERATE <sup>a</sup>	-
Serious adverse events at 4 weeks to 1 year Assessed via self-report and medical records	Study population 4 per 100	5 per 100 (4 to 6)	RR 1.20 (0.90 to 1.60)	2411 (6 RCTs)	⊕⊕⊖⊖ LOW <sup>b</sup>	2 studies reported no events; effect estimate based on the four studies in which events were reported

\*The estimated number of events in the intervention group (and its 95% confidence interval) is based on the assumed number of events in the comparison group and the relative effect of the intervention (and its 95% CI). For cessation, the assumed number of events in the control group is based on assumed quit rates for NRT assuming receipt of limited behavioural stop-smoking support (as per Hartmann-Boyce 2018a). The assumed risk for adverse events and serious adverse events is a weighted mean average of quit rates across control groups in contributing studies.

CI: Confidence Interval; RCT: randomized controlled trial; RR: Risk ratio

#### GRADE Working Group grades of evidence

**High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect

**Moderate certainty:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

