Manufacturer's Declaration of Conformity with TGA mandated Standards for Nicotine Vaping Products

Liber Pharmaceuticals Pty Ltd

This declaration of conformity is made in acknowledgement of Liber Pharmaceutical's obligations as Product Sponsor to supply Nicotine Vaping Products (**NVPs**) in conformance with:

- Therapeutic Goods (Standard for Nicotine Vaping Products) Order 2021 (**TGO 110**); and
- The microbiological standards for medicines outlined in section 11 (1) of Therapeutic Goods (Microbiological Standards for Medicines) Order 2018 (**TGO 100**).

Sponsor's name:	Liber Pharmaceuticals Pty Ltd (ABN 81 646 586 334).
Business address:	Suite 8, 35 Old Northern Road, Baulkham Hills NSW 2153.
Products:	Nicovape Q cartridges: • 59 mg/ml (Classic, Coolmint, Cherry). Nicovape Q SD cartridges: • 35 mg/ml (Classic, Coolmint, Cherry). • 20 mg/ml (Classic, Coolmint, Cherry).

This declaration of conformity is issued under the sole responsibility of the Sponsor.

The Sponsor declares that the conformance information provided in Annexure 1 - TGA mandated Standards for NVPs, below is based upon Liber's product development and quality assurance programs and evaluation by an ISO 17025 accredited third-party laboratory in accordance with Good Laboratory Practices (**GLP**).

Signed for and on behalf of Liber Pharmaceuticals,

01/10/2021

Head of Product: Oliver Kershaw Date

01/10/2021

Chief Operating Officer: Scott Wilson Date

Annexure 1 – TGA mandated Standards for NVPs (page 1)

TGO 110 Requirement		Requirement Details	Nicovape® Q Compliance
Labelling Requirements To comply each piece of information must be either: • included on, or attached to, the container or primary pack of the product (including by way of over-stickering), or • set out in information supplied with the product (e.g. in an information sheet).	Ingredient List	a. The name of the active ingredient in the product (which must only be nicotine in base and/or salt form(s)). For nicotine salt products, the particular type of each nicotine salt in the product must be listed	Compliant
		b. For flavoured products, either the word "flavour", or a description including the word "flavour" (e.g. "cherry flavour"), or the name of each ingredient in the flavour, and	Compliant
		c. The names of all other excipient ingredients.	Compliant
	Nicotine Concentration	a. For nicotine base products, the nicotine base form concentration in mg/mL, OR	Compliant
		b. Nicotine salt products, the equivalent nicotine base form concentration in mg/mL. Specifying the concentration of the nicotine salt(s) in the product will not satisfy this requirement.	Compliant
	Warning Statements	a. KEEP OUT OF REACH OF CHILDREN.	Compliant
		b. Avoid contact with eyes.	Compliant
		c. Avoid contact with skin.	Compliant
Packaging Requirements	Child-Resistant Packaging Must comply with following sections of TGO 95 (child-resistant packaging requirements)	a. section 8 (general requirements); and	Compliant
		b. where the product is in a reclosable package—section 9 (reclosable packages), other than subsection 9(6); and	N/A
		c. where the product is in a non-reclosable package—section 10 (non-reclosable packages).	Compliant
	Tamper-evident packaging non-mandatory	Code of practice for tamper-evident packaging of therapeutic goods	Compliant

Annexure 1 – TGA mandated Standards for NVPs (page 2)

TGO 110 Requirement		Requirement Details	Nicovape® Q Compliance
Ingredient Requirements	Nicotine is the only permitted active ingredient	Nicotine (whether in base and/or salt form(s)) is the only active ingredient allowed in unregistered nicotine vaping products - these products must not contain any other active ingredients (subsection 7(1) of TGO 110). It is not appropriate to add other active ingredients to nicotine vaping products as they would not be needed to assist in the cessation of smoking or nicotine addiction.	Compliant
	Actual vs labelled nicotine concentration / content	The actual nicotine base form, nicotine salt and/or equivalent base form concentration or content in the nicotine vaping product must be within 90-110% of that stated: a. on or attached to the container or primary pack of the product (including on an over-sticker), or b. in information provided with the product label or packaging.	Compliant
	Nicotine (or equivalent base form) concentrations ≤ 100mg	Unregistered vaping products must have: a. for nicotine base products, a base form concentration, b. for nicotine salt products, an equivalent base form concentration, of no more than 100 mg/mL (subsection 7(1) of TGO 110).	Compliant
	No prohibited ingredients added to product	The substances specified in 'Schedule 1-Prohibited ingredients' of TGO 110 must not be added as ingredients in unregistered nicotine vaping products: 1. 2,3-pentanedione 2. acetoin 3. benzaldehyde 4. cinnamaldehyde 5. diacetyl 6. diethylene glycol 7. DL-alpha-tocopheryl acetate 8. ethylene glycol	Compliant

Annexure 1 – TGA mandated Standards for NVPs (page 3)

TGO 110 Requirement		Requirement Details	Nicovape® Q Compliance
Record Keeping Obligations for Australian Sponsors	Maintains records demonstrating conformance with TGO 110	a. Copies of the labels of the product showing the information required under TGO 110.	Compliant
		b. Records showing the design of the packaging used for the product and how it meets the child-resistant packaging requirements in TGO 110.	Compliant
		c. Evidence that the product conforms to each of the Ingredient requirements in TGO 110, such as a declaration from the manufacturer and/or a Certificate of Analysis (or similar document(s)).	Compliant
TGO 100 Requirement		**Requirement Details**	**Nicovape® Q Compliance**

Microbiological Standards	Domestically supplied NVPs are subject to the requirements of subsection 11(1) of TGO 100 (Microbiological Standards for Medicines)	**Therapeutic Goods (Microbiological Standards for Medicines) Order 2018 (TGO 100)**
		11 Microbiological attributes of a non-sterile medicine
		(1) A non-sterile medicine, other than a complementary medicine oral dosage form containing raw material of natural (animal, vegetal or mineral) origin, must comply with the relevant acceptance criteria for microbiological quality.
		Liber has applied the following criteria for microbiological quality:
		• the European Pharmacopoeia, Microbiological Quality of Non-Sterile Pharmaceutical Preparations and Substances for Pharmaceutical use (5.1.4); applying,
		  • the European Pharmacopoeia, Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests (2.6.12); and
		  • the European Pharmacopoeia, Microbiological Examination of Non-Sterile Products: Test for Specified Microorganisms (2.6.13).
			Compliant