PHARMCHEM TECHNICAL SERVICES PTY LTD

Technical Consultancy to the Pharmaceutical and Life Science Industries
ACN 107 645 303

LETTER OF ORGANIC AUDIT

Formulation Assessment - *Organic*

The following table is a review and assessment of conformance of the ingredients as "organic".

Zinclear XP Dispersion Range Ingredient	Function	Source	NOP Compliant	NSF/ANSI-305-2016 Compliant & Ref.	% Allowed
Zinc Oxide	UV block	Mined mineral	**Yes**	**Yes**	
Aluminum Oxide	UV block	Mined mineral	**Yes**	**Yes**	
Zinc Oxide/Aluminium Oxide Blend	UV block	Mined mineral	**Yes**	**Yes**	
Isostearic Acid	Carrier	Botanical	**Yes**	**Yes** E.2.1, E.2.3, E.2.7, 6.5	no limit
Polyglcerol-3-polyricinoleate	Carrier	Botanical	**Yes**	**Yes** E.2.4, E.2.5, 6.5	NMT 98
Cocos Nucifera Oil (Coconut Oil)	Carrier	Botanical	**Yes**	**Yes** Certified by supplier	no limit
Helianthus Annuus Seed Oil (Sunflower Oil)	Carrier	Vegetable Oil	**Yes**	**Yes** Certified by supplier	no limit

Tennyson, S.A. 5022, Australia Phone: +61 (0)401 657 477 Email: pharmche@ozemail.com.au

eQual assurance

CERTIFICATE OF CONFIDENCE

This is to certify that

Advance ZincTek Limited

1821 Ipswich Road, Rocklea QLD 4106, Australia
81 Shettleston Street, Rocklea QLD 4106, Australia
112 Radium Street, Welshpool WA 6106, Australia
Charles Street, Bentley WA 6102, Australia

conforms to the requirements of

ISO 9001:2015

Quality management systems

The research, development, manufacture and sale of advanced materials.

Certificate number:	AVLQ01-CCCQ03	**Certified date:**	2 September 2019
Approval date:	18 October 2021	**Expiry date:**	31 August 2024

Robert Howell
DipMgt
Assurance Manager
Equal Assurance

ISO 9001 certified Equal Assurance

JAS-ANZ

Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 2: Schedule of Conditions

Licence Number:

MI-2019-LI-02603-1

Granted to:

Antaria Pty Ltd
ABN: 36 092 404 727

Manufacturing Site Address:

81 Shettleston Street
ROCKLEA QLD 4106

In addition to the statutory conditions that have been imposed on all licences to manufacture therapeutic goods under Section 40(4) of the *Therapeutic Goods Act 1989* and Regulations 19, 20 and 21 of the Therapeutic Goods Regulations 1990, the conditions specified below have been imposed on this licence under Section/s 40(1) and/or 40(2) of the *Therapeutic Goods Act 1989*:

The manufacture of non-sterile APIs is limited to zinc oxide.

Persons currently nominated under Section 37(1)(e) of the Act as having control:

Production:	Michael Smeaton
Quality Control:	Marissa Melvin

Originally Imposed: **17 September 2019** Date Revised: **25 March 2021**

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-2019-LI-02603-1

This licence is subject to the requirements of the *Therapeutic Goods Act 1989*, and its Regulations.

Section 40(4) of the *Therapeutic Goods Act 1989* and Regulation 19, 20, 21 and 22 of the Therapeutic Goods Regulations 1990 impose various statutory conditions on all licences to manufacture therapeutic goods.

In addition to that, the specific conditions mentioned in Part 2 of this licence have been imposed under Section 40(1) or 40(2) of the *Therapeutic Goods Act 1989*.

Originally Granted: **17 September 2019** Date Revised: **25 March 2021**

This Licence is the property of the Therapeutic Goods Administration and must be returned or destroyed upon demand.
This Licence remains valid until otherwise suspended or revoked by the Therapeutic Goods Administration.
The status of an Australian Licence may be viewed at https://www.ebs.tga.gov.au/

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TGA Health Safety Regulation