

Certificate of Analysis Release for Supply

Customer Name	Ora Health Pty Ltd				
Sponsor Name	Ora Health Pty Ltd				
Brand Name	Ora				
Product Name	Adaptogen Tonic+				
AUST L	370557	Our Product Code	IMMTON60-ORA	Version No.	01
Shelf Life	24 months			Supersedes No.	00

Physical	Test Item	Test Method	Specification	Result
	Dosage Form	Visual	Capsule, hard	Conforms
	Physical Appearance	Visual	Yellow to brownish powder in a size 00el Natural Vegetable cellulose capsule	Conforms
	Capsule Size	Visual	00el	Conforms
	Dimensions	Calipers	25.30 mm (±0.30)	25.30 mg
	Average Fill Weight	BP Appendix XII C	Average Weight: 680.00 mg Range: 629.00 to 713.00 mg	680.00 mg
	Uniformity of Fill Weight	BP Appendix XII C	NMT 2 out of the 20 of the individual capsules deviate from the average weight by more than ±7.5% and none deviate by more than ±15%	Conforms
	Average Full Weight	BP Appendix XII C	Average Weight: 810.00 mg Range: 749.25 to 870.75 mg	783.00 mg
	Disintegration	BP Appendix XII A	NMT 30 minutes	8' 03"
	Microbial	Test Item	Test Method	Specification
Total aerobic microbial count		BP / TGO100	Not more than 10 000 CFU per g or per mL	<10 cfu/g
Total Yeasts & Moulds		BP / TGO100	Not more than 100 CFU per g or per mL	<10 cfu/g
Bile-tolerant Gram negative Bacteria		BP / TGO100	Not more than 100 CFU per g or per mL	<10 cfu/g
Staphylococcus aureus		BP / TGO100	Not detected per 1g or 1mL	ND per 1.0g
Escherichia coli		BP / TGO100	Not detected per 1g or 1mL	ND per 1.0g
Salmonella		BP / TGO100	Not detected per 10g or 10mL	ND per 10.0g

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Heavy Metals & Solvents	Test Item	Test Method	Specification			Result
	HM – Arsenic (inorg.)	USP/TGO101	NMT 1.5 ppm			<1.5 ppm
	HM - Cadmium	USP/TGO101	NMT 0.5 ppm			<0.5 ppm
	HM - Lead	USP/TGO101	NMT 0.5 ppm			<0.5 ppm
	HM - Mercury	USP/TGO101	NMT 0.2 ppm			<0.2 ppm
	Residual Solvents	Ph Eur/TGO101	Complies with TFO101			Complies
Chemical	Test Item		Label Claim Unit/Capsule	Release Limits % Label Claim	Expiry Limits % Label Claim	Result
	Astragalus membranaceus dry		2250.00mg	*	*	2250.00 mg*
	Eleutherococcus senticosus root dry		1500.00 mg	*	*	1500.00 mg*
	Schisandra chinesis fruit dry		1500.00 mg	*	*	1500.00 mg*
	Quercetin dihydrate		125.00 mg	90-120***	90-120***	117.04 mg
	Riboflavin		750.00 mg	*	*	750.00 mg*
	Nicotinamide		0.0125 mg	90-150	90-150	0.0185 mg

@	<i>Interim specifications, to be reviewed after 3 batches</i>
&	<i>Full testing on the first 3 batches, will be routinely tested starting on the 4th. batch</i>
#	<i>References the current BP or USP Monograph</i>
*	<i>Identified and then quantified by input. This material cannot be assayed on the finished product blend due to matrix interference and/or non-availability of BP/USP test method.</i>
**	<i>±1/2 log₁₀ applies to probiotic enumeration due to inherent variability in microbial plate count methods.</i>
***	<i>Release limits are Sponsor-specified.</i>

The manufacturing and packaging batch documentation and analysis results were found to be in compliance with cGMP, Market Authorisation and the Product Specification. Any deviations have been reviewed and completed.