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Co-creating wellness

Certificate of Analysis
Release for Supply

Customer Name	**Ora Health Pty Ltd**				
Sponsor Name	**Ora Health Pty Ltd**				
Brand Name	**Ora**				
Product Name	**Mag³ Mood**				
AUST L	372559	Our Product Code	MAGMOO150-ORA	Version No.	03
Shelf Life	36 months			Supersedes No.	02

Physical	**Test Item**	**Test Method**	**Specification**	**Result**
	Dosage Form	Visual	Powder, oral	Conforms
	Physical Appearance@	Visual	Brownish to off-white/beige coloured free flowing powder	Conforms
	Dosage Size	Calc.*****	5.0g	5.0g
	Average Fill Weight	In-house	Target weight ±5.0%	150.9g
Microbial	**Test Item**	**Test Method**	**Specification**	**Result**
	Total aerobic microbial count	BP / TGO100	Less than or equal to 10,000 cfu's/g	<200 cfu/g
	Total Yeasts & Moulds	BP / TGO100	Less than or equal to 100 cfu's/g	80 cfu/g
	Bile-tolerant Gram negative Bacteria	BP / TGO100	Less than or equal to 100 cfu's/g	<10 cfu/g
	Staphylococcus aureus	BP / TGO100	Not detected/g	ND
	Escherichia coli	BP / TGO100	Not detected/g	ND
	Salmonella	BP / TGO100	Not detected/10g	ND

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Residual Solvents**	**Test Item**	**Test Method**	**Specification**			**Result**
	Residual Solvents	EP 5.4/TFO101	Not exceed values listed in EP 5.4			Conforms
Elemental Impurities ***	**Test Item**	**Test Method**	**Specification**			**Result**
	Arsenic	USP/TGO101	NMT 2.0 ppm			<2 ppm
	Cadmium	USP/TGO101	NMT 1.0 ppm			<1 ppm
	Lead	USP/TGO101	NMT 5 ppm			<5 ppm
	Mercury	USP/TGO101	NMT 0.2 ppm			<0.2 ppm
Chemical ******	**Test Item**		**Target Quantity (mg/5.0gram)**	**Release %**	**Expiry %**	**Result**
	TOTAL Magnesium		310.00	90-125	90-125	338.00
	Melissa officinalis leaf ext. dry conc.		375.00	QBI'ed	QBI'ed	375.00
	Withania somnifera root ext. dry conc.		240.00	QBI'ed	QBI'ed	240.00
	Cordyceps sinesis fruiting body ext. dry conc.		500.00	QBI'ed	QBI'ed	500.00

*	*Identified then quantify by input – (QBI'ed)*
**	*Starting materials are assessed and verified to comply to the requirements of EP 5.4 and current TGO .*
***	*Starting materials are assessed and verified to comply to the requirements of ICH Q3D /USP <2232> and current TGO to allow the finished product to meet the specified limits.*
****	*Test methods for assay and quantitative analysis of chemical active ingredients are held by the contracted testing laboratories who under GMP/TGA requirements will have validated test methods or where a monograph is available, will test according to the compendia I method.*
*****	*Dosage size is calculated to l.0g unless otherwise specified. If alternative dosages size id nominated, this will be taken directly from the finished product label.*
#	*Unless specified the standards comply to the most recent monograph*
&	*Will be assayed on a rotational basis once history is established*
@	*Interim specifications, to be reviewed after 3 batches*
^	*Food products will not be tested, results will be taken from starting materials COA*

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.