



Australian Government
Department of Health
Therapeutic Goods Administration

Certificate of Analysis

I, Megan Yamakawa, being an Official Analyst appointed under Regulation 25 of the Therapeutic Goods Regulations 1990, certify that a sample of therapeutic goods, bearing TGA sample number 1408002845, has been examined and analysed.

The sample was submitted by Complementary Compounding Services (Ballina, NSW)

The goods were represented to be:

ARTG Number: N/A
Name: MELATONIN 3 mg Modified Release Caps
Sponsor: Complementary Compounding Services
Batch Number: 210714-082348 **Expiry Date:** 17-January-2015
Storage Conditions: Store at room temperature **Dosage Form:** capsule

Results of the examination and analysis were as follows:

TEST	RESULT	REQUIREMENT
Sample Appearance	Transparent hard capsules containing white powder. Capsules were contained in a white plastic bottle with a white plastic screw cap.	
Dissolution (multiple time points)	15.7% released in 40 mins, 25.6% released in 80 mins, 32.9% LC released in 120 minutes (average of 6 capsules)	
Content of Melatonin by HPLC	97.3 %	90.0 - 110.0 % LC
Uniformity of dosage units - content uniformity (BP)	Acceptance Value (AV) = 10.2 (Individual results: 96.3, 90.3, 101.0, 92.4, 98.6, 95.5, 97.3, 100.4, 101.8, 98.9 % LC)	AV = 15.0 or less

Abbreviations: HPLC = high performance liquid chromatography; LC = label claim; BP = British Pharmacopoeia 2014

Certificate Number: 1408002845

Analyst Signature:

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