



Australian Government
Department of Health
Therapeutic Goods Administration

Certificate of Analysis

I, Dilanthi Manley, 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 1408002859, 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:	SEA SICKNESS CAPS (Scopolamine 0.4 mg)		
Sponsor:	Complementary Compounding Services		
Batch Number:	Not specified	Expiry Date:	31-January-2015
Storage Conditions:	Room temperature	Dosage Form:	Capsule

Results of the examination and analysis were as follows:

TEST	RESULT	REQUIREMENT
Sample Appearance	Clear, hard capsules containing fine, light tan coloured powder. The capsules were enclosed in 3 separate white, labelled, plastic containers with relevant seals intact.	
Identification (UPLC)	Hyoscine	
Uniformity of Dosage Units - Content Uniformity of Hyoscine Hydrobromide	Acceptance Value (AV) = 63.3 (Individual results: 96.3, 77.0, 117.6, 121.2, 156.1, 82.5, 88.8, 109.2, 70.6, 113.6 % LC)	AV = 15.0 or less (BP)
Drug Screen by UPLC/PDA (UPLCD01)	Caffeine detected; content estimated to be 102.5 mg/capsule. Chlorpheniramine maleate detected; content estimated to be 4.4 mg/capsule. Results are consistent with the label.	See below *
Content of Hyoscine Hydrobromide by UPLC	103.3 %	90.0 - 110.0 % LC

* Requirement : No undeclared pharmaceutical active ingredient detected.

Abbreviations: LC = label claim; UPLC/PDA = ultra performance liquid chromatography/photodiode array detector; BP = British Pharmacopoeia 2014

Certificate Number: 1408002859

Analyst Signature :

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