



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

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## Certificate of Analysis

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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 1408002844, 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:** NIFEDIPINE 0.5% OINTMENT  
**Sponsor:** Complementary Compounding Services  
**Batch Number:** 210714-082637  
**Storage Conditions:** Room temperature  
**Expiry Date:** 22-October-2014  
**Dosage Form:** Ointment

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Results of the examination and analysis were as follows:

TEST	RESULT	REQUIREMENT
Sample Appearance	White plastic jar with a white plastic lid containing pale yellow ointment.	
Related substances (BP)	Impurity A = 0.17%; Impurity B = 10.48%; Largest unknown impurity = 0.71%; Total unknown impurities = 0.94%	See below*
Content of Nifedipine by HPLC	100.3 %	90.0 – 110.0 % LC

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\* Limits for formulated preparations for nifedipine in the BP: Impurity A & Impurity B  $\leq 0.5\%$  each, Any other secondary impurity  $\leq 0.2\%$ , Total secondary impurities  $\leq 1.0\%$ .

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

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Certificate Number: 1408002844

Analyst Signature:

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