



Australian Government

Department of Health  
Therapeutic Goods Administration

# Laboratory Report

OLSS ref: Project 1561  
RCU ref: RCU 14900

## Re: Plexus Slim Accelerator Plus

### Background

On the 10<sup>th</sup> of December 2013, OLSS Chemistry received the following samples of Plexus Slim products and an accompanying Minute dated the same from [REDACTED] of the TGA Regulatory Compliance Unit (RCU). Individual details of each sample including affixed RCU sticker numbers and assigned TGA sample numbers are given in **Table 1**. Samples were received in a large resealable plastic bag sealed with TGA seal number RCU3137.

**Table 1\_ Sample Details:**

Sample name	Batch (Lot) No.	Expiry date	RCU Sticker No.	TGA Sample No.
Plexus Slim Accelerator Plus capsules	091313	10/2015	SU 0048915	<b>1312004273</b>
Plexus Slim 7-Day Challenge	091314	Not evident	SU 0048916 (on sachet)	<b>1312004274</b>
Plexus Slim 3-Day Trial Pack	091314	Not evident	SU 0048913 (on sachet)	<b>1312004275</b>
Plexus Slim 3-Day Trial Pack	illegible	Not evident	SU 0048914 (on sachet)	<b>1312004276</b>

Samples of 'Plexus Slim Accelerator' capsules have previously been tested by OLSS (Project 1465, TGA sample numbers **1304001506**, **1304001508-R1** and Project 1506, TGA sample number **1308002719** refer). These samples were found to contain **1,3-dimethylamylamine (DMAA)** which is listed in Appendix C of the SUSMP<sup>1</sup>.

The RCU has requested that the OLSS analyse the capsules of Accelerator Plus in the current samples to ascertain if the capsules contain any DMAA or any undisclosed Schedule 4 (prescription only) medicines. The RCU also wishes to know the levels of the labelled ingredient **5-hydroxytryptophan** in the capsules, with reference to tryptophan, as products containing daily dosages of tryptophan above 100mg are included in Schedule 4 of the SUSMP.

<sup>1</sup> Standard for the Uniform Scheduling of Medicines and Poisons, 2013

## Examination and analysis

The samples were visually examined, photographed<sup>2</sup> and analysed. Certificates of analysis for the samples are provided with this report. The results of the examination and analysis of the samples are reviewed below.

### (i) Visual examination

- **Plexus Slim Accelerator Plus (1312004273)**

The sample consisted of a labelled white plastic bottle, sealed with shrink wrap seal around the lid and an intact induction seal, containing 60 white, size 0 capsules. The capsules were unmarked and filled with a light brown powder. The average capsule fill weight was 562.6 mg (average of 10 capsules).

The ingredients listed as they appear on the bottle were: Niacin (as Niacinamide) 20mg, Vitamin B6 (as Pyridoxine hydrochloride) 30mg, Vitamin B12 (as Methyl cobalamin) 500mcg, Folic Acid 400mcg, Calcium (as Calcium glycinate) 50mg, Chromium (as Chromium picolinate) 1.5mg, Proprietary blend of 950mg: {Yerba Mate (*Ilex paraguariensis*) leaf extract, Higenamine, Hordenine, Hawthorn (*Crataegus monogyna*) leaf extract, 5-HTP (5-Hydroxytryptophan from *Griffonia simplicifolia* seed extract), Green tea (*Camellia sinensis*) leaf extract.

- **Plexus Slim 7-Day Challenge (1312004274)**

The sample consisted of a heat sealed, re-sealable labelled plastic sachet (primary pack) containing 7 sealed powder-filled stick sachets and a sealed clear plastic bag labelled 091314 containing 7 capsules. The labelling on the primary pack indicated that the stick sachets contained Plexus Slim™ powder<sup>3</sup> and the capsules were Plexus Slim™ Accelerator Plus.

The capsules were white, size 0, unmarked and filled with a light brown powder. The average capsule fill weight was 530.2 mg (average of 3 capsules).

The ingredients listed on the sachet for the Accelerator capsules were: Niacin (as Niacinamide) 10mg, Vitamin B6 (as Pyridoxine hydrochloride) 15mg, Vitamin B12 (as Methyl cobalamin) 250mcg, Folic Acid 200mcg, Calcium (as Calcium glycinate) 25mg, Chromium (as Chromium picolinate) 750mcg, Proprietary blend of 475mg: {Yerba Mate (*Ilex paraguariensis*) leaf extract, Higenamine, Hordenine, Hawthorn (*Crataegus monogyna*) leaf extract, 5-HTP (5-Hydroxy tryptophan from *Griffonia simplicifolia* seed extract), Green tea (*Camellia sinensis*) leaf extract.

- **Plexus Slim 3-Day Trial Packs (1312004275 and 1312004276)**

Both samples contained a folded cardboard information brochure with an attached compact disc and a heat sealed, re-sealable, labelled, plastic sachet. The contents in each sachet were similar to the 7-Day Challenge sample (1312004274), except the 3-Day packs each only contained 3 stick sachets and 3 capsules.

The average capsule fill weights were 559.9mg and 565.4mg for 1312004275 and 1312004276, respectively, based on averages of 2 capsules each.

The ingredients listed on the sachets for the Accelerator Plus capsules were the same as for 1312004274.

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<sup>2</sup> The photographs are located in TRIM container 2013/013711, record number R13/997176.

<sup>3</sup> OLSS previously tested a sample of Plexus Slim™ powder (Project 1465, TGA sample numbers 1304001508) and no undeclared pharmaceutical drugs were detected. Powder sachets in the current samples were not requested to be tested.

## (ii) Testing

Analyses were conducted on aliquots taken from the pooled contents of capsules. The number of capsules pooled for each sample are given in **Table 2**. The samples were screened by in-house UPLC/PDA<sup>4</sup>, GC/MS<sup>5</sup> and LC/MS<sup>6</sup> methods.

All samples had similar profiles by UPLC/PDA and GC/MS.

**5-Hydroxytryptophan (5-HTP)** was identified in the samples by UPLC/PDA analysis by comparison of retention time and UV spectrum with a reference standard. Further confirmation was obtained by LC/MS. The contents of **5-hydroxytryptophan** in the samples were estimated by UPLC and the results are given in **Table 2**.

**Table 2\_ Estimated contents of 5-hydroxytryptophan**

TGA sample No.	Number of pooled capsules	Content of 5-HTP /capsule
<b>1312004273</b>	10	44.8 mg
<b>1312004274</b>	3	45.9 mg
<b>1312004275</b>	2	50.4 mg
<b>1312004276</b>	2	52.2 mg

All the samples contained compounds giving library matches for caffeine and herbal markers such as epigallocatechin gallate, rutin and quercetin in the UPLC screen. Samples **1312004274-6** also each had a peak with a library match for the herbal marker compound chlorogenic acid.

A significant unidentified peak present in the UPLC screen of **1312004273** was further investigated and found to be consistent with the labelled ingredient **higenamine**. This peak was also present in the other samples. Higenamine is a naturally occurring benzyl isoquinoline alkaloid and is not scheduled.

Peaks consistent with caffeine and the labelled ingredient **hordenine** were detected in all samples in the GC/MS screen. Hordenine was not detected in the UPLC screens of the samples however it may well co-elute with 5-HTP. Hordenine is a naturally occurring phenethylamine compound and is not scheduled.

**1,3-dimethylamylamine (DMAA)** was **not detected** at or above the schedulable limit of 10ppm in all the samples.

## Conclusions

The labelled ingredient **5-Hydroxytryptophan** (AAN = oxitriptan) was detected in all the samples at contents ranging from 45 to 52 mg/capsule. Given the dosage instructions on the labelling of 1 to 2 capsules per day and the highest value found (in **1312004276**) of 104.4 mg/day, this is equivalent to 96.8 mg/day of tryptophan. Also, there is a possibility that the estimated values of **5-Hydroxytryptophan** are slightly elevated above the actual values due to co-elution of hordenine.

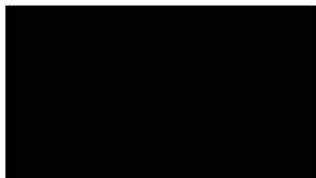
Dosages of tryptophan above 100mg/day are included in the Schedule 4 of the SUSMP, dosages below that level are not scheduled.

<sup>4</sup> Ultrahigh Performance Liquid Chromatography with Photo Diode Array detection

<sup>5</sup> Gas Chromatography/ Mass Spectrometric detection

<sup>6</sup> Liquid Chromatography with Mass Spectrometric detection

**1,3-Dimethylamylamine (DMAA)** was **not detected** in any of the samples at or above the scheduling limit of 10ppm.



OLSS Chemistry

13<sup>th</sup> February 2014



Director, OLSS Chemistry



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

## Certificate of Analysis

I, [REDACTED] 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 1312004273, has been examined and analysed.

The sample was submitted by TGA Regulatory Compliance Unit [REDACTED]

The goods were represented to be:

<b>ARTG Number:</b>	n/a		
<b>Name:</b>	Plexus Slim Accelerator Plus		
<b>Sponsor:</b>	not specified		
<b>Batch Number:</b>	Lot: 091313	<b>Expiry Date:</b>	31-October-2015
<b>Storage Conditions:</b>	n/a	<b>Dosage Form:</b>	capsule

Results of the examination and analysis were as follows:

TEST	RESULT	REQUIREMENT
Sample Appearance	The sample consisted of a white labelled plastic bottle sealed with shrink wrap around the lid and an induction seal. The bottle contained white, size 0, hard gelatine capsules filled with a fine light brown powder. The average capsule fill weight was 562.6 mg(average of 10 capsules).	
Drug Screen by GCMS (GCMSD01)	Hordenine detected. Library match for caffeine was present.	see below *
Identification (LCMS)	5-Hydroxytryptophan (AAN = Oxitriptan).	
Profile by LCMS	1,3-Dimethylamylamine (DMAA) was not detected (less than 10ppm). Peak consistent with labelled ingredient higenamine (with m/z 272.13) was present.	
TGA Seal Number	RCU3137	
TGA RCU Number	SU 0048915	
Identification (UPLC)	5-Hydroxytryptophan.	

\* Requirement : No undeclared pharmaceutical active ingredient detected.

**Abbreviations:** GCMS = gas chromatography with mass spectrometer detector; LCMS = (high performance) liquid chromatography with mass spectrometer detector; UPLC/PDA = ultra performance liquid chromatography/ photodiode array detector; AAN = Australian Approved Name

Certificate Number: 1312004273

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Analyst Signature : [REDACTED]

Issued:


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TEST	RESULT	REQUIREMENT
Drug Screen by UPLC/PDA (UPLCD01)	5-Hydroxytryptophan was detected and its content estimated to be 44.8 mg/capsule. Peaks having library matches for epigallocatechin gallate, rutin, quercetin and caffeine were present.	see below *

\* Requirement : No undeclared pharmaceutical active ingredient detected.

**Abbreviations:** GCMS = gas chromatography with mass spectrometer detector; LCMS = (high performance) liquid chromatography with mass spectrometer detector; UPLC/PDA = ultra performance liquid chromatography/ photodiode array detector

Certificate Number: 1312004273

Analyst Signature : 

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## Certificate of Analysis

I, [REDACTED] 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 1312004276, has been examined and analysed.

The sample was submitted by TGA Regulatory Compliance Unit (Phil Rohan)

The goods were represented to be:

**ARTG Number:** n/a  
**Name:** Plexus Slim - 3 day trial pack - Accelerator Plus capsules  
**Sponsor:** not specified  
**Batch Number:** illegible  
**Storage Conditions:** n/a  
**Expiry Date:**  
**Dosage Form:** capsule

Results of the examination and analysis were as follows:

TEST	RESULT	REQUIREMENT
Sample Appearance	The sample consisted of a folded cardboard information brochure with an attached compact disc and a heat sealed labelled plastic sachet. The sachet contained 3 sealed stick packs and a sealed plastic bag containing 3 white, hard gelatin, size 0 capsules. Capsules were filled with a fine light brown powder. The average fill weight of a capsule was 565.4 mg based on 2 capsules.	
Drug Screen by GCMS (GCMSD01)	Hordenine detected. Library match for caffeine was present.	see below *
Identification (LCMS)	5-Hydroxytryptophan (AAN = Oxitriptan)	
Profile by LCMS	1,3-Dimethylamylamine (DMAA) was not detected (less than 10ppm).	
TGA Seal Number	RCU3137	
TGA RCU Number	SU 0048914 (on sachet)	

\* Requirement : No undeclared pharmaceutical active ingredient detected.

**Abbreviations:** LCMS = (high performance) liquid chromatography with mass spectrometer detector; GCMS = gas chromatography with mass spectrometer detector; UPLC/PDA = ultra performance liquid chromatography/ photodiode array detector, AAN = Australian Approved Name

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Analyst Signature : [REDACTED]

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TEST	RESULT	REQUIREMENT
Identification (UPLC)	5-Hydroxytryptophan.	
Drug Screen by UPLC/PDA (UPLCD01)	5-Hydroxytryptophan was detected and its content estimated to be 52.2 mg/capsule. Peaks having library matches for epigallocatechin gallate, chlorogenic acid, rutin, quercetin and caffeine were present.	see below *

\* Requirement : No undeclared pharmaceutical active ingredient detected.

**Abbreviations:** LCMS = (high performance) liquid chromatography with mass spectrometer detector; GCMS = gas chromatography with mass spectrometer detector; UPLC/PDA = ultra performance liquid chromatography/ photodiode array detector

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The sample was submitted by TGA Regulatory Compliance Unit (Phil Rohan)

The goods were represented to be:

**ARTG Number:** n/a  
**Name:** Plexus Slim - 3 day trial pack - Accelerator Plus capsules  
**Sponsor:** not specified  
**Batch Number:** Lot: 091314  
**Storage Conditions:** n/a  
**Expiry Date:**  
**Dosage Form:** capsule

Results of the examination and analysis were as follows:

TEST	RESULT	REQUIREMENT
Sample Appearance	The sample consisted of a folded cardboard information brochure with an attached compact disc and a heat sealed labelled plastic sachet. The sachet contained 3 sealed stick packs and a sealed plastic bag containing 3 white, hard gelatin, size 0, capsules filled with a fine light brown powder. The average fill weight of a capsule was 559.9 mg based on 2 capsules.	
Drug Screen by GCMS (GCMSD01)	Hordeinine detected. Library match for caffeine was present.	see below *
Identification (LCMS)	5-Hydroxytryptophan (AAN = Oxitriptan)	
Profile by LCMS	1,3-Dimethylamylamine (DMAA) was not detected (less than 10ppm).	
TGA Seal Number	RCU3137	
TGA RCU Number	SU 0048913 (on sachet)	

\* Requirement : No undeclared pharmaceutical active ingredient detected.

**Abbreviations:** GCMS = gas chromatography with mass spectrometer detector; UPLC/PDA = ultra performance liquid chromatography/ photodiode array detector; LCMS = (high performance) liquid chromatography with mass spectrometer detector, AAN = Australian Approved Name

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Analyst Signature : [REDACTED]

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TEST	RESULT	REQUIREMENT
Identification (UPLC)	5-Hydroxytryptophan.	
Drug Screen by UPLC/PDA (UPLCD01)	5-Hydroxytryptophan was detected and its content estimated to be 50.4 mg/capsule. Peaks having library matches for epigallocatechin gallate, chlorogenic acid, rutin, quercetin and caffeine were present.	see below *

\* Requirement : No undeclared pharmaceutical active ingredient detected.

**Abbreviations:** GCMS = gas chromatography with mass spectrometer detector; UPLC/PDA = ultra performance liquid chromatography/ photodiode array detector; LCMS = (high performance) liquid chromatography with mass spectrometer detector

Certificate Number: 1312004275

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The sample was submitted by TGA Regulatory Compliance Unit (Phil Rohan)

The goods were represented to be:

**ARTG Number:** n/a  
**Name:** Plexus Slim 7 day Challenge – Accelerator Plus capsules  
**Sponsor:** not specified  
**Batch Number:** Lot : 091314  
**Storage Conditions:** n/a  
**Expiry Date:**  
**Dosage Form:** capsule

Results of the examination and analysis were as follows:

TEST	RESULT	REQUIREMENT
Sample Appearance	The sample consisted of 7 white, hard gelatin, size 0 capsules filled with a fine light brown powder, contained in sealed clear plastic bag. The bag of capsules was contained in a heat sealed, resealable, labelled sachet which also contained 7 sealed, powder-filled, stick sachets. The average capsule fill weight was 530.2 mg(average of 3 capsules).	
Drug Screen by GCMS (GCMSD01)	Hordenine detected. Library match for caffeine was present.	see below *
Identification (LCMS)	5-Hydroxytryptophan (AAN = oxitriptan).	
Profile by LCMS	1,3-Dimethylamylamine (DMAA) was not detected (less than 10ppm).	
TGA Seal Number	RCU3137	
TGA RCU Number	SU 0048916 (on sachet)	

\* Requirement : No undeclared pharmaceutical active ingredient detected.

**Abbreviations:** UPLC/PDA = ultra performance liquid chromatography/ photodiode array detector; LCMS = (high performance) liquid chromatography with mass spectrometer detector; GCMS = gas chromatography with mass spectrometer detector, AAN = Australian Approved Name

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Analyst Signature : [REDACTED]

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TEST	RESULT	REQUIREMENT
Identification (UPLC)	5-Hydroxytryptophan.	
Drug Screen by UPLC/PDA (UPLCD01)	5-Hydroxytryptophan was detected and its content estimated to be 45.9 mg/capsule. Peaks having library matches for epigallocatechin gallate, chlorogenic acid, rutin, quercetin and caffeine were present.	see below *

\* Requirement : No undeclared pharmaceutical active ingredient detected.

**Abbreviations:** UPLC/PDA = ultra performance liquid chromatography/ photodiode array detector; LCMS = (high performance) liquid chromatography with mass spectrometer detector; GCMS = gas chromatography with mass spectrometer detector

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