

# Testing of melatonin products imported into Australia

## Background

Melatonin is primarily used to assist with sleep-related issues. In Australia, melatonin products are classified as pharmacist-only medicines or prescription-only medicines.

The Therapeutic Goods Administration (TGA) has tested 18 imported melatonin products that were intercepted at the Australian border on suspicion that they were substandard or falsified. The testing period spanned 22 January 2025 to 9 September 2025. This testing involved assessing the average content of melatonin compared to the labelled amount and the variation in the content across individual dosage units.

## Testing

Variations in the amount of active ingredient result from the manufacturing process of pharmaceutical products. Investigating the uniformity of content for dosage units assesses this variation. A general guideline for solid dosage units is that the content of active should typically fall within 90.0% – 110.0% of the amount appearing on the label. The Relative Standard Deviation (%RSD) is a statistical measure of the spread of the content of the units tested relative to the average content of the all the units tested per product. A lower %RSD results from a lower amount of variation in the content of the active ingredient across the individual dosage units, while a higher %RSD indicates a broader spread in the content.

For each sample, testing was conducted on 10 individual units to assess the average content and the uniformity between the 10 units for the product.

Of the 18 samples tested, 8 had content greater than 10% of the labelled amount of melatonin. Another 4 samples had content less than 10% of the labelled amount. Six of the samples had variation in the content of melatonin (%RSD) of more than 6.0%.

The testing summary results are summarised in **Appendix 1**.

## Conclusions

Of the 18 samples tested, 5 were found to have an acceptable average content (90.0% – 110.0% of label claim) and variation of melatonin (greater than 6.0%). Another sample was labelled as being homeopathic and as such was not expected to contain detectable amounts of melatonin, which was confirmed by the testing.

Twelve of the samples were found to have an average melatonin content significantly different to the label claim, with five of these samples deviating from the labelled amount by more than 50%.

One of these 12 samples was labelled to contain 10 mg of melatonin but was found to contain no melatonin in any of the 10 units tested.

Six of the samples showed significant variation in the uniformity of the individual units tested, with the %RSD greater than 6.0%. Samples 1, 2 and 15 were from the same manufacturer and exhibited extremely large variation with %RSD values above 20%.

## Details and results of melatonin content investigation

#	Sample Name	Labelled Amount	Average	Range	% RSD
1	Sleepose-10 10 mg tablets	10 mg	41.6%	21.3% – 58.9%	24.3%
2	Sleepose-3 3 mg tablets	3 mg	250.6%	118.4% – 416.8%	33.2%
3	Vitafusion Sleep Well Melatonin Gummies	1.5 mg	117.2%	106.2% – 123.8%	4.3%
4	Live Nature's Melatonin 10 mg Capsules	10 mg	0.0%	0.0% - 0.0%	N/A
5	Sanofi Novanuit Triple Action 1mg Melatonin + Plant extracts Tablets	1 mg	89.1%	75.6% – 99.4%	8.9%
6	The Smurfs Kids Gummy Restful Sleep Melatonin 1mg Gummies Smurf Berry Flavor	1 mg	165.1%	155.4% – 169.7%	2.6%
7	Spring Valley Extra Strength Melatonin 10mg Tablets	10 mg	124.6%	118.7% – 136.1%	4.0%
8	CVS Health Melatonin 3 mg Tablets	3 mg	115.6%	111.8% – 121.4%	2.3%
9	Natrol Melatonin 5mg Gummies Strawberry flavor	5 mg	157.1%	140.2% – 170.3%	8.4%
10	Natrol Melatonin 5mg Fast Dissolve Tablets	5 mg	109.1%	97.9% – 113.8%	4.3%
11	Bioglan Sleep Tablets Homeopathic Preparation	6X (homeopathic)	N/A	N/A	N/A
12	Natrol Sleep Advanced Melatonin 10mg Time Release Tablets	10 mg	116.6%	111.9% – 122.9%	3.5%
13	Solgar Melatonin 3mg Nuggets	3 mg	107.9%	103.8% – 111.5%	2.5%
14	Life Extension Melatonin 300 mcg Vegetarian Capsules	300 µg	85.1%	79.3% – 97.1%	7.7%
15	Sleepose-3 Nutraceutical Melatonin 3mg Tablets	3 mg	127.8%	95.1% – 173.9%	22.9%
16	CURE-STRESS Melatonin 10 mg Softgel Capsules	10 mg	102.4%	98.9% – 106.2%	2.4%
17	'Metorip-20 Melatonin Mouth Dissolving Tablets 20 mg	20 mg	97.1%	92.9% – 105.4%	4.3%
18	MZS Melatonin Tablets	3 mg	95.3%	94.3% – 98.4%	1.6%