New Zealand standardised oral formulation batch sheet

Melatonin suspension 1 mg/mL (60 mL)

Patient's name		**Storage condition**	**In a refrigerator**	**At room temperature**
NHI		Temperature	2-8°C	≤ 25°C
Date compounded		Shelf life	30 days	30 days
Batch number		Recommended storage	☑	May be stored at room temperature if this is more practical and temperatures greater than 25°C are avoided

Ingredients required and formula:

Ingredient	Supplier	Batch number	Expiry date	Standard formula	Quantity dispensed	Dispensed by	Checked by
Melatonin 2 mg modified-release tablets (Vigisom)¥				30 tablets			
Ora-Blend®	Perrigo			to 60 mL			
OR							
Ora-Plus®	Perrigo			30 mL			
Ora-Sweet®	Perrigo			30 mL			

Ora-Blend SF® or Ora-Sweet SF® (sugar free) can be substituted?	Yes
Calculations performed by	
Calculations checked by (pharmacist)	
Area cleared for processing by	

Instructions to compound suspension:

Note: this formulation relates to the Vigisom brand of melatonin modified-release tablets 2 mg only as this is the only funded formulation.

1. **If Ora-Blend® unavailable**: Pre-mix the Ora-Plus® and Ora-Sweet® to form the diluent.
2. Crush tablets in mortar to a fine powder.
3. Add diluent (Ora-Blend® or prepared diluent) to form a smooth paste.
4. Gradually add the diluent and transfer to the final measuring flask, rinsing the mortar well. Mix well.
5. Make up to the final volume and mix well.
6. Label and package product appropriately.

Labels

Attach product label and auxiliary labels:	Label checked by

Melatonin suspension 1 mg/mL (60 mL)

Final yield	_____ mL	Checked by	
Final appearance of product	Off-white suspension.		
Container	Amber plastic bottle.		
Compounded by	*Name:*	*Signature:*	*Date:*
Final check and product release	*Name:*	*Signature:*	*Date:*

Special instructions:

- ¥ Modified release formulations are designed to release medicine into the circulation over a prolonged period (12 to 24 hours) and usually contain a greater amount of medicine than immediate-release formulations.
  It is not normal practice to crush modified release products to administer an oral dose. For individual doses crushing the formulation can result in dose dumping where a large amount of medicine is released at once, and a potentially toxic quantity of the medicine is introduced into the systemic circulation.
  However, when formulated into an extemporaneous compounded oral product the risk of dose dumping is negated with the total amount of medicine being formulated into an oral liquid to give the final concentration of the compounded formulation. An aliquot is then taken from the compounded formulation for a required dose.

1. Shake well before use.
2. Store in a refrigerator.

References:

1. Johnson CE, Cober MP, Thome T, et al. *Am J Health Syst Pharm*, 2011; **68**(5): 420-423.
2. Friciu M, Taslim S, Zaraa S, et al. *J Pharm Prac Res*, 2016; **46**(1): 28-33.

Prepared by	New Zealand Compounding Working Group		
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