



The Compositional Guidelines Officer
Office of Complementary Medicines
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Compositional Guidelines Officer

CHC Comments – Draft Compositional Guideline for Citrus bioflavonoids extract

Thank you for providing the complementary healthcare industry an opportunity to provide comment on the recently released draft compositional guideline for Citrus bioflavonoids extract. The Complementary Healthcare Council (CHC) supports the draft with the following comments:

General Comments

The CHC would like to suggest that for consistency, the compositional guideline should be laid out in a similar format to that of a compendial monograph, as seen in approved default standards. For example, members have suggested it would be useful if similar section headings were used in the guidelines.

The CHC would like to further suggest that the compositional guideline be linked to the substance Australian Approved Name (AAN). This could be included in '*Name of the Ingredient*' section or as a stand alone section under this.

Given that residual solvents are a legislated requirement to test for, and that this substance can be produced through solvent extraction, the CHC suggests specifications be included into the compositional guideline as outlined in the approved default standards.

Finally, the CHC supports the fact that the species of citrus fruits are not listed under the definition of the ingredient; this will result in capturing most of the substances being supplied and used in Listed medicines on the market.

Specific comments

- The CHC notes the range 15-60% w/w of flavonoids and questions whether this information should be displayed on the product label for consumer awareness. A product that contains 15% flavonoid vs. one that contains 60% will vary considerably in price; if the amount of flavonoid is not being displayed on the product label, consumers may not understand why there is such a significant difference. However, given the impact this suggestion may have on industry, the CHC suggests this issue be presented to the Office of Complementary Medicines/Industry Consultative Group for further discussion before a final decision is made.
- Further to the allowable range of flavonoids, the CHC is aware that it is possible to obtain a bioflavonoid extract with a flavonoid content of up to 95% through using a simple hydroethanolic extraction process. It is therefore suggested that only a lower limit be stated in the compositional guideline i.e. '*It contains a minimum of 15% w/w of flavonoid*'.

- Under the assay section, Quercetin is specified with an acceptance criteria of <0.1%. The CHC notes that this is no longer required to be controlled and suggests it should be removed from the compositional guideline.
- The CHC questions the solubility specifications stated in the compositional guideline as they appear to be conflicting compared to other specification documents observed by industry. For example, it has been suggested that in general, this material would be soluble in ethanol and acetone and relatively insoluble in water. Furthermore, no test is prescribed for solubility in the document and, given a range of test may be used, the CHC suggests that solubility be removed as a requirement from the compositional guideline.
- It is noted that a pH has been included under the description section of the compositional guideline. This is not a very useful or relevant test for this specific substance and therefore should be removed.
- The CHC also suggests that 'Ash' be removed from the characteristics section of the compositional guideline as many extracts of this substance will include excipients that may affect the results obtained.
- Abbreviations need to be added to the end of the document e.g. BP, Ph. Eur etc.

If you have any further questions relating to the matters raised in this submission, please do not hesitate to contact me.

Yours sincerely



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Scientific & Technical Manager

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