



Melatonin in food supplements

Background

Melatonin is a hormone that is produced in the pineal gland of the brain and plays a key role in regulating the sleep-wake cycle. There are several approved melatonin-containing medicinal products in Europe e.g. for the short-term treatment of primary insomnia (poor quality of sleep) available on prescription only. Food supplements containing melatonin have also been on the market in Europe for several years, partly as a result of the EU Commission's positive vote on two health claims. In addition, there have been several court rulings on the classification of melatonin as a food ingredient.

Authorized health claims

By means of Regulation (EU) No 432/2012, two health claims for melatonin were added to the Community list. One claim concerns the use of melatonin to alleviate the subjective feelings of jet lag with a dosage of at least 0.5 mg melatonin per portion. The other claim allows the statement "Melatonin contributes to the reduction of time taken to fall asleep". To be able to use this claim, the food must contain 1 mg melatonin per portion. Health claims are initially approved without a general legal classification of the substance in question in the member states. As the use of substances with a nutritional or physiological effect in food supplements is not fully harmonized across the EU, particularly in the area of food supplements, this means that despite a positive vote for a health claim, individual member states can restrict or prohibit its use due to health concerns.

Labeling and dosing

As the classification of whether a product is a food or a medicinal product is always a case-by-case assessment, the correct labeling of products is essential to avoid the impression of a medicinal product. The labeling requirements also demand clearly stating the amount of melatonin contained per portion on the packaging. The dosage of melatonin should be carefully chosen to comply with the legal requirements in the country where it is marketed.

Analytics

Two different analytical methods, depending on the product group, are used to determine melatonin in food supplements.

For melatonin-containing active ingredients and mono-products, an HPLC-UV method is used which is strongly based on the monograph Melatonin of the Ph. Eur. For complex products, such as tea blends or infusions thereof, the analysis method is based on LC-MS.

We would be happy to advise you on the selection of the appropriate method and product-specific validation as well as on the use and labeling of melatonin in food supplements.



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