
<2800> Multi-Ingredient Dietary Supplement Products—Development of Quality Tests

Type of Posting: General Chapter Prospectus

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Expert Committees: NBDS and BDSHM

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Proposed Title: <2800> *Multi-ingredient Dietary Supplement Products - Development of Quality Tests*

Suggested audience: Dietary supplement manufacturers producing multi-ingredient (other than multi-vitamins or multi-minerals) dietary supplement products and testing laboratories.

Estimated proposal *PF*: 47(2) [Mar.-Apr. 2021]

Background information: Multi-ingredient products are common across the dietary supplement spectrum from hair, skin and nails, to allergy to digestive health and other categories. Because of the flexibility in combinations for dietary supplements ingredients and the rapidly changing nature of the marketplace, it is not possible to develop monographs for each combination, yet because of the number of products on the market, quality standards are extremely important. While individual monographs are not feasible, after a round table meeting of manufacturers, an informational general chapter approach was identified as a first step.

Preliminary outline: The aim of this chapter is to establish guidelines for development of quality tests for multi-ingredient dietary supplement products. The chapter will be applicable to the products for which there are existing dosage form or ingredient monographs for the ingredients found in the multi-ingredient product. The chapter is not intended to cover multi-ingredient products, such as multi-vitamins, that have applicable monographs. This chapter will focus on common product quality test requirements and will provide suggestions for development of appropriate test methods for multi-ingredient products.

Anticipated activities: USP is requesting early input from stakeholders on a new proposed General Chapter <2800> *Multi-ingredient Dietary*

Supplement Products - Development of Quality Tests which is planned to be published for comment in *Pharmacopeial Forum* 47(2) [Mar.-Apr. 2021].

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