Beta Carotene Preparation

Type of Posting: Revision Bulletin

Posting Date: 29–Jan–2016

Targeted Official Date: 01–Feb–2016

Expert Committee: Non-Botanical Dietary Supplements

Reason for Revision: Compliance

In accordance with the Rules and Procedures of the Council of Experts, the Monographs-Non-Botanical Dietary Supplements Expert Committee has revised the Beta Carotene Preparation monograph. The purpose for the revision is to remove the specification for the all-trans-beta carotene content of NLT 95.0% stated in the Definition section and in the Acceptance criteria of the test for Content of Beta Carotene. Additionally, the Expert Committee requested the disclosure of the percentages of cis- and trans-isomers in the total beta carotene at the time of product manufacture and release be added to the Labeling section. Other revisions were also made to resolve the compliance issues.

- Change the relative response factor of all-trans-alpha carotene from 1.1 to 1.0 in the tests for Content of Beta Carotene.
- Change the resolution requirement between all-trans-beta carotene and 9-cis-beta carotene from 1.5 to 1.2 in the test for Content of Beta Carotene.
- Change the acceptance criteria for Total related compounds in the test for Alpha Carotene and Other Related compounds from NMT 5.0% to NMT 5% (no decimal figure).
- Additionally, minor editorial changes have been made to update the monograph to current USP style.

The Beta Carotene Preparation Revision Bulletin supersedes the currently official monograph. This Revision Bulletin will be incorporated in the Second Supplement to the USP 39–NF 34.

Should you have any questions, please contact Huy Dinh, Senior Scientific Liaison (301-816-8594 or htd@usp.org.)

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