COMMENTARY—*Food Chemicals Codex* (*FCC*)

Eighth Edition, Second Supplement

March 1, 2013

In accordance with USP's Rules and Procedures of the Council of Experts ("Rules"), USP publishes all proposed revisions to the *Food Chemicals Codex* (FCC) for public review and comment in the *FCC Forum* (FCCF), USP's journal for public notice and comment for *FCC*. After comments are considered and incorporated as the Food Ingredients Expert Committee (FIEC) deems appropriate, the proposal may advance to official status or be republished in *FCCF* for further notice and comment, in accordance with the Rules and Procedures. In cases when proposals advance to official status without republication in *FCCF*, a summary of comments received and the FIEC's responses are published in the *Commentary* section of the USP Website at the time the revision is published.

The *Commentary* section below is not part of the text of the monograph or general test or assay. Rather, it explains the basis of the FIEC's response to public comments. If there is a difference between the contents of the *Commentary* section and the monograph or general test or assay, the text of the monograph prevails. In case of a dispute or question of interpretation, the language of the monograph text, alone and independent of the *Commentary* section prevails.

For further information, contact:
USP Executive Secretariat
U.S. Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790 USA
execsec@usp.org

No comments were received for the following proposals:

Appendices

Appendix II: Physical Tests and Determinations:

Thin-Layer Chromatography

Appendix III: Chemical Tests and Determinations:

Fluoride Limit Test

Lead Limit Test

Monographs

3-Benzyl-4-Heptaone

Alginate-Konjac-Xanthan Polysaccharide Complex

Ammonium Salts of Phosphatidic Acid

Ammonium Polyphosphate

o-Anisaldehyde

Anisyl Butyrate

Anisyl Phenylacetate

Anisyl Propionate

Benzaldehyde Propylene Glycol Acetal

Benzenethiol

Calcium Phosphate, Monobasic

(+)-Carvone

(-)-Carvone

Cyclamic Acid

Cyclohexanecarboxylic Acid

High-Fructose Corn Syrup

Pectins

Polydextrose

Rebaudioside A

Rosemary Extract

Sodium Potassium Polyphosphates, Glassy

Sodium k-Malate

Sodium Hydrogen $_{DL}$-Malate

Taurine

$_{L}$-Tryptophan

COMMENTARY— *FCC* Eighth Edition, Second Supplement

Monograph/Sections: Pectin / Impurities, Organic Impurities, methanol, ethanol, and isopropanol
Expert Committee: Food Ingredients
No of Commenters: 1
Comment summary #1: The commenter indicated that the calculation for the proposed method is not accurate, and suggested USP maintain the formula identical to the calculation currently in *USP 35–NF 30* or correct the explanation with regard to C_U as follows: C_U = concentration of sample (pectin) in sample solution (g/mL). The commenter also observed that the line that describes W as weight of the sample taken to prepare the *Sample solution* (mg) is not used in the proposed formula, and thus should be removed.
Response: Comment incorporated.

Monograph/Sections: High-Fructose Corn Syrup / Multiple
Expert Committee: Food Ingredients
No of Commenters: 1
Comment summary #1: The commenter suggested changing the *Assay* specification of "NLT 55.0% to NLT 54.0% consists of fructose."
Response: Comment not incorporated. This suggested change is outside the scope of the June 2012 *FCC Forum* revision, and sufficient supporting data was not submitted.
Comment summary #2: The commenter suggested replacing: "An acceptable alternative method is to omit air ashing step in furnace program and use matrix modifier. If matrix modifier is used instead of air-ashing, prepare *modifier solution* as directed below," with the following to clarify the intention of the revision: "An acceptable alternative method is to replace the air in the ashing step of the furnace program with argon and use matrix modifier. If the matrix modifier is used instead of air ashing, prepare *Alternate modifier solution* as directed below."
Response: Comment incorporated.
Comment summary #3: The commenter suggested renaming the "*Modifier Stock Solutions"* section as *"Alternate Modifier Stock Solutions"* to align it with the term described in *Analysis* section.
Response: Comment incorporated.
Comment summary #4: The commenter suggested replacing "*Modifier Solution"* with *"Alternate Modifier Solution"* to align with the term described in *Analysis* section.
Response: Comment incorporated.
Comment summary #5: The commenter suggested changing the *Alternate Modifier Solution* section to specify that the solution is prepared using 10,000 ppm magnesium nitrate and not 10,000 ppm magnesium or 10,000 ppm magnesium nitrate hexahydrate.
Response: Comment not incorporated. The current description clearly directs the user how to prepare the *Alternate Modifier Solution.*

Monograph/Section: Polydextrose / Description
Expert Committee: Food Ingredients
No of Commenter: 1
Comment summary #1: The commenter suggested replacing the statement "1% citric acid or up to 0.1% phosphoric acid on a weight basis" with statement "1% citric acid and/or up to 0.1% phosphoric acid on a weight basis."
Responses: Comment incorporated.

Monograph/Section(s): Rosemary Extract / Multiple
Expert Committee: Food Ingredients
No. of Commenters: 2
Comment Summary #1: The commenter indicated that the term "powdered rosemary extract" was in conflict with a statement in the *Description* that indicates that "rosemary extract occurs as powder or liquid."
Response: Comment incorporated. The synonym "Powdered Rosemary Extract" has been removed from the Chemical Information section of the monograph to clarify the subject of the monograph.
Comment Summary #2: The commenter requested the removal of "deodorized" from the *Description* and "flavoring agent" from the *Function* section of the monograph on the basis that these terms are contradictory.
Response: Comment not incorporated. The *Description* is clear that deodorizing is a process that may be carried out on the material, which is allowed in approved ingredients. A deodorized product is not inconsistent with the antioxidant function of the ingredient.
Comment Summary #3: The commenter requested modification of the use of the word "antioxidant" in the *Functions* section in the *Description*, particularly given that this function is not confirmed by any analysis or requirement in the monograph.
Response: Comment not incorporated. The commenter did not make a specific request or offer an analytical method or any specifications. The material has been approved as an antioxidant in Europe and the *Functions* section is informational and non-comprehensive in nature.
Comment Summary #4: The commenter indicated that they have concerns about the thin-layer chromatographic procedures proposed in the *Identification* section of the monograph. They indicate that similar separations can be performed using high-performance liquid chromatography (HPLC) and that the HPLC methods currently used in parts of the industry and found in literature are more efficient for industry chemists. The commenter believes that the second thin-layer chromatographic procedure included in *C. Thin-Layer Chromatography (Nonpolar Compounds)* is repetitive of the *Assay* and unnecessary. The commenter did not suggest a specific alternate procedure to thin-layer chromatography.
Response: Comment not incorporated. Thin-layer chromatographic procedures were suggested by and supported by the sponsor of the monograph and are included not only to identify the ingredient, but also to differentiate rosemary extract from similar plant extract materials that would be potential contaminants or adulterants. Both thin-layer chromatography techniques are required for proper identification of the ingredient.

The Expert Committee will consider future revisions to the monograph when appropriate and upon the receipt of the necessary supporting data.

Comment Summary #5: The commenter requested that hexane be added to the *Description* section as an allowed extraction solvent on the basis that the approval for E392 in the European Union does include hexane-extracted ingredients. They also indicate that products utilizing extractions of acetone and hexane as well as ethanol and hexane also are available

Response: Comment incorporated.

Comment Summary #6: The commenter requested that the limit of acetone under *Residual Solvents* be changed from "NMT 100 ppm" to "NMT 500 ppm," because this is the allowable limit in the European Union regulations.

Response: Comment incorporated.

Comment Summary #7: The commenter requested that the requirement in the *Acceptance criteria* under the *Assay* for the ratio of carnosic acid to carnosol (currently given as "NLT 7%) be removed or changed to "NLT 3:2." The commenter indicates that commercial extracts widely vary and that these ratios will depend on the type of leaves, storage, extraction process, and other factors. Data was submitted to demonstrate the variability of this ratio. The commenter further states that the proposed requirement is unrealistic and would essentially disallow the use of approved ingredients.

Response: Comment incorporated.

Monograph/Section(s): Sodium DL-Malate / Assay, Organic Impurities
Expert Committee: Food Ingredients
No. of Commenters: 2

Expert Committee Initiated Change #1: The Expert Committee deleted the phrase "previously dried" in the *Sample* section of the *Assay* and replaced the phrase "on the dried basis" in the *Acceptance criteria* of the same test with "calculated on the anhydrous basis" to align the wording of the test with the *General Instructions* policy in the *FCC.*

Expert Committee Initiated Change #2: The Expert Committee deleted the note at the beginning of the test for *Fumaric and Maleic Acids* in *Organic Impurities* in order to reflect the proper usage of USP Reference Standards.

Monograph/Section(s): Sodium Hydrogen DL-Malate / Organic Impurities
Expert Committee: Food Ingredients
No. of Commenters: 1

Expert Committee Initiated Change #1: The Expert Committee deleted the note at the beginning of the test for *Fumaric and Maleic Acids* in *Organic Impurities* in order to reflect the proper usage of USP Reference Standards.

Monograph/Section(s): Alginate-Konjac-Xanthan Polysaccharide Complex / Chemical Information
Expert Committee: Food Ingredients
No. of Commenters: 1

Comment Summary #1: The commenter requested the addition of the synonym "PolyGlycopleX" to the monograph. This synonym exists in the CAS registry as well as regulatory documents, which were provided for reference.
Response: Comment incorporated.
Expert Committee Initiated Change: The Expert Committee added the synonym "Polysaccharide Complex KAX" to the Chemical Information section of the monograph to assist users in understanding the subject of the monograph.

Monograph/Section(s): Appendix V, Pepsin Assay / Multiple
Expert Committee: Food Ingredients
No. of Commenters: 2
Comment Summary #1: The commenter suggested changing the preparation of the *Substrate solution* to allow for the preparation of the solution using USP Hemoglobin Protease Substrate RS "or equivalent" material.
Response: Comment not incorporated. This test was validated and determined suitable by the Expert Committee as written.
Comment Summary #2: The commenter requested the addition of 1-2 drops of SQF/GFSI approved antifoam to the instructions for preparing the *Substrate solution* because of the general difficulty in preparing solutions of hemoglobin and the potential for generation of foam in the solution.
Response: Comment not incorporated. This test was validated and determined suitable for use by the Expert Committee as written.
Comment Summary #3: The commenter requested that the standard curve preparation instructions be changed to eliminate use of duplicate blank solutions for each of the *Standard solutions*. According to the commenter, blanks rarely change, thus they request one blank tube instead of two.
Response: Comment not incorporated. The Expert Committee will consider future revisions to the monograph when appropriate and upon the receipt of the necessary supporting data.
Comment Summary #4: The commenter requested the addition of stability indicating wording to the preparation of the *Substrate solution* so that users know how long the solution may be stored and when fresh substrate should be prepared.
Response: Comment not incorporated. The test was validated and determined suitable for use by the Expert Committee as written. The Expert Committee will consider future revisions to the monograph when appropriate and upon the receipt of the necessary supporting data.
Comment Summary #5: The commenter requested that specific concentrations be prescribed for the *Standard solutions* and that the instructions be changed to require a single dilution of the *Standard solution* instead of four.
Response: Comment not incorporated. The test was validated and determined suitable for use by the Expert Committee as written. The Expert Committee will consider future revisions to the monograph when appropriate and upon the receipt of the necessary supporting data.
Comment Summary #6: The commenter requested that a schematic be added to the proposed method that includes the different sample, standard, and blank tubes, along with specific steps that apply to each tube.

Response: Comment not incorporated. The Expert Committee found that the requested information is already provided in the text of the method.

Comment Summary #7: The commenter requested that the proposal be changed to give specific identification of each of the sample, standard, and blank tubes required in the *Procedure* for ease of use.

Response: Comment not incorporated. The Expert Committee believes that the method contains all necessary elements for repeating the procedure as it is written.

Comment Summary #8: The commenter requested that the temperature range of the water bath described under *Procedure* be changed from "25˚± 0.1˚" to "25˚±0.5˚." They indicate that the existing tolerances are too narrow to be achieved at ambient temperature with basic laboratory equipment.

Response: Comment not incorporated. The test was validated and determined suitable for use by the Expert Committee as written.

Comment Summary #9: The commenter requested that the wording of the *Procedure* be changed to specify a temperature requirement at which the solutions should rest once the reaction has been ended.

Response: Comment not incorporated. The test was validated and determined suitable for use by the Expert Committee as written. The Expert Committee will consider future revisions to the monograph when appropriate and upon the receipt of the necessary supporting data.

Comment Summary #10: The commenter requested that the phrase "1-cm cuvette" in the *Procedure* be changed to "1-cm quartz cuvette" to clarify the cuvette used in the measurements.

Response: Comment incorporated.

Comment Summary #11: The commenter requested that the equation for calculating Pepsin Activity be changed to allow for the use of a single *Standard solution* instead of a standard curve.

Response: Comment not incorporated. The test was validated and determined suitable for use by the Expert Committee as written. The Expert Committee will consider future revisions to the monograph when appropriate and upon the receipt of the necessary supporting data.