



## **Commentary Food Chemical Codex (FCC), Tenth Edition First Supplement**

September 1, 2016

In accordance with USP's provisionally-approved Rules and Procedures of the 2015-2020 Council of Experts (CoE Rules), and except as provided in Section 8.01(e) Immediate Standards, USP publishes proposed revisions to the Food Chemicals Codex (FCC) for public review and comment in the FCC Forum (FCCF), USP's venue for providing public notice and receiving public comment on an FCC proposed standard. After comments are considered and incorporated as the Food Ingredients Expert Committee (FIEC) deems appropriate, the proposal may advance to effective status or be republished in FCCF for further notice and comment, in accordance with the CoE Rules. In cases when proposals advance to effective status without republication in the FCCF, a summary of comments received and the FIEC's responses are published on the Commentary section of the USP website at the time the revision is published.

The Commentary 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 prevails.

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**Comments were received for the following when they were proposed in the Food Chemicals Codex Forum (FCCF):**

- [Sodium Oleate](#)
- [Turmeric Oleoresin](#)

**No Comments were received for the following when they were proposed in the Food Chemicals Codex Forum (FCCF):**

- Bacillus Coagulans Gbi-30, 6086
- Creatine Monohydrate
- L-Carnitine L-Tartrate
- RRR-Alpha-Tocopheryl Acid Succinate
- Saccharin
- Sodium Acid Pyrophosphate
- Sodium Phosphate, Dibasic
- Sodium Phosphate, Tribasic
- Spectrophotometric Identification Tests
- Spice Oleoresins

**Monograph/Section:** Sodium Oleate/Specific Tests

**Expert Committee:** Food Ingredients

**Expert Committee-initiated Change #1:** The test and specification for *Free Fatty Acids* was removed from the monograph, because this test is not relevant for Sodium Oleate.

**Monograph/Sections:** Turmeric Oleoresin/Multiple Sections

**Expert Committee:** Food Ingredients

**Number of Comments:** 15

### **Description**

**Comment Summary #1:** The commenter suggested revising the underlined sections of the first sentence as follows, “Turmeric Oleoresin occurs as a mixture of deep brownish-orange viscous oily fluid, pasty semisolids, or hard amorphous solids.”

**Response:** Comment not incorporated. The EC noted that “mixture” is an extraneous word and may be confusing and that the term “fluids” is already included in the *Description*.

**Expert Committee-initiated Change #1:** The sentence, “It is the combination of color and flavor principles,” was added based on the description of this ingredient in 21 CFR 73.615.

**Comment Summary #2:** The commenter suggested deleting the statement, “but some oleoresins are processed to remove aromatic compounds,” because the removal of aromatic compounds contradicts the use of turmeric oleoresin as an aromatic compound.

**Response:** Comment not incorporated. As indicated in the monograph, some turmeric oleoresin products are used as colors and are processed to remove aromatic compounds.

### **Identification**

**Comments Summary #3:** The commenters suggested replacing the “color value 1500” with equivalent curcuminoid content, because it is more meaningful to indicate the equivalent curcuminoids than “color value 1500.”

**Response:** Comments not incorporated. The Expert Committee will consider future revisions to the monograph upon the receipt of the necessary supporting data.

**Comment Summary #4:** The commenter indicated that the wavelength for color value measurement should be changed from 460nm to 420-430nm

**Response:** Comment not incorporated. The proposed monograph is based on the *Japan Specifications and Standards for Food Additives (JSSFA)*, which has operating conditions set at 420-430nm.

### **Assay**

**Comment Summary #5:** The commenter suggested adding the flow rate to the HPLC operating conditions.

**Response:** Comment incorporated.

**Comment Summary #6:** The commenter suggested including volume of diluent used to prepare the sample solution.

**Response:** Comment incorporated.

**Comment Summary #7:** The commenter suggested including the number of replicate injections used to calculate the %RSD.

**Response:** Comment incorporated.

**Comment Summary #8:** The commenter suggested clarifying the percent of peak height used for measuring peak width in tailing factor calculation.

**Response:** Comment not incorporated. As indicated in *Appendix II: Physical Tests and Determinations: A. Chromatography: High-Performance Chromatography* the tailing factor is calculated at 5% of peak height.

**Comment Summary #9:** The commenter requested that the HPLC be further optimized to shorten the total run time.

**Response:** Comment not incorporated. The Expert Committee will consider future revisions to this monograph upon the receipt of the necessary supporting data.

**Comment Summary #10:** The commenter suggested simplifying the existing formula used for calculating the percent content of bisdesmethoxycurcumin, desmethoxycurcumin, and curcumin in the portion of the sample taken, to avoid confusion.

**Response:** Comment not incorporated. The existing formula is consistent with the style used for *FCC* monographs.

**Comment Summary #11:** The commenter suggested replacing the proposed HPLC method with that used in the *USP–NF* monographs for Powdered Turmeric, Turmeric, and Curcuminoids.

**Response:** Comment not incorporated. The Expert Committee will consider future revisions to this monograph upon the receipt of the necessary supporting data.

**Comment Summary #12:** The commenter requested replacing the existing *Diluent* acetonitrile with methanol, ethanol, or acetone because of toxicity of acetonitrile.

**Response:** Comment not incorporated. The Expert Committee will consider future revisions to this monograph upon the receipt of the necessary supporting data.

**Comment Summary #13:** The commenter suggested including a UV method instead of the existing HPLC-UV method for the *Assay*, because the UV method generates more reliable results.

**Response:** Comment not incorporated. The Expert Committee will consider future revisions to this monograph upon the receipt of the necessary supporting data.

### ***Organic Impurities***

**Comment Summary #14:** The commenter suggested including limits for benzene and toluene. The commenter further indicates that these solvents are used to produce industry grade oleoresins.

**Response:** Comment not incorporated. The Expert Committee will consider future revisions to the monograph upon the receipt of the necessary supporting data.

### ***General***

**Comment Summary #15:** The commenter suggested adding a test for volatile compounds, because it would help to identify potential adulteration of turmeric oleoresin with volatile compounds.

**Response:** Comment not incorporated. The Expert Committee will consider future revisions to the monograph upon the receipt of the necessary supporting data.