

## Wheat Starch

Type of Posting: Notice of Adoption of Harmonized Standard

**Posting Date:** 29–Feb–2012 (updated 28–Feb–2017\*)

Official Date: 01–Dec–2012

**Expert Committee:** Monographs—Excipients

\*Coordinating Pharmacopeia: EP

A harmonized standard for Wheat Starch has been approved by the Pharmacopeial Discussion Group (PDG) as described in its PDG Sign-Off Cover Page. Having reached Stage 6 of the PDG process, the Wheat Starch monograph has been formally approved by the USP Monographs—Excipients Expert Committee in accordance with the Rules and Procedures of the 2010–2015 Council of Experts.

Changes from the existing USP–NF monograph include:

- Updated Carbon Dioxide flow rate in Limit of Sulfur Dioxide test to be consistent with the text in the monograph and sign off text.
- Eliminated black diamond notation for Microbial Tests, as procedures are now fully harmonized within PDG.

The Wheat Starch monograph will be incorporated into and become official with the Second Supplement to USP 35–NF 30.



\*Should you have any questions about the Benzyl Alcohol monograph, please contact Dr. Tong (Jenny) Liu (240-221-2072 or <a href="mailto:jyl@usp.org">jyl@usp.org</a>). For any questions about the PDG and its processes, please see the Pharmacopeial Harmonization Group or contact Richard Lew at (240-221-2060 or <a href="mailto:jyl@usp.org">rll@usp.org</a>).

\*The previous PDG sign-off Cover Pages and Stage 6 postings are included as below:

- Download the Wheat Starch monograph—Stage 6
- Download the Wheat Starch PDG Sign-Off Cover Pages:
  - 04-Nov-2015 (Revision on Rev. 2 sign-off cover sheet)
  - o <u>15-Jun-2011</u>, Rev. 2
  - o 29-Oct-2007, Rev. 1
  - o 24-Oct-2001
- Previous Stage 6 postings:
  - Stage 6, PF 35 (3), 2009
  - Stage 6, PF 30 (5), 2004
  - Stage 6, PF 30 (4), 2004
  - Stage 6, PF 30 (2), 2004
  - Stage 6, PF 28 (3), 2002