Sodium Chloride

Type of Posting: Notice of Adoption of Harmonized Standard

Posting Date: 21–Nov–2014

Targeted Official Date: 01–Dec–2015

Expert Committee: Monographs—Excipients

Coordinating Pharmacopoeia: European Pharmacopoeia

A revision to the harmonized standard for Sodium Chloride has been approved by the Pharmacopeial Discussion Group (PDG) as described in its PDG Stage 6 Rev. 3 Sign-Off Cover Page. Having reached Stage 6 of the PDG process, the Sodium Chloride 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.

On December 27, 2013, USP announced the approval of General Notices section 5.60.30 “Elemental Impurities in USP Drug Products and Dietary Supplements” with an official date of December 1, 2015. This General Notices section will make applicable General Chapters <232> Elemental Impurities—Limits and <2232> Elemental Contaminants in Dietary Supplements. The implementation of General Chapters <232> and <2232> also will include removal of all references to General Chapter <231> Heavy Metals from monographs and General Chapters in the USP-NF. In order to fully implement the omission of <231>, the test of Heavy Metals in this monograph is deleted with the official date of December 1, 2015, according to the General Notices in USP38–NF33.

Changes from the existing USP–NF monograph include:

- In the beginning of the monograph,
  - Added a statement of “Portions of this monograph that are national USP text, and are not part of the harmonized text, are marked with symbols to specify this fact.”
- Added symbols to the non-harmonized sections: Arsenic, Appearance of Solution, Bacterial Endotoxins Test, Sterility Tests, Packaging and Storage, Labeling.
- Barium
  - Clarified the Analysis procedure and updated the acceptance criteria as “Any opalescence in the test solution is not more intense than that in the reference solution.”
- Ferrocyanides
  - Changed concentration of sulfuric acid from “0.1N” to “2.5 g/L.”
- Limit of Phosphates
  - Changed from “Sulfomolybdic acid solution” to “Sulfomolybdic acid TS”
- Magnesium and Alkaline-Earth Metals
  - In Analysis, changed from “0.2 g of eriochrome black T trituration” to “0.15 g of eriochrome black T trituration”
- Sulfate
  - Added a note of “All solutions used for this test must be prepared with distilled water.”
  - Deleted Standard sulfate solution A; Renamed “Standard sulfate solution B” as “Standard sulfate solution”
  - Updated the verbiage in solution preparation and acceptance criteria.
- Heavy Metals
  - Deleted the test according to section 5.60.30 in General Notices. The official date will be Dec. 1, 2015.
- In addition, the monograph has been edited to be consistent with the current USP style guide, such as in Limit of Bromides and Loss on Drying.

The Sodium Chloride monograph will be incorporated into and become official with the Second Supplement to USP 38–NF 33.

Should you have any questions about the Sodium Chloride monograph, please contact Kevin Moore (301-816-8369 or ktm@usp.org). For any questions about the PDG and its processes, please see the Pharmacopeial Harmonization website or contact Emily Meyer (301-230-7438 or eam@usp.org).

- Download the Sodium Chloride monograph – Stage 6
- Download the Sodium Chloride PDG sign-off documents:
  - Nov. 6, 2013, Rev. 3