
[<788> Particulate Matter in Injections](#)

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Expert Committee: General Chapters—Dosage Forms

Reason for Revision: Invalid Cross Reference

In accordance with the Rules and Procedures of the 2010–2015 Council of Experts, this is to provide notice that the USP General Chapters—Dosage Forms Expert Committee intends to add national text to General Chapter <788> Particulate Matter in Injections to address the invalid cross references to “Small Volume Injections” and “Large Volume Injections” in monographs.

In 2007, General Chapter <788> Particulate Matter in Injections was harmonized. Prior to harmonization the terms “Large Volume Injections” and “Small Volume Injections” were used in the chapter, and throughout the *USP–NF*, to describe injections with a volume less than or greater than 100 mL, respectively. After harmonization, the terms in <788> changed to “Large Volume Parenterals” and “Small Volume Parenterals”. It has been discovered that over 100 monographs use the terms “Large Volume Injections” or “Small Volume Injections,” while <788> uses different terms.

To address this issue of invalid cross references between General Chapter <788> and monographs, it is being proposed to add national text to the chapter that states: “For the purpose of this chapter, small volume parenterals is synonymous with small volume injections and large volume parenterals is synonymous with large volume injections.”

The General Chapter <788> Particulate Matter in Injections Revision Bulletin supersedes the currently official version published in the *USP 35–NF 30* and will be incorporated in *USP 36–NF 31*.

Should you have any questions, please contact Desmond Hunt, Ph.D. (301-816-8341 or dgh@usp.org).

- [Download the General Chapter <788> Particulate Matter in Injections Revision Bulletin](#)

*On 05 July 2012, the incorporated publication was changed from "Second Supplement to *USP 35–NF 20*" to "*USP 36–NF 31*" in the fourth paragraph of this notice.