
BRIEFING

Oxaliplatin Injection. This proposal, based on the specification in an FDA tentatively approved ANDA, was published on the USP website as a Draft 1 USP Pending Monograph revision and has been available for public comment for more than 90 days. No comments were received. The SM3 Expert Committee has approved the revision as an Authorized USP Pending Monograph revision. Currently, there is a *USP–NF* monograph for this drug product in the *First Supplement* to the *USP33–NF28 Reissue* (p. R-955), to become official Oct. 1, 2010, which differs in the lower limit for pH in the test for *pH* under *Specific Tests*. The proposed change will be adopted into the *USP–NF* once the sponsor’s product is fully approved by the FDA.

(SM3: F. Mao.)
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Oxaliplatin Injection

v.1 Authorized May 1, 2011

SPECIFIC TESTS

- **pH (791):** Between 3.8 and 7.0, using a polymer combination electrode