Nicardipine Hydrochloride Injection

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In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 2 Expert Committee has revised the Nicardipine Hydrochloride Injection monograph. The purpose of this revision is to widen the pH upper limit from 3.0–3.9 to 3.0–4.2, to remove the sorbitol requirement in the Definition, and to also add “If present” to the Content of Sorbitol test to allow flexibility and to accommodate FDA-approved drug products with different formulations using different excipients. In addition, based on comments received, the acceptance criteria for sorbitol are deleted from the Definition.

The Nicardipine Hydrochloride Injection monograph Revision Bulletin supersedes the currently official monograph.

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