- **pH ⟨791⟩:** ▲For products formulated with vancomycin hydrochloride,▲ (TBD) 4.5–5.5 for products stored at room temperature; 3.0–5.0 for products maintained in a frozen state; ▲3.9–5.5 for products formulated with vancomycin and stored at room temperature▲ (TBD)
- **Bacterial Endotoxins Test ⟨85⟩:** NMT 0.33 USP Endotoxin Units/mg of vancomycin
- **Particulate Matter in Injections ⟨788⟩:** Meets the requirements for small-volume injections or large-volume injections, whichever is applicable
- **Sterility Tests ⟨71⟩,** *Test for Sterility of the Product to Be Examined, Membrane Filtration***:** Meets the requirements, except use water instead of diluting *Fluid A*
- **Other Requirements:** Meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging*. Store as directed by product label.

Change to read:

- **Labeling:** It meets the requirements in *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*. For the product stored in a frozen state, the label states that it is to be thawed just before use, describes conditions for proper storage of the resultant solution, and directs that the solution is not to be refrozen. ▲The label states whether the product contains Vancomycin or Vancomycin Hydrochloride.▲ (TBD)
- **USP Reference Standards ⟨11⟩**
  USP Vancomycin Hydrochloride RS

Page Information:

Not Applicable

DocID: