

Vancomycin Injection

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Expert Committee	Biologics Monographs 4 - Antibiotics

In accordance with the Rules and Procedures of the Council of Experts, the Biologics Monographs 4 - Antibiotics Expert Committee has revised the Vancomycin Injection monograph. The purpose of the revision is to accommodate FDA approved drug products formulated with vancomycin free base, along with vancomycin hydrochloride.

- The *Definition* is revised to include vancomycin free base.
- The *Sample solution* in the *Composition of Vancomycin* test is revised to include concentration of vancomycin free base.
- The test for *pH* is revised to include acceptance criteria for products formulated with vancomycin and stored at room temperature.
- The *Labeling* statement is revised to indicate whether the product contains Vancomycin or Vancomycin Hydrochloride.

The Vancomycin Injection Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Ying Han, Senior Scientist II (301-692-3294 or ying.han@usp.org).