

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**209481Orig1s000**

**CLINICAL MICROBIOLOGY/VIROLOGY**  
**REVIEW(S)**

**Division of Anti-Infective Products  
Office of Antimicrobial Products (OND/CDER)  
Clinical Microbiology Review**

<b>Date:</b>	5/18/2016
<b>Clinical Microbiology Reviewer:</b>	<b>Simone M. Shurland</b>
<b>NDA/ANDA # (Supplement #):</b>	<b>209-481</b> (Original: SDN 001, 004)
<b>Date Company Submitted:</b>	7/20/2016; 10/28/2016
<b>Date received by CDER:</b>	7/20/2016; 10/28/2016
<b>Date Assigned:</b>	7/20/2016
<b>Applicant Name:</b>	Mylan Pharmaceuticals 781 Chestnut Ridge Road Morgantown, WV 26505  Contact Person: Anil Sachdeva Senior Director, Regulatory Affairs Phone: 304-554-4884 E-mail: anil.sachdeva@mylan.com
<b>Proprietary Name:</b>	--
<b>Established Name:</b>	Vancomycin hydrochloride
<b>Dosage Form (Route of Administration):</b>	Injection (Intravenous)
<b>Dosage Strength</b>	250 mg/vial, 750 mg/vial, 1.25 g/vial, 1.50g/vial
<b>Recommended Action:</b>	<b>Non-approvable (due to CMC deficiencies)</b>

**EXECUTIVE SUMMARY**

Vancomycin HCL is a tricyclic glycopeptide derived from *Amcolatopsis orientalis*. The product marketed by the Applicant, Mylan Pharmaceuticals, is Vancomycin HCL for Injection USP lyophilized powder in the following strengths 250 mg/vial, 750 mg/vial, 1.25 g/vial and 1.50g/vial. The Applicant has filed this NDA under Section 505(b)(2) of the Federal Food and Drug and Cosmetic Act using the Fresenius Kabi USA/LLC Vancomycin HCL (ANDA 62-663) as the reference listed drug (RLD). No new clinical microbiology data was submitted to the NDA. The Applicant is relying on the Agency findings of efficacy and safety of Vancomycin HCL for intravenous injection in support of the proposed species included in the product labeling.

**SUMMARY AND RECOMMENDATIONS**

The labeling will be reviewed when the application is found to be adequate.

Simone M. Shurland, PhD.  
Clinical Microbiology Reviewer  
DAIP HFD-520  
May 17, 2016

Concurrence: Dmitri Iarikov, M.D., Acting Deputy Division Director

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/s/  
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SIMONE SHURLAND  
05/16/2017

DMITRI IARIKOV  
05/16/2017