DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Biotechnology Equity Research
Lazard Capital Markets LLC
Attention: Timothy J. Smith
30 Rockefeller Plaza
New York, NY 10020

MAR 07 2006

Reference Number: OGD #05-1435

Dear Mr. Smith:

This letter is in response to your correspondence dated November 22, 2005. You request that the Office of Generic Drugs (OGD) provide advice regarding bioequivalence (BE) studies for Vancomycin Hydrochloride (HCl) Capsules.

OGD provides the following comments:

1. Vancomycin is a highly soluble drug and the reference listed drug product (RLD) is rapidly dissolving. Waivers of in-vivo bioequivalence testing can be requested in abbreviated new drug applications (ANDAs), provided the test product is rapidly dissolving at the conditions specified in the guidance *Waiver of in vivo BA and BE studies for IR solid oral dosage forms based on a biopharmaceutics classification system (BCS Guidance)*. Dissolution data in various media on 12 dosage units each of test and reference products (for both strengths) should be provided as follows:

Apparatus:	USP Apparatus I (basket)
Rotation speed:	100 rpm
Medium:	0.1N HCl (or 0.1N HCl with NaCl at pH 1.2), pH 4.5 Acetate buffer, and pH 6.8 phosphate buffer
Volume:	900 mL
Temperature:	37°C
Sampling times:	5, 10, 15, 20, 25, 30, and 40 minutes or as needed for profile comparison

2. In addition, please conduct dissolution testing using the USP 29 method for your stability and quality control programs.

If you have any questions, please call Lizzie Sanchez, Pharm.D., Special Assistant to the Director, Division of Bioequivalence, at (301) 827-5847. In future correspondence regarding this issue, please include a copy of this letter.

Sincerely yours,

Gary J. Buehler, R.Ph.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Mintz Levin
Attention: Linda D. Bentley
One Financial Center
Boston, MA 02111

MAR 07 2006

Reference Number: OGD #05-1400

Dear Ms. Bentley:

This letter is in response to your correspondence dated November 4, 2005. You request that the Office of Generic Drugs (OGD) provide advice regarding bioequivalence (BE) studies of Vancomycin Hydrochloride (HCl) Capsules.

OGD provides the following comments:

1. Vancomycin is a highly soluble drug and the reference listed drug product (RLD) is rapidly dissolving. Waivers of in-vivo bioequivalence testing can be requested in abbreviated new drug applications (ANDAs), provided the test product is rapidly dissolving at the conditions specified in the guidance *Waiver of in vivo BA and BE studies for IR solid oral dosage forms based on a biopharmaceutics classification system (BCS Guidance)*. Dissolution data in various media on 12 dosage units each of test and reference products (for both strengths) should be provided as follows:

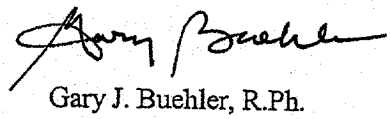
Apparatus:	USP Apparatus 1 (basket)
Rotation speed:	100 rpm
Medium:	0.1N HCl (or 0.1N HCl with NaCl at pH 1.2), pH 4.5 Acetate buffer, and pH 6.8 phosphate buffer
Volume:	900 mL
Temperature:	37°C
Sampling times:	5, 10, 15, 20, 25, 30, and 40 minutes or as needed for profile comparison

2. In addition, please conduct dissolution testing using the USP 29 method for your stability and quality control programs.

Please note: For vancomycin HCl capsules, OGD is not recommending the use of vancomycin fecal measurements in the evaluation of bioequivalence.

If you have any questions, please call Lizzie Sanchez, Pharm.D., Special Assistant to the Director, Division of Bioequivalence, at (301) 827-5847. In future correspondence regarding this issue, please include a copy of this letter.

Sincerely yours,



Gary J. Buehler, R.Ph.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research