DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Infinium Capital Corp.
Attention: Bernadine Leung, Ph.D.
67 Yonge St., Suite 602
Toronto, Ontario, Canada
M5E 1J8

MAR 0 1 2006

Reference Number: OGD #06-0200

Dear Dr. Leung:

This letter is in response to your correspondence dated February 3, 2006. You request that the Office of Generic Drugs (OGD) provide bioequivalence recommendations regarding Vancomycin Hydrochloride Capsules, 125 mg and 250 mg. OGD provides the following comments:

1. Vancomycin is a highly soluble drug and the reference listed drug (RLD) product is rapidly dissolving. Waivers of *in-vivo* bioequivalence testing can be requested in abbreviated new drug applications (ANDAs), provided that 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.

If you have any questions, please call Christina Thompson, Pharm.D., Project Manager, Division of Bioequivalence at (301) 827-5847In future correspondence regarding this issue, please include a copy of this letter.

Sincerely yours,

Dale P. Conner, Pharm.D.
Director
Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

OGD # 06-0200