



MINISTRY OF HEALTH
Brazilian Health Surveillance Agency

INSPECTION ORDER IN BIOEQUIVALENCE CENTERS

Nº 16/2006/GGMED/ANVISA/MS

Date: 19/10/2006

Bioequivalence Center: Relclin - Reliance Clinical Research Services Ltda (RCRS)


Address: : Dhirubhai Ambani Life Science Centre, Thane Belapur Road, Navi Mubai, Índia

Activities carried out: Clinical, Analytical and Statistical

Inspection team: Kátia Andrea Domingos de Moraes and Daniela Vieira dos Reis

Period: 06 a 10/11/2006

We assign the inspectors **Kátia Andrea Domingos de Moraes** and **Daniela Vieira dos Reis**, representatives of the Brazilian Sanitary Surveillance Agency, for inspection in the Bioequivalence Center Relclin - Reliance Clinical Research Services Ltda (RCRS), to verify the compliance to Good Practices in Bioavailability/Bioequivalence of Medicines, in accordance with the Law Nº 9,782/99 and Resolution R.D.C./ANVISA No 103, of 08 of May of 2003.


ANTÔNIO CARLOS DA COSTA BEZERRA
General Office of Medicines
ANVISA/MS/BRAZIL

INSPECTION STATEMENT

During the technique visit, the inspection team were taken care of by Mr./Mrs. Dr. Adeep Bagati, responsible for the position of Head of the Bioequivalence Center. The Inspection Report will be directed to the representative company in Brazil – Whyte International Farmacêutica do Brasil Ltda.

_____, 6/11/, 2006.

Kátia A. D. de Moraes
Kátia A. D. de Moraes
GGMED/ANVISA/MS

Daniela Vieira dos Reis
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Representative
Bioequivalence Center