



National Tuberculosis Lead Research Programme

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15 May 2001

To whom it may concern

BIOAVAILABILITY / BIOEQUIVALENCE STUDY

We hereby confirm that the following study was conducted on behalf of Novartis South Africa (Pty) Ltd as part of a joint venture between the National Tuberculosis Research Programme of the Medical Research Council of South Africa and the Department of Pharmacology at the University of Cape Town, and in conjunction with the World Health Organisation (WHO) Collaborating Centre for Drug Policy which is based in the pharmacology department. International standards for bioavailability testing were followed, and the following report was issued:

"Bioavailability and bioequivalence of Rifampicin, Isoniazid, Pyrazinamide and Ethambutol as a single dose in a fixed dose formulation Rimstar 4-FDC compared to equivalent doses of single reference preparations of the four drugs. Study report dated December 1999"

The above joint venture was approved by the Global Tuberculosis Programme of the WHO for the determination of bioavailability and bioequivalence of fixed-dose combination products for the treatment of tuberculosis.

Yours faithfully

Dr P B Fourie
Director