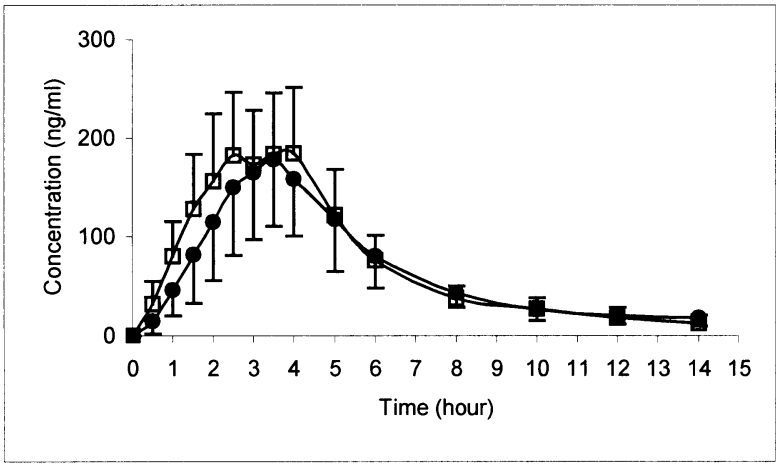
Dyanil 5mg is <u>BIOEQUIVALENT</u> to Daonil® 5mg

Dynapharm (M) Sdn Bhd proudly presents the FIRST BIOEQUIVALENT Glibenclamide from the ASEAN region.



Plot of mean plasma glibenclamide concentration vs time with standard deviation following a single oral dose of 5 mg glibenclamide. Mean ± SD (• = reference, Daonil, □ = test, Dyanil)

Daonil 5 mg tablet and Dyanil 5 mg tablet, given as equal-labelled oral dose in healthy fasting adult subjects, are bioequivalent, i.e. equivalent in terms of $AUC_{0-\infty}$ (extent of absorption) and in terms of Cmax (rate of absorption). These results are confirmed by the 90% CI of the log of both parameters, which are within the stipulated ranges:

90%CI Log_{10} Cmax 103.2 – 126.1 **90%CI Log_{10} $AUC_{0-\infty}$ 99.1 – 120.2**

About Glibenclamide:

Glibenclamide is a second generation sulphonylurea oral hypoglycaemic agent that been widely used in the treatment of non-insulin dependant diabetes mellitus (NIDDM) or Type II diabetes.

Glibenclamide is classified as Class II/IV with the Biopharmaceutics Classification System (BCS). Such compounds are poorly soluble but highly permeable. Due to its poor solubility, a standard pharmacopoeia dissolution testing method *(in-vitro)* is not available. Furthermore, the *in-vitro* results poorly predict the bioavailability *(in-vivo)* of Glibenclamide.

Bioavailability of Glibenclamide is influenced by the quality of raw materials and the advanced manufacturing process. The similar bioavailability of a generic Glibenclamide is only proven through Bioequivalence Studies.

About the Clinical Research Centre:

The Bioequivalence Study was conducted in **Info Kinetics Sdn Bhd / *Gleneagles* Clinical Research Centre**, a premier pharmacokinetics provider in the Pan-Asian region. Info Kinetics provides contract services to conduct and manage Phase I – IV Clinical Trials including Bioavailability and Bioequivalence Studies. All processes are conducted in accordance to ICH-GCP guidelines. Info Kinetics is ISO 9001:2000 certified and ISO/IEC 17025 accredited. Info Kinetics has been audited by numerous clinical trial Sponsors' representatives and national drug regulatory authorities .