# Comparison of In Vitro Bioavailability of Proprietary Propranolol Preparations

by

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## SUMMARY

Dissolution rate studies were conducted to compare the release rate of propranolol from two proprietary preparations. Propranolol was released at a faster rate from Rexigen* when compared to Inderal* which suggests that plasma levels of the drug would be higher in patients taking the former preparation. Both preprations showed satisfactory dissolution but problems may be encountered if a patient stabilized on one brand were to change to the other.

## INTRODUCTION

Propranolol is frequently used in Zimbabwe for treating a variety of disorders, primarily hypertension and cardiac arrhythmias. The effectiveness of propranolol has been shown to be largely dependent on the plasma concentration [1] which in turn is dependent on absorption of the drug from a solid dosage form when administered orally.

A correlation between *in vitro* dissolution and *in vivo* bioavailability has been shown[2,3] and it was therefore decided to compare the dissolution pattern of two proprietry propranolol preparations.

## METHODS

**Dissolution.** The Sartorious solubility simulator was used according to manufacturers' specifications to compare dissolution rate of Inderal and Rexigen tablets.

**Propranolol assay** A 0.5 ml aliquot of dissolution fluid was mixed with 0.75 ml 2% potassium nitrate and 0.25 ml concentrated sulphuric acid. After 10 minutes 1 ml of 5% urea was added and absorption read at 360 nm. Propranolol concentrations of 10 — 50 μg/ml obey Beers law.[4] Absorbances from test samples were converted to propranolol concentrations using a standard curve. Each assay was performed in triplicate, results being represented as the mean with standard error of the mean.

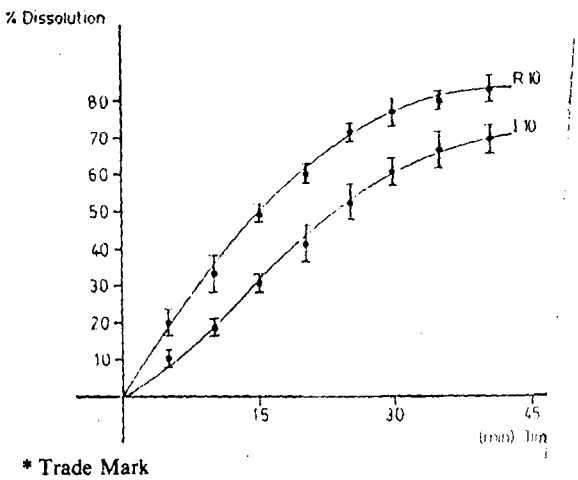
## RESULTS AND DISCUSSION

Comparison of dissolution of the 160 mg tablets was not possible using the solubility simulator due to mild effervescence produced on disintegration of Inderal 160 mg. With the 10,40 and 80 mg tablets Rexigen showed the fastest dissolution rate (Fig. 1a, b and c) the difference being most marked with the 40 mg strength.

Over a period of 40 minutes Rexigen showed greater release of propranolol with final dissolution of 83%, 88% and 95% of stated propranolol content while that for Inderal was 69%, 83% and 86% for the 10, 40 and 80 mg tablets respectively. It is apparent from these results that more propranolol was released at a faster rate from Rexigen than from Inderal preparations with the difference between the 40 mg tablets being greatest. By extrapolation to the *in vivo* situation one can assume that plasma levels of propranolol would be higher if patients took Rexigen as opposed to Inderal which may cause problems clinically in cases where a patient stabilized on one brand changed to the other.

Problems of this nature have been encountered and as Inderal is considered a standard propranolol preparation the manufacturers of Rexigen are presently reformulating the product to produce a harder tablet with dissolution charateristics comparable to those of the standard.

Figure 1: Comparison of dissolution of Rexigen* (R) and Inderal* (I) brands of propranolol.
(a) 10 mg




* Trade Mark

Figure 1: Comparison of dissolution of Rexigen* (R) and Inderal* (I) brands of propranolol.
(b) 40 mg

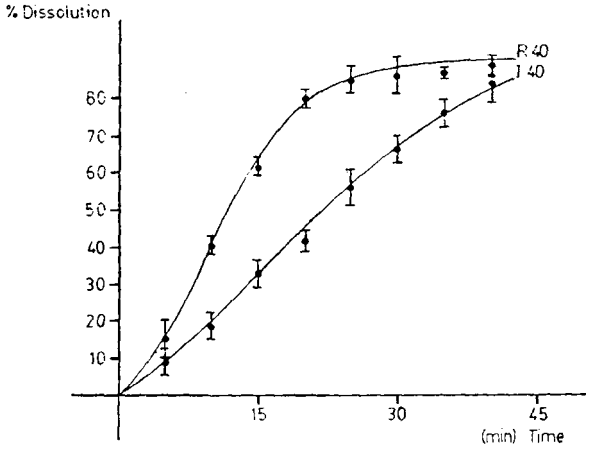
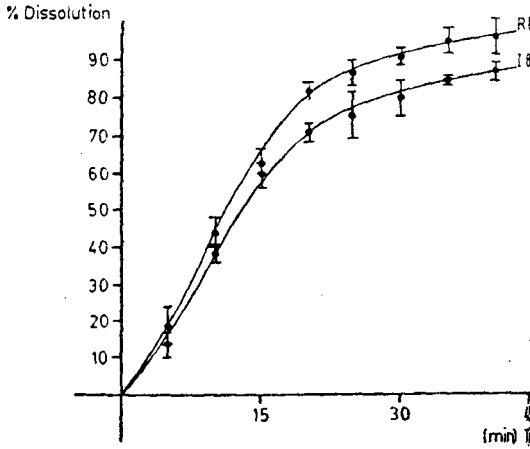



Figure 1: Comparison of dissolution of Rexige (R) and Inderal* (I) brands of propranolol.
(c) 80 mg

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