ISSN: 3048-6181 www.wjphr.org 2025, Volume 2, Issue 12. Page: 10-13.

World Journal of Pharmaceutical and Healthcare Research

Review Article

ASSESSMENT OF PHARMACEUTICAL EQUIVALENCE AND *IN VIRTO* RELEASE OF SOME PROPRANOLOL HCL TABLET 40MG MARKETED IN SUDAN UNDER BIOWAIVER CONDITIONS

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Article Info
Article Received: 05 November 2025,
Article Revised: 25 November 2025,
Published on: 01 December 2025.

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https://doi.org/10.5281/zenodo.18348902

How to cite this Article:
Hajer M. Ahmed1, Mohammed E. Adam2, Fatehalrahman F. Magbool*3 (2025). ASSESSMENT OF PHARMACEUTICAL EQUIVALENCE AND *IN VIRTO* RELEASE OF SOME PROPRANOLOL HCL TABLET 40MG MARKETED IN SUDAN UNDER BIOWAIVER CONDITIONS. World Journal of Pharmaceutical and Healthcare Research, 2(12), 10–13.

ABSTRACT

In this research bioequivalence study was carried out on three brands of Propranolol HCL tablet 40mg marketed in Sudan. by estimation content%, hardness, disintegration time and the content uniformity of Propranolol HCL tablets and to establish biowavier criteria and requirement by study the dissolution of Propranolol HCL tablets of the innovator d and test products (brand A) and (brand B) in media of pH 1.2, 4.5 and 6.8, First the pharmaceutical equivalence of the three brands using official methods. Second the biowaiver studies were carried according to WHO guidelines. The results of the study of the three brands revealed that the three brands complied with the requirement of the official tests of content%, hardness, disintegration time and the content uniformity. The two sample drugs are bioequivalent to innovator drug as they qualify the WHO criteria for biowaiver (both the sample drugs and innovator are very rapidly dissolving i.e. the amount of released is ≥ 85% of labeled amount in 15 min.) and so there is no need to carry out in vivo bioequivalence studies.

KEYWORDS: Propranolol HCL, Bioequivalence, Content uniformaty, Official method.

INTRODUCTION

Bioequivalence is the study of different brands of a same drug and its dosage forms. Two different formulations of a same drug are bioequivalent when their rate of dissolution and absorption is same. As there is an increase in production and consumption of generic drugs, the need for bioequivalence study is also rising.[1]

Nowadays drug's cost increases due to the expensive original drug. This cost can be reduced by substituting cheaper generic copies. For this, generic copy should be therapeutically equivalent to the original drug. In order to find this, bioequivalent studies are conducted.

Bioavailability is defined in the Act as "the rate and extent to which the active moiety is absorbed from a drug product and becomes available at the site of action. For drug products that are not intended to be absorbed into the bloodstream, Bioavailability may be estimated by measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of action"[2]

A biowaiver means that in vivo bioavailability and/or bioequivalence studies may be waived (i.e. not considered necessary for product approval). Instead of conducting expensive and time-consuming in vivo studies, a dissolution test could be adopted as the surrogate basis for the decision as to whether two pharmaceutical products are equivalent. At That time the biowaiver was only considered for scale up post approval change (SUPAC) to pharmaceutical products. Recently, the application of the bio waiver concept has been extended to approval of certain orally administered generic products.[3]

The biopharmaceutics classification system (BCS) concept was developed by Gordon Amidon in 1995. The BCS is guidance for assessment of the drug absorption. It is classification system involving scientific framework of drug classification based on their aqueous solubility and intestinal permeability. There are three major factors of BCS that governs the rate and extent of drug absorption from dosage form. They are dissolution, solubility, and intestinal permeability.[4]

Propranolol hydrochloride is highly soluble and highly permeable active pharmaceutical product belonging to class1. According to WHO technical report, Propranolol

hydrochloride in vitro equivalence may be evaluated under biowaiver condition for BCSclass1.[5]

Propranolol is a nonselective beta-adrenergic receptor blocking agent possessing no other autonomic nervous system activity. It specifically competes with beta-adrenergic receptor agonist agents for available receptor sites.[6]

MATERIALS AND METHODS

Propranolol hydrochloride powder (working standard) was gifted from Abdelmoneim Medical Industries (Sudan),. Propranolol hydrochloride brands were collected from the local private pharmacies. Table 1 while other reagents were gifted from Azal pharmaceutical, Sudan.

Table 1: Propranolol hydrochloride tablet brands.

Items	Batch NO	Mfg	Exp
innovator	LR781	May 2015	April 2020
A	66292	November 2015	November2020
B	1509692	September 2015	September 2018

Reagents

Hydrochloric acid. Sodium hydroxide. Sodium acetate. Glacial acetic acid. Potassium chloride. Potassium phosphate mono basic**.**

Instruments

U-V spectrophotometer (model: 1800, serial NO: A11454805715CD, shimadzu-Japan),
Dissolution tester (model: PTWS1000, serial NO: 15819, Pharma test- Germany), Electronic balance (model: ED2295, serial NO: 25703758, USA),

pH meter (model: PP20, serial NO: 25453020, USA),
Disintegration tester (Mp disintegration test apparatus - 1901) and Erweka Tester (model TBH -30, United Kingdom).

Experimental Physiochemical parameters

Active content of generic and innovator brands were assessed using the British pharmacopeia 2015 method[7], while physiochemical parameters were done using United State Pharmacopeia 2014 method.[8]

Dissolution Study

The dissolution profile of Propranolol hydrochloride tablet of each brand was assessed according to WHO guidelines where 900 mL of buffer pH 1.2, 4.5 and 6.8 using US P dissolution apparatus I at 100 revolutions per minute and at 37 ± 0.5 °C were used. Twelve tablets of each brand were placed in the medium in all experiments, 5-mL sample aliquots were withdrawn at, 10, 15, 30, and 45 min using syringe. All samples were filtered through 0.45-µm membrane filters. The absorbance of each solution was measured at 290nm.

RESULTS AND DISCUSSION

Propranolol is a nonselective beta-adrenergic receptor blocking agent, indicated for the treatment of hypertension, angina pectoris, myocardial infarction and prophylaxis for common migraine headache. It is essential to carry out post authorization safety studies to ensure that the marketed brands are effective and safe. There are many brands available in Sudan local market. The literature data relevant to the decision to allow a waiver of in vitro bioequivalence testing for approval of immediate release of solid dosage form from containing Propranolol HCL strongly suggested that the drug is class 1 according to BCS. To our best knowledge there was no previous of biowaiver studies carried out on Propranolol HCL in Sudan.

The aim of the present study was to study of the safety, efficacy, and possible interchangeability of the different generic Propranolol HCL tablet brands with the innovator by using simple and cost effective in vitro dissolution method. For the purpose of the study, two generic Propranolol HCl tablet brands were randomly selected and collected from the local market, and their physicochemical properties and release profiles were compared with the innovator according to British Pharmacopeia for content percent of the different brands and according to United state Pharmacopeia for the other physicochemical properties. The results were illustrated in (Table 2) which showed that all the brands studied fulfilled the compendia specification for uniformity of weight, diameter, thickness, hardness, disintegration, content of active ingredient and dissolution. This indicates the two test brands are pharmaceutically equivalent to innovator.

Table 2: Physiochemical parameters of three different brands of Propranolol hydrochloride tablets.

Items	Weight uniformity(m g)	Diameter (mm)	Thickness (mm)	Hardness (N)	Disintegration (Min)	Assay (%)
innovator	205.2±0.88	8.5±0.05	3.27±0.57	87.4±4.43	4.67±9.58	96.48
A	190.5±0.42	8.02±0.07	3.65±0.51	73.7±6.56	1.67±26.9	96.97
B	212.5±0.67	7.94±0.07	3.18±0.93	132.7±11.1	5.33±8.31	97.10

As three brands are pharmaceutically equivalent dissolution test was carried out for the three products to establish bioequivalence between different brands. The test was carried out in three different media of different pH (pH1.2 (simulated gastric fluid without enzymes), pH4.5, and pH6.8 (simulated intestinal fluid without enzymes) to cover the whole GIT environment and results were presented (Table 3) and (Fig. 1, 2, 3)

Table 3: Dissolution test result of the three brands of Propranolol hydrochloride tablet.

medium	Time	Innovator % released	A% Released	B% Released
PH 1.2	10	87.85	92.03	92.06
	15	92.96	92.10	92.38
	30	93.93	92.24	92.16
	45	94.01	92.36	91.66
PH 4.5	10	86.20	84.56	90.30
	15	89.26	88.71	90.91
	30	89.93	88.93	90.85
	45	89.87	88.93	90.90
H 6.8	10	85.99	95.17	95.65
	15	93.63	95.47	96.08
	30	94.70	95.62	95.99
	45	94.83	95.59	96.20

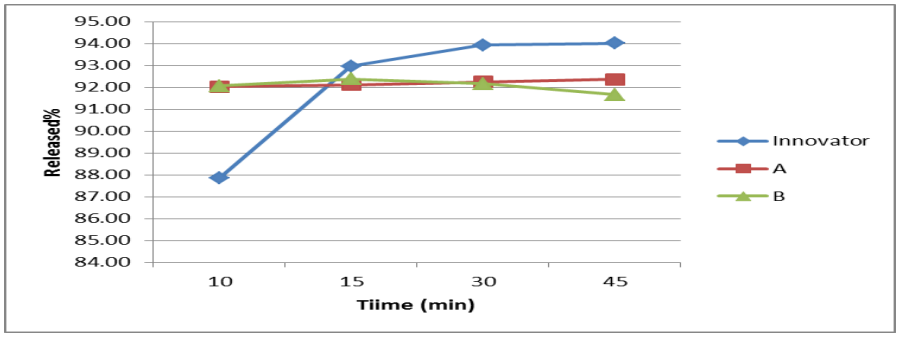

Figure (1): Dissolution graph of Propranolol hydrochloride tablets 40 mg (innovator and test products) in pH 1.2

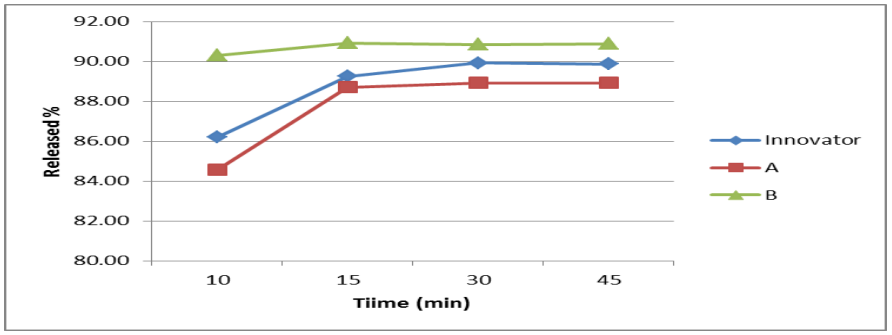

Figure (2): Dissolution graph of Propranolol hydrochloride tablets 40 mg (innovator and test products) in pH 4.5.

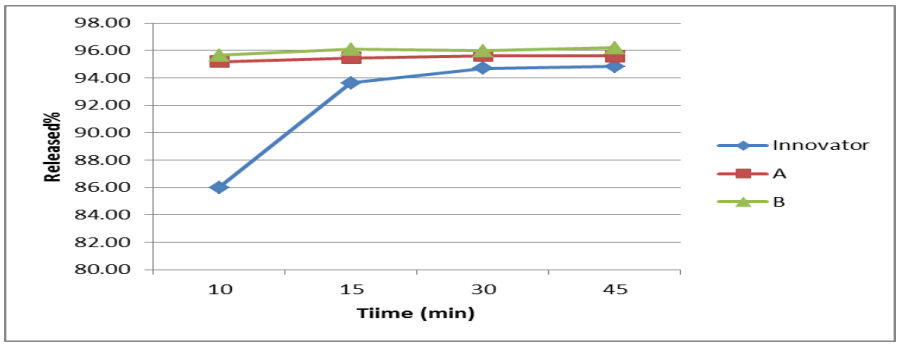

Figure (3): Dissolution graph of Propranolol hydrochloride tablets 40 mg (innovator and test products) in pH 6.8.

According to WHO guideline, class 1 drugs are considered to be bioequivalent if in vitro dissolution show that both generic and innovator products are very rapidly dissolving (dissolving amount greater than 85% in15 min). In present study Propranolol HCl of innovator and test products the amount released ≥85 % of labeled amount in 15 min. So from these results the two generic products and innovator product seems to be equivalent which does not necessitate carry out of calculation of the similarity factor.

CONCLUSION

From these results the conclusion could be drawn that the three brands are pharmaceutically equivalent with respect to the physicochemical characteristics and have similar in vitro release. They meet the requirement of the biowaiver according to WHO guidelines for biowaiver and there is no need to carry in vivo bioequivalence studies.

ACKNOWLEDGEMENT

The author would like to thanks Azal pharmaceutical industry, Abdelmoneim Medical Industries and Shanghai pharmaceutical industry for providing tools and chemicals**.**

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