TRY THE SMART CHOICE IN THE MANAGEMANET OF ANGINA.

TRIMETAZIDINE HCl

TRYME MR

35 mg Modified-Release Tablet

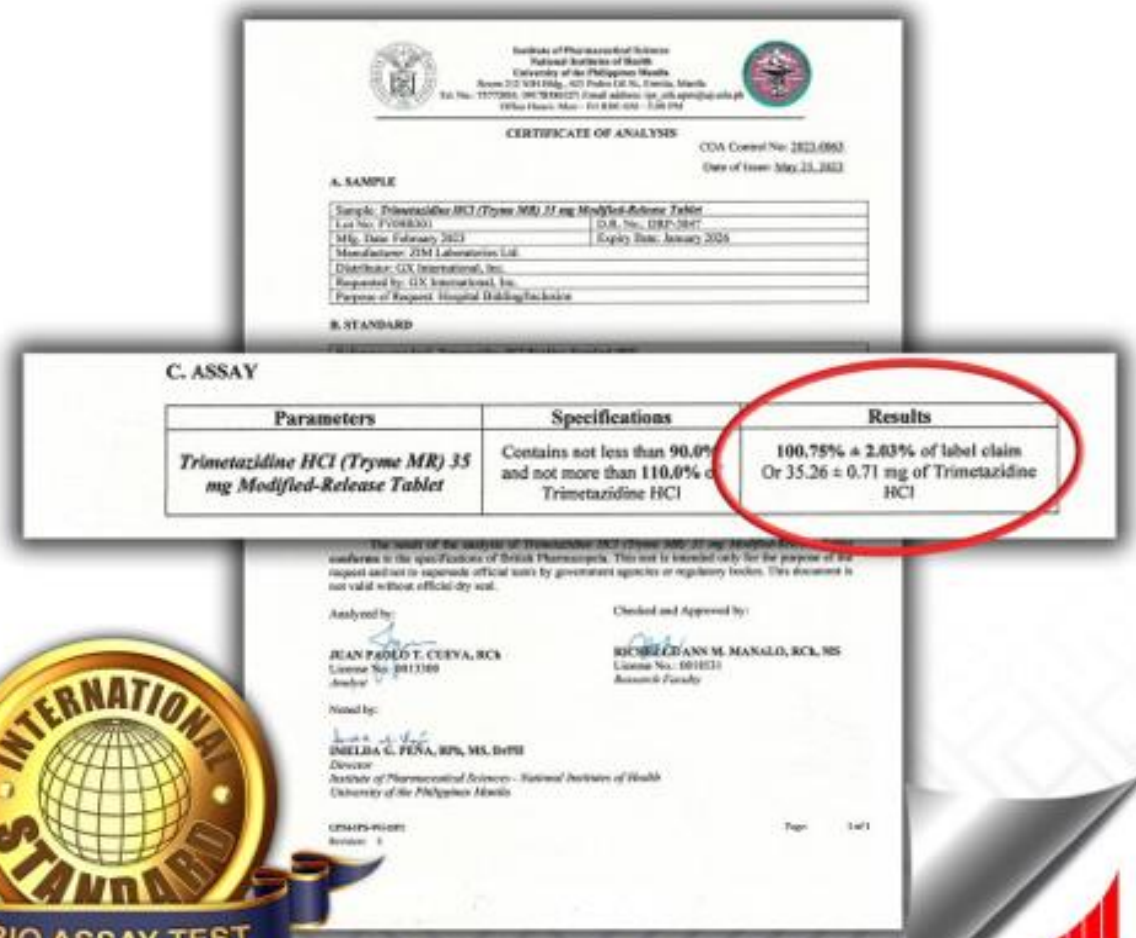
Metabolic Energizer of the Heart

TRIMETAZIDINE HCl

TRYME MR

35 mg Modified-Release Tablet

TRY THE SMART CHOICE IN QUALITY



Institute of Pharmaceutical Sciences
National Institutes of Health
University of the Philippines Manila

CERTIFICATE OF ANALYSIS

CDA Control No: 2023-0063
Date of Issue: May 23, 2023

A. SAMPLE

Sample: *Trimetazidine HCl (Tryme MR) 35 mg Modified-Release Tablet*	
Lot No.: FY08B301	D.R. No.: DRF-2047
Mfg. Date: February 2023	Expiry Date: January 2026
Manufacturer: JSM Laboratories Ltd.	
Distributor: GX International, Inc.	
Requested by: GX International, Inc.	
Purpose of Request: Hospital Bidding/Inclusion	

B. STANDARD

C. ASSAY

Parameters	Specifications	Results
Trimetazidine HCl (Tryme MR) 35 mg Modified-Release Tablet	Contains not less than **90.0%** and not more than **110.0%** of Trimetazidine HCl	**100.75% ± 2.03%** of label claim Or 35.26 ± 0.71 mg of Trimetazidine HCl

The result of the analysis of Trimetazidine HCl (Tryme MR) 35 mg Modified-Release Tablet conforms to the specifications of British Pharmacopeia. This test is intended only for the purpose of the request and not to supersede official tests by government agencies or regulatory bodies. This document is not valid without official dry seal.

Analyzed by:

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INTERNATIONAL STANDARD

BIO ASSAY TEST

GX INTERNATIONAL

TRIMETAZIDINE HCl

TRYME MR

35 mg Modified-Release Tablet

TRY THE SMART CHOICE IN EFFICACY

CONFIDENTIAL

On Sai Clinical Research Pvt. Ltd.	BIOEQUIVALENCE STUDY REPORT OF TRIMETAZIDINE HYDROCHLORIDE TABLETS MR 35 mg		
	Version No. : Final	Dated : 19/09/2016	STUDY CODE: OS/TRHY/06-16/09
	Supercedes No. : Nil	Dated : Nil	

Statistical Method: The log transformed PK parameter values of C_{max}, AUC_{0-t} and AUC_{0-inf} were subjected to ANOVA using GLM procedure. 90% confidence intervals of the difference between test and reference means were calculated to test the two-one sided hypotheses for concluding bio-equivalence. The statistical analysis was carried out for pharmacokinetic parameters of Trimetazidine using SAS Version 9.1.3.

SUMMARY - CONCLUSIONS

Primary Pharmacokinetic Parameters:

Trimetazidine

Average of PK parameters of two periods of Test and Reference Formulation

Pharmacokinetic Parameters	Test Product (B) N=24	Reference Product (A) N=24
C_{max} (ng/mL)	66.36	67.14
AUC_{0-t} (ng × hr/mL)	527.564	516.007
AUC_{0-inf} (ng × hr/mL)	533.815	521.798

CONCLUSION: Based on the above bioequivalence data, it is concluded that the test formulation i.e. Trimetazidine Hydrochloride Tablets MR 35 mg containing Trimetazidine HCl 35 mg of Rainbow Life Sciences Pvt. Ltd., India is bioequivalent to reference formulation i.e. VASTAREL MR (Trimetazidine) Tablets containing Trimetazidine HCl 35 mg of LES Laboratoires Servier Industrie, France in healthy human male subjects under fasting conditions.

The Test and Reference Product were well tolerated.

The Test and Reference Product were well tolerated.

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CLINICAL RESEARCH PVT. LTD. SANGLI

GX INTERNATIONAL

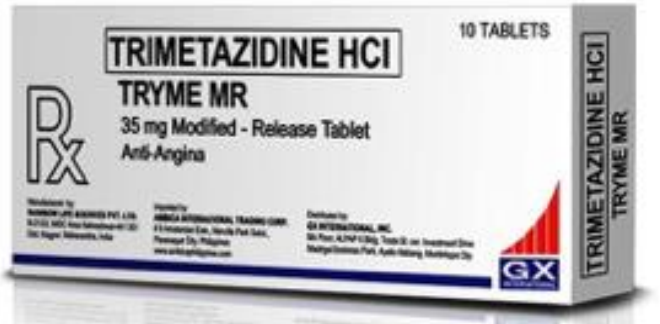
TRIMETAZIDINE HCl

TRYME MR

35 mg Modified-Release Tablet

TRY THE SMART CHOICE IN PATIENT COMPLIANCE

The Metabolic Energizer of the Heart



Price Comparison

Brand	Strength	Price	Additional Burden to Patients
TRYME MR	35 mg	₱ 15.75	₱ 0.00
Vastarel	35 mg	₱ 36.00	₱ 20.25
Vestar	35 mg	₱ 24.75	₱ 9.00

Available in mercury drug | southstar drug | Rose Pharmacy | watsons

GX