

Tizanidine Hydrochloride Capsules **2 mg, 4 mg, and 6 mg**

COMPARATIVE
BIOAVAILABILITY
STUDIES

(6 mg)

Tizanidine Hydrochloride Capsules

PRODUCT INFORMATION

Product:	Tizanidine Hydrochloride Capsules	
Approval Date:	February 03, 2012	
Indication:	Short-acting drug indicated for the management of spasticity.	
Description:	2 mg	Hard gelatin capsule with blue opaque body and blue opaque cap imprinted "APO T2" in black ink.
	4 mg	Hard gelatin capsules with white opaque body and blue green opaque cap imprinted "APO T4" in black ink.
	6 mg	Hard gelatin capsules with blue opaque body and blue opaque cap imprinted "APO T6" in black ink.

COMPARATIVE BIOAVAILABILITY STUDIES OF TIZANIDINE HYDROCHLORIDE CAPSULES AND ZANAFLEX CAPSULES™

	Fasting Biostudy:	Food Effect Biostudy:
Study Design:	Comparative, Randomized, 2-Way Crossover Bioavailability Study	Comparative, Randomized, 2-Way Crossover Bioavailability Study
Subjects:	Normal, healthy, human volunteers	Normal, healthy, human volunteers
Dose Administered:	1 X 6 mg (1 capsule)	1 X 6 mg (1 capsule)

Sprinkle-in-Applesauce Fasting Biostudy:

Comparative, Randomized, 2-Way Crossover Bioavailability Study

Normal, healthy, human volunteers

1 X 6 mg (1 capsule)

Tizanidine Hydrochloride Capsules

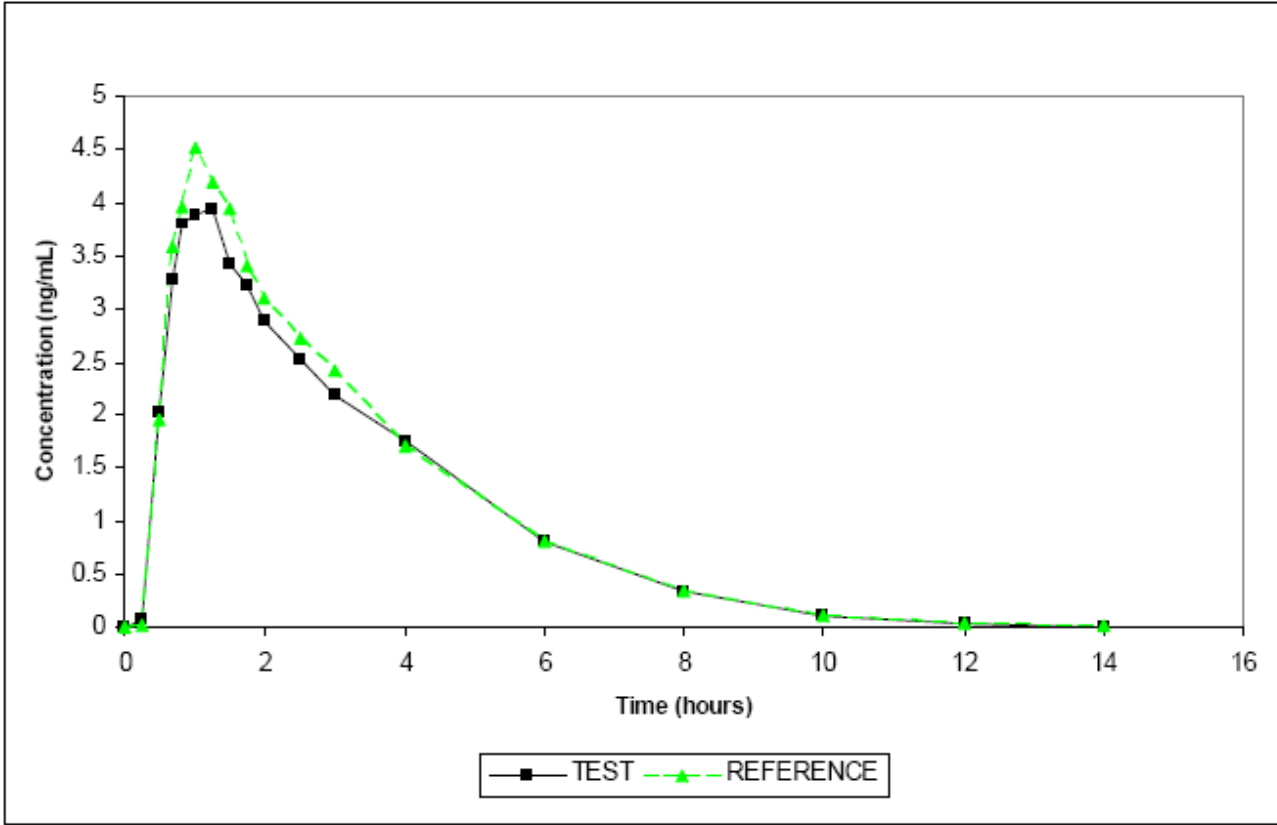
PRODUCT INFORMATION

FASTING BIOSTUDY

	Tizanidine Mean (% C.V.)		90% Confidence Intervals * (test/reference)
	Apotex Corp. Tizanidine HCl Capsules	Zanaflex Capsules™ (Tizanidine HCl Capsules)	
AUCt (ng*h/mL)	11.695	11.665	92.05 – 109.20
AUCinf (ng*h/mL)	12.179	12.139	92.28 – 109.07
Cmax (ng/mL)	4.099	4.298	84.38 – 107.80

*based on log-transformed data

Mean Plasma Tizanidine Concentration
-- Fasting Study --



TEST: Tizanidine Hydrochloride Capsules, 6 mg

REFERENCE: Zanaflex Capsules™, 6 mg

Tizanidine Hydrochloride Capsules

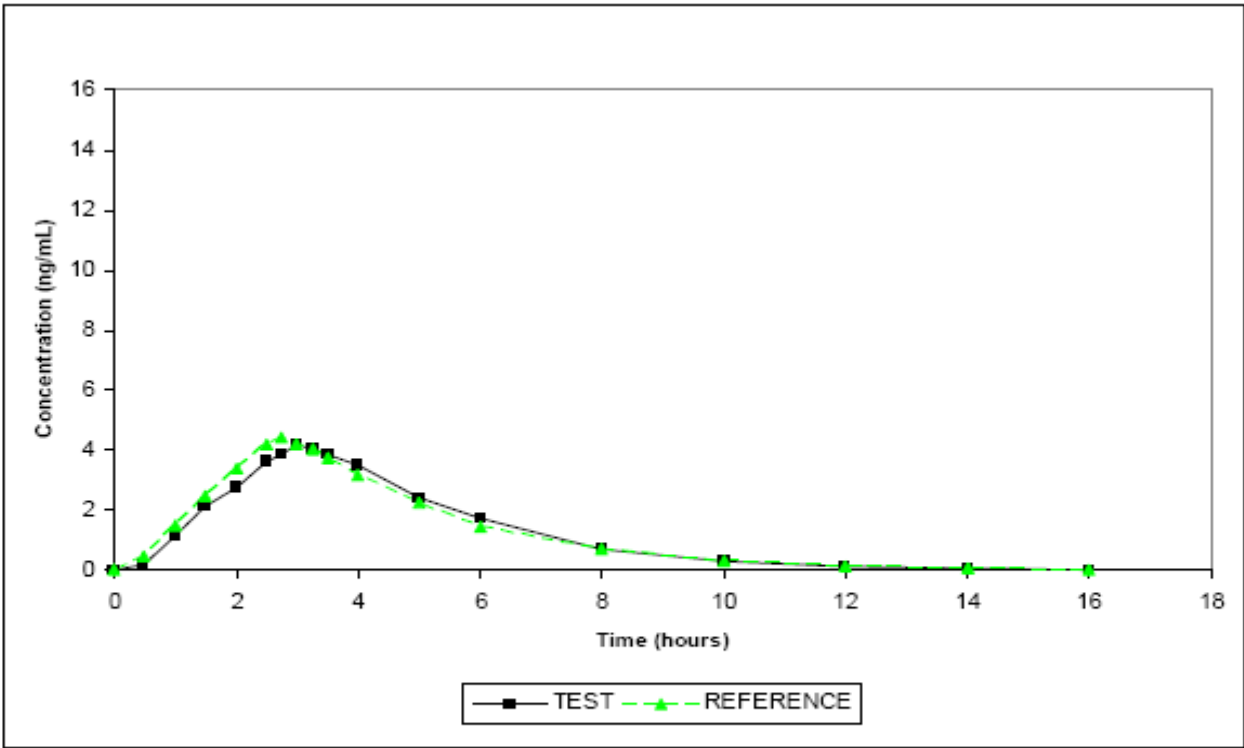
PRODUCT INFORMATION

FOOD EFFECT BIOSTUDY

	Tizanidine Mean (% C.V.)		90% Confidence Intervals * (test/reference)
	Apotex Corp. Tizanidine HCl Capsules	Zanaflex Capsules™ (Tizanidine HCl Capsules)	
AUCt (ng*h/mL)	14.264	13.784	95.20 – 112.49
AUCinf (ng*h/mL)	14.748	14.257	95.51 – 112.03
Cmax (ng/mL)	3.759	3.872	88.75 – 106.21

*based on log-transformed data

Mean Plasma Tizanidine Concentration
--Fed Study --



TEST: Tizanidine Hydrochloride Capsules, 6 mg

REFERENCE: Zanaflex Capsules™, 6 mg

Tizanidine Hydrochloride Capsules

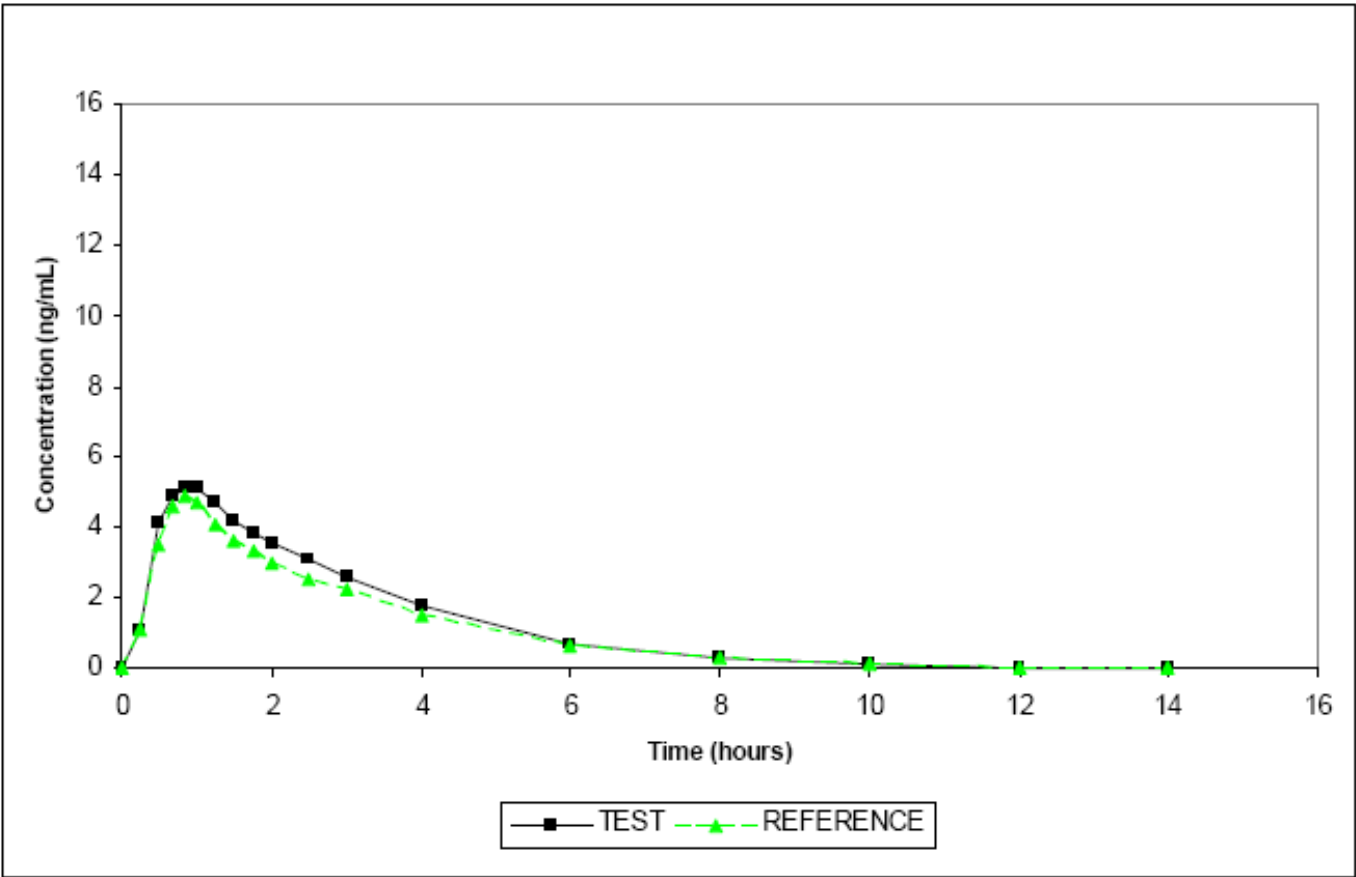
PRODUCT INFORMATION

SPINKLE-IN-APPLESAUCE FASTING BIOSTUDY

	Tizanidine Mean (% C.V.)		90% Confidence Intervals * (test/reference)
	Apotex Corp. Tizanidine HCl Capsules	Zanaflex Capsules™ (Tizanidine HCl Capsules)	
AUCt (ng*h/mL)	13.477	11.869	105.27 – 122.48
AUCinf (ng*h/mL)	14.004	12.338	105.57 – 122.03
Cmax (ng/mL)	4.962	4.647	98.07 – 116.24

*based on log-transformed data

Mean Plasma Tizanidine Concentration
-- Sprinkle-in-Applesauce Fasting Study --



TEST: Tizanidine Hydrochloride Capsules, 6 mg

REFERENCE: Zanaflex Capsules™, 6 mg