

LEVETIRACETAM EXTENDED-RELEASE TABLETS

500 mg and 750 mg

COMPARATIVE
BIOAVAILABILITY
STUDIES
(500 mg and 750 mg)

Levetiracetam Extended-Release Tablets

PRODUCT INFORMATION

Product:	Levetiracetam Extended-Release Tablets	
Approval Date:	September 12, 2011	
Indication:	Is indicated as adjunctive therapy in the treatment of partial onset seizures in patients ≥ 16 years of age with epilepsy.	
Description:	500 mg	White, oval, biconvex coated tablets, engraved with "APO" on one side and "LXR 500" on the other side.
	750 mg	White, capsule shaped, biconvex coated tablets engraved with "APO" on one side and "LXR 750" on the other.

COMPARATIVE BIOAVAILABILITY STUDIES OF LEVETIRACETAM ER TABLETS AND KEPRA XR™

	Fasting Biostudy: 500 mg Tablets	Food Effect Biostudy: 500 mg Tablets
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 500 mg (1 tablet)	1 X 500 mg (1 tablet)

	Fasting Biostudy: 750 mg Tablets
Study Design:	Comparative, Randomized, 2-Way Crossover Bioavailability Study
Subjects:	Normal, healthy, human volunteers
Dose Administered:	1 X 750 mg (1 tablet)

Levetiracetam Extended-Release Tablets

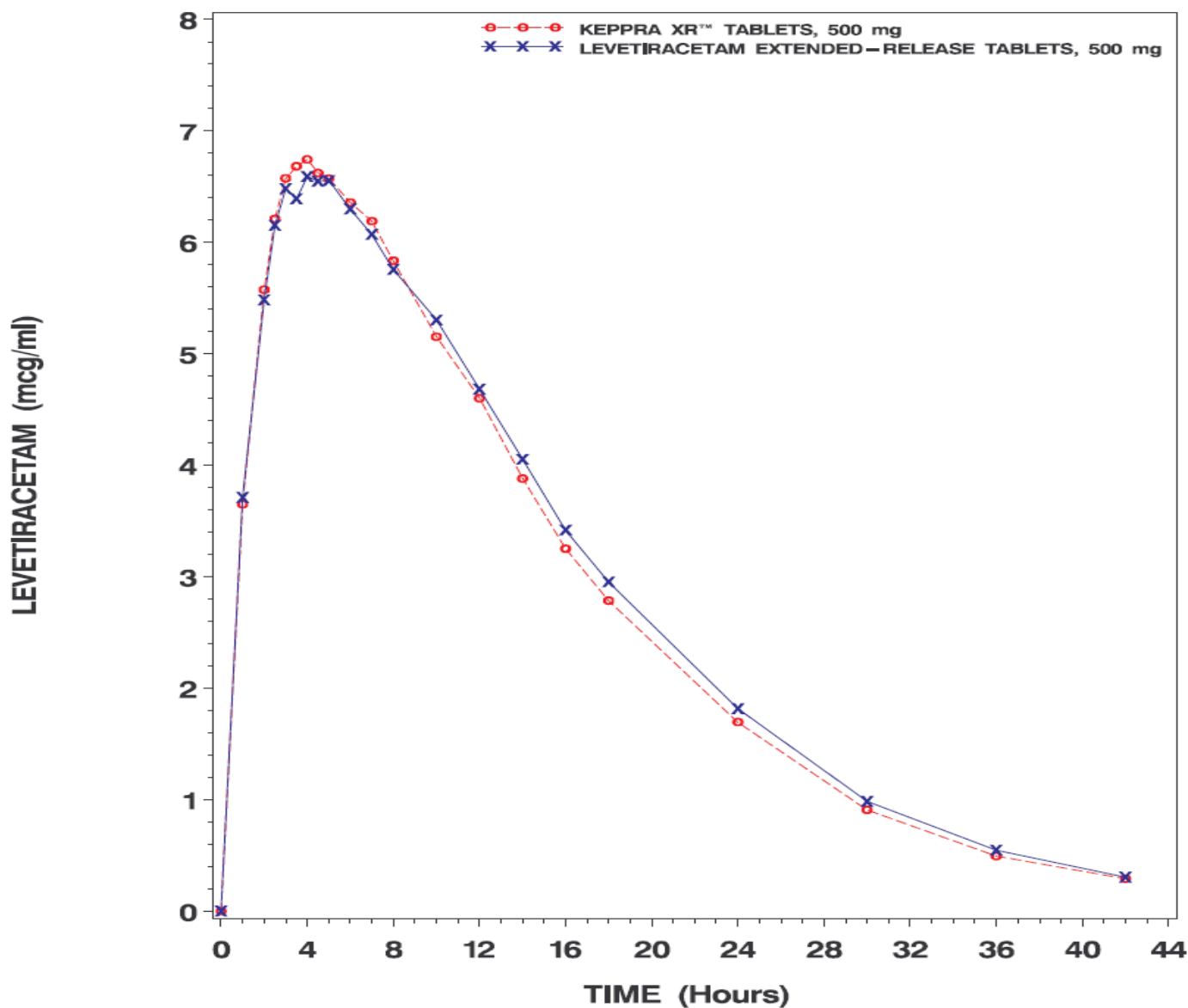
PRODUCT INFORMATION

FASTING BIOSTUDY : 500 mg

	Levetiracetam Mean (% C.V.)		90% Confidence Intervals * (test/reference)
	Apotex Corp. Levetiracetam ER Tablets	Keppra XR™ (Levetiracetam ER Tablets)	
AUCt (mcg*h/mL)	117.596 (18)	114.867 (26)	94.9 – 123.8
AUCinf (mcg*h/mL)	120.841 (18)	118.021 (26)	95.1 – 122.8
Cmax (mcg/mL)	7.038 (24)	7.143 (28)	92.7 – 112.6

*based on log-transformed data

Mean Plasma Levetiracetam Concentration
-- Fasting Study --



Levetiracetam Extended-Release Tablets

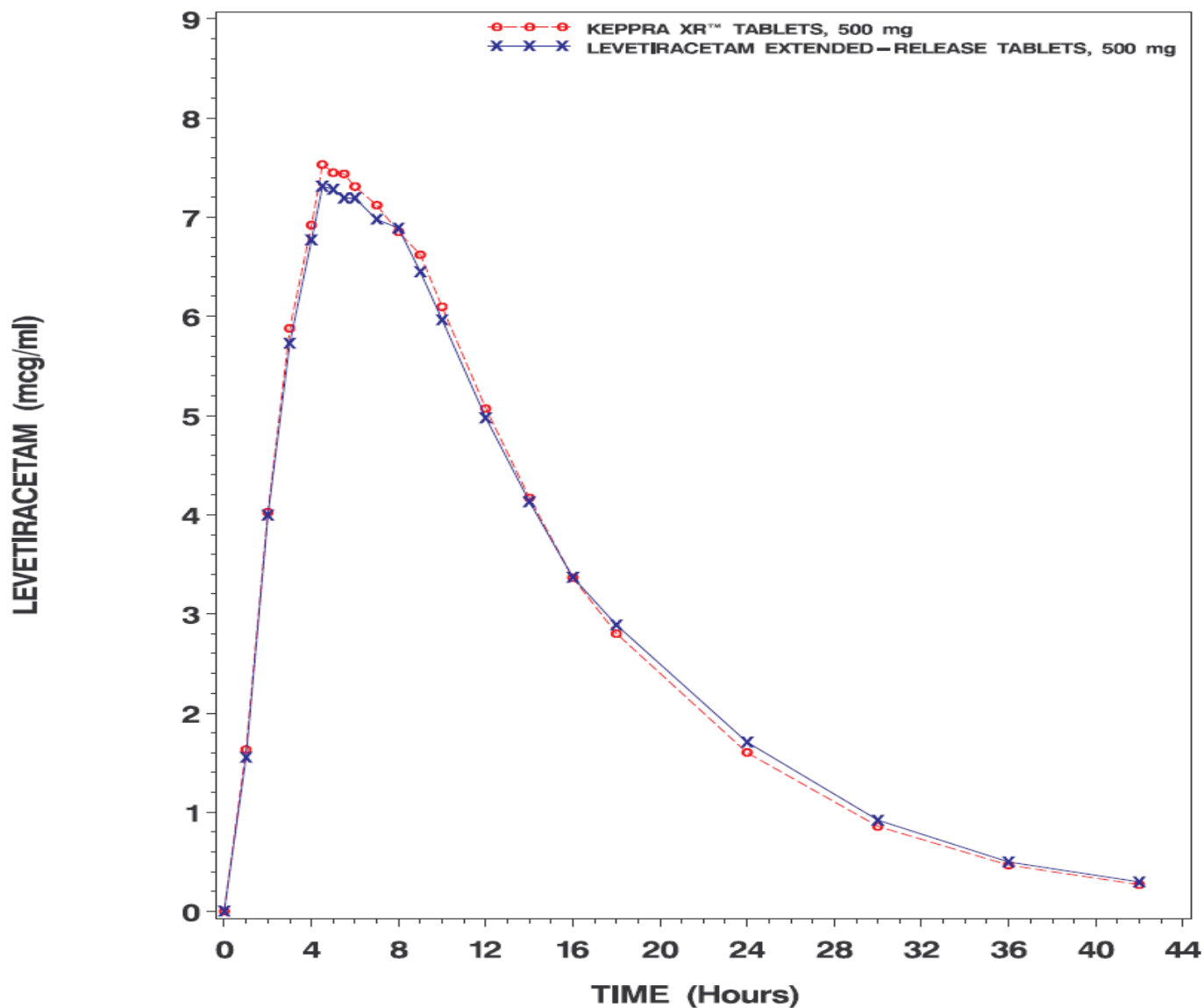
PRODUCT INFORMATION

FOOD EFFECT BIOSTUDY-500 mg

	Levetiracetam Mean (% C.V.)		90% Confidence Intervals * (test/reference)
	Apotex Corp. Levetiracetam ER Tablets	Keppra XR™ (Levetiracetam ER Tablets)	
AUCt (mcg*h/mL)	118.062 (12)	117.910 (12)	98.8 – 101.5
AUCinf (mcg*h/mL)	121.204 (12)	120.731 (12)	99.0 – 101.8
Cmax (mcg/mL)	7.904 (20)	7.998 (16)	95.0 – 101.6

*based on log-transformed data

Mean Plasma Levetiracetam Concentration
--Fed Study --



Levetiracetam Extended-Release Tablets

PRODUCT INFORMATION

FASTING BIOSTUDY : 750 mg

	Levetiracetam Mean (% C.V.)		90% Confidence Intervals * (test/reference)
	Apotex Corp. Levetiracetam ER Tablets	Keppra XR™ (Levetiracetam ER Tablets)	
AUC _t (mcg*h/mL)	192.076 (17)	187.501 (19)	98.6 – 106.9
AUC _{inf} (mcg*h/mL)	197.373 (17)	192.462 (19)	98.7 – 107.2
C _{max} (mcg/mL)	10.446 (23)	10.945 (25)	90.6 – 101.0

*based on log-transformed data

Mean Plasma Levetiracetam Concentration
-- Fasting Study --

13.1.2 Average Concentration – Time Profile for All Subjects

