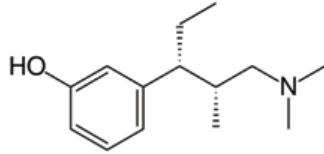


Tapentadol

Homogeneous Enzyme Immunoassay (HEIA)

IMMUNALYSIS

Formula: C₁₄H₂₃NO



Systematic Name: 3-((1R,2R)-3-(dimethylamino)-1-ethyl-2-methylpropyl)phenol hydrochloride

Brand Name: Nucynta®

NEW and EXCLUSIVELY
from Immunalysis

Accurate and reliable

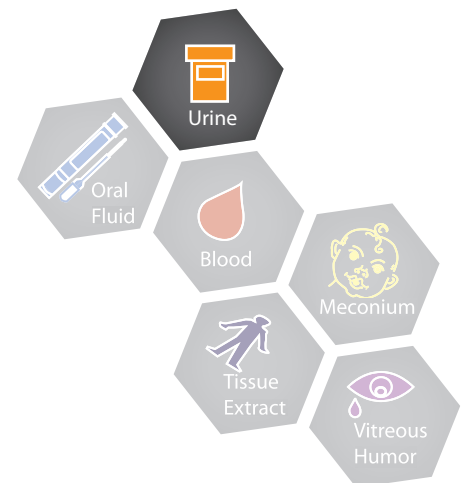
Ready to use

About Tapentadol: Tapentadol is a centrally-acting synthetic analgesic with a dual mode of action as an agonist at the μ -opioid receptor and as a norepinephrine reuptake inhibitor. The drug is used to manage moderate to severe acute pain. It provides analgesia at similar levels of more potent narcotic analgesics such as Hydrocodone, Oxycodone and Meperidine with a more tolerable side effect profile.¹

Administration: Oral, round tablets available in 50, 75 and 100 mg strengths

Elimination: Tapentadol and its metabolites are excreted via the kidneys (99%). The terminal half-life is on average 4 hours. The major pathway of tapentadol metabolism is conjugation with glucuronic acid to produce glucuronides. A total of 3% of drug was excreted in urine as unchanged drug. Tapentadol is additionally metabolized to N-desmethyl tapentadol (13%) by CYP2C9 and CYP2C19 and to hydroxy tapentadol (2%) by CYP2D6, which are further metabolized by conjugation.²

Abuse Potential: Tapentadol can be abused in a manner similar to other opioid agonists, legal or illicit. It is generally abused by crushing, chewing, snorting or injection. These practices pose a significant risk to the abuser that could result in overdose and death.²



1. Tzschentke TM, Christoph T, Kgel B, Schiene K, Hennies HH, Englberger W, Haurand M, Jähnel U, Cremers TI, Friderichs E, De Vry J. (1R,2R)-3-(3-Dimethylamino-1-ethyl-2-methyl-propyl)-phenol Hydrochloride (Tapentadol HCl): a Novel μ -Opioid Receptor Agonist/Norepinephrine Reuptake Inhibitor with Broad-Spectrum Analgesic Properties. Journal of Pharmacology and Experimental Therapeutics. 2007 Oct;323(1):265-76

2. NUCYNTA® (tapentadol) immediate-release oral tablets Full Prescribing Information, Revised: 11/2010, PriCara®, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.



Tapentadol (HEIA)



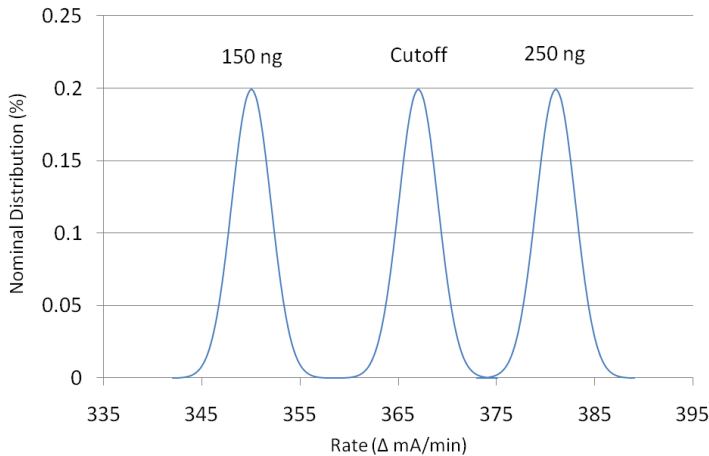
Assay Specifications

Methodology: Homogeneous Enzyme Immunoassay

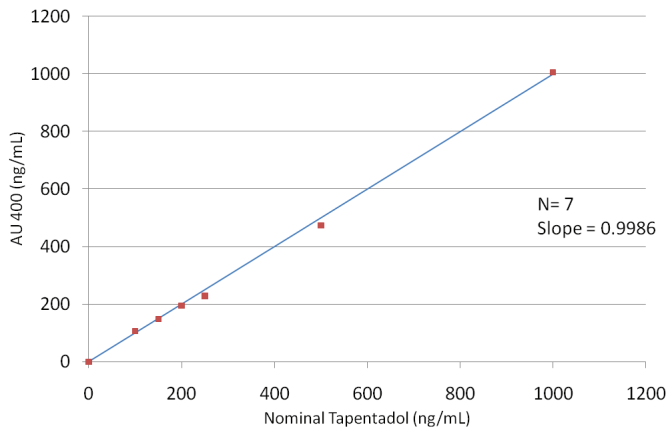
Cutoff: 200 ng/mL

Calibration Range: 0-1000 ng/mL

Overlap: Tapentadol 200 ng/mL Cutoff



Tapentadol Analytical Recovery: 200 ng/mL Cutoff



Tapentadol (HEIA) Ordering Information

Catalog#	Description
343-0100	100 mL kit
343-0500	500 mL kit
C343-10-2	150 and 250 ng/mL Controls
C343-10-5	0, 100, 200, 500, 1000 ng/mL Calibrators
Neg-10-1	10 mL Negative urine control

Cross Reactivity

Analytes	Analyte Conc. (ng/mL)	Tapentadol Conc. (ng/mL)	Cross Reactivity (%)
Tapentadol	200	200	100
Tapentadol-glucuronide (primary metabolite)	800	200	25
N-desmethyl-tapentadol (secondary metabolite)	10,000	200	2
Tramadol	50,000	200	0.4

Nonhydrolyzed Confirmation (50 ng/mL)

HEIA (200 ng/mL)	Nonhydrolyzed Confirmation (50 ng/mL)	
	Positive	Negative
Positive	72	2
Negative	2*	115

*Discrepant negative HEIA specimen values:

Specimen 1 HEIA screen: 42 ng/mL confirmation: 52 ng/mL
Specimen 2 HEIA screen: 32 ng/mL confirmation: 72 ng/mL

Semi-Quantitative Precision at 200 ng/mL

Inter-day Precision (n = 80)

Conc. ng/mL	Mean Conc. (ng/mL)	C.V.%
100 ng/mL Calibrator	99.0	6.7
150 ng/mL (Control LOW)	149.5	2.9
200 ng/mL Calibrator	193.2	2.6
250 ng/mL (Control HIGH)	249.0	7.6
500 ng/mL Calibrator	481.1	4.1
1,000 ng/mL Calibrator	947.2	6.1



Reference standards available at Cerilliant.
We rely on Cerilliant standards.