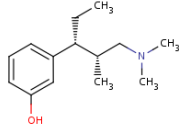


Tapentadol

Homogeneous Enzyme Immunoassay (HEIA™)

IMMUNALYSIS

Formula: C₁₄H₂₃NO



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

Brand Name: Nucynta®

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

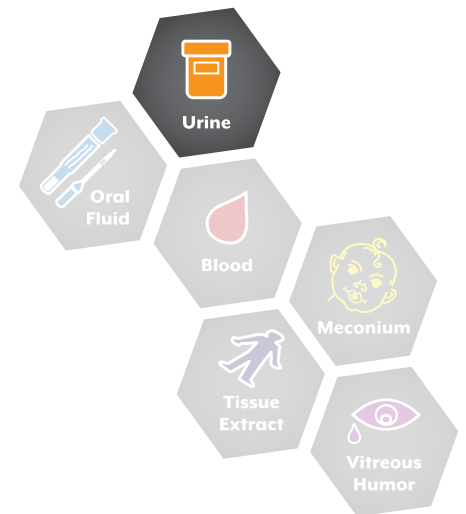
Elimination: Tapentadol and its metabolites are excreted via the kidneys (99%). The terminal half-life is on average 4 hours. The major pathway of Tapentadol metabolism is conjugation with Glucuronic Acid to produce glucuronides. A total of 3% of drug is excreted in urine as unchanged drug. Tapentadol 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

Exclusively
from Immunalysis

Accurate and reliable

Ready to use



1. Tzschentke, T.M. et al. (1R,2R)-3-(3-Dimethylamino-1-ethyl-2-methyl-propyl)-phenol Hydrochloride (Tapentadol HCl): A Novel-Opioid Receptor Agonist/ Norepinephrine Reuptake Inhibitor with Broad-Spectrum Analgesic Properties. *Journal of Pharmacology and Experimental Therapeutics*. 323(1): 265-76 (2007).

2. PiCara®, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. NUCYNITA® (Tapentadol) Immediate-Release Oral Tablets Full Prescribing Information. Rev 11/10.



Tapentadol (HEIA™)



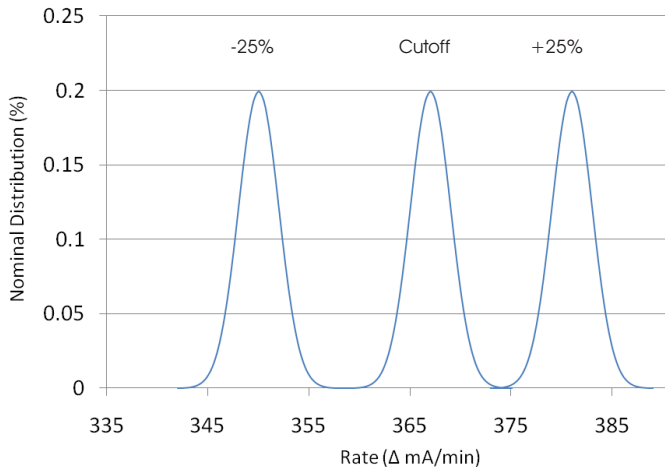
Assay Specifications

Methodology: Homogeneous Enzyme Immunoassay

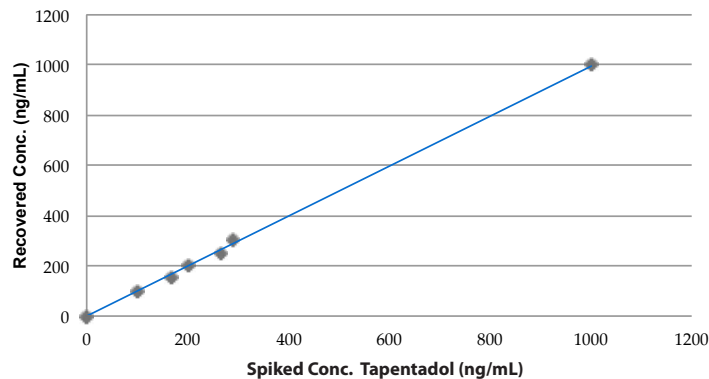
Cutoff: 200 ng/mL

Calibration Range: 0-1000 ng/mL

Overlap: Tapentadol (200 ng/mL Cutoff)



Analytical Recovery: Tapentadol



ORDER - Tapentadol (HEIA)

Catalog #	Description
343-0025 / -0100 / -0500	25 mL / 100 mL / 500 mL Kit
C343-10-1	200 ng/mL Calibrator
C343-10-2	150 and 250 ng/mL Controls
C343-10-5	0, 100, 200, 300, 1000 ng/mL Calibrators
Neg-10-1	10 mL Negative Urine Control

Cross-Reactivity

Analyte	Analyte Concentration (ng/mL)	Tapentadol Equivalent (ng/mL)	Cross-Reactivity (%)
Tapentadol	200	200	100
Tapentadol Glucuronide	800	200	25
N-Desmethyl Tapentadol	10,000	200	2
Chlorpromazine	40,000	200	0.5
Cyclobenzaprine	100,000	200	0.2
Doxepin	100,000	200	0.2
Imipramine	50,000	200	0.4
Tramadol	50,000	200	0.4
Trimipramine	30,000	200	0.7

LC-MS/MS Confirmation (50 ng/mL)

HEIA (200 ng/mL)	LC-MS/MS 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

Interday Precision (n = 80)

Concentration (ng/mL)	Mean Concentration (ng/mL)	CV%
100 Calibrator	96.5	7.0
150 Control LOW	152.3	6.8
200 Calibrator	189.8	5.8
250 Control HIGH	240.9	6.1
300 Calibrator	301.0	8.3
1000 Calibrator	972.1	5.7