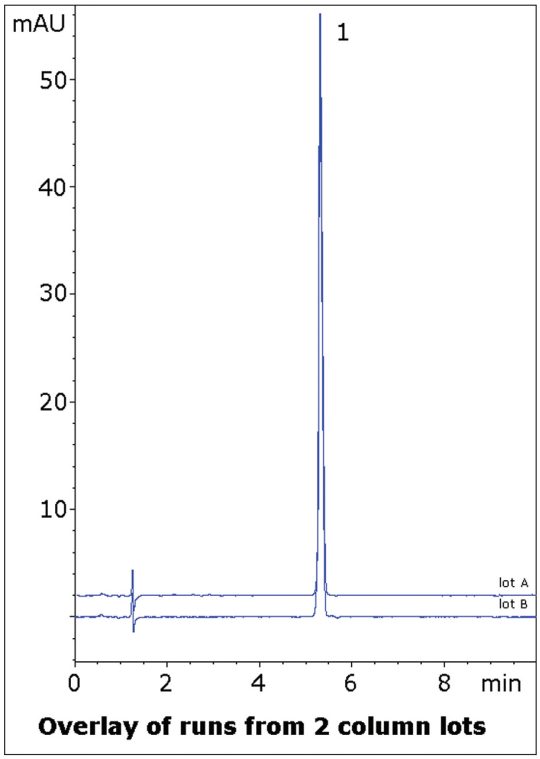
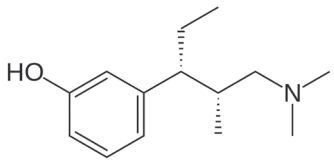
Nucynta® (Tapentadol HCl) Tablet

Assay method for analgesic amine



Overlay of runs from 2 column lots



Tapentadol

Note: Tapentadol is an analgesic compound used to treat moderate to severe pain. It efficacy is due to two modes of action: One is an agonist of the μ-opioid receptor and another as a norepinephrine reuptake inhibitor.

Method Conditions

Column: **Cogent Diamond Hydride™**, 4μm, 100Å

Catalog No.: 70000-7.5P

Dimensions: 4.6 x 75 mm

Mobile Phase: A: DI H_2O / 0.1% formic acid (v/v)
B: Acetonitrile / 0.1% formic acid (v/v)

Gradient:

time (min.)	%B
0	95
1	95
6	40
7	95

Post Time: 3 min

Injection vol.: 1μL

Flow rate: 1.0 mL/min

Detection: UV 271 nm

Sample: 75mg strength Nucynta® tablet was ground and weighed in a 25mL volumetric flask. A portion of 50/50 solvent A/solvent B diluent was added and the flask was sonicated 10 min. It was then diluted to mark and filtered with a 0.45μm nylon syringe filter (MicroSolv Tech Corp.). The filtrate was diluted 1:5 for HPLC injections.

Peak: 1. Tapentadol HCl

t_0: 0.9 min

Discussion

Tapentadol can be a problematic compound for HPLC analysis due to the amine. Tertiary amines are often particularly difficult to obtain a good peak shape for. Using reversed phase methods, notable tailing is observed in several published reports in the literature. The Cogent Diamond Hydride column, however, obtains a sharp peak for this analyte due to its unique retention mode.

Data from two column lots shown in the figure illustrates the reproducibility of the material from batch to batch.

MANUFACTURED BY:
MICROSOLV TECHNOLOGY CORPORATION

9158 Industrial Blvd NE
Leland, NC 28451

p: 1.732.380.8900
f: 1.910.769.9435

customers@mtc-usa.com
www.Cogent-HPLC.com