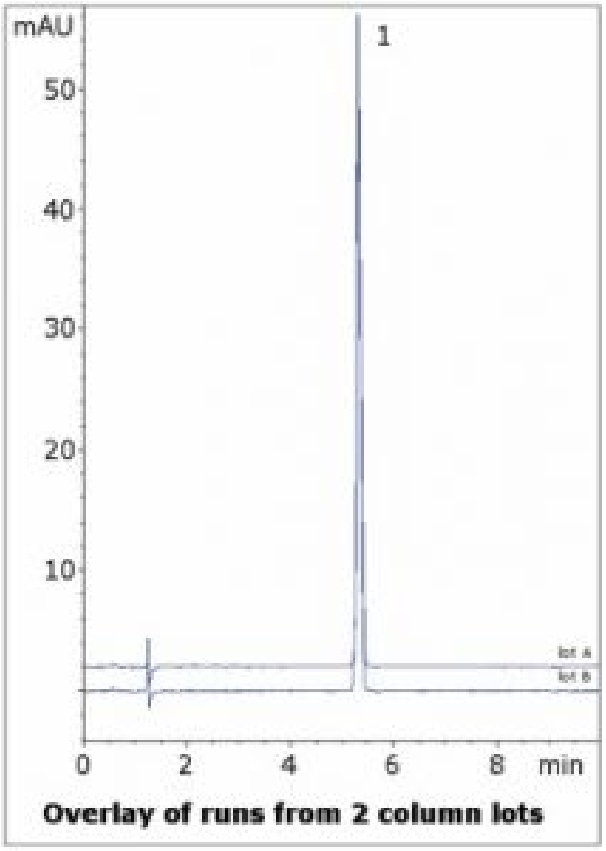
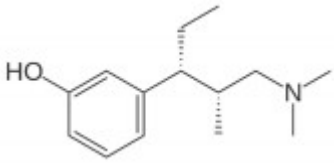
Tapentadol HCl Tablet Analyzed by HPLC – AppNote

Assay Method for the Analgesic Nucynta

Tapentadol can be a problematic compound for HPLC analysis due to the Amine functional group. Tertiary amines are often particularly difficult to obtain a good peak shape using Reversed Phase methods. Peak tailing has been reported in several published papers in the literature.

With this Method, a sharp Peak is obtained due to the unique retention mode. Data from two column lots shown in the figure illustrates the reproducibility of the Method and its robustness.





Peak:

Tapentadol HCI

Method Conditions

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

Catalog No.: 70000-7.5P

Dimensions: 4.6 x 75mm

Mobile Phase:

A: DI Water / 0.1% Formic Acid (v/v)

B: Acetonitrile / 0.1% Formic Acid (v/v)

Gradient:

Time *(minutes)*	%B
0	95
1	95
6	40
7	95

Post Time: 3 minutes

Injection vol.: 1µL

Flow rate: 1.0mL / minute

Detection: UV @ 271nm

Sample Preparation: 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 minutes. 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.

t_0: 0.9 minutes

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

Attachment

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MicroSolv Technology Corporation
9158 Industrial Blvd. NE, Leland, NC 28451
tel. (732) 380-8900, fax (910) 769-9435
Email: customers@mtc-usa.com
Website: www.mtc-usa.com
Date: 07-22-2024