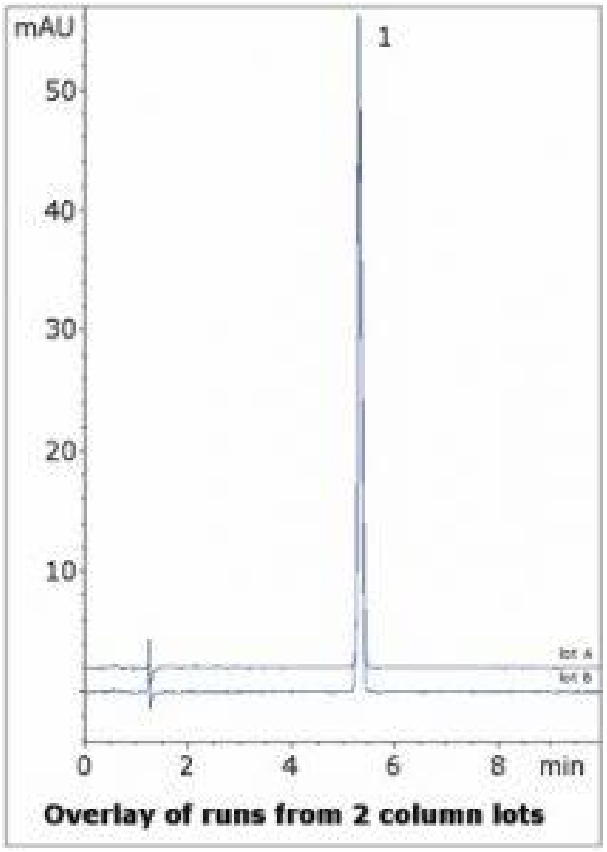
Tapentadol HCl Tablet Analyzed by HPLC - AppNote

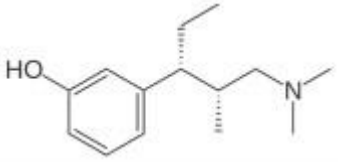
Assay Method for the Analgesic Nucynta

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.



Overlay of runs from 2 column lots



Peak:

Tapentadol HCl

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.*

COGENT HPLC Columns™

Attachment

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