

New Drugs: CAT Meeting-August, 2000

Zaleplon (Sonata®)

Structure:



Manufacturer: Wyeth-Ayerst Laboratories

FDA Status: August 13, 1999 – Approved as schedule IV

CAS registry No.: Unknown

Chemical Name: N-[3-(3-cyanopyrazol [1,5-alpyrimidin-7-yl]-N-ethylacetamide

Molecular formula: C₁₇H₁₄N₅O

Molecular weight: 304

Therapeutic

Category: Short acting, rapid onset hypnotic for insomnia

Bio-availability: 30%

Volume of

Distribution (V_d): 1.3 L/kg

Dose: 10 mg

Half-Life (T_{1/2}): 1.1 hours

Extraction Information:

-Liquid/Liquid chlorobutane extraction:

-A single step liquid/liquid extraction from a basic solution will work, however, it CANNOT be back extracted into an acidic layer.

-Behaves somewhat like a basic drug, however extracts more like a low dose benzodiazepine

-Preliminary method: Liquid/Liquid extraction along with solid phase

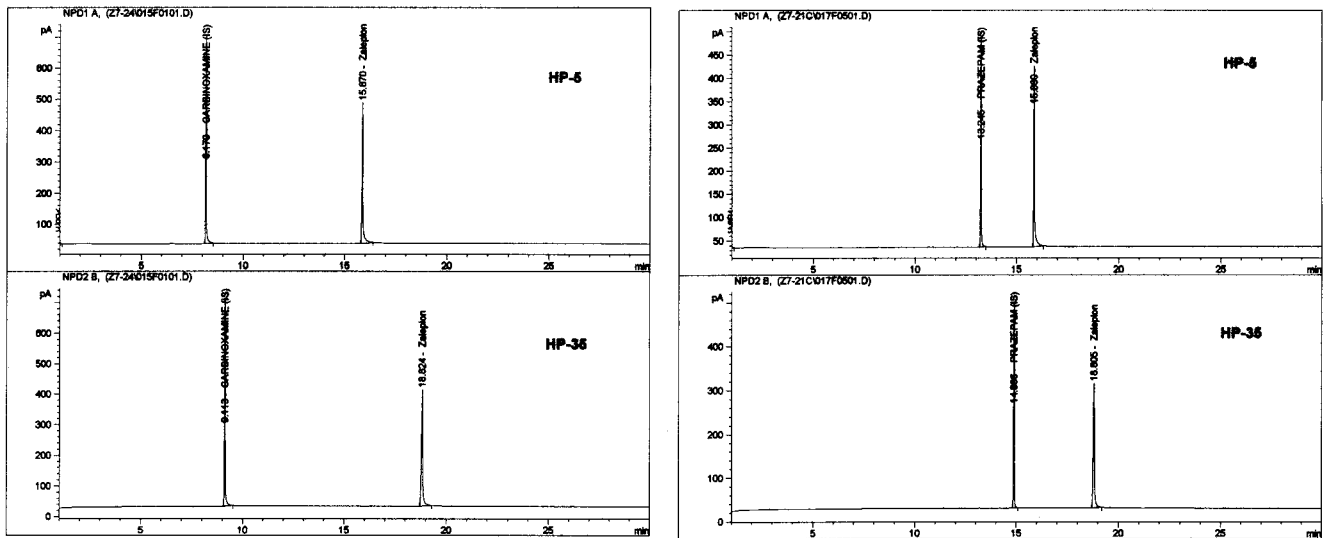
-2-ml sample size (Prazepam as internal standard)

- 2-ml of 20% sodium carbonate, 5-ml toluene-Rotate 20 minutes, Centrifuge, Decant
- Solid phase extraction utilizing a pure silica column
 - Prep columns with methanol and toluene
 - Pour on sample
 - Wash with toluene, chloroform and hexane
 - Elute with acetonitrile:methanol (60:40)
- Evaporate, reconstitute with methanol

Instrumentation:

-GC/NPD: Oven program: 140-300°C 0.50 min initial hold, 10°C/min ramp, 10.5 min final hold, total analysis time 27 min.
 Columns: HP-5 & HP-35 (15m x 0.25 um x 0.25 i.d)
 Limit of Detection: 5 ng/ml
 Limit of Quantitation: 10 ng/ml
 Linearity: At least up to 1000 ng/ml

Chromatograms: Carbinoxamine vs. Prazepam as Internal standards



-GC/MS: Ions 248, 305 263, 262

