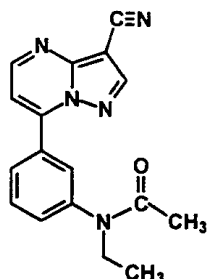


# New Drugs: CAT Meeting-August, 2000

## 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:** C<sub>17</sub>H<sub>14</sub>N<sub>5</sub>O

**Molecular weight:** 304

### Therapeutic

**Category:** Short acting, rapid onset hypnotic for insomnia

**Bio-availability:** 30%

### Volume of

**Distribution (V<sub>d</sub>):** 1.3 L/kg

**Dose:** 10 mg

**Half-Life (T<sub>1/2</sub>):** 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

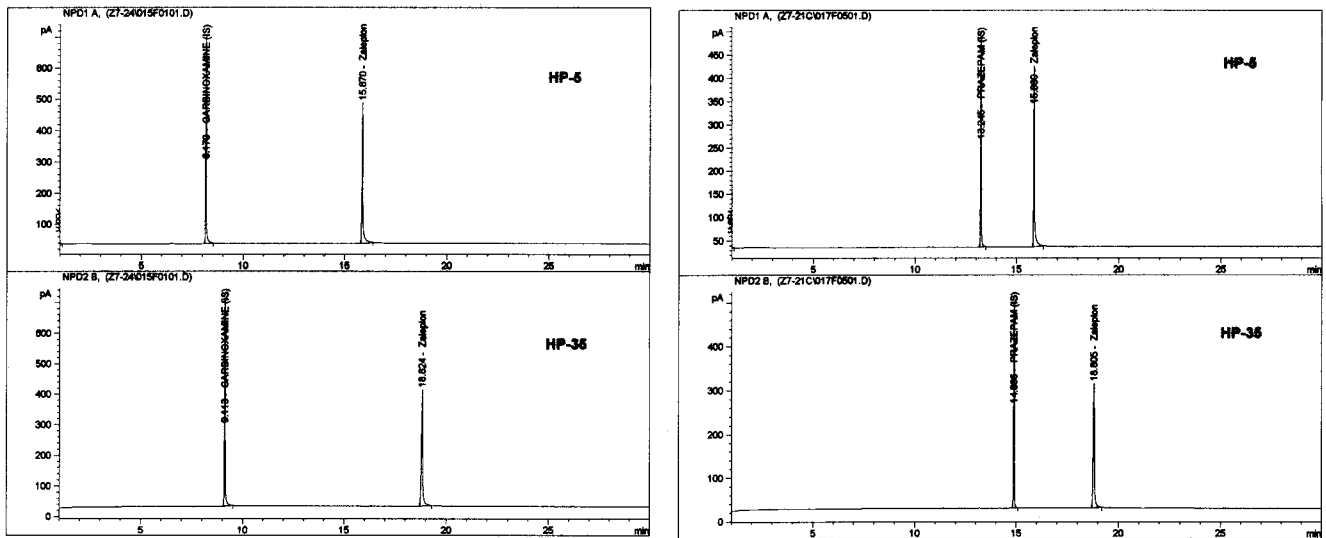
-2-ml sample size (Prazepam as internal standard)

- 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

