

# Application Data

No. 1024A

ChromaNik Technologies Inc.

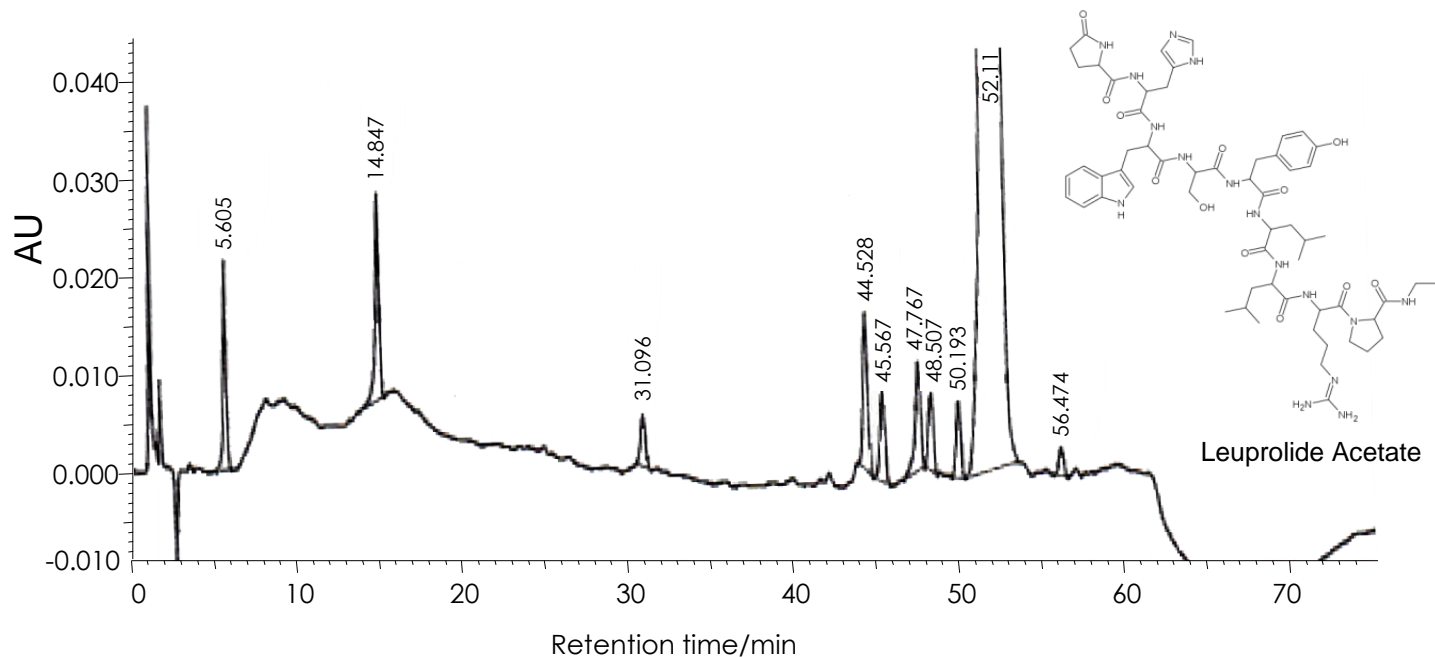
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Chromatographic Purity Test

Source Reference USP 2010

Leuprolide Acetate

SunShell C18, 2.6  $\mu$ m 100 x 4.6 mm i.d.



Column: SunShell C18, 2.6 $\mu$ m 100 x 4.6 mm i.d.

Mobile phase: A) Triethylamine 15.2g/L adjust the pH 3.0 with o-Phosphoric Acid

B) Acetonitrile/ n-Propyl alcohol(3:2)

Gradient Program Time (min) 0 4 60 68 76

%A (%) 95 95 80 95 95

%B (%) 5 5 20 5 5

Diluent Mobile Phase A(17 parts) + Mobile Phase B(3parts)

Flow rate : 1.0. mL/min

Detection : UV@229 nm

Column Temperature : 50  $^{\circ}$ C

Sample Temperature : 4  $^{\circ}$ C

Sample: Solution 100 mg Leuprolide Acetate in 100 mL Diluents

Injection Volume : 20  $\mu$ L

Degradation solution a) 5 mL Sample /standard solution 1 mg/mL) dilute to 50 mL Water

b) Solution (a) 5 mL +100 mL 1N NaOH.

c) Shake Vigorously and place in Oven at 100  $^{\circ}$ C for 1 hour

d)Cool and add 50 $\mu$ L 1M Phosphoric Acid