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Application Data

No. 1015A

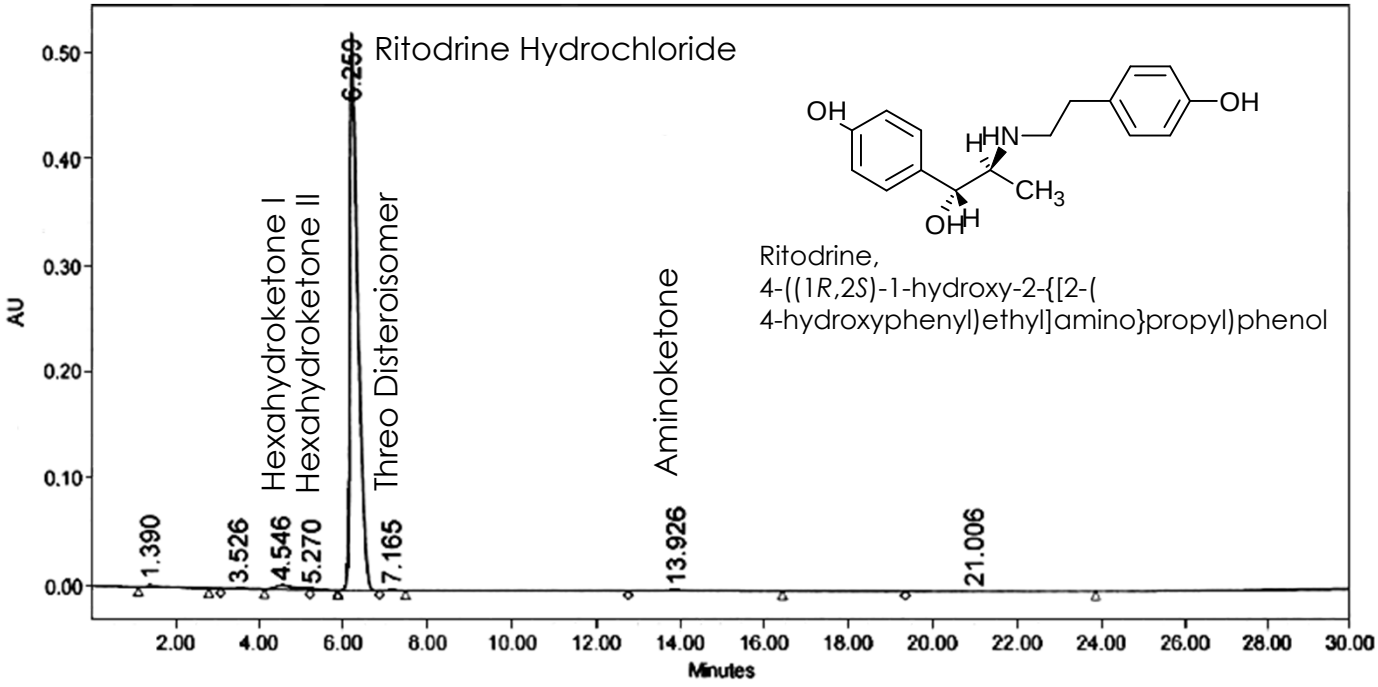
ChromaNik Technologies Inc.

塩酸リトドリン

British Pharmacopea 2009 Related substances Test

Ritodrine Hydrochloride

Sunniest C8 5 µm, 250 x 4.6 mm i.d.



Ritodrine,
4-((1*R*,2*S*)-1-hydroxy-2-{[2-(
4-hydroxyphenyl)ethyl]amino}propyl)phenol

Column: Sunniest C8 5 µm, 250 x 4.6 mm

Mobile phase:

Solution A,: 6,6 g Diammonium Hydrogen Orthophosphate + 1.1 g.Sodium Heptane sulphonate dissolved in 700 mL water and adjust the pH to 3.0 with 85% orthophosphoric acid

Solvent B, Methanol 300mL

Mix Mobile phase solution A and B

Flow rate: 2.0 mL/min

Temperature: ambient room temperature

Detection: UV 214 nm

Test probe : 0.10 % w/v Ritodrine Hydrochloride in Mobile phase

Injection volume: 20 µL

System suitability requirements

Relative retention with respect to Ritodrine

Impurity Tyramine RRT 0.3

Impurity Hexahydroketone II RRT 0.65

Impurity Hexahydroketone I RRT 0.85

Impurity Threo Disteroisomer RRT 1.15

Impurity Aminoketone RRT 2.3

Resolution between Threo Disteroisomer and Ritodrine Hydrochloride not less than 1.5

Observations

- Sunniest C8 column offers resolution of 2.8 between Threo Disteroisomer and Rotodrine.
- Sunniest C 8 column offers RRT and resolution within the prescribed Pharmacopeal requirements.