LT038

GL Sciences Inc.

Analysis of Scopolamine and Hyoscyamine in Scopolia Extract in Accordance with the Japanese Pharmacopoeia

Scopolia extract powder is derived from Scopolia japonica Maxi. It is a crude drug prepared by drying the roots and extracting the active ingredients. It contains approximately 0.1 % scopolamine and hyoscyamine in the dried product (atropine in this racemic mixture). It is used in combination with over-the-counter stomach drugs as an antispasmodic and analgesic because it reduces the secretion of stomach juice and excessive motility of the gastrointestinal tract, and prevents the transmission of pain.

The Japanese Pharmacopoeia employs an HPLC method with ODS-column for the determination of scopolamine and hyoscyamine in scopolamine extract powder. The following system suitability items are specified.

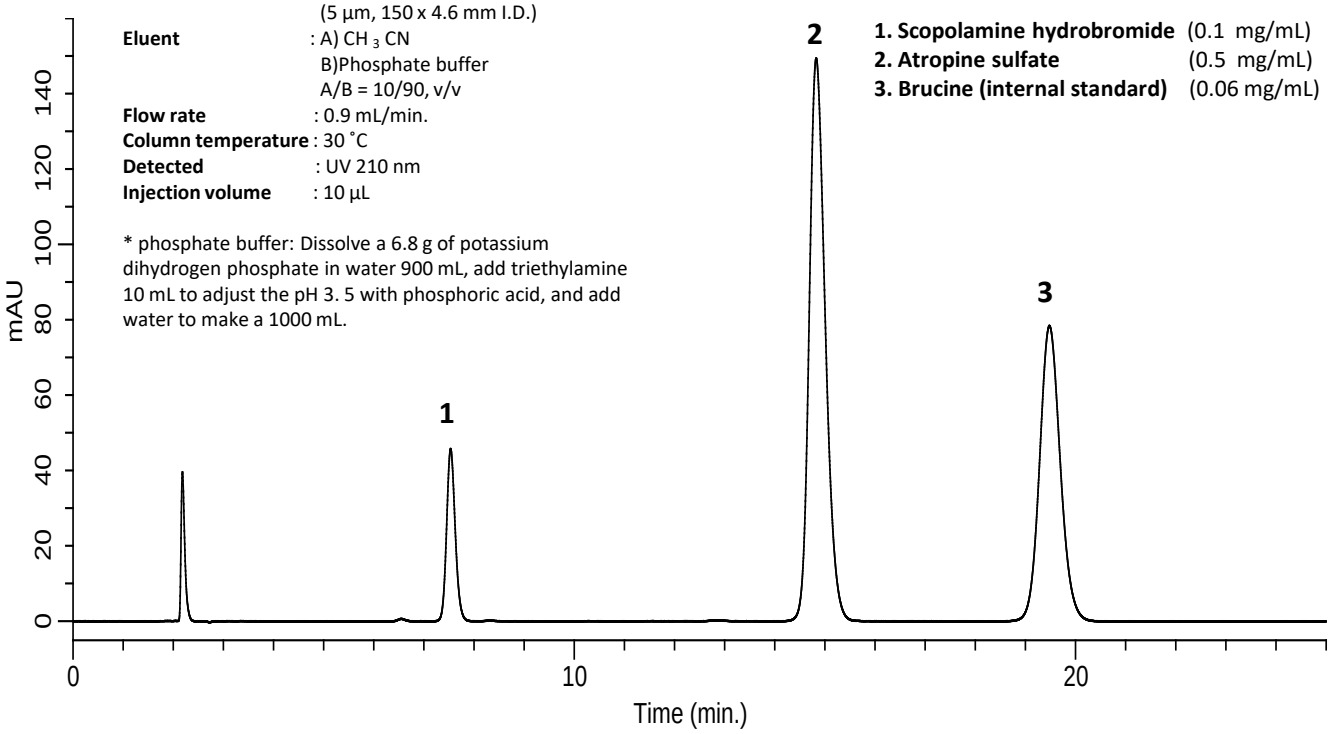
(T. Fukaya)

Example: Measurement of standard

HPLC conditions

Column : Inertsil ODS-SP (5 µm, 150 x 4.6 mm I.D.)
Eluent : A) CH_3CN B)Phosphate buffer A/B = 10/90, v/v
Flow rate : 0.9 mL/min.
Column temperature : 30 ˚C
Detected : UV 210 nm
Injection volume : 10 µL

* phosphate buffer: Dissolve a 6.8 g of potassium dihydrogen phosphate in water 900 mL, add triethylamine 10 mL to adjust the pH 3. 5 with phosphoric acid, and add water to make a 1000 mL.



System suitability test

When analyzed under the above HPLC conditions,

1. Scopolamine, atropine, and the internal standard are eluted in this order.
2. The resolution of scopolamine and atropine is 11 or greater
3. The resolution between atropine and the internal standard is 4 or greater.

Our results

Separation order: meets specifications
Resolution: scopolamine-atropine: 16.8
Atropine-internal standard: 7.1

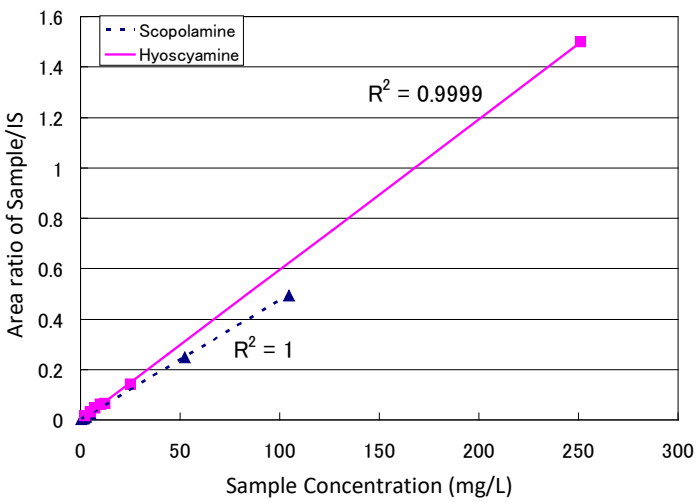


Figure 1 Calibration curve for scopolamine and hyoscyamine.

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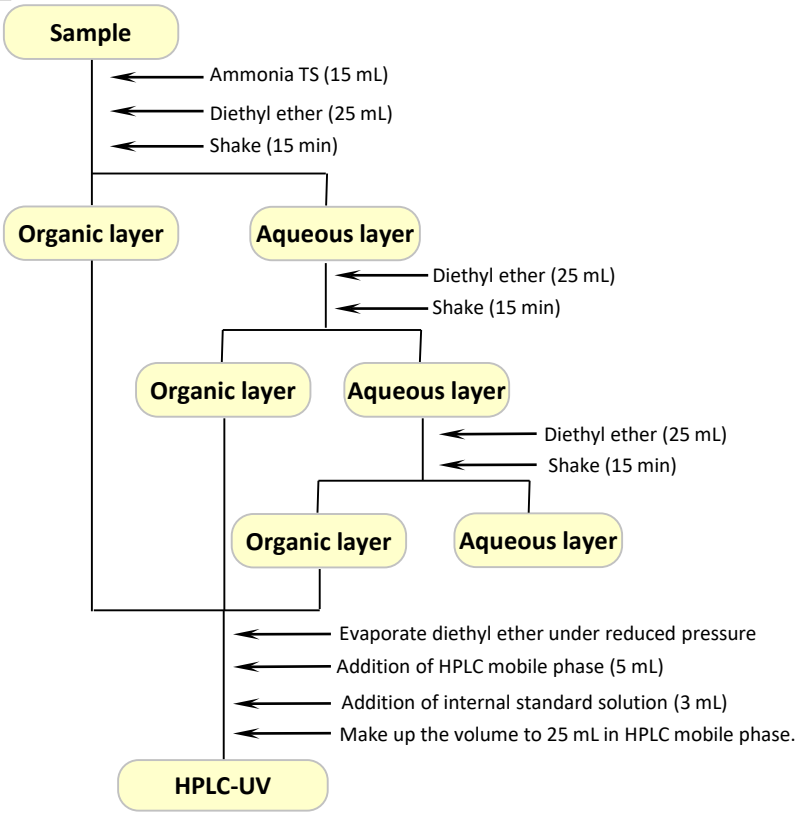
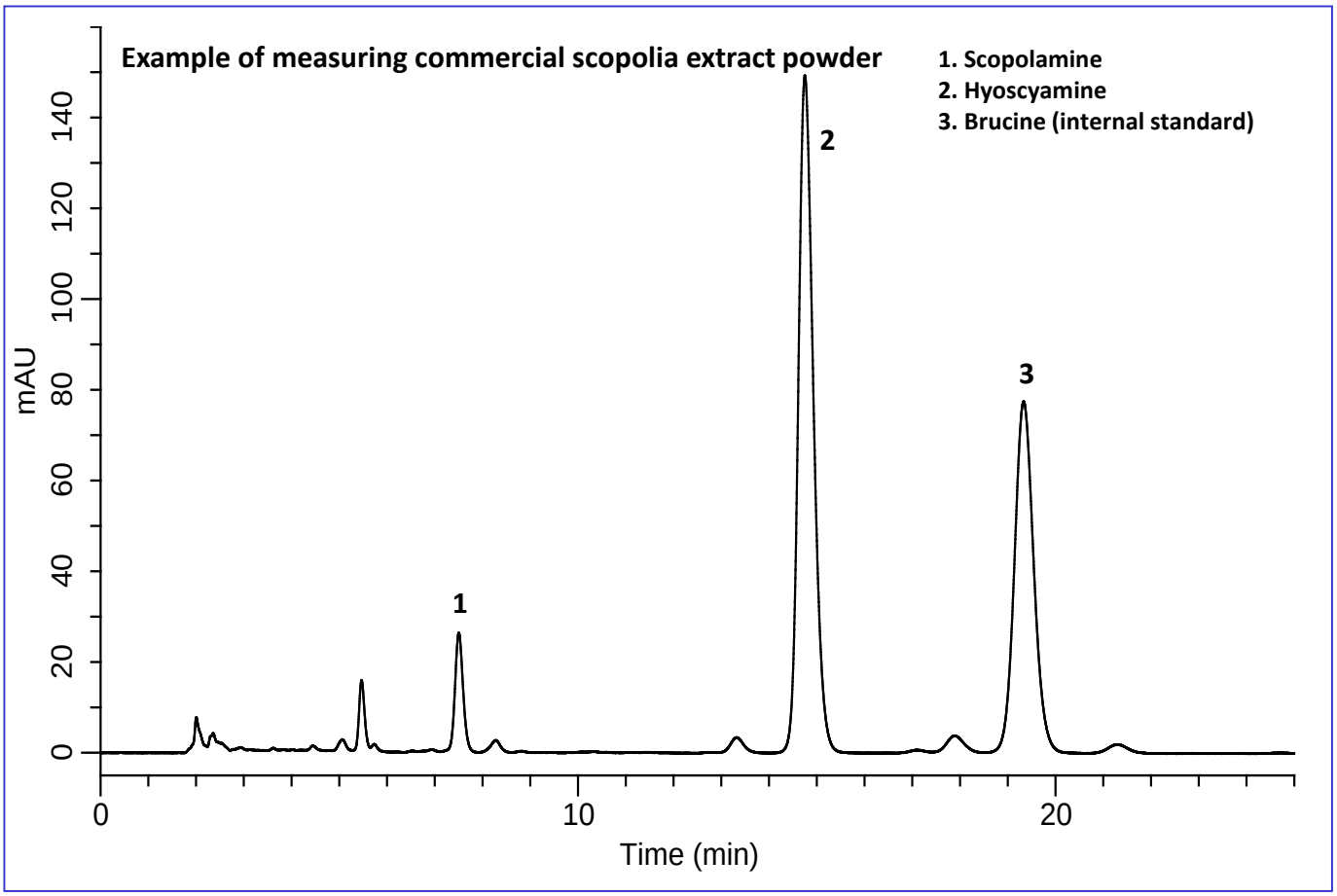
Analysis of scopolamine and hyoscyamine in JP Scopolia Extract

Example of pretreatment



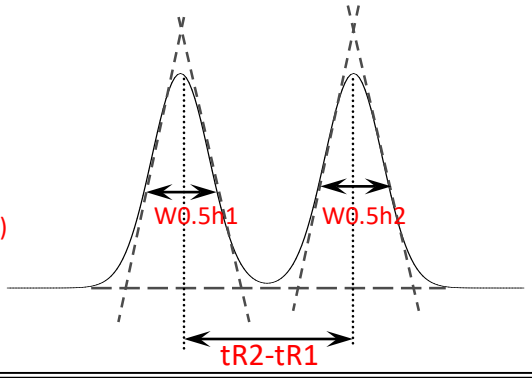


Overview of Resolution

Resolution is a measure of the separation between two peaks and is derived from the retention time and width of two peaks. The greater the number, the greater separation of the two peaks. To calculate resolution, the following formula is used:

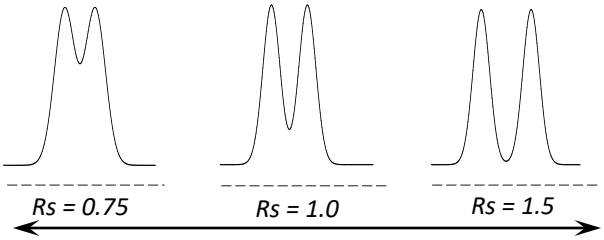
$$R_s = 1.18 \times \frac{(t_{R2} - t_{R1})}{(W_{0.5h1} + W_{0.5h2})}$$

tR1, tR2: Retention time of components 1, 2 (tR2 > tR1)
W 0.5h1, W 0.5h2: peak half-width of components 1, 2
(Half-width: peak width at peak half height)



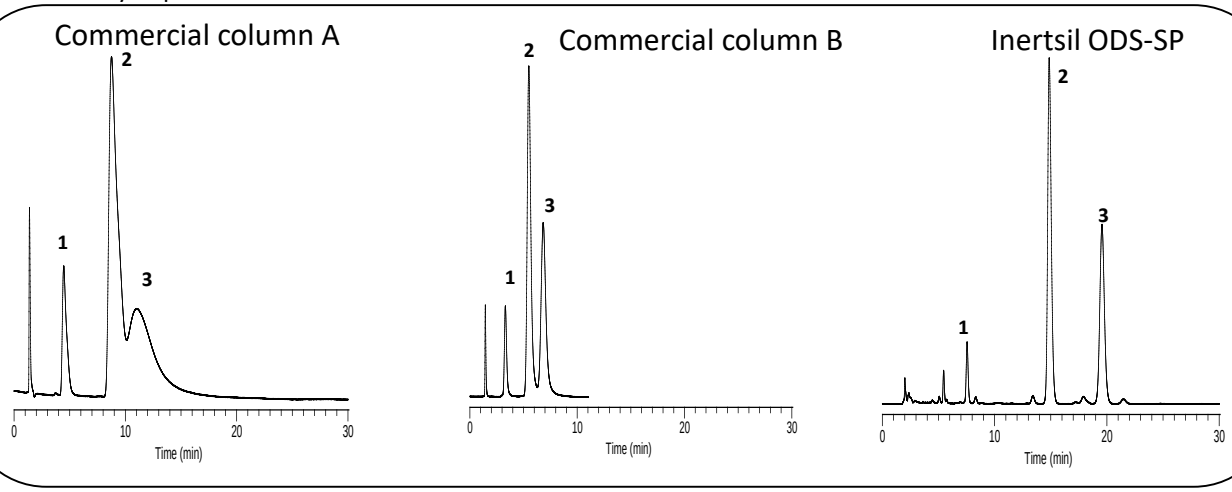
Generally, it is considered that determination is possible with a resolution of 1 or more, and complete separation is considered to have been achieved with a resolution of 1.5 or more.

Resolution tends to increase with increased distance in the retention times of the two peaks and with narrower peak widths.



The degree of separation is influenced by the length and type of column, composition of the eluent, column temperature, etc., but is particularly influenced by the type of column. As an example, the results of analyzing the same samples on three ODS columns with different binding modes and different binding amounts of the ODS groups are shown below.

The separation behavior of the same "ODS" column is significantly different, indicating that column selection is extremely important.



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