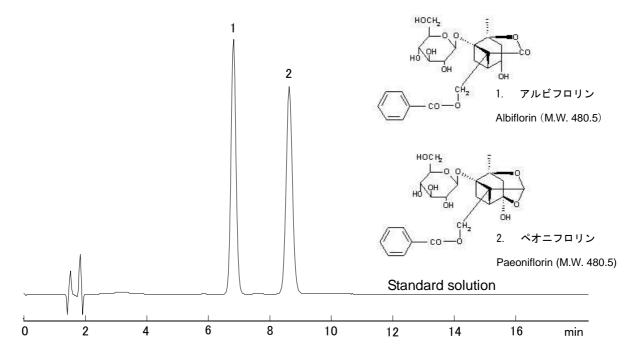
芍薬はボタン科シャクヤクの根を乾燥させた生薬で, 乾燥状態で 2%以上のペオニフロリンを含んでいます. ペオニフロリンはモノテルペン配糖体であり, 抹消血管拡張, 抗炎症など多くの薬理作用を有しています.

日本薬局方では、芍薬中のペオニフロリンの定量法として ODS カラムを用いた HPLC 法が採用されていますが、第 15 改正日本薬局方から、システム適合性での分離度の比較に用いる化合物が、p-ヒドロキシアセトフェンからアルビフロリンに変更になりました。

Poeny belongs to Paeoniaceae. Its dried root is used as a Chinese medicine. The dried root contains 2% of paeonflorin, a glycosilated monoterpene. Paeoniflorin is known to cause teleangiectasia and show anti-inflammatory effect.

The Japanese Pharmacopeia designates an HPLC method with a C18 column for its determination. A reference compound used for its system suitability test was switched from *p*-hydroxyacetophenone to albiflorin in the 15th Revision.



[HPLC Conditions]

Column : CAPCELL PAK C₁₈ MGII S5 ; 4.6 mm i.d. x 150 mm

Mobile phase : $H_2O / CH_3CN / H_3PO_4 = 850 / 150 / 1$

Flow rate : 1 mL / min Temperature : 20 $^{\circ}$ C Detection : UV 232 nm Inj. vol. : 10 μ L

Sample dissolved in $: 50\%CH_3CN \cdot H_2O$, each $100 \mu g / mL$

 $\frac{1}{2}$ 1 μ g /mL = 1 ppm

システム適合性

第15改正日本薬局方では、以下の項目がシステム適合性試験として定められています。

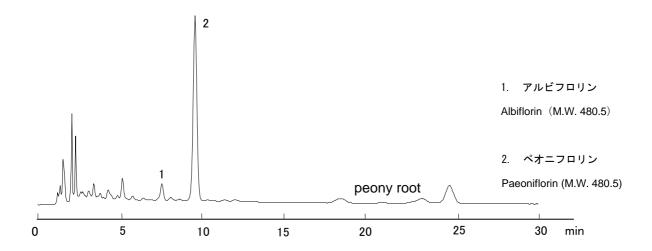
- 1. アルビフロリン、ペオニフロリンの溶出順位
- 2. 2成分の分離度は 2.5以上
- 3. 連続 6 回測定時のペオニフロリン面積値の相対標準偏差 1.5%以下 結果は、1. ⇒ 適合、2. ⇒ 5.1 で適合、3. ⇒ 0.32 % と良好な値が得られました。

System suitability test

The Japanese Pharmacopeia 15th revision includes the following items in system suitability test of the compound.

- 1. Eluting order of albiflorin and, thereafter, paeoniflorin
- 2. Resolution between the above two compounds should be 2.5 or greater.
- 3. Paeoniflorin peak area of six replicates should show relative standard diviation of 1.5% or smaller.

The method with a CAPCELL PAK C_{18} MGII S5 passsed all of the above three items (1. passed, 2. resolution = 5.1, and 3. RSD = 0.32%).



Pretreatment

: Peony root was cut into small pieces, and ground in a mortar with a pestle. 0.5 g of the ground peony root was dispersed in a mixed solvent (50 mL, water / methanol = 1 / 1). The dispersion was refluxed for 30 min. After cooling it down, the dispersion was filtered with filter paper. The residue was rinsed with the mixed solvent. The filtered liquid and the mixed solvent used for rinsing were added together and adjusted to 100 mL in a volumetric flask. A small amount of the solution was further filtered with a 0.2-µm filter, and introduced to HPLC.