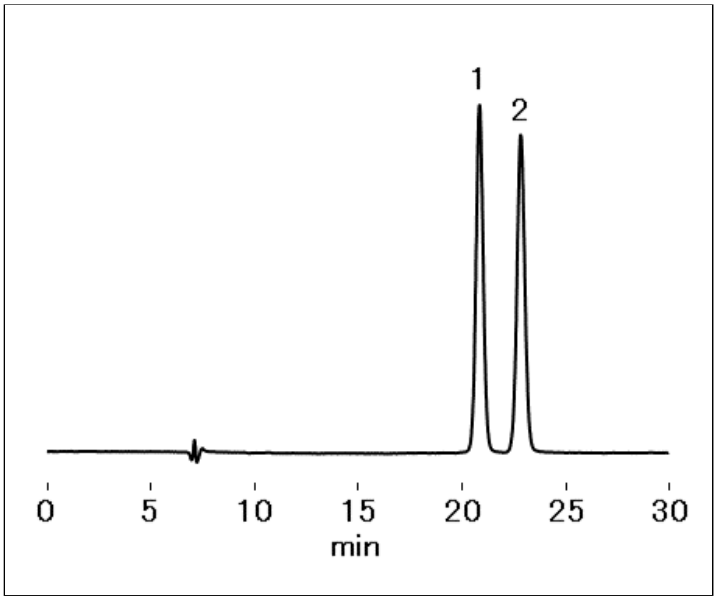
Analysis of Epinephrine According to USP (In-Process Revision) (CDBS-453)

In-Process Revision of Pharmacopeia Forum 44 (6) of the USP(United States Pharmacopeia),
To determine the optical purity of epinephrine injection, analytical methods using L45 packing material have been published,

The ORpak CDBS-453 confirmed the following requirements were met for the use of optical resolution:

System suitability requirements:
Resolution of (*R*) -epinephrine and (*S*) -epinephrine : Rs ≧ 1.5
Relative standard deviation of the peak area (RSD) : ≦ 2.0 %
The signal / noise ratio in the sensitivity solution : ≧ 10



Sample : 10 μL

System suitability solution (Epinephrine hydrochloride 20 μg/mL (in *Solution A))
1. (*R*)-Epinephrine
2. (*S*)-Epinephrine

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Column       : Shodex ORpak CDBS-453 (4.6 mm I.D. x 150 mm)
Eluent       : *Solution A/CH3CN=99/1
Flow rate    : 0.3 mL/min
Detector     : UV (280 nm)
Column temp. : 25 °C
*: 0.75 g/L Ammonium acetate aqueous solution adjusted to pH 4.0
     with Glacial acetic acid
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