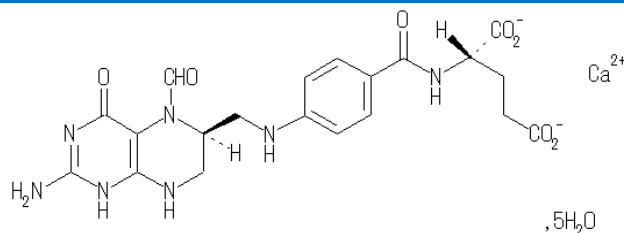


Calcium levofolinate pentahydrate:Impurity H



Column : CHIRALPAK[®] HSA 0.40cmΦ × 15cmL
Mobile phase : Buffer* / 2-propanol R / Acetonitrile R = 890 / 100 / 10 (v / v / v)
Flow rate : 1.0mL/min.
Injection volume : 10μL
UV detection : 286nm
Column temperature : 40°C
 * Buffer : Dissolve 9.72 g of *Sodium dihydrogen phosphate R* in 890 mL of *water R* and adjust to pH 5.0 with *sodium hydroxide solution R*.

System suitability

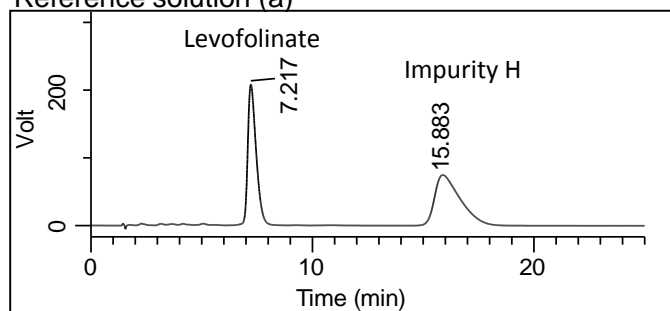
Reference solution (a):

Dissolve 10.0 mg of *Calcium folinate CRS* in *water R* and dilute to 20.0 mL with the same solvent.

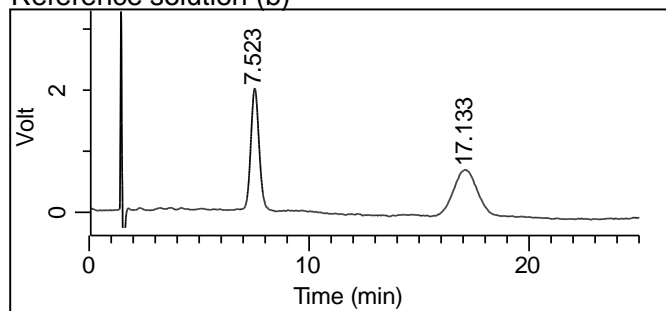
Reference solution (b):

Dilute 1.0 mL of reference solution (a) to 100.0 mL with *water R*.

Reference solution (a)



Reference solution (b)



	Requirement	Result
Resolution	Minimum of 5.0 between the peaks due to Levofolinate and to impurity H (reference solution (a))	7.2
Peak Area	The sum of the areas of the 2 peaks is 100 per cent. The peak area of impurity H is 48 per cent to 52 per cent. In the chromatogram obtained with reference solution (b) 2 clearly visible peaks are obtained.	51.5%

For details of monograph, please check pharmacopoeia.