Analysis of Related Substances in Cefcapene Pivoxil Hydrochloride by SEC

The Japanese Pharmacopoeia (15th Edition) defines two purity test methods using HPLC for the quality control of cefcapene pivoxil hydrochloride, a cephem antibiotic. It is prescribed for the treatment of urinary tract infections.

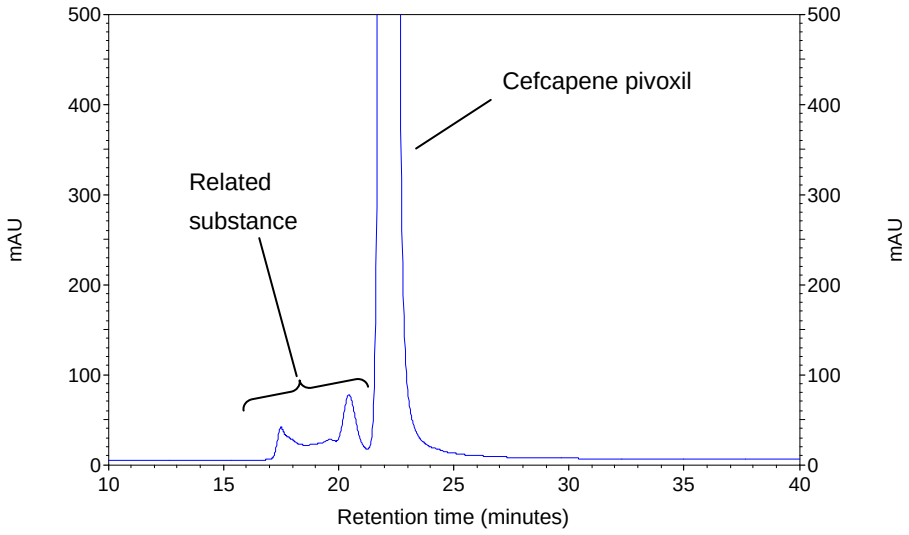
The first is a method for determining related substances (polymer impurities) in the formulation by size exclusion chromatography using a column packed with a styrene-divinylbenzene copolymer gel. Shown below is an application chromatogram of the antibiotic on a TSKgel G2000H_{HR} column using size exclusion chromatography with an organic solvent (GPC). It is clear that the polymer impurities are well separated from cefcapene pivoxil hydrochloride and it is thus possible to confirm the purity of the formulation.

Tosoh's TSKgel G2000H_{HR} columns contain rigid polystyrene beads that are compatible in a variety of organic solvents, including DMF, which was the solvent used in this procedure. TSKgel G2000H_{HR} columns are the column of choice for testing the purity of cefcapene pivoxil hydrochloride according to the Japanese Pharmacopoeia method.

Table 1. Conditions

Column:	**TSKgel G2000H_{HR}, 5µm, 7.8mm ID x 30cm**
Mobile phase:	30mmol/L LiBr in DMF
Flow rate:	0.33mL/min Flow rate is adjusted such that cefcapene pivoxil hydrochloride retention time is approximately 22 minutes.
Detection:	UV@280nm
Temperature:	25°C
Injection vol.:	20µL

Figure 1. Chromatogram of cefcapene pivoxil hydrochloride



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