European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

European Directorate for the Quality of Medicines & HealthCare
European Pharmacopoeia (Ph. Eur.)
7, Allée Kastner CS 30026, F-67081 Strasbourg (France)
Tel. +33 (0)3 88 41 20 35 Fax. + 33 (0)3 88 41 27 71
For any questions: www.edqm.eu (HelpDesk)

Ph. Eur. Reference Standard - LEAFLET

CEFRADINE FOR PEAK IDENTIFICATION CRS batch 2

Intended use

This leaflet supplements the currently valid European Pharmacopoeia monograph(s) and/or general chapter(s) describing the suitable use of this Reference Standard.

Further information about the Reference Standards is available in the on-line catalogue currently at http://crs.edqm.eu (such as, batch validity statement and material safety data sheet).

Instruction

A chromatogram obtained with cefradine for peak identification CRS batch 2 is attached.

Until the implementation of 07/2010:0814 use cefradine for peak identification CRS batch 2 as follows:

Reference solution (d). Dissolve ►6 mg of cefradine for peak identification CRS (containing impurities C, D and E) in 1.0 ml of mobile phase A.

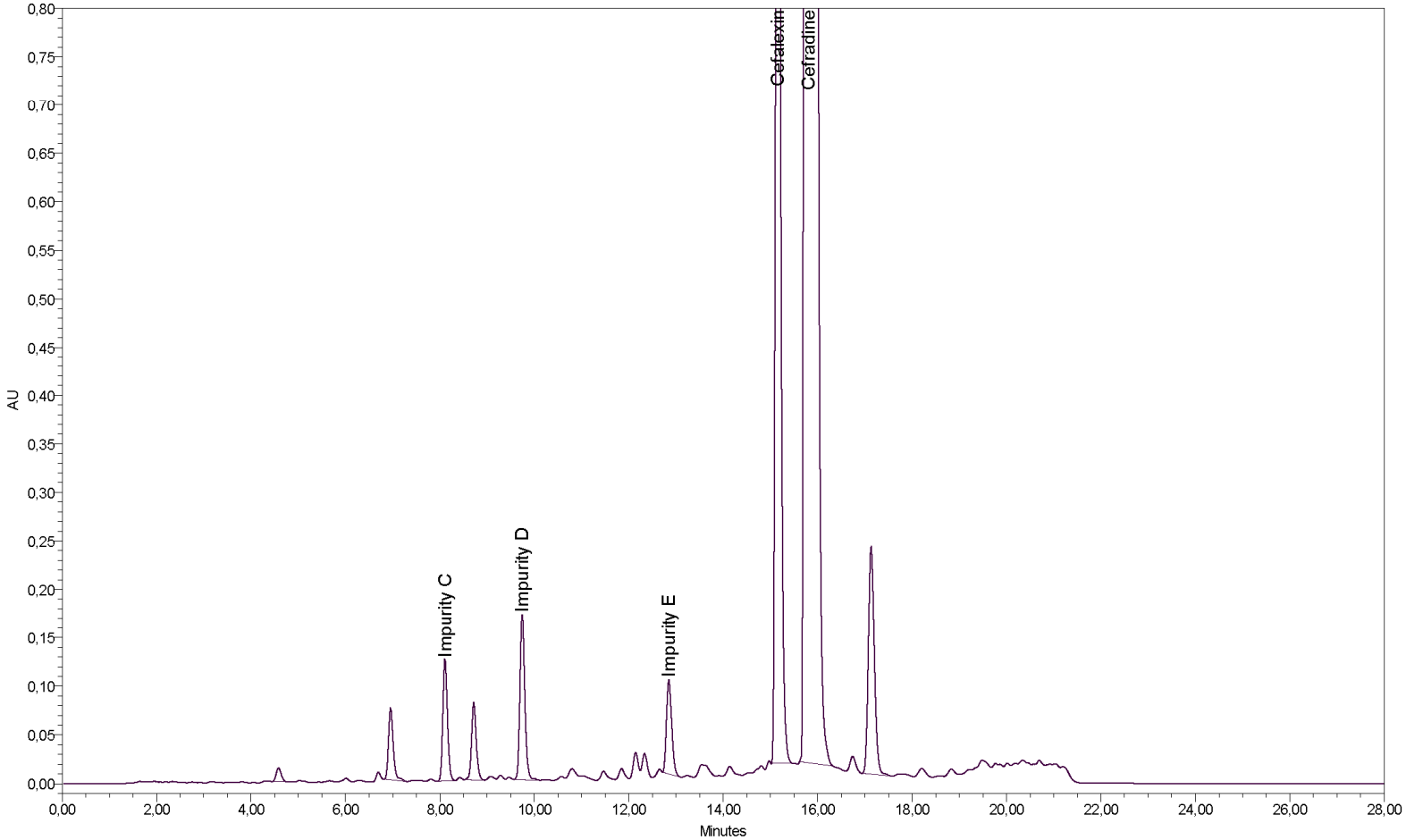
Reference solution (e). Dissolve the contents of a vial of cefradine impurity mixture CRS (impurities A and G) in 1.0 ml of mobile phase A.◄

Identification of impurities: use the chromatogram supplied with cefradine for peak identification CRS and the chromatogram obtained with reference solution (d) to identify the peaks due to impurities ►C, D and E. Use the chromatogram supplied with cefradine impurity mixture CRS and the chromatogram obtained with reference solution (e) to identify the peaks due to impurities A and G.◄

Annex

LIQUID CHROMATOGRAPHY REPORT

Cefradine for peak identification CRS batch 2



Project Name: LC06169_LC6171CefradineImpMixt

Result Id 1302