

Quality & Risk Management Section (QRMS)

To whom it may concern

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CO/jb

Note to users of:

Ph. Eur. Somatropin/desamidomatropin resolution mixture CRS (Cat. No. Y0000711)

The Ph. Eur. Somatropin/desamidomatropin resolution mixture CRS (Cat. No. Y0000711) is used to prepare the system suitability resolution solution for the test for related proteins described in the Ph. Eur. monographs 0950 (Somatropin), 0951 (Somatropin concentrated solution) and 0952 (Somatropin for injection).

In order to overcome the temporary shortage of this CRS and until the establishment of the replacement batch, it is advised to prepare the resolution solution using the Ph. Eur. Somatropin CRS batch 3 (Cat. No. S0947000) and the following procedure:

1. Reconstitute the contents of a vial of Ph. Eur. Somatropin CRS batch 3 with 1.9 ml of 0.05 M Tris-HCl buffer (pH 7.5) to obtain a solution at about 2 mg/mL. If it is intended to keep the solution for multiple uses, consider filtration through a sterile filter.
2. Cap the vial and allow the solution to stand for a minimum of 2 days at room temperature to obtain sufficient amounts of desamidomatropin so that the system suitability criteria can be assessed as prescribed in the monographs (see example chromatogram below).

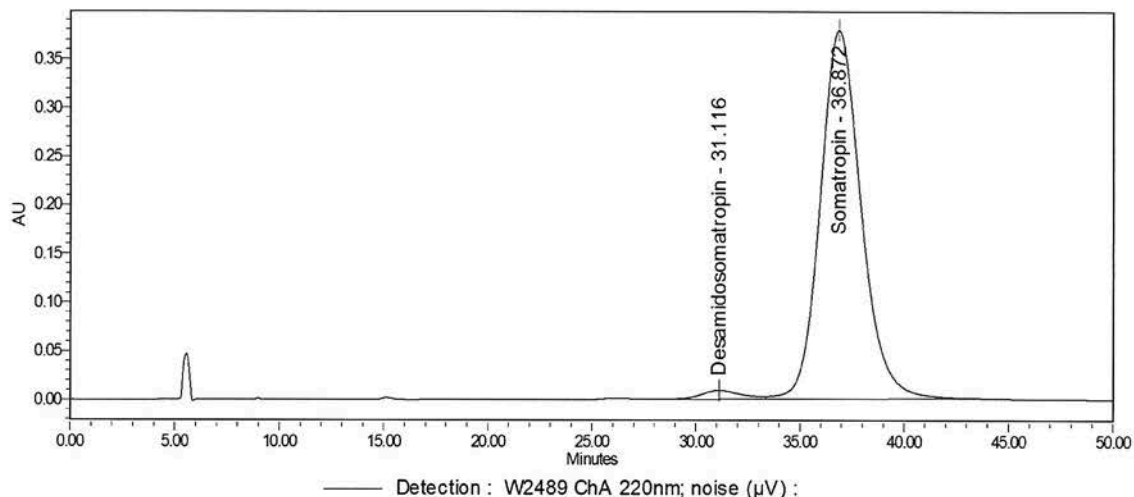


Fig.1 : Chromatogram of the Somatropin CRS batch 3, reconstituted and kept for 2 days at room temperature.

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