

SUMMARY

The validation of an analytic method, constitutes an important instrument to guarantee the quality of the medication,

Presently work was demonstrated the applicability of the analytic method proposed by the USP 26, even introducing significant changes, for the analysis of the Enalapril Maleato for cromatografía líquida de alta Performance (HPLC) in the Peru, the one which subsequently you been worth. With which settles down a documented evidence that the analytic method is able to complete in consistent and repetitive form the established specifications.

The results are presented obtained in the validation of the analytic method by cromatografía líquida de alta performance (HPLC). Previous to the beginning of the validation, one carries out a rehearsal of adaptability of the system, with which was proven the good operation of the system of pumping, injector, oven and detecting.

The method was validated, following a work methodology elaborated previously in a validation protocol, where different parameters were analyzed like they are: Selectivity, Linealidad, Precision, Accuracy, Range and the adaptation of the system.

Defined the conditions the analyses begin for the evaluation of the validation parameters and it is demonstrated by means of the experimental design and the procedures statistical employees that the Selective proposed analytic method because they are not evidenced that the degradation products interfere in the analysis of the active principle, a percentage of purity of pick of 100% is also obtained; it is lineal because one obtains a correlation coefficient $r = 0,99987$; it is he/she specifies since for the repetibilidad a RSD of 0,64% it is obtained; and for the reproducibilidad a RSD of 0,88% is obtained; and finally it is exact because one obtains a percentage of recovery of 99,88%.

Completing the established validation parameters in the official works, he/she was proven this way the validity of the analytic method.

Key words: Validation, Cromatografía, Enalapril maleato.