IMPLEMENTATION OF QUALITY CONTROL OF PEDIATRIC CYTOTOXIC DRUG PREPARATIONS: PILOT TRIAL WITH ETOPOSIDE.

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Background
Lack of quality control of cytotoxic preparations
Reduction of the security of the chemotherapy circuit.

Purpose:
Develop and to validate a fast, simple qualitative and quantitative analytical method to control the concentrations of Etoposide preparations in hospital.

Materials and methods

Chemical and reagents: Salted serum NaCl 0,9% for dilution and Etoposide
Apparatus: Spectral and absorbance measurements were made on an UV-visible spectroscopy
Working solutions: Appropriate aliquot portions of Etoposide solution (20mg/ml) were diluted in NaCl 0,9 % to obtain a calibration range covered all pediatric therapeutic concentration.
Selection of Wavelengths: Solutions were scanned in UV-visible for identification.
Assay of Etoposide in reconstituted preparation (samples):
• Ten etoposide preparations. One milliliter was withdrawn from each bag and diluted with NaCl 0,9%.
• Absorbances of solutions were measured at the maximal wavelength and calibration curve was constructed.
• Amounts of Etoposide were determined by referring to the calibration curve.
Validation of the method: The validation of the method is carried out according to guideline ICH Q2

Results
Wavelength: Absorbances of samples were measured in 283nm.
Identification qualitative: Etoposide was identified by comparing absorption spectra of the samples to reference spectra. The same spectra were observed with a wavelength of maximum absorption (283 nm).
Quantitative analysis: The proposed method has successfully estimated the amount of Etoposide.
Validation of the method:
• Linearity: Linear regression of absorbance gave equation y = 0.008x - 0.0022 with R²= 0.999.
• Precision: Relative standard deviation (RSD) was 0.56 indicating method is precise.
• Accuracy: Recovery 100,12 %, RSD: 0,312 %
Amount of samples:
• RSD: 0,714 %

Conclusion
This trial is the first in our hospital center and in our country. The method was validated and the concentrations of all simples were exactes, it can be used for routine quality control analysis of Etoposide. This trial allow us, in the future, to implement analytical control for all cytotoxic measured by UV-visible.

References