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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.

Overdose
Serious side effects

Sub-dosage
Treatement inefective

Purpose:

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

Materials and methods

Chemical and reagents: Salted serum NaCl 0,9% for dilution and Etoposide

Appartus: Spectral and absorbance measurements were made on an UV-visible spectroscopy

Working solutions: Appropriate aliquot portions of eEoposide 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 reconstitued 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 One milliliter was withdrawn from each bag and diluted with NaCl 0,9%.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 **R^2= 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 %**

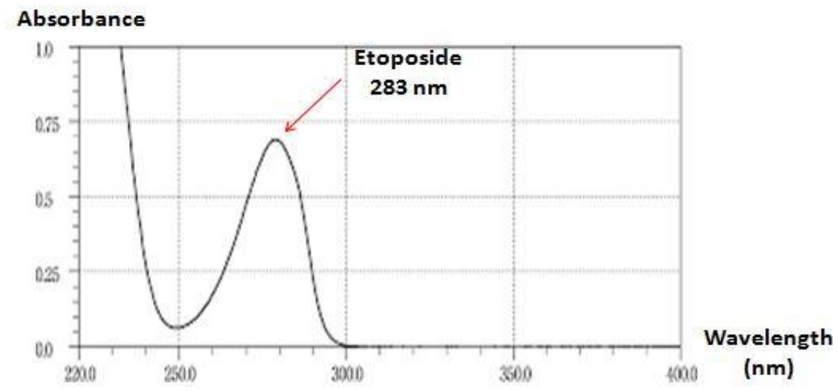

Figure 1: Spectra UV of Etoposide

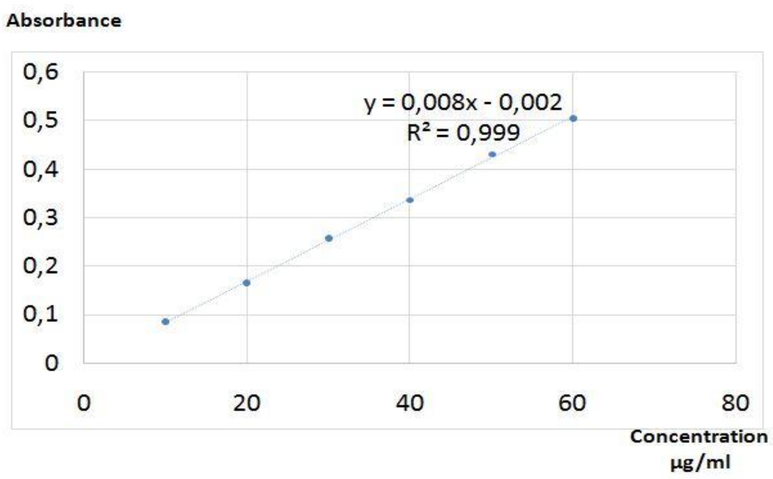

Figure 2: Calibration curve of Etoposide

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

BASUYAU. Comparaison de deux mesures physiques pour le contrôle de la dose des préparations injectables de médicaments anticancéreux avant administration: application au 5-FU. Journal de pharmacie clinique. Vol 19, Numéro 1, Mars 2000.