APPLICATION OF A MATRIX RISK TO AN APPROPRIATE COMPOUNDING PROCESS OF AFLIBERCEPT AND RANIBIZUMAB INTRAVITREAL INJECTIONS

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OBJECTIVES

To analyze risks associated with preparation of intravitreal injections (aflibercept and ranibizumab) in our pharmacy department to classify them according to their risk level.

METHODS

A risk assessment was conducted to determinate the risk level that had to be applied in the preparation of aflibercept and ranibizumab intravitreal injections.

We used two documents as a base: “Guide to good manufacturing practice for medicinal products in hospital pharmacy services”, promoted by our national Ministry of Health, and a form elaborated by Group of Pharmaceutical Compounding of our national association of hospital pharmacists to calculate in an easy and quick way the final risk level.

Six items were analyzed:
- Preparation procedure
- Route of administration
- Drug safety profile
- Number (quantity) of prepared units
- Sensitivity to microbiological contamination
- Distribution of the sterile preparation

The assessment of each one resulted in a letter which ranged from the lowest (A) to the highest (D) risk. Combination of all let us to classify every drug preparation procedure in an appropriate level. If we obtained at least a “D”, it was considered a high risk preparation; if there were a “C” or at least 3 “B” (and none “D”), it had a medium risk and if less than 3 “B” (and none “C” and “D”) were present, it was classified as a low risk preparation.

RESULTS

In the case of aflibercept and ranibizumab intravitreal injections we obtained more than one “C” (and none “D”) when matrix risk was applied and their preparation process was considered to have a medium risk level. It implies they had to be prepared at a laminar flow cabinet in a clean room and be stored in a refrigerator for 9 days.

CONCLUSION

Matrix risk application to the compounding process of aflibercept and ranibizumab intravitreal injections in our pharmacy department has allowed us to classify them according to their appropriate risk level and to check their preparation and conservation conditions.