PRACTICAL APPLICATION OF RISK ASSESSMENT IN PHARMACY PREPARATIONS BASED ON EUROPEAN RESOLUTION CM / RES AP (2011) 1

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Background
The European Resolution CM/ResAP(2011)1, by affirming the importance of medicinal products prepared in pharmacy, says that before setting up a preparation, clinical needs of the patient should be evaluated in relation to the risk associated. The resolution states that it is necessary to adopt strict protocols of preparation to ensure the quality of the product, in addition to Pharmacopoeial requirements.

Purpose
To assign numerical risk value to each preparation in order to assess risk/benefit ratio and then to apply an adequate system of quality assurance.

Materials and methods
After the recent drafting by our National Society of Compounding Pharmacists (SIFAP) of a Position Paper on risk assessment, based on the Resolution, pharmacists and technicians of our hospital pharmacy collaborated to classify preparations as low, medium-low, medium-high and high risk, by assigning the values, as tabulated in the document, for pharmacological risk, preparation process risk, risk depending on number of preparation per year. By entering the values obtained and using a defined formula by specific excel worksheet we calculated the overall risk value (VR).

\[ VR = X + (Y \times Z) \]

**X = Pharmacological risk**

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*Active Ingredient

**Y = Preparation process risk**

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**Z = Risk related to number of preparation per year**

| Under 10 preparations | 0.8 |
| From 10 to 50 preparations | 0.8 |
| From 50 to 500 preparations | 0.8 |
| Over 500 preparations | 1.5 |

Results
Ten preparations, (non-sterile, sterile, oncology IV, intrathecal, TPN), have been analyzed and classified using this method, resulting in different values. It was also noted that different formulations, with the same active molecule and therapeutic use, can generate different values. E.g., spironolactone obtained a value of 34.6 (low risk) as oral suspension versus 325 (high risk) as unit-dose oral powder. This instrument can be used to support the choice between different options of formulation, as well as a stimulus for development and improvement of quality, safety and effectiveness of drugs prepared in pharmacy.

Conclusions
The method of risk assessment proposed is very useful for the activities performed in our laboratory; however, there are some aspects which require further reflection, such as how much computerization and automation of processes or specialization of operators, related to the annual amount of products prepared, affect the overall risk value related to pharmacy preparations.