Introduction: Any type of unhealthy and out-of-conformity situation in the work environment that may offer damage to the health and physical integrity of the worker is called occupational risk. The mapping of occupational risks, as well as their severity, is intrinsically related to the work activities developed in the execution of the activities and the environment. The risks can be classified according to their characteristics: physical, chemical, biological, accidental and ergonomic, and these must be properly managed. On January 3, 2022, the new wording of the NS01 of the Ministry of Labor and Social Security came into effect, which now establishes the compulsory adoption of a Risk Management Program - RMP that must minimally identify the dangers and possible injuries or wounds; evaluate and classify the occupational risks; determine, implement, and monitor preventive measures. To meet this standardization, it was necessary to establish a risk analysis methodology that is able to evaluate the different types of risks facing the different and complex processes related to the life cycle of the pharmaceutical product (from technological development to the distribution of the finished product).

Objective: The objective of this research is to study the occupational risk analysis methodology that best fits the processes and types of risks related to pharmaceutical processes.

Methodology: The research was classified as applied and exploratory, and as to the procedures, bibliographic and documental research were adopted, as well as tabulation and comparative analysis of the several methodologies and case study in the processes of a production area, a quality control laboratory, a research laboratory, a maintenance area and ambulatory of the BM.

Results: After tabulating the various methods, analyzing them by identifying the strong and weak points and applying the tools to the pharmaceutical processes it was found that the established risk analysis models in ISO 31.010 - Risk Management - Techniques for the risk assessment process needed adaptations for applicability in the proposed program. These were adapted and, consequently, a model applied and validated in a case study was proposed.

Conclusion: The study allowed the identification of the most appropriate tool for the management of occupational risks related to the processes of the life cycle of the pharmaceutical product, allowing a more robust analysis of the risks, supporting in a more adequate way the decision making related to the OSH management system.

Keywords: HSO; Risk management; Pharmaceutical industry