



## RISK ANALYSIS IN THE PRODUCTION OF EFFERVESCENT TABLETS WITH HERBAL EXTRACTS: A CASE STUDY OF *MORUS ALBA L*

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**Relevance:** in modern conditions, there is a growing interest in drugs and biologically active additives containing plant extracts. Special attention is paid to dosage forms with high bioavailability and ease of use, which include effervescent tablets. However, the production of this dosage form involves a number of technological risks: the sensitivity of active substances to moisture and temperature, the need to comply with GMP requirements, as well as the instability of the quality of plant raw materials. In this regard, the task of analyzing the risks of the production of effervescent tablets with plant extracts is urgent.

**Purpose of the study:** to analyze the technological risks at the production stages of effervescent tablets with white mulberry extract (*Morus Alba L.*).

**Materials and methods:** the following methods were used in the work: an analytical review of scientific literature and the pharmaceutical market, methods of comparative analysis of technological schemes, risk assessment based on criteria of frequency of occurrence and degree of impact on product quality.

**Results:** the study revealed that the main critical factors in the production of effervescent tablets with herbal extracts are:

1. Moisture – hypersensitivity of *Morus Alba L.* extract. resistance to moisture leads to the destruction of active substances and a decrease in effervescence. To minimize this risk, it is necessary to use moisture-proof packaging (aluminum blisters, tubes with desiccants).
2. Temperature regime – high temperatures at the stage of drying and pressing can destroy flavonoids and vitamins. Optimization of the granulation technology and the use of mild drying modes make it possible to maintain the extract activity.
3. The quality of the raw materials – mulberry extract may have a different content of biologically active substances depending on the growing conditions. Standardization of the extract by marker substances (for example, by the content of rutin and quercetin) ensures quality stability.
4. Organoleptic properties – the extract has a specific taste, which may reduce the consumer appeal of the drug. The solution is to introduce flavors (lemon, orange) and sweeteners (aspartame, sucralose).

FMEA (Failure Mode and Effects Analysis) risk assessment showed that the highest level of risk (RPN = 180) is associated with exposure to moisture, the average level of risk (RPN = 120) is associated with fluctuations in extract quality, and the low level (RPN < 80) is associated with organoleptic characteristics.

**Conclusions:** thus, the production of effervescent tablets with *Morus Alba L* extract It requires an integrated approach, including standardization of plant raw materials, optimization of technological modes and protection of the product from moisture. The economic efficiency of the



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project confirms the feasibility of introducing these products into industrial production, and risk analysis minimizes possible technological and organizational problems.