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ФАРМАЦЕВТИЧНІ ТЕХНОЛОГІЇ, СТАНДАРТИЗАЦІЯ ТА ЗАБЕЗПЕЧЕННЯ ЯКОСТІ ЛІКАРСЬКИХ ЗАСОБІВ



Харків, 16 червня 2026

RATIONALE FOR THE DEVELOPMENT OF COMBINED ANALGESICS IN SOFTGEL CAPSULE FORM

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Introduction. An analysis of the Ukrainian pharmaceutical market for 2023–2025 shows a growth in sales of medicines in group N02 (analgesics), which rank second according to the ATC classification. This group of medicines consistently holds the second position in terms of pharmacy sales in Ukraine. This justifies the relevance of developing combined analgesics in soft capsules, which have a rapid onset of action and improved gastrointestinal tolerability.

Objective of the study – to conduct an analysis of scientific literature and a patent search on the use of combined analgesics in the form of soft capsules and, based on the review, to preliminarily determine the qualitative composition of the drug under development.

Materials and methods. Systematic-analytical, generalization, and analogy methods were used to evaluate publications and patent sources.

Results: Combined analgesics have advantages over single-component drugs: they improve compliance, reduce side effects when using lower doses of each component, and allow for a broader coverage of pain syndromes. The patent search revealed developments of soft gelatin capsules with ibuprofen, dexibuprofen, and their combinations with paracetamol or other components; however, Ukraine currently lacks a drug that combines ibuprofen and paracetamol in a soft gelatin capsule. Based on the review, a preliminary composition was formed: paracetamol and ibuprofen (active substances), polyethylene glycol-400/600 (solvent), potassium hydroxide (pH stabilizer). Also, the combination of dexibuprofen and paracetamol in a softgel capsule offers a synergistic approach to pain management, combining the effectiveness of two different mechanisms of action with an improved delivery system. Dexibuprofen is a Non-Steroidal Anti-Inflammatory Drug that inhibits Cyclooxygenase enzymes, reducing inflammation and pain at the site of injury (peripheral action). It is the active S(+)-isomer of ibuprofen, meaning it provides the same relief with a lower dose and less metabolic strain on the body. Paracetamol works primarily on the central nervous system to elevate the overall pain threshold and reduce fever. Together, they provide superior pain relief compared to taking either drug alone, often referred to as "multimodal analgesia."

Soft gelatin capsules are superior to traditional tablets for several reasons: faster absorption and improved bioavailability. The active ingredients are already in a liquid or semi-liquid state within the capsule. Once the shell dissolves, the medication is available for immediate absorption, leading to a faster onset of action. Liquids inside softgels can enhance the solubility of dexibuprofen (which is lipophilic), ensuring more of the drug enters the bloodstream effectively.

Conclusions: Considering the trends in the development of drugs in group N02, the development of a combined analgesic in the form of softgel capsule form is relevant and promising.