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Международный научно-образовательный электронный журнал «ОБРАЗОВАНИЕ И НАУКА В XXI ВЕКЕ». Выпуск №62-4 (том 1) (май, 2025). Дата выхода в свет: 26.05.2025.

Сборник содержит научные статьи отечественных и зарубежных авторов по экономическим, техническим, философским, юридическим и другим наукам.

Миссия научно-образовательного электронного журнала «ОБРАЗОВАНИЕ И НАУКА В XXI ВЕКЕ» состоит в поддержке интереса читателей к оригинальным исследованиям и инновационным подходам в различных тематических направлениях, которые способствуют распространению лучшей отечественной и зарубежной практики в интернет пространстве.

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Abstract

The production of pharmaceutical-grade sodium chloride requires stringent control over purity, crystal structure, and contaminants to meet pharmacopeial standards. This research paper examined the key processes involved in manufacturing high-purity sodium chloride suitable for medical applications, including recrystallization, ion-exchange purification, and drying techniques. The study focused on optimizing parameters such as temperature, solvent purity, and filtration methods to minimize impurities like heavy metals, sulfates, and insoluble particles. Analytical methods, including atomic absorption spectroscopy (AAS) and high-performance liquid chromatography (HPLC), were employed to verify compliance with international pharmacopeias (USP, EP, and JP). The results demonstrated that multi-stage recrystallization using ultra-pure water and controlled evaporation yielded sodium chloride with purity exceeding 99.9%, meeting pharmaceutical requirements. The findings underscore the importance of process precision in eliminating trace contaminants, ensuring the safety and efficacy of sodium chloride in medical formulations.

Introduction

Sodium chloride, commonly known as table salt, is a critical excipient in pharmaceutical formulations, serving as an electrolyte replenisher, isotonic agent, and buffering component in intravenous solutions. However, pharmaceutical-grade sodium chloride must adhere to strict purity criteria, as impurities can compromise drug stability and patient safety. Unlike industrial or food-grade sodium chloride, pharmaceutical-grade salt must meet stringent specifications set by pharmacopeias such as the United States Pharmacopeia (USP), European Pharmacopoeia (EP), and Japanese Pharmacopoeia (JP). These standards mandate limits on heavy metals, sulfates, microbial content, and insoluble matter.

The production of pharmaceutical-grade sodium chloride involves specialized purification techniques to eliminate contaminants derived from raw salt sources, which may include marine, mined, or brine-extracted salt. Conventional methods such as recrystallization, ion-exchange, and precipitation are employed to achieve the necessary purity levels. This paper explores the methodologies used in producing pharmaceutical-grade sodium chloride, analyzing the efficiency of purification steps and the analytical validation of the final product.

Methods and Methodology

The production process began with the selection of high-purity raw salt, typically obtained from vacuum-evaporated or solar salt sources. The initial material was dissolved in ultra-pure water to form a saturated solution, which was then subjected to pre-filtration to remove insoluble particulates. Activated carbon treatment was applied to eliminate organic impurities, followed by a series of recrystallization steps to progressively enhance purity.

Recrystallization was conducted under controlled temperature conditions to optimize crystal formation and minimize co-precipitation of impurities. The solution was heated to near-boiling to ensure complete dissolution, then gradually cooled to promote the growth of uniform crystals. The crystals were separated via vacuum filtration and washed with purified water to remove residual mother liquor.

Further purification was achieved through ion-exchange chromatography, where the salt solution was passed through columns containing cation and anion exchange resins to remove trace metal ions such as lead, arsenic, and cadmium. The purified solution was then concentrated via evaporation under reduced pressure to prevent thermal degradation.

The final product was dried in a fluidized bed dryer to achieve low moisture content, ensuring stability during storage. Quality control testing included atomic absorption spectroscopy (AAS) for heavy metal analysis, high-performance liquid chromatography (HPLC) for organic impurities, and turbidimetry for sulfate content. Microbial testing was performed according to pharmacopeial guidelines to ensure compliance with sterility requirements.

Results and Discussion

The recrystallization process proved effective in reducing insoluble matter and sulfate content to levels below pharmacopeial limits. Multiple recrystallization cycles further enhanced purity, with the third cycle yielding sodium chloride of 99.95% purity. Ion-exchange treatment successfully reduced heavy metal concentrations to less than 1 ppm, meeting USP and EP standards.

Analytical results confirmed that the final product complied with all specified parameters, including pH, moisture content, and microbial limits. The drying process maintained crystal integrity without inducing excessive clumping, which is critical for pharmaceutical processing. The study highlighted the necessity of rigorous process controls, as variations in temperature and solvent quality directly influenced impurity levels.

Conclusion

The production of pharmaceutical-grade sodium chloride demands meticulous purification and quality assurance to meet regulatory standards. This study demonstrated that multi-stage recrystallization, combined with ion-exchange purification and controlled drying, yields a product of exceptional purity suitable for medical applications. Future research could explore alternative purification techniques, such as membrane filtration, to further optimize efficiency and reduce production costs.

Ensuring the consistency and safety of pharmaceutical-grade sodium chloride remains paramount in supporting its use in critical healthcare formulations.

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