Salts, buffers and stabilisers in pharmaceuticals

Sredstva Regionale Chemie offers inorganic salts and chemistry that comply with regulations and standards for formulations

Pharma salts are acid or base compounds of sufficient purity and quality for use in pharma composition. Buffers are solid or aqueous agents that are used to maintain an adequate PH level of a formulation. Stabilisers are used to help APIs maintain the desirable properties of the product until consumption. Many APIs are plagued with issues such as poor solubility and bio-availablity, thereby affecting the formulation. Hence, a strong need arises to address the problem faced.

Choosing the right one

The past decades have seen revolutionary changes in drug discovery and development. In search of more potent and highly specific drugs, more and more selection of highly insoluble compounds are selected. Hence, salt forms are critical to solve the problem. The selection of an appropriate salt form for a potential drug candidate is an opportunity to modulate its characteristics to improve bioavailability, stability, Manufacturability, and patient compliance. Salt forms must be chosen based on early stages of drug development, aqueous solubility, degree of crystallinity, etc.

Buffering agents such as citrates, phosphate and acetates are commonly used to ensure solubility and stability of formulations such as biotherapeutics. Recognising the importance of pKa is the first step in choosing a buffer that has a value close to middle of the range requirement. Other factors like desired temperature, purity and cost of a buffer are decisive factors as well.

Selecting a stabiliser involves practical considerations; relating to a drug such as solubility of a drug in a stabiliser solution, lipophilicity, etc. Stabiliser-related parameters involve concentration of a stabiliser that affects the adsorption efficiency, hydrophobicity, viscosity, affinity for a drug, and dispersibility, among the most common.

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"Overcoming formulation challenges is critical to bring a finished dosage into a market"

Conclusion

Developing a stable formulation is a time-consuming and expensive process. Excipient choice has typically been a trial-and-error process involving the preparation of numerous different formulation variations and placing them on accelerated stability. The need for new excipients as well as a better understanding of the existing excipients is highly desirable. Overcoming formulation challenges is critical to bring a finished dosage into a market.

Bibliography

1. SP Scientific Products. (2020, December 15). Buffer and Excipient Selection: How to Maximize Rapid Throughput Formulation Development. News-Medical. Retrieved on March 19, 2022 from https://www.news-medical.net/whitepaper/20201210/Buffer-and-Excipient-Selection-How-to-Maximize-Rapid-Throughput-Formulation-Development.aspx.
2. Bansal AK. Kumar L. Amin A. Salt Selection in Drug Development. Pharmaceutical Technology. 2008:3. March 2008. Accessed April 9, 2021
3. Stoll, V. S., Blanchard, J. S. (1990) Buffers: Principles and Practice. Methods in Enzymology. 182, 24-38

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Ethyl Acetate	Sodium Caprate	Sodium Benzoate