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STABILITY OF INSULIN: A REVIEW ON THE IMPACT OF THE STORAGE CONDITIONS

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ABSTRACT

Insulin, a life-saving hormone used in the treatment of diabetes, is exceptionally sensitive to various environmental factors. Its structural integrity and therapeutic efficacy can be significantly compromised by improper storage and handling. As a protein-based drug, insulin is susceptible to both physical and chemical degradation, which can result in reduced potency, increased immunogenicity, and potentially adverse patient outcomes. Understanding and mitigating these risks is essential for ensuring insulin remains safe and effective from the point of manufacture to patient administration. Several environmental factors influence insulin stability, with temperature being the most critical. Insulin must typically be stored between 2°C and 8°C to maintain its effectiveness. Exposure to temperatures outside this range, especially prolonged heat, can denature the protein, causing it to lose its functional conformation. Freezing insulin is equally detrimental, as it can lead to the formation of aggregates or fibrils that are not only inactive but may also provoke immune reactions. Light exposure, particularly ultraviolet (UV) light, can also induce chemical degradation through oxidation of amino acid residues, affecting the molecule's structure and activity. In addition, insulin's stability is pH-dependent; extreme pH conditions can cause hydrolysis or deamidation, altering the molecule's charge and solubility.

KEYWORDS: Insulin, Diabetes, Storage, Environmental factors.

INTRODUCTION

Insulin, a peptide hormone secreted by the beta cells of the pancreas, plays a vital role in regulating blood glucose levels. By promoting glucose uptake into cells and inhibiting hepatic glucose production, insulin maintains glucose homeostasis within a narrow physiological range. Since its groundbreaking introduction in clinical practice during the early 1920s, insulin has transformed the treatment of diabetes, becoming the primary therapy for individuals with type 1 diabetes and a widely used intervention in advanced cases of type 2 diabetes.[1]

Despite its therapeutic importance, insulin's protein-based structure makes it inherently unstable. It is highly sensitive to various external factors such as temperature, light exposure, mechanical agitation, and pH fluctuations. These factors can induce both physical and chemical degradation, potentially reducing insulin's potency, altering its pharmacokinetics, and even increasing its immunogenicity.[2] For example, exposure to high temperatures can cause protein denaturation, while freezing may lead to aggregation or precipitation. Similarly, prolonged exposure to light—especially ultraviolet radiation—can trigger oxidative reactions that compromise molecular integrity.[3]

As the global prevalence of diabetes continues to rise, the demand for insulin is expected to grow significantly.[4] This has brought renewed focus to the importance of maintaining insulin stability throughout its lifecycle—from production and distribution to patient storage and use. Ensuring proper storage conditions is especially challenging in low-resource settings and rural regions where refrigeration is unreliable or unavailable. In such environments, insulin may be exposed to temperature extremes and other stressors that degrade its quality and effectiveness.[5]

To address these challenges, there has been increasing emphasis on developing thermostable insulin formulations capable of withstanding wider temperature ranges without loss of efficacy.[6] Advances in formulation science, including the use of stabilizing excipients, protective packaging, and modified insulin analogs, have contributed to improving insulin's shelf life and resistance to degradation. Additionally, strengthening cold chain logistics,[7] educating healthcare providers and patients on proper storage practices, and implementing community-level solutions such as solar-powered fridges are critical strategies to preserve insulin stability.[8]

In conclusion, insulin stability is not only a pharmaceutical concern but a public health priority.[9] Protecting insulin from environmental degradation ensures consistent[10] therapeutic outcomes and is essential for safeguarding the lives of millions living with diabetes—especially in parts of the world where maintaining ideal storage conditions remains a daily struggle.[11]

Scope and Significance

Stability concerns not only affect the therapeutic performance of insulin but also contribute to economic losses and adverse patient outcomes.[16] Understanding the mechanisms of degradation and the influence of storage variables is vital for manufacturers, healthcare professionals, pharmacists, and patient.[17] The scope of this review encompasses insulin's degradation pathways, formulation strategies, cold chain logistics, global regulatory considerations, and innovative stabilization approach.[18]

DISCUSSION

Physicochemical Nature of Insulin and Its Stability

Profile

Insulin is a polypeptide hormone composed of two amino acid chains: the A chain with 21 residues and the B chain with 30 residues.[19] These chains are linked by two inter-chain disulfide bonds and stabilized further by one intra-chain disulfide bond within the A chain.[20] This specific configuration is essential for maintaining insulin's three-dimensional conformation,[21] which is critical for its biological activity, particularly its ability to bind to insulin receptors and exert its glucose-lowering effects.[22]

However, insulin's intricate structure makes it highly sensitive to environmental stress. It is prone to physical instability, including aggregation, fibrillation, and precipitation, especially under conditions of agitation, temperature fluctuation, or pH changes.[23] In addition to physical changes, insulin is also susceptible to chemical degradation processes such as deamidation,[24] oxidation of methionine and cysteine residues, and hydrolysis. These modifications can reduce its potency, alter pharmacodynamics, and potentially trigger immunogenic responses.[26] Therefore, preserving insulin's stability is essential to ensure its safety and therapeutic effectiveness.

Factors affecting stability include:

- Temperature extremes (below 2°C and above 25°C)
- Exposure to light
- Mechanical stress (shaking, vibration)
- pH variations
- Contaminants or leachable compounds from packaging

Temperature: A Critical Determinant

Insulin is best stored at 2°C to 8°C. Temperature excursions outside this range can result in significant potency loss.

Thermal Degradation Mechanism

- Heat causes unfolding of the tertiary structure, exposing hydrophobic residues.
- This leads to aggregation, especially at >25°C.
- Freezing (<0°C) causes crystal formation that denatures the protein irreversibly.

Temperature Range	Stability Duration	Observed Degradation
2–8°C	24–30 months	Minimal
25°C	4–6 weeks	Slight potency loss
>30°C	1–2 weeks	Aggregation, denaturation
<0°C	<1 week	Irreversible loss

Photodegradation: Role of Light Exposure

Insulin is highly photosensitive. Ultraviolet and visible light can break disulfide bonds and oxidize methionine residues, leading to loss of function.

Key effects of light

- Yellowing of solution
- Potency reduction (up to 20–30% in 24 hrs of sunlight)
- Increased immunogenicity

Mechanical Agitation and Vibration

Agitation during transportation or handling leads to physical instability.[31] This includes the formation of insulin fibrils, which can block needles and cause injection-site reactions.

Common causes:

- Shaking by patients
- Transport via rough roadways
- Poor storage practices in pharmacies

Mechanical Action	Resulting Effect
Vigorous shaking	Fibrillation, aggregation
Repeated vibration	Cloudiness, potency loss
Air travel (unprotected)	Pressure-related denaturation

pH and Chemical Instability

Insulin is stable at **pH 7.0–7.8**. Outside this range:

- **Deamidation** of asparagine (Asn) to aspartic acid
- **Oxidation** of methionine and cysteine residues
- **Hydrolysis** of peptide bonds

Formulations use buffering agents like phosphate or acetate to maintain pH and ensure stability.[36]

Packaging, Formulation and Excipients

Stabilizing excipients include:

- **Phenol and m-cresol** – antimicrobial and protein stabilizers
- **Zinc** – aids in hexamer formation (stable form)
- **Glycerol** – prevents aggregation in rapid-acting insulins Modern insulin formulations also use smart packaging:
- Amber-colored vials
- Prefilled insulin pens with auto-injectors
- Temperature-monitoring labels

Regulatory Guidelines and Cold Chain Management

Global health authorities emphasize stringent storage protocols.

- **WHO** recommends 2–8°C from production to delivery.[40]
- **FDA/EMA** require real-time stability testing under ICH guidelines (Q1A–Q1E).
- **Pharmacopoeias (USP/BP/IP)** list specific handling and shelf-life data.[42]

Agency	Recommended Storage	Maximum Room Temp Exposure
WHO	2–8°C	28 days at ≤25°C
US FDA	2–8°C	28 days at ≤30°C
EMA	2–8°C	4 weeks at ≤25°C

Real-World Issues in Developing Countries

In tropical countries, especially where electricity is unreliable, insulin degradation is a major concern.

- Patients often store insulin in clay pots or underground
- Distribution chains may lack proper refrigeration
- Temperature monitoring is rarely practiced

This necessitates urgent innovation in **thermostable insulin**, low-cost **insulated containers**, and **solar-powered refrigeration.**[44]

Recent Research and Innovations

1. **Heat-stable insulin analogs**: Modified with stabilizing amino acids and excipients.
2. **Biodegradable packaging** with embedded cooling elements.[45]
3. **Mobile apps and IoT devices** to alert users of unsafe temperatures.
4. **Freeze-dried insulin**: For easier transportation in disaster relief and remote areas.

Enhancing Storage Practices at the Patient Level

Many patients, especially in resource-limited settings, are unaware of insulin's storage requirements. Educational programs must emphasize:

- **Never freezing insulin**, even during cold seasons.
- **Avoiding sunlight exposure**—especially in hot climates.
- **Using clay pots, thermos flasks, or insulated containers** when refrigerators are unavailable.
- Keeping insulin away from kitchen stoves, car dashboards, or window sills.[49]

Improving Cold Chain Infrastructure

Cold chain management must be robust from **manufacturing to patient delivery**.

Suggestions include:

- Solar-powered refrigerators in rural clinics
- Thermal sensors and smart packaging that alert when the temperature goes beyond the threshold [50]
- WHO-prequalified cold boxes and transport containers
- Government or NGO-led programs to distribute insulated insulin storage kits

Regulatory and Quality Control Improvements

Regulatory bodies can play a key role in stability assurance by:

- Requiring **real-time and accelerated stability testing** under ICH **Q1A–Q1E guidelines**[55]
- Making **temperature logging mandatory** during storage and transportation.
- Incentivizing manufacturers to invest in **thermostable formulation.**

Formulation and Technological Innovations

Pharmaceutical research should focus on:

- Creating **insulin analogs with heat-tolerant structures**.
- Developing **powdered insulin formulations** reconstituted just before injection.
- Exploring **nanoparticle carriers and PEGylation** for protection against degradation.
- Investing in **auto-injector pens** with inbuilt thermal indicators.[60]

Digital and Remote Monitoring Solutions

Modern technology can bridge cold chain gaps:

- Mobile applications for patients to log storage temperature and get alerts.
- IoT-enabled transport crates that transmit real-time data to logistics teams.
- QR-code scanning on vials to confirm batch integrity and last scanned temperature.[61]

CONCLUSION

Insulin is more than a medication—it is a lifeline for millions of individuals living with diabetes worldwide. As the cornerstone of diabetes management, particularly for type 1 diabetes and many advanced cases of type 2 diabetes, insulin's therapeutic value is unquestionable. However, its inherent physicochemical instability presents significant challenges that go beyond scientific formulation. Addressing these challenges requires coordinated, sustained efforts from scientists, healthcare professionals, policymakers, and patients alike.

This review has explored the complex degradation pathways of insulin, which include physical changes like aggregation and precipitation, as well as chemical processes such as deamidation, oxidation, and hydrolysis. These degradative processes are often accelerated by external factors, including elevated temperatures, exposure to light, agitation, and fluctuations in pH. Improper handling during transport, storage, or patient use can reduce insulin's potency, alter its pharmacological properties, and compromise patient outcomes.

Although pharmaceutical advancements have led to the development of more stable insulin analogs, convenient delivery systems, and extended shelf lives, the responsibility of ensuring insulin's stability does not rest solely on manufacturers. It is a shared obligation that extends to every stakeholder across the insulin supply chain. In particular, addressing the practical challenges of cold chain logistics—especially in low- and middle-income countries where refrigeration may be unreliable or unavailable—is of critical importance. Failure to maintain appropriate storage conditions can lead to significant medication wastage and inconsistent therapeutic efficacy.

Moving forward, embracing innovation will be key to overcoming these challenges. Research into thermostable insulin formulations, improved packaging technologies, and solar-powered refrigeration units can enhance insulin's stability in diverse settings. Meanwhile, strengthening public health infrastructure and implementing clear policies for insulin storage and distribution can help ensure consistent quality from factory to bedside.

Equally important is the role of grassroots education. Patients and caregivers must be empowered with practical knowledge about how to properly store and handle insulin. Community health workers, pharmacists, and clinicians all play a role in this educational effort.

In conclusion, improving insulin stability is not simply a technical issue—it is a matter of global health equity. A comprehensive approach that integrates formulation science, public health policy, technological innovation, and community education can dramatically improve insulin outcomes, reduce preventable waste, and most importantly, ensure that every dose of insulin administered is safe, effective, and life-sustaining.

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