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Photostability Study of Biopharmaceutical Products

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ABSTRACT:

The photostability studies are carried out to demonstrate that the appropriate light exposure does not result in unacceptable changes in dosage forms photodegradation may be observed as blenching or as discoloration of products. The other effects include cloudy appearance of a product, a loss in activity of biomolecules or viscosity, precipitation of active principles, and alteration in critical quality attributes (CQA) of products. However, many drugs are found to decompose when exposed to light. This study envisaged the evaluation of the photostability of selected biomolecule formulations, namely Lysozyme 1mg tablet and Lysozyme powder for oral solution 1mg/mL. A samples shall be exposed to light providing an overall illumination of not less than 1.2 million Lux hours and an integrated near ultraviolet energy of not less than 200 watt hours/square meter. The findings of this study indicate that Lysozyme powder for oral solution at 1mg/mL, packaged in an aluminum pouch, shows no significant quality changes, while Lysozyme 1mg Tablets in Alu-Alu blister packs offer superior protection against photodegradation, maintaining lysozyme activity and moisture content better than PVC/PVDC blister packs.

Keywords: Photostability of biomolecules and Lysozyme

1 INTRODUCTION:

The importance of photostability testing within the pharmaceutical industry is well established, and numerous papers have sought to clarify, as well as improve upon, existing regulatory guidance. [1] The field of pharmaceutical industry has garnered focus due to the necessity for experimental design and data analysis that aid in different manufacturing, packaging, and testing processes to maintain product integrity. As indicated in existing literature, a notably underexplored area is the comprehension of photostability testing required for the safe administration of photosensitive pharmaceutical products.[4] The antibiotic has created a lot of medical miracles and made a lot of diseases disappear, for instance, pneumonia, meningitis, puerperal fever, septicemia, tuberculosis, etc. Today in the 21st century, the development of drug-resistant bacteria makes people shocked. So-called drug-resistance bacteria is the resisting of the medicine produced by a bacterium.[3] After the bacterium kept in touch with the medicine many times, the bacterium showed a low susceptibility to the medicine. The recombinant human lysozyme is a well-known bacteriolytic enzyme whose name is 1,4-β-N-lysozyme or peptidoglycan N-acetyl muramyl hydrolase. It hydrolyzes β-1,4 glycoside bonds between N-acetylmuramic acid and N-acetylglucosamine in the peptidoglycan of the bacterial cell wall. Because of its bactericidal activity, lysozyme has been of interest as an anti-virus, anti-tumor anti-inflammation and immunological regulation agent in medicine.[9] Stabilization of protein/enzymes during storage is important as maintaining their native structure represents a critical challenge in protein formulation. The selected biomolecule lysozyme is stable at -20°C with retention of maximum antibacterial activity. Lysozyme is often regarded as a potential help to overcome the problem of traditional antibiotic resistant bacterial infections. This interest explains the extensive research of lysozyme modifications to improve the applications in medicine, veterinary, crop production, feed, and food preservation. [9] The enzymes are quite stable in aqueous solutions for short periods but the pharmaceutical product must have adequate stability over storage periods of several months or years. The stabilization of lysozyme through complexation offers a promising solution to overcome temperature sensitivity. The present invention has developed a Lysozyme complex which is difficult to administer in dosage form. Researchers overcome this disadvantage by making a drug delivery system comprising an oral tablet or reconstitutable powder composition for an oral liquid formulation which is easy to administer, more patient compliant, offers immediate effects, and has high physical stability and longer shelf life. [7] Photostability deals with the effect of light on stability of pharmaceutical products. Light can influence the active principle in a drug formulation as well as final product or package. [2] In this manner, photostability deals with the effect of light (photons) on stability of pharmaceutical substances.[2,5]

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2. MATERIALS AND METHODS

2.1.1. Materials of Lysozyme powder for oral solution 1mg/mL

Lysozyme (3X crystal) Egg white (Muramidase) HSN 35079099 from Sisco Research Laboratories pvt Ltd. Micrococcus lysodeikticus ATCC No.4698 from Sigma-Aldrich, Sodium phosphate (monobasic) from Merck Ltd. Sucrose was purchased from M.B. Sugar and pharmaceutical Ltd and polyvinylpyrollidone (PVK K-30) was purchased from BASF Ltd. Tutti-Frutti Flavor from Firmenich. Photostability chamber manufactured by Newtronics, Water was deionized and double distilled.

2.1.2 Methods of Lysozyme powder for oral solution 1mg/mL

To perform a photostability study on Lysozyme powder for oral solution 1mg/1mL to assess stability on exposure to UV and cool white fluorescent light. The drug products photo-stability testing sample should be exposed to both the cool white fluorescent and near-ultraviolet lamp. A sample shall be exposed to light providing an overall illumination of not less than 1.2 million Lux hours and an integrated near ultraviolet energy of not less than 200 watt hours/square meter to allow direct comparisons to be made with the drug product. The Lysozyme powder for oral solution pouch/sachet makes the sample pack into two sets. One set shall be wrapped with Aluminum foil and considered as a **Control sample** and other set shall be kept open and considered as an **Exposed sample**. Both these sets shall be exposed to UV light and Fluorescent light in a photostability chamber as per figure 1. After the completion of illumination of 1.2 million lux hours and integrated near ultraviolet energy of 200 Watt hours/square meter, samples shall be analyzed for Lysozyme activity, pH, and water content.[8,12]

Diagram of Sample Exposure:

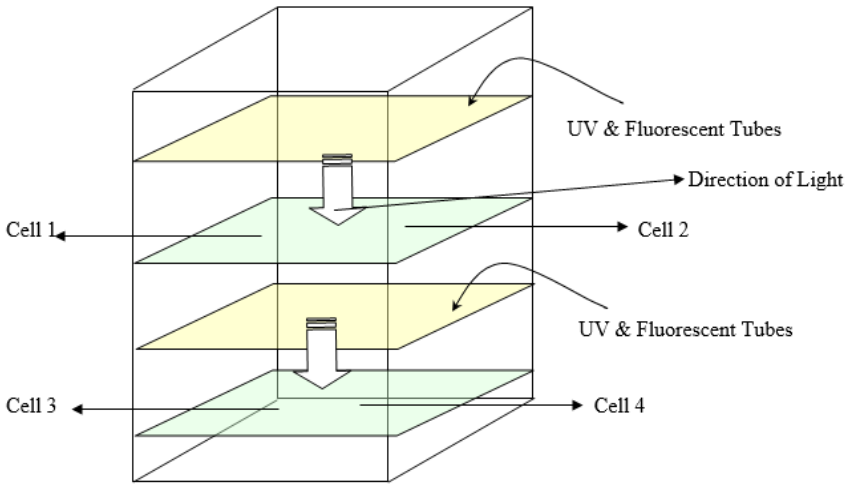

Figure 1 : UV and Fluorescent Tubes direct exposure to Sample Tray.

2.2.1 Materials of Lysozyme 1mg Tablet

Lysozyme (3X crystal) Egg white (Muramidase) HSN 35079099 from Sisco Research Laboratories pvt Ltd. Micrococcus lysodeikticus ATCC No.4698 from Sigma-Aldrich, Sodium phosphate (monobasic) from Merck Ltd. Sucrose was purchased from M.B. Sugar and pharmaceutical Ltd and polyvinylpyrollidone (PVK K-30) was purchased from BASF Ltd. Lactose monohydrate (Pharmatose DCL-11) was purchased from DFE, sodium starch glycolate purchased from JRS, Colloidal Silicon dioxide (Aerosil-200) purchased from Evonik and Magnesium stearate (Ligamed) purchased from peter greven. Photostability chamber manufactured by Newtronics. Water was deionized and double distilled.

2.2.2 Methods of Lysozyme 1mg Tablet

To perform a photostability study on Lysozyme 1mg Tablet to assess stability on exposure to UV and cool white fluorescent light. The drug products' Photo-stability testing sample should be exposed to both the cool white fluorescent and near-ultraviolet lamp. The sample shall be exposed to light providing an overall illumination of not less than 1.2 million Lux hours and an integrated near ultraviolet energy of not less than 200 watt hours/square meter to allow direct comparisons to be made with the drug product. The Lysozyme 1mg tablets are packed in Alu-Alu and PVC/PVDC blister and the sample packets are into two sets. One set shall be

wrapped with Aluminum foil and considered as a **Control sample** and other set shall be kept open and considered as an **Exposed sample**. Both these sets shall be exposed to UV light and Fluorescent light in a photostability chamber as per figure 1. After the completion of illumination of 1.2 million lux hours and integrated near ultraviolet energy of 200 Watt hours/square meter, samples shall be analyzed for Lysozyme activity and water content. [8,12]

3. RESULT AND DISCUSSION

3.1 Photostability of Lysozyme powder for oral solution 1mg/mL

The photostability of Lysozyme powder for oral solution 1mg/mL was performed according to ICH Q1B guidance. The samples were exposed 1.2 million lux hours of light using light sources such as cool white fluorescent and near ultraviolet lamps.

The results are presented in below Table No.1

Table 1 Photostability study of B.No. LU/SPMP/01/03

Samples	**pH**	**Lysozyme activity**	**Water content**
	3.5-6.5	Not less than 80%	Not more than 6.0%
Control Samples	4.41	96.2	3.52
Exposed Samples	5.13	94.7	4.43

The results of this study indicate that no significant change is observed in the quality of a product during this study and parameters comply with specifications over the studied period hence, the drug product can be considered as photostable.

3.2 Photostability of Lysozyme 1mg tablet

The photostability of Lysozyme 1mg tablet was performed according to ICH Q1B guidance. The samples were exposed to 1.2 million lux hours of light using light sources such as cool white fluorescent and near ultraviolet lamps. The results are presented in below Table 2.

Table 2 Photostability study of B.No. LT/1/09-23/03

Samples	**Packs**	**Lysozyme activity (%)**	**Water content (%)**
		Not less than 80%	**Not more than 6.0%**
Control Samples	PVC/PVDC	96.4	3.54
Exposed Samples		63.6	4.12
Control Samples	Alu-Alu	97.1	3.71
Exposed Samples		90.4	3.92

A photostability study was conducted on Lysozyme 1mg tablets packed in Alu-Alu and PVC/PVDC blister packs. The results demonstrated that Alu-Alu packs provided superior protection against photodegradation, maintaining lysozyme activity and water content. It can be attributed to an inherent property of the materials. Alu-Alu packs opacity (ʊ = 0.5-1.0) effectively blocked ultraviolet and visible light, thereby preventing photodegradation of lysozyme 1mg tablet. Moreover, Alu-Alu packs excellent barrier properties characterized by water vapor transmission rate (WVTR) of ≤ 0.05g/m2/day and an oxygen transmission rate (OTR) of ≤ 0.05mL/m2/day, further minimized the risk of degradation. In contrast PVC/PVDC packs transparency (ʊ = 0.1-0.5) and higher permeability (WVTR = 0.5-1.5g/m2/day and OTR =0.5-1.5mL/m2/day) increased exposure of lysozyme 1mg tablet to light, moisture and oxygen thereby loss of lysozyme activity.

The results of this study indicate that Alu-Alu packs provide better protection against photodegradation by maintaining lysozyme activity and water content. Therefore, Alu-Alu packs are recommended for packaging Lysozyme 1mg tablet to ensure their stability and potency.

4. CONCLUSION

The photostability evaluation and the photostability testing of the biomolecules products are an important part of the formulation studies, providing information on their intrinsic photostability characteristics and enabling the development of stable, safe, and effective products. Although photostability testing per ICH Q1B has been in place for more than a decade, there remains a clear gap for photostability testing aimed at ensuring the safety and efficacy of pharmaceutical products while they are being used by the patient. From the results of the present study, it was concluded that Lysozyme powder for oral solution packed in aluminium pouch and Lysozyme Tablet packed in Alu-Alu blister have photostable. The knowledge of the photostability of drugs and their mode of degradation helps to guide the formulator in the assessment of the product and thus make modifications necessary to prolong its shelf life under the proposed storage conditions. The objective of these studies is to ensure product quality along with all of the necessary attributes during their storage and use.

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