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# Study of Stability and Expiration Date of Intralin Powder in Bottles 0.5 and 1.0 G

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## Abstract

The study of antibiotics as a potential drug, in addition in order to develop effective methods for assessing quality in preclinical stage includes the establishment of stability and expiry date. This study regulatory requirement is necessary to establish the time during which the substance remains unchanged physical, chemical, biological properties, i.e. suitable to all requirements of regulatory documentation. Justification of the established expiry date of the substance is included in the section of the registration dossier on the methods of quality assessment. The purpose of this study is to establish the expectancy duration and stability of the antibiotics of the cephalosparin group of a number produced by ?Jurabek Laboratories? JV LLC.

***Index terms***— stability, intralin, accelerated aging, IR spectrum, UV spectrum, HPLC.

## 1 Introduction

tability (sustainability) is a factor in the quality of medicines. The criterion for the stability of a medicinal substance is the preservation of its quality, i.e. appearance, solubility, authenticity, good quality and quantitative content. The decrease in the quantitative content of the pharmacologically active substance in the drug confirms its instability. The decrease in the quantitative content of the drug by 10% should not occur within 3-4 years in the finished dosage forms.

To increase stability, chemical processes occurring during storage of drugs are investigated and methods are created to inhibit these processes. The solution of these problems is possible only on the basis of the development of methods for analyzing medicinal substances in the presence of their decomposition products. The results of these studies are taken into account when developing the technology of obtaining drugs and ND.

Products of organic synthesis make up a significant part of the arsenal of medicines of modern medicine. Despite the significant number of drugs used in medical practice, the search for more effective and safe ones is constantly underway. Largely, this refers to groups of drugs used to treat inflammatory processes caused by bacterial microflora [1,2].

## 2 II.

## 3 Material and Methods

Material of the study is the substance ”Intralin” -(cefazolin sodium salt/5-thia-1-azabicyclo [4.2.0] octa-2-Author ? ? ? ?: Tashkent Pharmaceutical Institute, Tashkent, Uzbekistan. e-mail: author.uzb@mail.ru en-2-carboxy, 3-[[(5-methyl-1,3,4-thiadiazole-2-yl) thio] methyl]-8-oxo-7-[[(1H-tetrazole-1-yl) acetyl] amino]-, sodium salt (?Y-trans)-) 0.5 or 1,0 g, powder for the preparation of injection solutions released by JV ”Jurabek Laboratories” LLC.

The experiments were carried out on 3 series of antibiotics obtained in the laboratory by the methods. All samples of antibiotics were pre-analyzed in accordance with the requirements of the FS project developed by the author. In determining the expiration dates, they were guided by the requirements of the Global Fund XI and the Interim Instruction I-42-2-82. According to these documents, the establishment of stability is possible using

the following methods: ? Test under long-term storage conditions; ? Testing under conditions of "accelerated aging" according to the Interim Instruction I 42-2-82. The method of "accelerated aging", based on the law of van't Hoff, establishes the relationship between the shelf life of the substance and storage temperature?? = ?? ?????????? 10

??? ? ?????? 10 Where, experimental substance series: t? is the temperature of experimental storage. t xp -storage temperature.

Investigations were carried out on 3 series of cefazolin substance (040113, 070113, 100113) at an experimental storage temperature of 60 º?. Samples were placed in vials of 0.5 or 1.0 g of the drug from a glass tube of the type FO-1-15 or 00-1-20 according to TU 64-2-10-87 or imported in accordance with ISO 8362-1 and ISO 8362-4, hermetically sealed with stoppers of rubber stamps I-51ili 52-599 / 1, or IR-119po TU 38.006108-90 or imported according to ISO 8362-2, compressed with aluminum caps of type K-2, as per ISO 6462-686 or imported according to ISO 8362-6. Quality control was carried out at time intervals (11.5 days), equivalent to 6 months of storage in natural conditions according to the indicators given in table 1 [4,5]. The results of the experiment (Table 2) showed that the cefazolin substance remains stable for 69 days of experimental storage, which corresponds to 1104 days of storage under natural conditions, calculated according to the van't-Hoff rule: compliance rate. Hence, the shelf life, which is 3 years. Storage temperature, which allows to ensure the established shelf life is:

The maximum allowable storage temperature is: Thus, as a result of the studies conducted by the method of "accelerated aging", the shelf life and temperature storage of the cefazolin substance has been established. Thus, a preliminary shelf life of 3 years can be established. The study of the stability of cefazolin was also carried out by the method of long-term storage. For this, cefazolin series 151210, 171210, and 201210 were stored in dry and dark place that ground-glass jars with ground glass stoppers at room temperature. Quality control was carried out on the main indicators, at intervals equal to 1 year of storage. Studies (tab. 3) showed that the stability of the substance cefazolin in long-term storage conditions is maintained for at least 3 years. III.

# 4 Conclusion

1. It was found that the stability and shelf life of the investigated drug, established by the method of "accelerated aging" at a temperature of 60 °C, is not less than 3 years, and the storage temperature is from 20 to 26 °C. 2. It is established that the substance of cefazolin in the conditions of long-term storage at room temperature in a dark place is not less than 3 years.

**1**

| Indicators | Methods | Standard |
|---|---|---|
| Description | Visual | Powder white or almost white, very hygroscopic |
| Solubility | Visual | Easily soluble in water, very little soluble in 96% alcohol |
| | Infrared spectrometry | 1. IR absorption spectrum of drug sample obtained in disks with potassium bromide (about 2 mg of the drug in 200 mg of potassium bromide) from 4000 to 450 cm "should correspond to the spectrum of<br><br>the RSO cefazolin sodium salt (about 2 mg of the RSO cefazolin |
| Authenticity | | sodium salt in 200 mg of potassium bromide). |

*[Note: UV Spectrophotometer2. The ultraviolet absorption spectrum of the solution in the region from 220 to 350 nm should have an absorption maximum at a wavelength of 272+2 nm. Chemical reactions 3. The drug gives a characteristic reaction to sodium. Quantitative content HPCL From 850 to 1050 mcg, calculated on the dry matter]*

Figure 1: Table 1 :

**2**

| Series | Life expectancy, in days | Description | IR-spectrum | Authenticity UV spectrum | Characteristic reaction to sodium | Quantitative content, % |
|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| | 0 | White or almost white crystalline odorless powder; | The spectrum RSO cefazolin corresponds to the spectrum of | Maximum at 272+2 nm. | Yellow precipitate | 99,9 |
| | 11,5 | -// - | -// - | -// - | -// - | 99,85 |
| 040123 | 23 | -// - | -// - | -// - | -// - | 99,86 |
| | 34,5 | -// - | -// - | -// - | -// - | 99,84 |
| | 46 | -// - | -// - | -// - | -// - | 99,96 |
| | 57,5 | -// - | -// - | -// - | -// - | 99,75 |
| | 69 | -// - | -// - | -// - | -// - | 99,71 |
| | 0 | White or almost white crystalline odorless powder; | The spectrum cefazolin RSO corresponds to the spectrum of | Maximum at 272 + 2 nm. | Yellow precipitate | 99,95 |
| | 11,5 | -// - | -// - | -// - | -// - | 99,97 |
| 070123 | 23 | -// - | -// - | -// - | -// - | 99,85 |
| | 34,5 | -// - | -// - | -// - | -// - | 99,84 |
| | 46 | -// - | -// - | -// - | -// - | 99,85 |
| | 57,5 | -// - | -// - | -// - | -// - | 99,72 |
| | 69 | -// - | -// - | -// - | -// - | 99,70 |
| | 0 | White or almost white crystalline odorless powder; | The spectrum cefazolin RSO corresponds to the spectrum of | Maximum at 272+2 nm. | Yellow precipitate | 99,90 |
| 100123 | 11,5 | -// - | -// - | -// - | -// - | 99,85 |
| | 23 | -// - | -// - | -// - | -// - | 99,82 |
| | 34,5 | -// - | -// - | -// - | -// - | 99,91 |
| | 46 | -// - | -// - | -// - | -// - | 99,93 |
| | 57,5 | -// - | -// - | -// - | -// - | 99,75 |
| | 69 | -// - | -// - | -// - | -// - | 99,72 |

Figure 2: Table 2 :

**3**

| Series | Expiry date, in years | Description | IR spectrum | Authenticity UF spectrum | characteristicreaction-tosodium | Quantitative content, % |
|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| | | White or almost white crystalline powder; | The spectrum corresponds to the spectrum of | Maximum at 272+2 nm. | Yellow precipitate | 99,40 |
| 151210 | | odorless | cefazolin RSO | | | |
| | 1 | -// - | -// - | -// - | -// - | 99,81 |
| | 2 | -// - | -// - | -// - | -// - | 99,79 |
| | 3 | -// - | -// - | -// - | -// - | 99,72 |
| | 0 | White or almost white crystalline powder; | The spectrum corresponds to the spectrum of | Maximum at 272+2 nm. | Yellow precipitate | 99,81 |
| 171210 | | odorless | cefazolin RSO | | | |
| | 1 | -// - | -// - | -// - | -// - | 99,78 |
| | 2 | -// - | -// - | -// - | -// - | 99,73 |
| | 3 | -// - | -// - | -// - | -// - | 99,69 |
| | 0 | White or almost white crystalline powder; | The spectrum corresponds to the spectrum of | Maximum at 272+2 nm. | Yellow precipitate | 99,87 |
| 201210 | | without smell | cefazolin RSO | | | |
| | 1 | -// - | -// - | -// - | -// - | 99,81 |
| | 2 | -// - | -// - | -// - | -// - | 99,78 |
| | 3 | -// - | -// - | -// - | -// - | 99,75 |

Figure 3: Table 3 :

[Rudakova] *About the recommendations of the WHO for the study of the stability of the reproduced pharmaceutical products. Farmateka, ? 1/96*, I P Rudakova . p. .

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