Determining of the Shelf-Life and Storage Conditions for an Antimicrobial Foam Cleanser

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Key words: foam cleanser; stability; microbiological purity; shelf-life; storage conditions

The stability of the antimicrobial foam cleanser for children developed in a polyethylene terephthalate container has been experimentally proven according to the following criteria: appearance, colour, odour, foam number, foam stability, pH value, the mass fraction of chlorides, microbiological purity, the mass content in the container. For a more objective and thorough analysis of the behaviour of the product during its shelf-life, as well as for comparative estimation of the quality of its laboratory and pilot scale batches kineastic viscosity has been additionally evaluated. When developing a foam cleanser gel with the complex antibacterial properties were used; they are regulated by the following normative documents – general specifications “Cosmetics for skin and hair cleaning”, specifications “Cosmetics for skin care and skin cleansers” and the research of microbiological contamination of the foam cleaning product developed. The requirements for microbiological safety of the foam cleanser gel with the complex antibacterial action have been determined according to the State Sanitary Regulations and Standards and specifications “Cosmetics for skin cleaning” developed by the scientists of NUPh. The modern formulation developed has been approved in the regional SES in Odessa and the hygienic conclusion for a new foam cleaning product for skin and hair cleaning for children has been received. The data obtained allow to set an optimum shelf-life of the product and it is 2 years at room temperature. Currently, the antimicrobial foam cleanser for children developed is produced by the pharmaceutical research centre “Beauty alliance”, Kyiv.

With the help of the complex research the composition and technology of a foam cleanser for children on the basis of modern surfactants have been developed. Shelf-life is an important indicator of the quality of any product. When developing the composition of a new product the shelf-life is determined experimentally by assessing the indicators specified in the corresponding normative documents (SPHU – the State Pharmacopoeia of Ukraine, DSTU – National Standards of Ukraine, TC – technical conditions, SOU – Standard of Ukrainian Companies), namely consumer, physical and chemical, microbiological and other indicators [2, 4, 12-15].

For more objective and thorough analysis of the behaviour of the product developed within the expiration date, as well as for comparative assessment of the quality of its laboratory and experimental industrial batches some indicators are additionally estimated, for example, the kinematic viscosity [3, 14]. In Ukraine when developing parapharmaceutical products the methods of determination of indicators and their characteristics (limit values) are used; they are regulated by the following normative documents: general technical conditions DSTU 4315:2004 “Cosmetics for skin and hair cleaning”, TC U 24.5-31240335-002:2007 “Cosmetics for skin care and skin cleansers” or technical conditions developed directly by the manufacturer.

Experimental Part

As objects of research the samples of a foam cleanser gel with the complex antibacterial properties were used. To determine the expiration date the gels were laid for storage in polyethylene terephthalate vials (TC U 25.2-19046619-012:2007) with the content of 250 ml with a dosing device (TC U 25363020-01-98) at the temperatures of (8-15)°С and (15-25)°С. The study of stability of the foam cleanser gel was performed on five batches of each product.

The aim of this work was to generalize the results of organoleptic, physical and chemical properties and microbiological purity of the product developed such as appearance, organoleptic characteristics (colour, odour), determination of the pH value, the mass fraction of chlorides, the foam-forming ability (the foam number, foam stability), the average weight of content of the pack and its tightness [1, 2, 4, 6]. The mass fraction of chlorides was determined by the method of GOST 26878 [6]. For quality evaluation of modern foam cleansers these indicators were included in TC U 24.5-31640335-002:2007 “Cosmetics for skin care and skin cleansers” developed by the pharmaceutical research centre “Beauty alliance”, Kyiv approved in the regional SES in Odessa (the hygienic conclusion of the state sanitary-hygienic enterprise No. 05.03.02-07/120201 from 06.12.2012 was received) and the State enterprise “Odessa Regional Centre for Standardization, Metrology and Certification”. The rheological properties of the foam cleanser gel were additionally determined using the method described in GOST 33-82 “Oil products. Methods of determination of the kinematic viscosity and calculation of the dynamic viscosity” [3].

Results and Discussion

Stability of one batch of the foam cleanser gels developed was evaluated immediately after preparation...
and every 6 months for 2.5 years of storage by the indicators presented in Tab. 1 (according to TC.U 24.5-31640335-002:2007).

As it is seen from Tab. 2, the experimental samples did not change the parameters under research according to the indicators studied for 2 years and 3 months at two temperature modes (in a cold place and at room temperature). The results of the study of stability of other four batches tested of each product developed were identical.

Appearance was assessed visually. Gel is a homogeneous jelly-like mass without any foreign impurities; there was precipitation or delamination within 15 months. Colour and odour corresponded to the standard. It has been experimentally proven that the pH value (10% solution) was stable for all batches of samples of foam cleanser gels. Its value was within the required range of 5.3-5.6, over the estimated period of storage (2 years). All samples of foam cleanser gels were stable.

The research conducted has shown that the foam number remains within 60.0-75.0, the foam stability is 0.85, the kinematic viscosity is not above 8000 mm²/sec.

It has been proven that the mass fraction of chlorides is also in the range of 2.9-3.1 within 2 years according to the specifications.

Thus, according to the physical and chemical indicators studied (Tab. 1) the product developed meets the requirements of TC U 24.5-31640335-002:2007.

The mass content of the foam cleanser product in a container was observed during the whole period of storage. It has been noted that all the samples had stable values, neither dried out nor delaminated.

It is known that the microbiological control is one of the most important indicators of quality when studying foam cleaning products. They must have a high microbiological purity in a humid environment (bathroom) for a specified expiration date. The main source of mic-

| Indicator                  | Characteristics and standards                  | Methods of control  |
|----------------------------|------------------------------------------------|---------------------|
| Appearance                 | homogenous gel-like mass                       | DSTU 5009           |
| Colour                     | corresponds to the colour of the raw material used | DSTU 5009           |
| Odour                      | corresponds to odour of the fragrances used     | DSTU 5009           |
| pH                         | 3.5-7.0                                        | GOST 29188.2        |
| Foaming capacity not less than: |                                             |                     |
| - foam number, mm           | 75.0                                           | GOST 22567.1        |
| - foam stability, standard units | 0.85                                         |                     |
| Mass fraction of chlorides, % | 5.5                                           | GOST 26878          |
| Kinematic viscosity not less than mm²/sec | 8000.0 .                                   | GOST 33-82          |
| Container content, g        | 260±12.0                                       | GOST 1770           |

| Table 1                     | The physical and chemical properties of the foam cleanser gel under research                                             |
|-----------------------------|--------------------------------------------------------------------------------------------------------------------------|
| Appearance                  | homogenous gel-like mass                                                                                                  |
| Colour                      | corresponds to the colour of the raw material used                                                                       |
| Odour                       | corresponds to odour of the fragrances used                                                                               |
| pH                          | 5.5±0.1                                                                    | 77.0±10.0            | 0.85       | 1.8±0.2  | 2.20       | 260±1.5    |
| Foaming capacity not less than: |                                                                     |                        |            |          |            |            |
| - foam number, mm           | 5.5±0.1                                                                    | 77.0±10.0            | 0.85       | 1.7±0.2  | 2.20       | 260±1.5    |
| - foam stability, standard units | 5.5±0.1                                                                 | 77.0±10.0            | 0.85       | 1.7±0.2  | 2.20       | 260±1.5    |
| Mass fraction of chlorides, % | 5.5±0.1                                                                    | 77.0±10.0            | 0.85       | 1.7±0.2  | 2.20       | 260±1.5    |
| Kinematic viscosity not less than mm²/sec | 5.5±0.1                                                                 | 77.0±10.0            | 0.85       | 1.7±0.2  | 2.20       | 260±1.5    |
| Container content, g        | 260±12.0                                                                   |                        |            |          |            |            |

| Table 2                     | The physical and chemical properties of the foam cleanser gel under research                                             |
|-----------------------------|--------------------------------------------------------------------------------------------------------------------------|
| shelf-life, months          | appearance | colour | odour | pH 10% solution | foaming capacity not less than: | mass fraction of chlorides, % | kinematic viscosity not less than mm²/sec | container content, g |
| start                        | homogenous gel-like mass | corresponds to the colour of the raw material used | corresponds to odour of the fragrances used | 5.5±0.1 | 77.0±10.0 | 0.85 | 1.8±0.2 | 2.20 | 260±1.5    |
| 3                            | -//-       | -//- | -//- | 5.5±0.1 | 77.0±10.0 | 0.85 | 1.7±0.2 | 2.20 | 260±1.5    |
| 6                            | -//-       | -//- | -//- | 5.5±0.1 | 78.0±10.0 | 0.85 | 1.7±0.2 | 2.20 | 260±1.5    |
| 9                            | -//-       | -//- | -//- | 5.5±0.1 | 77.0±10.0 | 0.87 | 1.7±0.2 | 2.20 | 260±1.5    |
| 12                           | -//-       | -//- | -//- | 5.5±0.1 | 78.0±10.0 | 0.86 | 1.7±0.2 | 2.20 | 260±1.5    |
| 15                           | -//-       | -//- | -//- | 5.5±0.1 | 78.0±10.0 | 0.85 | 1.9±0.1 | 2.20 | 260±1.5    |
| 18                           | -//-       | -//- | -//- | 5.5±0.1 | 77.0±10.0 | 0.85 | 1.8±0.2 | 2.20 | 260±1.5    |
| 21                           | -//-       | -//- | -//- | 5.5±0.1 | 78.0±10.0 | 0.85 | 1.8±0.2 | 2.20 | 260±1.5    |
| 24                           | -//-       | -//- | -//- | 5.5±0.1 | 78.0±10.0 | 0.86 | 1.7±0.2 | 2.20 | 260±1.5    |
| 27                           | -//-       | -//- | -//- | 5.5±0.1 | 78.0±10.0 | 0.86 | 1.7±0.2 | 2.20 | 260±1.5    |

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robial contamination of cosmetic products is the raw material, namely extracts and thickeners that are excipients. Water as a solvent is also a favourable medium for development of microorganisms. Despite the fact that microbes in viscous media are growing significantly slower than in the liquid ones, they can survive for a long time in the cosmetic product itself and multiply in it. The long-term use of cosmetic products contaminated by microorganisms may lead to the secondary outbreaks of infection and cause severe diseases. Cosmetic products may contain a variety of microorganisms, which penetrate in the process of preparation, – the primary contamination [1, 5, 7-11, 17].

The microbiological contamination level of the foam cleanser developed within 27 months was studied with the periodicity of every 6 months according to the indicators presented in Tab. 3.

Indicators and safety standards for products of perfumery and cosmetic industry are set by the State Sanitary Regulations and Standards 2.2.9.027-99 “Sanitary rules and safety norms for products of perfumery and cosmetics industry” [1] and the technical conditions according to which the requirements for microbiological safety parameters of the foam cleanser gel with the complex antibacterial action have been determined. The results of the periodic control of microbiological purity of the gel developed are presented in Table 4.

The data obtained have proven that during the long-term storage (27 months) at room temperature the foam cleanser developed in the polyethylene terephthalate containers with a plastic dosing device did not contain conditionally pathogenic microflora and is microbiologically pure. These data allowed to get the hygienic conclusion on the cleanser for children skin care No. 05.02-06/37542 in the regional SES of Odessa. It gives permission for production and use of this product on the territory of Ukraine.

CONCLUSIONS

1. The stability of the foam cleanser gel developed has been studied at room temperature and in a cool place within 27 months according to the following indicators: appearance, colour, odour, the mass fraction of chlorides foam number, foam stability, pH value of 10% solution, kinematic viscosity, the mass content in the container, microbiological purity.

2. It has been proven that the foam cleanser for children developed meets the requirements listed in the TC U 24.5-31640335-002:2007 “Cosmetics for skin cleaning” developed by the pharmaceutical research centre “Beauty alliance”, Kyiv and the scientists of NUPh.

3. On the basis of the research conducted it has been proven that the foam cleanser for children is recommended to store in polyethylene terephthalate vials with a plastic dosing device at room temperature for 24 months.

4. The formulation developed has been approved in the regional SES of Odessa and the hygienic conclusion for a new foam cleaning product for skin and hair cleaning for children has been received. It gives permission for production and use of this product on the territory of Ukraine.

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ВИЗНАЧЕННЯ ТЕРМІНІВ ПРИДАТНОСТІ ТА УМОВ ЗБЕРІГАННЯ АНТИМІКРОБНОГО ПІНОМИЙНОГО ЗАСОБУ

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Ключові слова: піномийний засіб; стабільність; мікробіологічна чистота; термін придатності; умови збереження

Експериментально доведена стабільність розробленого антимікробного дитячого піномийного засобу у поліетилентетрафталатовій тарі за наступними показниками: зовнішній вигляд, колір, запах, пінне число, стійкість піни, рН, масова частка хлоридів, мікробна чистота, маса вмісту засобу у флаконі. Для більш об'єктивного та ретельного аналізу поведінки розробленого засобу протягом терміну придатності, а також для порівняння результатів використання продукції, виконано контроль або аналіз середовища при збереженні засобу.

Проведені дослідження рівня мікробіологічного забруднення розробленого піномийного гелю з комплексної антибактеріальної дією відповідно до ДСанПіН і Технічних умов, розроблених виробником у співпраці з ученими НФаУ. Розроблену сучасну рецептуру затверджено в обласній СЕС м. Одеси, отримав гігієнічний висновок на дитячий піномийний засіб для очищення шкіри та волосся.

Отримані дані дозволили встановити оптимальний термін збереження розробленого засобу –
ОПРЕДЕЛЕНИЕ СРОКА ГОДНОСТИ И УСЛОВИЙ ХРАНЕНИЯ АНТИМИКРОБНОГО ПЕНОМОЮЩЕГО СРЕДСТВА
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Ключевые слова: пеномоеющее средство; стабильность; микробиологическая чистота; срок годности; условия хранения

Экспериментально доказана стабильность разработанного антимикробного детского пеномоеющего средства в полиэтилентерефталатовой таре по следующим показателям: внешний вид, цвет, запах, пенное число, стойкость пены, значение рН, массовая доля хлоридов, микробная чистота, масса содержимого во флаконе. Для более объективного и тщательного анализа поведения разработанного средства в течение срока годности, а также для сравнительной оценки качества лабораторных и опытно-промышленных серий дополнительно оценивали значение кинематической вязкости. При разработке пеномоеющего средства использованы методики определения этих показателей и их характеристики (границы значений), которые регламентируются следующими нормативными документами: Загальні технічні умови «Косметичні засоби для очищення шкіри та волосся», Технические условия. «Засоби косметичні для догляду та очищення поверхні шкіри» и Проведенные исследования уровня микробиологического загрязнения разработанного пеномоеющего средства. Установлены требования к микробиологическим показателям безопасности разработанного пеномоеющего геля с комплексным антибактериальным действием соответственно ДСанПіН и Техническим условиям, которые были разработаны совместно с учеными НФаУ, «Засоби для догляду та очищення поверхні шкіри». Разработанная современная рецептура утверждена в областном СЭС г. Одессы, получено гигиеническое заключение на новое детское пеномоеющее средство для очищения кожи и волос. Полученные данные позволили установить оптимальный срок годности разработанного средства – 2 года при комнатной температуре. В данное время разработанное детское антимикробное пеномоеющее средство выпускается фармацевтическим научно-исследовательским центром «Альянс красоты», г. Киев.