буферний розчин pH 2,2 : Ацетонітрил (43 : 57), швидкість рухомої фази - 2 мл/хв, температура термостату колонки – 30 °С, довжина хвилі – 214 нм. Об'єм інжекції – 5 мкл). Було перевірено лінійність методики у діапазоні 8 – 240 мкг/мл, що охоплює діапазон застосування для усіх досліджуваних найменувати лікарських засобів. Також доведено, що методика не чутлива до незначних змін умов хроматографування (швидкість потоку ± 0,1 мл/хв, Температура хроматографічної колонки ± 5 °С, зменшення об'єму інжекції). Оцінку робасності правильності та прецизійності методики проводили для кожного з найменувань досліджуваних лікарських засобів в характерному для кожного з найменувань діапазоні, можливість використання оптимізованої методики доведено. На основі отриманих результатів складено алгоритм дій як при проведенні уніфікацій аналітичних методик так і при проведенні розробки методів контролю допоміжної речовини, для якої розроблено уніфіковану методику.

Висновки

Розроблено альтернативну методику контролю бензалконію хлориду у 26 найменуваннях рідких лікарських засобів. Розроблена методика дозволяє скоротити час контролю до 5 разів та економить понад 3 місяці безперервної роботи хроматографу;

Складено алгоритм дій при проведенні уніфікації методик, що полягає в наступному: Узагальнення наявної інформації про лікарські засоби → Вибір найбільш перспективної для доопрацювання методики / уніфікація підготовки стандартного зразку → Перевірка специфічності для усіх об'єктів контролю → Перевірка лінійності методики у діапазоні, достатньому для усіх об'єктів контролю → Проведення валідації методики для усіх об'єктів контролю → Внесення змін та впровадження у рутинну роботу.

MARKETING RESEARCHES OF THE COUNTRIES-MANUFACTURERS PREPARATIONS OF HYALURONIC ACID

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Introduction

According to the studies that were conducted by Grand View Research, Inc., it is expected that the global market for hyaluronic acid will reach USD 15.4 billion by 2025. Such factors as aging that influences on the skin, internal organs, including the joints and desire to obtain fast and visible results in a shorter time, promote the rapid development of the market of hyaluronic acid.

A lot of people suffer because of the disease of musculoskeletal system apparatus that leads to the question — as it to treat, and what it depends on. The majority of experts converge on the opinion that most joint problems can be solved with the help of hyaluronic acid. The increasing of obesity, which leads to osteoarthritis and joint pain have increased the demand for hyaluronic acid injections for the treatment.

The market is developing rapidly in connection with the increased acceptance of aesthetic procedures in developed regions. Cosmetic surgeries are booming with approximately 14 million invasive procedures are performed annually. In 2013 hyaluronan facial fillers which are used in correction measures have received FDA approval. Efficient and obvious results of fillers for skin regeneration based on hyaluronic acid is the basis for the development of this segment.

Increases of the using of hyaluronic acid in cardiovascular implants such as stents and vascular grafts and the compatibility with preparations for anti-aging. New opportunities for the using of hyaluronic acid in the field of tissue engineering and regenerative medicine will present the market with lucrative future growth opportunities.

Hyaluronic acid is a promising molecule recently proposed for diseases of the upper respiratory tract, for example, for the treatment of acute rhinopharyngitis by inhalation with hyaluronic acid.

Thus, in the world there are many reasons for the growth of the market of preparations that contain hyaluronic acid.

Aim of research

The aim of the work is marketing research on the countries-manufacturers of preparations hyaluronic acid in the pharmaceutical market of Ukraine.

Materials and methods

Were used marketing and statistical methods of research from electronic and paper sources of the information. The object of the work was the information about registered medicines and medical-cosmetic products in Ukraine containing hyaluronic acid, at the period 2016-2017.

Results

According to the State register of medicines in Ukraine (2017 yar) the range of hyaluronic acid preparations on the domestic pharmaceutical market is very limited and presents by the 7th producing countries. Ukraine and Korea (produced in Korea, packaging in Ukraine) produces 3 denominations representing 24 %. Ukrainian pharmaceutical company produces 2 preparations with a full production cycle and covers 16% of the market preparations of hyaluronic acid. Also Italy and Germany registered for 2 medicines and occupy 16%. Such countries like Japan, Hungary and Ireland supply by 1 preparation on the domestic market which accounted for 8 % respectively.

Medication with hyaluronic acid presented in various dosage forms. Because the active studying of the unique properties of synovial fluid - viscosity (ability to absorb low-frequency mechanical stress) and elasticity (the absorption and distribution of high-frequency and weight of loads) has established a clear correlation between preservation of the mechanical properties of synovial fluid and molecular weight and concentration of hyaluronic acid. Therefore, the most effective is the use of hyaluronic acid as part of preparations in the form of solutions for injection. Among them are 56% of injection solutions for internally-articular application.

Ophthalmic segment comprises eye drops which amounted by 8%.

Such pharmaceutical form as a gel with a unique formula of zinc hyaluronate is a key element of the modern treatment of wounds. Thus, among the 5 types of medical forms, gels with salt of hyaluronic acid for external application in tubes make up 8%.

A special medical form is a solution for inhalation using in polymer containers. Hyaluronic acid, besides moisturizing and repairing effects prevents adhesion of antigens (allergens and microorganisms) on mucous membrane which has a preventive effect in such diseases, such as allergic rhinitis. The number of such medical forms is also 8% of all items.

The next stage was a study on the appointment of drugs with hyaluronic acid and use for treatment in different directions.

It is established that the most active hyaluronic acid is used for the treatment of diseases of the musculoskeletal traumatic changes of the cartilages and joints, arthrosis, arthritis, synovitis, osteoarthritis. These medicines will not just s a substitute for synovial fluid, but restore the synthesis of high molecular weight of hyaluronic acid, similar to normal, the sinoviocites of the joints affected by chronic degenerative or inflammatory process. Distribution by mechanism of action in such diseases is 40% of the range of products with hyaluronic acid.

The using of injections of hyaluronic acid (during operations to treat cataracts, the installation of corneal transplants, surgery for glaucoma) and eye drops in ophthalmology is 32%.

A part of preparations for the treatment of upper respiratory tract is 16%, injections and gels for the treatment and regeneration of the skin on the domestic market are use only in 8% containing in its composition hyaluronic acid.

Conclusions

The range of products with hyaluronic acid on the domestic market is very limited during the studied period. The results of analysis of the market established in the pharmaceutical market the presence of products of domestic producers with partial and full production cycle. Also the market presents preparations of manufacturers from Italy, Germany, Japan, Hungary and Ireland.

It is established that the most active hyaluronic acid is used for the treatment of diseases of the musculoskeletal system. he analysis of literary sources showed that the most effective is the using of hyaluronic acid in the composition of the preparations in the form of solutions for injection for internally-articular application.

As part of the global trend of hyaluronic acid market growth, it is expedient to introduce drugs from domestic producers on the pharmaceutical market.

THE SEARCH OF A STANDART SAMPLE FOR QUALIFICATION OF THE DIFFERENTIAL SCANNING CALORIMETRYMETHOD FOR THE TASK OF CERTIFICATION OF PHARMACEUTICAL STANDART SAMPLES

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Introduction. As a rule, the value assignment of the content (X_{RS}) for the primary pharmaceutical reference standards (phRS), which are intended for the quantitative determination and are individual substances of high purity, is found by subtracting the content of impurities found from 100% (the mass balance method). In this case, the correctness of the X_{RS} value obtained, or "purity", needs to be confirmed by an independent method ("alternative" or "orthogonal" method). Differential scanning calorimetry is one of these methods.

Differential scanning calorimetry is one of the thermo-analytical techniques. A calorimeter measures the heat into or out of a sample. A differential calorimeter measures the heat of sample relative to a reference. A differential scanning calorimeter does all of the above and heats the sample with a linear temperature ramp. Differential scanning calorimetry is a technique in which the difference in the amount of heat required to increase the temperature of a sample and reference are measured as function of temperature. Both the sample and reference are maintained at nearly the same temperature throughout the experiment. Generally, the temperature program for a Differential scanning calorimetry analysis is designed such that the sample holder temperature increases linearly as a function of time. Only a few mg of material are required to run the analysis. Differential scanning calorimetry is the most often used thermal analysis method, primarily because of its speed, simplicity, and availability. It is mostly used for quantitative analysis.

Differential scanning calorimetry is used to study phase transitions such as melting and exothermic decompositions, and glass transitions. In these experiments, molecules change from one conformation to another. It also establishes specific temperature points termed thermal transition temperatures or melting points for samples in solid, suspended or dissolved form. It is used as an industrial quality control technique as it can establish sample purity and detect the presence of impurity in a drug formulation, for instance. It gives a wealth of information regarding both the physical and energy properties of the substance.

The pharmaceutical industry needs to have drugs which have been precisely characterized for the purpose of accurately defining the parameters of production. This includes knowing at what temperature undesirable phase changes will occur, for instance, crystallization of a drug. The conditions can then be adjusted to produce the desired phase, e.g. the amorphous powder form.

Aim: In the pharmaceutical sector the standard requirements for specifications for the quality control (QC) of drugs are set in advance, and only in exceptional cases they take into account the specificity of a particular drug.

Certification of RS (CRS) involves the solution of various problems – in particular, the determination of purity (the average value is found) and the evaluation of uniformity (for destructive methods the result of a single determination with a significant heterogeneity of RS is closely related to the sample weight RS used). If in the first case the required value of uncertainty can be achieved by increasing the number of analyses, in the second case, the possibility of using the analysis method can be determined by the capabilities of the device/method of analysis. Consideration of the application of DSC for the certification of phRS based on metrological requirements for them has not been carried out yet.