Creating the new technology capsule of Amlodipine Besylate

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Создание новой технологии капсулы Амлодипин безилата

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Abstract: *nowadays, in the developed countries, cardiovascular diseases are widespread and arterial hypertension is one of the threatening diseases. Amlodipine besylate is the medicine which is used to treat arterial hypertension at different stages of the disease. Amlodipine Besylate is used in medicine as antianginal and hypotensive medical product. The antianginal and hypotensive effects of Amlodipine Besylate assist the vasodilator, balance the heart performance, diminish vasopressor reactions and it also has other features that effect the cardiovascular system. Amlodipine Besylate is used in form of 5 and 10 mg tablets and capsules in medical practice. However uzbek local pharmaceutical companies do not produce Amlodipine Besylate in form of capsules. For this, it is vital to create the technology of production Amlodipine Besylate in capsules.*

Аннотация: *в настоящее время в развитых странах сердечно-сосудистые заболевания распространены и артериальная гипертензия является одним из опасных болезней. Амлодипин бесилат - это лекарство, которое используется для лечения артериальной гипертензии на разных стадиях заболевания. Амлодипин бесилата используется в медицине в качестве антиангинального и гипотензивного лекарственного средства. Создает антиангиналный и гипотензивный эффекты. Амлодипин бесилата способен помочь сосудорасширяюще сбалансировать работу сердца. Уменьшает вазапрессорные реакции, а также имеет другие особенности, которые влияют на сердечно-сосудистую систему. Амлодипин бесилат используется в медицинский практике в форме: 5 и 10 мг таблеток и капсул. Однако узбекские местные фармацевтические компании не производят Амлодипин бесилата в капсулах.*

Keywords: *cardiovascular diseases, Amlodipine Besylate, HPLC method, HPLC pick, capsule volume.*
Ключевые слова: *сердечно-сосудистые заболевания, Амлодипин бесилат, метод ВЕЖХ, пик ВЕЖХ, объем капсулы.*

Purpose: In the future we would like to offer Amlodipine Besylate capsules production to the pharmaceutical companies. The technology of production Amlodipine Besylate in 5 mg capsules has been states as target of our paper, because this dosage is favorable in use. And create the methods of suppressive control of quality Amlodipine Besylate capsules. That is why our purpose is to check Amlodipine Besylate capsules quantity with high accuracy HPLC method.

Methods and raw materials: We have conducted our research with Amlodipine Besylate, produced by Rakshit Drugs PVT, LTD company in 2014, in India batch number 005 06 2014 AB. Saccharose, glucose, lactose, starch, calcium and magnesium stearate and other this kind of substances have been used in our research.

It is very important to study the technological characteristics of Amlodipine Besylate substance to prepare the capsule volume. And choose the capsule volume wich answers to regulations and easy to produce in the factory.

The quantity analysis of derived Amlodipine besilat capsules was checked in HPLC method. We used Agilent 1200 HPLC apparatus to check the capsules. To define Amlodipine besilat's authenticity and quantity different methods were used, for example: photocolorimeter, spectrophotometry and HPLC. In experiments to define amlodipine besilat capsules quantity HPLC method was used. We offered to use HPLC method to determine amlodipine besilat's quantitative analysis based on USP.

Results: Amlodipine Besylate substance microscopic research was carried out using the microscope produced by US Company «Bipolan» magnified 500-1000 times. Under the optic microscope the Amlodipine Besylate crystals are mainly rectangular shape and there are some amorphic crystals as well.The average length of crystals is 38.5 mkm, the average width is 15.5 mkm and the calculated form factor is 2.48.

The characteristics such as fractional content, friability, relative distribution, compaction fact, pressing were checked according to the methods in XI state pharmacopeia and other generally accepted methods. The results of Amlodipine Besylate substance technological characteristics study is in table #1.

According to the results in table #1, it can be stated that Amlodipine Besylate substance has negative technological characteristics and to produce the capsule volume it is essential to use adjuvant to maintain Amlodipine Besylate technological characteristics [1].

Table 1. The results of Amlodipine Besylate substance technological characteristics

№	Technological characteristics	Measure unit	Showing
1	Fractional content: 500 + 250 mkm 250 + 100 mkm 100 + 50 mkm 50 mkm	 % % % %	 3.31 7.28 31.36 58.05
2	Friability	Kg/h	No friability in practice
3	Relative distribution	Kg/m3	384.26
4	Compressibility	H	2.5
5	Compaction factor		6.41
6	Residual moisture	%	0.53

Based on the above mentioned, before granulation adding the adjuvant, we prepared the capsule volume and studied its technological characteristics. The adjuvant substances stated in the table and anti-friction substances were used separately or used in different combination and altogether 15 capsule volumes were created and their technological characteristics were studied before the granulation. Thus, the capsule volume friability is (0-3kg/h) and relative distribution is (270-360 kg/m^3) and the results were not satisfactory. Therefore the following studies of Amlodipine Besylate capsule volumes were conducted after the granulation. The results of the study show that the capsule volume obtained after the granulation have positive technological characteristics. According to these, such characteristics as the fraction content, friability, relative distribution were noted best [2].

The offered method - HPLC method to check the purity and quantity of amlodipine besilat proved its sensitiveness and accuracy and it matches the standards. It was also proved that the findings of the amlodipine besilat main substance purity and quantity checking match the pharmacopeia standards. The granulation process was used during the creation of amlodipine besilat capsules, which we offer. As we used the method of granulation at the creation of amlodipine besilat substance, we found that the composition was not disturbed and it was proved when we compared the quantity of amlodipine besilat substance before granulation process. In accordance with the world standard requirements, it is required to check the content uniformity if the main substance is 5 gr or less in solid medicines [3]. Accordingly, we also checked this index of amlodipine besilat capsules.

Conclusion: The positive technical characteristics of Amlodipine Besylate capsule volume after the granulation were identified and the possibility of medicine production using the capsule volumes were revealed

The HPLC method which we offered to define quantity and content uniformity of amlodipine besilat matched with the sensitiveness and accuracy requirement of pharmacopeias. Accordingly, we confirmed that amlodipine besilat active substance quantity matches pharmacopeias requirement.

The results of the conducted research shows that the following technology of the formulation was chosen to produce granulated capsule volume of Amlodipine Besylate 5 mg.

References

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