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STANDARTIZATION OF MINITABLETS WITH LORATADINE AS A NEW PEDIATRIC FORMULATION

Yeleken G.K.*, Kurmangaliyeva G.B., Ustenova G.O., Dilbarhanov R.D.
*Kaz NMU named after S.D. Asfendiyarov Almaty, Kazakhstan

Keywords:
Allergy, minitablets, loratadine, UV-spectrophotometry.

Abstract
Article presents the results of studies evaluating the quality of the developed children's dosage form for the treatment of allergy (mini tablets loratadine content). content of loratadine in mini tablets identified using uv-spectrophotometry. established concentration of active substance in mini tablets, was with in 6,66 ± 0,5 %.

Introduction

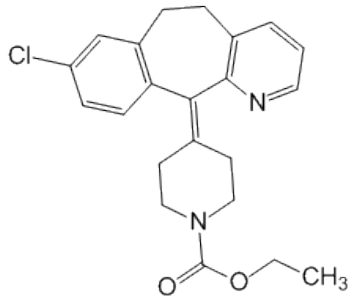
Allergy problem today - one of the most important for medicine. According to WHO, allergic reactions are found in 20% of the world population [1].According to researchers (Chukin M., 2006; Pogorelskaya S.A., 2007; Kaznacheeva L.F., 2009), despite the fact that allergic diseases known to man for more than two and a half thousand years, in the modern world problems issues related to the diagnosis, treatment and prevention of allergy, are very relevant [2].

Purpose of study

The purpose of this study is to develop a structure and standardization of children's formulation antihistamine action.To achieve this goal it is necessary to carry out the following tasks:

1. Develop composition and technology for the production of children's dosage form (DLF) antihistamine action.
2. To standardize and establish quality standards resulting formulation.

As the active substance we chose loratadine - H1-histamine receptors blocker (long acting) that inhibits the release of histamine and leukotriene C4 from mast cells[3]. Loratadine prevents the development and facilitates the allergic reactions, has antipruritic, anti-allergic, anti-exudative effect, reduces the permeability of capillaries, prevents tissue swelling, relieves spasms of smooth muscles.Anti-allergic effect develops after 30 minutes, reaching a maximum after 8-12 hours and lasts 24 hours. Loratadine has no effect on the central nervous system and is not addictive (since it does not penetrate the *blood–retinal barrier*). Molecular mass – 382,88 g/mol [4].



For the development of quality standards of the dosage form is necessary to know the physical and chemical constants of the substance, which will be developed according to the methods of standardization of the finished product.When designing not only the amount of active substances and excipients should be taken into account, but

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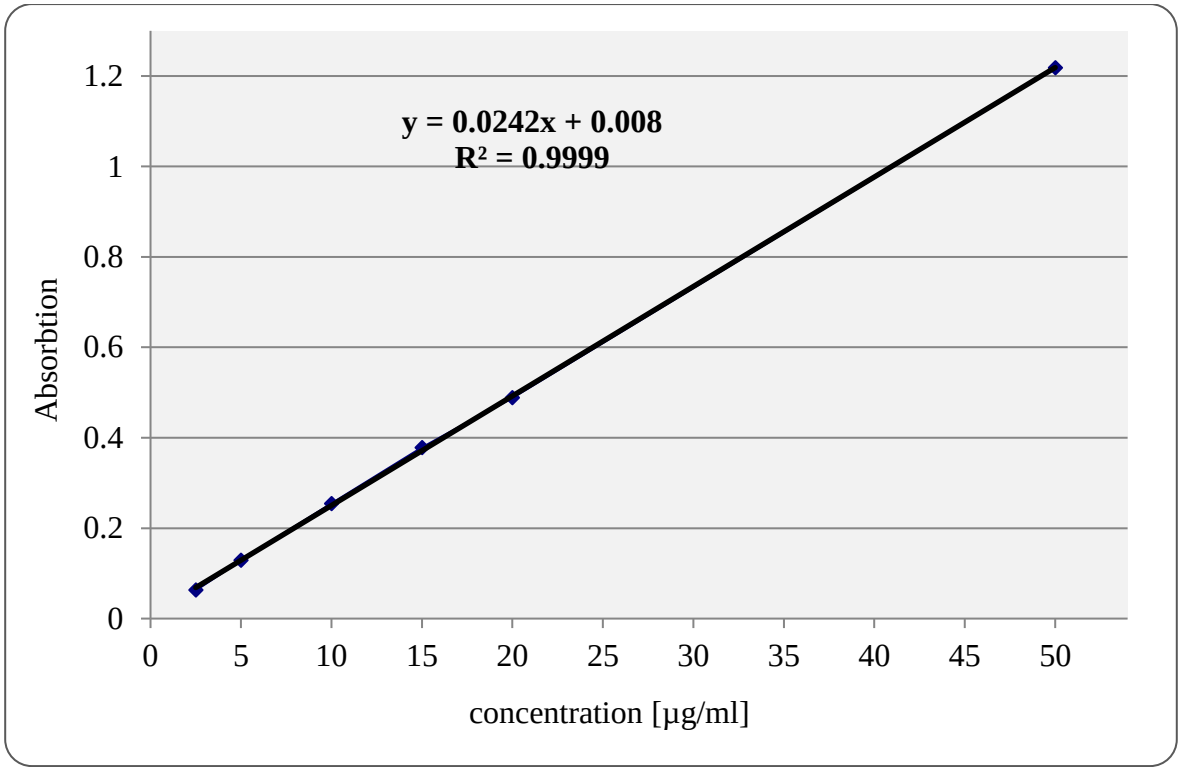
also of great importance must be technology and premises. To assess the reliability of all elements of the production cycle, as well as the detailed preparation and planning of the various phases and steps necessary to adhere to the algorithm of organization of pharmaceutical production[5].

Physical properties of loratadine are: substance of a white crystalline powder that is practically insoluble in water, easily soluble in Et-OH and 0.1 N hydrochloric acid solution.

The UV spectrum of the substance of loratadine was recorded on a spectrophotometerUV/VIS, type V-530. For this substance was weighed accurately, 0.1 g was placed in a volumetric flask of 100 ml, dissolved in a small volume Et-OH 96% and was adjusted to the mark with solvent(solutionA). From the resulting solution A 0.3 ml was taken and placed in a volumetric flask, afterwards adjusted to 25 ml with the same solvent up to the mark(solution B).Resultingsolutionwasanalyzedinrangeof 220-300 nm.As a comparison (control) 96% Et-OH was used. Results are shown in graph below.



Graph 1.UV-spectrof loratadine substance

Using spectrophotometer «UV/VIS, type V-530» Jasco, Easton, USA, we acquired loratadine specter.
To create the formulation in nearly all cases, the use of a one or other excipient required.

As excepients for minitablets formulation were chosen: microcellulose;
ВкачествевспомогательныхвеществприизготовлениимининтаблетокбыливыбраныМКЦ,
colloidal silicon dioxide, pregelatenized corn starch and lactose monohydrate.
When designing model composition mixtures, six different formulations were formed containing different excipients and loratadine concentration of 0.5 mg.Compositions of designed minitablets are presented below in the table 1.

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Table 1. Compositions.

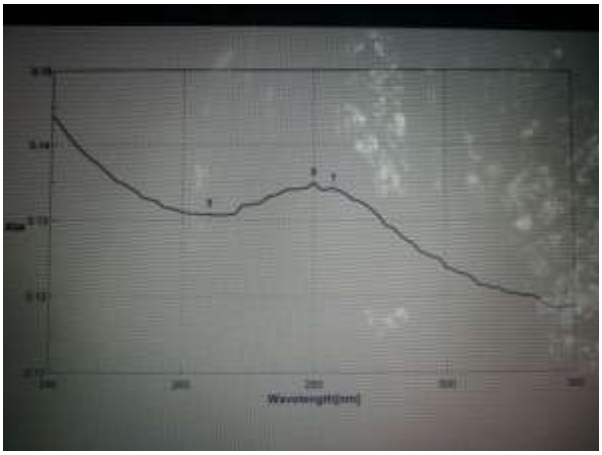
Название	**Состав, мг**
Loratadine	0,5
Flowlac 100 (Lactose monohydrate)	-
Vivapur 102 (microcellulose)	6,0
Corn starch	0,57
Ac-Di-Sol (Crosscarmelose)	0,37
Starch 1500 (Pregelatenizedstarch)	-
Magnesium stearate	0,03
Aerosil 200 (colloidal silicon dioxide)	0,03
Mass of one tablet	7,5 мг

In appearance loratadine mini tablets are white, smooth, all of the same size same size, 2 mm diameter.

Thus, upon examination of technological characteristics for six composition models, composition №5 was selected, since it showed the best results on the process parameters in the study compared to the other, and therefore, it was further tested, we identified and quantified the content of the main active ingredient.

The quantitative content of loratadine was determined by UV spectrophotometry.

The Methodology Of The Analysis Was As Follows
Sample was weighed (1 g), placed in a flat bottom flask of 100 ml and poured with solvent (96% Et-OH). Then, the resulting solution is filtered into another flask of 100 ml, and adjusted with the same solvent up to the mark. Next, an aliquot of 5 ml was taken into a 25 ml flask and adjusted to the mark with 96% Et-OH.Using spectrophotometer «UV/VIS, type V-530», the optical density was cheked in the range 220–350 nm (pic. 4). As a comparison (control) 96% Et-OH was used.



UV-specter of loratadine in formulation.

Further concentration of loratadine in the dosage form was calculated by formula1

$$x=(A_x \times C_{ct} \times W / A_{nt} \times m \times V) \times 100\ \% \qquad (1),$$

whereX concentration of substance, %; Ax – the optical density of the substance; Cct – standard solution concentration, %; W dilution;

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Act the optical density of the standard solution; m sample weight, г; V aliquotvolume, ml. The results of the quantitative determination of loratadine in the minitablete presented table.

The data obtained showed that loratadine content in minitablets is within 0,218 ± 0,02%. Thus, in study quality of dosage form was evaluated based on active substance content.

The quantitative content of the loratadineminitablets was determined by UV-spectrophotometry. Using spectrophotometer «UV/VIS, type V-530»the optical density was cheked in the range 220–350 nmand established, thatloratadine content in minitablets is within 0,218 ± 0,02%.

References

1. Борисова Е.О. Антигистаминные средства: этапы развития // Фарм. вестник. 2005. № 17 (380).
2. Camelo-Nunes I.C. New antihistamines: a critical view // J. Pediatr. (Rio J). 2006. Vol. 82, № 5 (Suppl.). P. S173-S180.
3. ГолопихоЛ.І. Лоратадин — новийантигістамінниййпрепарат // Фармацевтичнийжурнал. — 1994. № 1. С. 101-102.
4. Jutel M., Blaser K., Akdis C.A. Histamine in chronic allergic responses // J. Invest. Allergol. Clin. Immunol. 2005. Vol. 15. P. 1-8.
5. ДатхаевУ.М., УстеноваГ.О., ЖакипбековК.С., БатырбековаА.С. Қазақстанреспубликасындағыфармацевтикалықөндірістіұйымдастырудыңнегізгішаралары / Вестник Алматинского технологического университета. 2013. № 5. С. 68-70.