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TECHNOLOGY AND STANDARDIZATION OF THE “PHYTIROL” TABLETS ON BASE OF IHPA, PREPARED FROM RICE FLOUR

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ТЕХНОЛОГИЯ И СТАНДАРТИЗАЦИЯ ТАБЛЕТОК «ФИТИРОЛ»

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ABSTRACT

"Phytirol" consists of phytin and dimedrol substances mixture. Phytin is a complex organic preparation of phosphorus containing mixture of calcium and magnesium salts of different inositphosphoric acids mainly inosithexaphosphoric acid and which is broadly used in medical practice. For the first time the scientifically motivated composition and technology of the tablets has been recommended on base of the study of technological characteristics of "Phytirol" substance. It has been established that qualitative and quantitative parameters of the "Phytirol" tablets appropriate to State Pharmacopoeia of the Russian Federation XIII requirements.

АННОТАЦИЯ

«Фитирол» состоит из смеси веществ фитина и димедрола. Фитин – комплексный органический препарат фосфора, содержащий смесь кальциевых и магниевых солей различных инозитфосфорных кислот, в основном инозитгексафосфорной кислоты, широко применяемый в медицинской практике. На основе изучения технологических характеристик субстанции «Фитирол» впервые рекомендован научно обоснованный состав и технология таблеток. Установлено, что качественные и количественные показатели таблеток «Фитирол» соответствуют требованиям ГФ РФ XIII.

Keywords: technological characteristics, tablet mass, physic-mechanical parameters of the "Phytirol" tablets.

Ключевые слова: технологические характеристики, масса таблетки, физико-механические показатели таблеток «Фитирол».

"Phytirol" consists of phytin and dimedrol substances mixture. Industrial source of raw material for phytin manufacturing (production) is rice bran, from which after its preliminary fry phytin is isolated by extraction method. Phytin is a complex organic preparation of phosphorus containing mixture of calcium and magnesium salts of different inositphosphoric acids mainly inosithexaphosphoric acid and which is broadly used in medical practice [5]. Pharmacological research of "Phytirol" has shown that preparation possesses expressed antihistaminic action, low toxicity and it does not influence essentially upon behaviorox animals. This work is dedicated to development of technology and standardization of the "Phytirol" tablets.

Technological properties of substances mixture named "Phytirol" have been studied according to methods described in literature [2, 3] with the aim of scientific motivation of auxiliary substances added to composition of the tablets which are presented in tabl.1. The results have shown that tablet mass possesses non positive technological properties. This indicates that there is a need for the introduction of auxiliary substances to composition of the tablets and undertaking of the humid granulation method. Several batches of the tablets have been prepared from tablet masses containing in their composition different amount of disintegration and connecting substances for selecting of the optimum correlation between "Phytirol" and auxiliary substances. Each batch has been wet by 3, 5 and 7% starch solution to get of the optimum humid mass. The humid mass has been dried in dry closet at the temperature not more 70^0C to remain optimum moisture. Dried masses have been granulated through strainer with hole diameter 1000 mkm and powdered. The model tablets have been prepared from different granulated tablet masses on manual hydro press. Description, toughness on break and disintegration of model tablets has been tested [4, 6]. The results obtained have shown that the "Phytirol" tablets of following composition: Phytin-0,25 g, dimedrol-0,05 g, starch -0,0465 g and calcium stearat-0,0035 g (average weight of the tablets – 0,35 g) are the most optimum. The rest batches of the tablets appropriate to State Pharmacopoeia of the Russian Federation XIII requirements neither on height or on toughness or on disintegration [1]. The technological process of the "Phytirol" tablets preparation consists of the following stages: preparation of substances, missing of starch and calcium stearat through strainer (the strainer № 32, SS (State standard) 4403-77), preparation (obtaining) of tablet mass. The phytin and dimedrol has been mixed in mixer. Duration of the mix is 15-20 minutes. Then, the mass has been moistened by 5% starch solution (paste). Mass has been dried in dry closet at the temperature 60-70^0C and the dry granulation has been conducted in universal granulator. Granulated mass has been powdered in mixer by mixture of the remained amount of potato starch and calcium stearat. After studying of technological characteristics of powdered granulated mass (tabl.1) it has been pressed by means of tablet machine as tablets with average mass 0,35 g. Mass has been pressed satisfactorily, does not adhere to press form. The "Phytirol" tablets were used for analysis, prepared in production conditions in laboratory of Open join-stock Company "Uzhimfarm" ("Uzchemfarm") named after K.S. Islambekova.

Table 1.

"Phytirol" substances mixture and tablet mass technological properties study results

Name of parameters	Measurement unit	Obtained results	
		Mixture (phytin and dimedrol)	Tablet mass
Composition of fraction: - 1000 + 500 - 500 + 250 - 250 + 125 - 125	mkm	1,74 18,34 61,21 17,10 1,51	2,09 26,85 18,93 35,41 16,72
Pour ability	kg/s 10^{-3}	1,43	3,79 ±0,60
Bulk (pour) density	kg/m^3	269,0	610,0±28,80
Ability for pressing	N	67,5	80,80 ± 4,10
Coefficient of: a compaction ability for pressing	 - -	 3,20 2,30	 2,40 ±0,28 1,90 ±0,58
Remaining moisture	%	10,20	11,0 ±0,40

Tablets physic-mechanical parameters were determined on methods, described in literature [4, 6]. The results of determination are presented in tabl.2.

Table 2.

Results of determination of "Phytirol" tablets physic - mechanical (qualitative) parameters

Qualitative parameters	Measurement Unit	Analysis results
Description	-	White colour tablets with imperceptible dots, even edge
Identity	-	Appropriates
Correlation of the height to diameter	%	32,70 ± 3,06
Deviation from average mass	%	0,35 ± 2,70
Disintegration	min	7-8
oughness on: - a detrition - a break	%	 99,39 ± 0,60 74,29 ± 3,26
Dissolution, not less	75%	94,67 ± 2,64
Quantitative contents of phytin	g ± %	0,1018 ± 0,88

Data given in tabl.1 and 2 indicates that all series (batches) of the experimental tablets appropriate to the State Pharmacopoeia of the Russian Federation XIII requirements [1].

The qualitative analysis. 0,1 g powder of pulverized tablets is dissolved in 1,5 ml of nitric acid, 1 g of ammonium nitrate and 3 ml of ammonium molybdate solution is added to obtained solution; the white (precipitate) sediment falls out (the phosphates).

0,6 g powder of pulverized tablets is shaken for 3 minutes with 15 ml of water and the obtained solution is filtered through paper filter (SS (state standard) 122026-76). Filtrate (filtered solution) gives the typical reaction on chlorides [4].

The quantitative determination (Assay). The determination of phytin. Approximately 0,65 g powder (accurately weighed sample) of pulverized tablets is dissolved in 4 ml 1 mol/l solution of hydrochloric acid in measured flask with capacity 200 ml, the obtained solution is diluted with water to 120 ml, 25 ml of 5% copper sulphate solution and 10 ml of sodium acetate solution is exactly added and the volume of solution is carried to the point (mark) with water and mixed. In 5 minutes liquid is filtered through dry filter (SS (state standard) 122026-76) rejecting the first 25 ml of filtrate (filtered liquid). 100 ml of filtrate (filtered liquid) is transferred (carried) into flask with grounded stopper, 2 g of potassium iodide is added and mixed and left for 10 minutes. Iodine obtained as a result of reactions is titrated with 0,1 mol/l sodium thiosulphate solution (the indicator -a starch). Parallel control experiment is conducted.

The content of the phosphoric anhydride in one tablet in gram (X) is calculated by formula:

$$X = \frac{(V\text{-}V_0)\cdot T\cdot F\cdot 200\cdot b}{a\cdot 100}$$

where: $(V\text{-}V_0)$ - a difference between volumes of titrant expensed for titration of control (reference) and test solutions;

b - average mass of the tablet, g;

a - accurately weighed sample of preparation, g.

1 ml of 0,1 mol/l sodium thiosulphate solution corresponds to 0,00782 g of P_2O_5 which must be not less 0,0926 g in one tablet. The method is tested on 5 series (batches) of the tablets. Results of the quantitative determination of phytin are statically processed and presented in table 3.

Table 3.

Results of the quantitative determination of phytin in "Phytirol" tablets

Sample mass, g	Obtained results		Metrological feature
	G	%	
0,6500	0,1027	41,09	f =4, t (P 95, f) = 2,78
0,6501	0,1015	40,60	X = 0,1018
0,6486	0,0990	39,60	$S^2 = 0{,}3\cdot 10^5$
0,6502	0,1030	41,20	S= 0,0016
0,6484	0,1026	41,04	$S_x = 0{,}72\cdot 10^3$
			□X = 0,002
			$□X_{ўр.} = 0{,}89\cdot 10^3$
			$□_x$ % = 1,96
			$□_{□x}$ % = 0,88

Data given in tabl.3 indicate that the relative (percentage) error of the phytin quantitative determination methods at confidential probability equal to 0,95 and number of experiments equal to 5 was 0,88 % and did not exceed permissible deviation norms (rates) for the current method of the analysis.

Thereby, proposed production technology of "Phytirol" tablets provides the obtaining of finished products with good quality.

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