UDK 615.453.3:616.33-002.44:549.67 **DEVELOPMENT OF COMPOSITION AND TECHNOLOGY OF GRANULES WITH CORNSILK EXTRACT AND NATURAL ZEOLITE** *Rybachuk V.D.*

National University of Pharmacy, Kharkov, Ukraine

Introduction. Some herbalists say that Cornsilk is best used when fresh, but it is also available in dried and extracted forms. Cornsilk is a completely safe herb to use in large or frequent doses when needed. It can confidently be taken by pregnant or breastfeeding women and can be used with benefit by the young or old. Cornsilk extract has strong choleretic effect. Cornsilk can be used to help alleviate symptoms that go along with the following conditions: bedwetting, cystitis, prostatitis, urinary tract infections, kidney stones, gout and hyperglycemia. It's also a natural source of vitamin K and potassium [2]. But for us is interesting its ability to treat many gall bladder dysfunction, such as cholecystitis. It is known that one of the functions of bile is the elimination of toxins. Thus bile helps to cleanse not only the liver but also blood. Toxins getting with the bile into the intestine must be withdrawn from the body. To do this, it is advisable to combine the drugs of cholagogue action and enterosorbents. In our research we propose to combine two components Cornsilk extract and Natural Zeolite.

Zeolites are microporous crystalline solids with well-defined structures. Generally they contain silicon, aluminium and oxygen in their framework and cations, water and/or other molecules within their pores. Many occur naturally as minerals, and are extensively mined in many parts of the world. Because of their unique porous properties, zeolites are used in a variety of applications with a global market of several milliion tonnes per annum. In the western world, major uses are in petrochemical cracking, ion-exchange (water softening and purification), and in the separation and removal of gases and solvents. Other applications are in agriculture, animal husbandry, construction and medicine. They are often also referred to as molecular sieves. Large amounts of research have been done on all the possible benefits of detoxing with Zeolite and studies show that they appear to balance pH within the body, reduce allergies, act as antioxidants, and aid liver function. Zeolites also appear to help with digestion and, most importantly, they may also help remove toxic metals from the body [3].

One natural Zeolite, Clinoptilolite, was discovered to assist in removing toxic metal toxins through urination without depleting the body's store of essential electrolytes [3]. These studies are extremely encouraging, because they suggest Zeolites can help with alleviating accumulated toxic metals.

The benefits of Zeolite have been known in the medical community for many years. They have been used for blood purification, Zeolites supplements have been used to detox the body of lead and also known to fight diarrhea and harmful organisms[3].

Such new combination will help to eliminate from the body toxins together with heavy metals and radionuclides.

Objective. To develop composition and technology of granules with Cornsilk

extract and Natural Zeolite.

Methods of investigation: The test objects were granules of natural zeolite together with the Cornsilk extract obtained by wet granulation using 5%, 7% and 10% of corn and potato starch pastes.

Fractional composition of the granules was determined using a standard set of sieves with a hole diameter 2.0; 1.0; 0.5 and 0.25 mm [1]. Friability of granules was determined using friability tester Pharma Test PTF 10E / ER, Germany. To determine the bulk density of the pellets we used instrument Pharma Test PTF PT-TD200, Germany [1].

Results. First we measured properties of granules based on the mix of zeolite and cornsilk extract in the ratio 2:1. We obtained granules by wet granulation using different binders. As binders we used corn starch and potato starch in the concentrations 5%, 7% and 10% each. Dried granules analysed on a special standard set of sieves with mesh sizes 2, 1, 0.5, 0.25 mm. Obtained results in percentage are shown in table 1.

	Diameter, mm				
Binder	≤0,25	0,5-0,25	1,0-0,5	2,0-1,0	<u>≥</u> 2
	%	%	%	%	%
5% potato starch	9.5	5	55	30	0.5
7% potato starch	0.3	0.5	1	97.2	1.5
10% potato starch	0	0	1.5	97.5	1
5% corn starch	17.46	4.9	33.6	43.24	0.8
7% corn starch	0.78	0.3	2.32	95.23	1.37
10% corn starch	0.1	0.18	0.5	91.52	7.7

Particle size distribution of granules

Table 1

n=5; P=95%

From the experimental data we can see, that increasing of binder concentration leads to increasing of granule size. But the best results of homogeneity in size shows granules obtained after adding 7% of corn starch paste and 7% and 10% potato starch pastes. Pastes with less concentration give many small particles after granulation. Last fact proves that concentrations of corn starch paste and potato starch paste less than 7% are not acceptable for this composition.

The next step of our investigation was to study rheological properties of prepared granules. The obtained results are shown in table 2.

Also we carried out a comparative study of the influence of binder type and concentration on flowability of granules. The obtained results showed that flowability changes with changing concentration of binder. The slowest were granules wetted by 5% pastes and the fastest – by 10% pastes (table 3).

The last experiment was to study disintegration time of granules. The best results showed granules wetted by 7% potato starch paste.

The values of Hausner's ratio differ. The best results shown granules made with 7% and 10% pastes. The same was for the Carr's index.

Taking into account all abave menthioned we choose as a binder for

granulation 7% potato starch paste. And we propose to include in technological flowchart the folow stages: preparation of raw materials, mixing of components and wet granulation, drying of granules, dry granulation and packing.

Table 2

Rheological properties of granules

Binder	Hausner's ratio	Carr's Index
5% potato starch	1.25	20
7% potato starch	1.15	13
10% potato starch	1.16	14
5% corn starch	1.23	20
7% corn starch	1.17	15
10% corn starch	1.09	10

n=5; P=95%

Table 3

Flowability properties of granules

Substance	Flowability, g/sec		
5% potato starch	5.4		
7% potato starch	9.5		
10% potato starch	11.2		
5% corn starch	3.5		
7% corn starch	8.7		
10% corn starch	9.6		

n=5; P=95%

Summary. 1. The composition and technology of granules with Cornsilk extract and Natural Zeolite was developed.

2. The influence of different types of binders on technological characteristics of granules was studied and it was determined that potato starch in concentration 7% is the optimal for maiking granules with natural zeolite and Cornsilk extract.

3. The obtained resultes may by ussful for further development of solid dosage forms with natural zeolite and herbal extracts.

References

1. Державна фармакопея України / ДП «Науково–експертний фармакопейний центр». – 1-е вид. – Х. : РІРЕГ, 2001. – С. 160–164;

2. Brown, D. Scientists have high hopes for corn genome / D. Brown // The Washington Post. – 2009. – N39. – P.88-92;

3. Grace, W. R. Zeolite Structure / W. R. Grace // Enriching Lives Everywhere. - 2010. - N42. - P. 36-40.