ATLANTIS PRESS
Advances in Biological Sciences Research, volume 7
1st International Symposium Innovations in Life Sciences (ISILS 2019)

Classification and Systematics of Medical Clay

Alexander Bondarev
Department of Pharmaceutical Technology
Belgorod State National Research University
Belgorod, Russia
alexbond936@yandex.ru

Elena Zhilyakova
Department of Pharmaceutical Technology
Belgorod State National Research University
Belgorod, Russia
ezhilyakova@bsu.edu.ru

Nina Bondareva
Department of Pharmaceutical Technology
Belgorod State National Research University
Belgorod, Russia
alexbond936@yandex.ru

Daria Fadeeva
Department of Pharmaceutical Technology
Belgorod State National Research University
Belgorod, Russia
fadeeva@bsu.edu.ru

***Abstract*—The aim of the work is to develop classification and systematics of Medical Clays. Tasks: to conduct screening marketing study of the pharmaceutical market of medical clays in Russia and neighboring countries; to develop classification and systematics of Medical Clays with their characteristics. The materials are electronic resources *eLIBRARY*, Russian Drug Register, own research results also. The methods are analysis and classification. Results. Conducted a screening marketing study of the pharmaceutical market of Medical Clays. It was established that at present in Russia there is one pharmaceutical substance of Medical Clay "Smectite Dioctahedral"; 8 drugs based on Dioctahedral Smectite are registered: 3 of them are made on the basis of domestic substances, 1 - made in France, 1 - made in the USA, 2 - made in China. The classification and systematics of Medical Clays has been developed, according to which Medical Clays are represented by three groups that determine their sorption properties: Palygorskite, Smectite and Kaolinite Clays. The atomic structure of the main minerals of Medical Clays is composed of two units: octahedral and Silicon-Oxygen tetrahedral. Medical Clays consisting of Montmorillonite and Kaolinite minerals have two types of pores; the specific surface area is higher for clays consisting of Montmorillonite and Palygorskite minerals; the cation exchange capacity is higher for the Montmorillonite mineral. Conclusion. The classification and systematics of Medical Clays has been developed, according to which Medical Clays are represented by three groups that determine their sorption properties: Palygorskite, Smectite and Kaolinite Clays.**

Keywords*—*Medical Clay, classification, systematics, Dioctahedral Smectite, Palygorskite, Kaolinite.

I. INTRODUCTION

The classification and systematics of mineral raw materials for the production of Medical Clays, as well as the normative documentation for its standardization, are absent in modern pharmaceutical technology. The undoubted practical and scientific significance in modern technology for obtaining new substances and dosage forms is the study of these problems, generalization and their systematization.

The aim of the work is to develop a classification and systematics of Medical Clays.

Tasks: to conduct screening marketing study of the pharmaceutical market of medical clays in Russia and neighboring countries; to develop classification and systematics of Medical Clays with their characteristics.

II. EXPERIMENTAL

The materials are electronic resources *eLIBRARY*, *Russian Drug Register*, own research results also. The methods are analysis and classification.

III. RESULTS AND DISCUSSION

In the historical aspect, clay as a therapeutic agent has been used throughout the existence of mankind. Since the 20th century, clays have undergone physical and chemical studies, their therapeutic effect and practical application in pharmacy and medicine are substantiated [1-3]. The term "Medical Clays" was first used by French scientists (Jean-Marie Tria, Jean-Pierre Dubuc, Saint-Jerome Marcel, 2006). To generalize the scattered concepts that characterize clays as therapeutic agents from the point of view of pharmaceutical technology, we proposed the following definition of "Medical Clay":

Medical Clay is a medicine containing substances of mineral origin, subjected to primary processing in order to remove non-clay solids and water-soluble salts, which has adsorption activity and is intended for the manufacture of drugs with an adsorption effect.

Medical Clays are represented by a mono- or polymineral composition with a mixed porous structure. Due to different formation conditions, individual representatives of clay minerals significantly differ in the form of macro-, meso- and micropores and in the ratios of their volumes. Three types of medical clays are used in pharmaceutical practice. Medical Clays are divided into Kaolinite, Smectite and

Palygorskite (Attapulgite) depending on the mineral prevailing in their composition [4].

We conducted screening studies of the Russian pharmaceutical market of medical clays in the dynamics of 2014-2019. In 2014, one pharmaceutical substance of Medical Slay “Smectite Dioctahedral” was registered in Russia; 4 drugs were registered: 3 of them were made on the basis of a substance produced in the USA, 1 - on the basis of a substance made in France. Thus, drugs from the Smectite Group are foreign or are made on the basis of substances of foreign manufacture. Medical Clay in the form of a medicine based on Kaolin and Palygorskite is not registered on the pharmaceutical market of Russia.

Generally accepted anatomical and therapeutic and chemical classification of Medical Clays is more expanded in the countries of the European Union, the. There are present a group of highly effective enterosorbents is represented by Medical Clays: Kaolin, Diosmectite, Attapulgite and their combinations. Attapulgite-based Medical Clay has not been registered in the Russian pharmaceutical market.

The Russian nomenclature of drugs based on Dioctahedral Smectite according to 2019 data is presented in table 1.

According to the table I eight drugs based on Dioctahedral Smectite were registered in Russia according to 2019 data: 3 of them are made on the basis of domestic substances, 1 from France, 1 from the USA, 2 from China. Thus, an increase in the assortment of drugs and pharmaceutical substances based on Dioctahedral Smectite was noted.

Currently, there is a synonymous variety of mineral clay names. To harmonize them, the requirements of the International Mineralogical Association were applied. The data obtained are presented in table II.

According to the presented Mineralogical Systematics, Medical Clays are represented by three groups that determine their sorption properties:

1. Palygorskite Clay based on the mineral Palygorskite is a layered tape Silicates;

2. Smectite Clay based on the mineral Montmorillonite is a layered Silicates with an expanding structural cell;

3. Kaolin Clay based on the Kaolin mineral is a layered Silicates with a rigid structural cell.

The composition and structure of minerals of Medical Clays determine their sorption properties. Clays consisting of Montmorillonite and Kaolinite minerals have two types of pores; the specific surface area is higher for clays consisting of Montmorillonite and Palygorskite minerals; the cation exchange capacity is higher for the Montmorillonite mineral. Clay minerals have pronounced ion-exchange properties, which is due to the small particle size and high specific surface that determine their increased adsorption ability.

Of all clay minerals, Montmorillonite has the highest absorption capacity. The high sorption capacity of Montmorillonite is explained by the fact that in its crystals the exchange of ions occurs not only on the external surface, but also inside the crystal lattice in the cavities between the silicon-oxygen tetrahedral layers. Sorption processes carried out by Montmorillonites occur according to three mechanisms:

1. according to the type of substitution by cations of the exchange cationic complex located both between elementary layers and on the basal surfaces of mineral particles;

2. using hydrogen bonds in external hydroxyl groups;

3. using valence "dangling" bonds at the edges and corners, at shear steps of crystal growth of Montmorillonite. Most often, all these processes take place with the predominance of any of them.

TABLE I. NOMENCLATURE OF DRUGS BASED ON DIOCTAHEDRAL SMECTITE ACCORDING (2019)

№	Trade name of the drug	Dosage form	Manufacturer	Name of substance; Producer of substance
1	Smectite dioctahedral	powder for oral suspension	“Regana”	Dioctahedral Smectite; “Pharmstandart-Leksredstva”, “Biopharmkombinat”, Russia
2	Dioctab® Solution Tablets	dispersible tablets	“Atoll”	Dioctahedral Smectite; “Shandong Lue Pharmaceutical Co., Ltd”, China
3	Smectite dioctahedral	powder for oral suspension	YuzhPharm	Dioctahedral Smectite; “YuzhPharm”, Russia
4	Endosorb	powder for oral suspension	Obolenskoye	Dioctahedral Smectite; “Shandong Xianle Pharmaceutical Co.”, China
5	Smecta®	oral suspension	“Ipsen Pharma”	Dioctahedral Smectite; “IpsenPharma”, France
6	Smecta®	powder for oral suspension	“Ipsen Pharma”	Dioctahedral Smectite; “IpsenPharma”, France
7	Neosmectin®	powder for oral suspension	“Otisifarm”	Dioctahedral Smectite; “Pharmstandard-Leksredstva”, Russia; “R.T. Vanderbilt Company Inc.”, USA
8	Diosmectite	powder for oral suspension	“Pharmacor Production”	Dioctahedral Smectite; “R.T. Vanderbilt Company Inc.”, USA

TABLE II. MINERALOGICAL SYSTEMATICS OF MEDICAL CLAYS

Section	Minerals and analogues		
Category	Minerals		
Class	Silicates		
Subclass	Phyllosilicates (layered silicates)		
Group	Palygorskit	Smectit	Kaolinit
Mineral	Palygorskit	Smectit	Kaolinit
Name of Medical Clay	Palygorskite Clay	Smectite Clay	Kaolinite Clay
Synonymous name	Attapulgite Clay	Smectite Dioctahedral, Smectite Clay, Bentonite clay, Montmorillonite Clay, Fuller's Earth	White Clay

The Kaolinite mineral is composed of one octahedral and one tetrahedral layers; there is no interpackage space. The Montmorillonite mineral is composed of one octahedral and two tetrahedral layers with the presence of interpacket space between the tetrahedral layers. The Palygorskite mineral is composed of one octahedral and two tetrahedral layers. Two Silicon-Oxygen elements, oppositely rotated to each other by the vertices of the tetrahedral, are connected into ribbons by ions in octahedral coordination.

Thus, the atomic structure of the main minerals of Medical Clays is composed of two units. The first structural unit is formed by octahedral. Each octahedron consists of two layers of close-packed oxygen or hydroxyl groups, in which the Aluminum, Iron or Magnesium atoms are arranged in octahedral coordination so that each of them is at an equal distance from six Oxygen or Hydroxyl groups. The second structural unit is formed by Silicon-Oxygen tetrahedral. In each tetrahedron, the Silicon atom is equally distant from four Oxygen or Hydroxyl groups located in the form of a tetrahedron with a Silicon atom in the center to balance the structure.

Studies at the Department of Pharmaceutical Technology of Belgorod State University for the study of the sorption characteristics of Medical Clays have shown that Medical Clays consisting of Montmorillonite and Kaolinite minerals have two types of pores; the specific surface area is higher for clays consisting of Montmorillonite and Palygorskite minerals; the cation exchange capacity is higher for the Montmorillonite mineral [5]. Of all clay minerals, Montmorillonite has the highest absorption capacity. The high sorption capacity of Montmorillonite is explained by the fact that in its crystals the exchange of ions occurs not only on the external surface, but also inside the crystal lattice in the cavities between the Silicon-Oxygen tetrahedral layers.

IV. CONCLUSION

Conducted a screening marketing study of the pharmaceutical market of Medical Clays. It was established that at present in Russia there is one pharmaceutical substance of Medical Clay "Smectite Dioctahedral"; 8 drugs based on Dioctahedral Smectite are registered: 3 of them are made on the basis of domestic substances, 1 - made in France, 1 - made in the USA, 2 - made in China. The classification and systematics of Medical Clays has been developed, according to which Medical Clays are represented by three groups that determine their sorption properties: Palygorskite, Smectite and Kaolinite Clays. The atomic structure of the main minerals of Medical Clays is composed of two units. The first structural unit is formed by octahedral. The second structural unit is formed by Silicon-Oxygen tetrahedral. Medical Clays consisting of Montmorillonite and Kaolinite minerals have two types of pores; the specific surface area is higher for clays consisting of Montmorillonite and Palygorskite minerals; the cation exchange capacity is higher for the Montmorillonite mineral. Of all clay minerals, Montmorillonite has the highest absorption capacity. The high sorption capacity of Montmorillonite is explained by the fact that in its crystals the exchange of ions occurs not only on the external surface, but also inside the crystal lattice in the cavities between the Silicon-Oxygen tetrahedral layers.

REFERENCES

[1] A.I. Vezentsev, S.N Dudina., A.A. Vezentsev "Development of enterosorbent based on clays of the Belgorod region," Belgorod State University Scientific Bulletin, Ser. natural Sciences, vol. 3(23), pp. 55-59, 2006.

[2] S.N. Aminov "Creation and pharmacotherapeutic study of antidiarrheal drug navbakhtit based on montmorillonite clay of Uzbekistan," Man and medicine: XI Ros. nat. Congr, 2004, pp. 755-756.

[3] D.P. Salo, N.N. Ovcharenko, F.D. Kruglitsky "Fine minerals in pharmacy and medicine," 1969.

[4] E.T. Zhilyakova, A.V. Bondarev, N.N. Bojko, D.K. Naplekov "Physical research of porosity of mineral sorbents," Journal of International Pharmaceutical Research, vol. 45, pp. 477-480, 2018.

[5] A.V. Bondarev, E.T. Zhilyakova, N.B. Demina, V.Y. Novikov "Study of Morphology of Sorption Substances," Drug development & registration, vol. 8(2), pp. 33-37, 2019.