MINERALOGICAL AND CHEMICAL STUDIES ON SOME MINERALS USED IN PHARMACEUTICAL INDUSTRIES IN EGYPT

BY

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Abstract

Background: Suitable minerals for use in the pharmaceutical industry can be derived from Egyptian desert. Aim: mineralogical & chemical studies on some minerals used in pharmaceutical industries in Egypt.

Large numbers of minerals are used in pharmaceutical industries as well as in cosmetic product.

Physiochemical properties of these minerals play an important role in using of these minerals in pharmaceutical industries; hence, these properties were evaluated and compared with commercial brands that stipulated with the enforced pharmacopoeia.

A material to be used in pharmaceutical formulations must have low or zero toxicity & non carcinogen.

And we were able through tests to prove that minerals under study conformed to international standards for minerals use in medicines and prescribed in British pharmacopeia (2009) & European Medicines Agency Pre-authorization Evaluation of Medicines for Human Use.

Introduction

The role of industrial minerals in pharmaceuticals falls into one of two main categories: excipients or active substance. The excipients have no intrinsic health benefit on their own; they are used solely as carriers, allowing the intake of minute amounts of active substances, in a practical way.

Minerals in pharmaceutical and cosmetic preparations a large number of minerals are used as active ingredients in pharmaceutical preparations as well as in cosmetic products. Some minerals have been used for therapeutic purposes since prehistoric times. The therapeutic activity of these minerals is controlled by their physical and physico-chemical properties as well as their chemical composition; a material to be used in pharmaceutical formulations must have low or zero toxicity.

Those minerals with a high sorption capacity and a large specific surface area can also function in pharmaceutical preparation as gastrointestinal and dermatological protectors, and anti-inflammatories and local anesthetics, while water-soluble species can be used as homeostatics, antianemics and decongestive eye drops. Likewise, minerals with a high heat retention capacity can serve as anti-inflammatories and local anesthetics, minerals with high astringency are used as antiseptics and disinfectants and minerals which react with cysteine can serve as keratolytic reducers

In other hand Water-soluble species can be utilized in cosmetic product as ingredients in toothpastes and bathroom salts. Those minerals with a high sorption capacity and a large specific surface area can function as creams, powders and emulsions while minerals with proper hardness can act as abrasives in toothpastes. Highly opaque minerals and minerals of high reflectance are used in creams, powders and emulsions. Likewise, minerals with high astringency are included in deodorants.

Acid neutralization increases the pH of the gastric fluid from 1.5–2.0 to ≥7, depending on mineral type. According to current opinion, an effective antacid is one that elevates the pH by 3–4 units, and causes the disappearance of "free acidity". When the pH of the gastric fluid exceeds 7, "acid rebound" may occur by which the parietal glands are stimulated in order to restore normal acidity.

Materials and Methods

Mineralogical analysis

X-ray Powder Diffraction (XRD) is most widely used for the identification of unknown crystalline materials (e.g. minerals and other inorganic compounds). Determination of unknown solids is critical to study in geology, environmental science, material science, engineering and biology.

Mineral analyses were carried out using the X-ray Powder Diffraction (XRD) technique at the Laboratories of the Central Metallurgical Researching and development Institute (CMRDI) to be used in determination the mineralogical composition of the studied samples, by means of X-ray diffraction (XRD) using a SIEMENSD 5000-type diffractometer with Cu Kα radiation, a graphite monochromator, 40k V, 30mA, at 10 counts/s over a 2θ range from 4º to 70º.

Chemical analysis

Uranium analysis in different processing stream was analyzed by an oxidimetric titration method using ammonium metavanadate. A previous uranium reduction was performed by ammonium ferrous sulfate in the presence of diphenylsulfonate as indicator until its color changes to slightly violet red color.

$U\ (^{g}/_{L}) = T.V_1/V.1000$ where:-

T: Titration intensity of NH_4VO_3 to U g/ml

V_1: Volume taken of NH_4VO_3 solution (ml)

V: Volume of sample (ml).

Thorium was chemically determined by the colored method using Arsenazo-III, as an indicator. The colored method was performed using a spectrophotometer technique. The accuracy and precision of both uranium as well as thorium element analysis were estimated using a series of international reference standards. All chemical and mineral analyses were carried out in the Nuclear Materials Authority laboratories, Cairo, Egypt.

2.2- Trace elements were carried out at Nuclear Materials Authority laboratories, Egypt by using X-ray fluorescence (XRF) techniques using Philips X-Unique II spectrometer (PW-1510) with automatic sample changer. The analytical error is estimated about ± 5 ppm. Absolute accuracy has been assessed by comparison with international reference materials analyzed along with the samples and is generally less than 2%.

2.3- Determinations of major oxides were carried out using wet chemical analytical technique with ±2 wt. % error for most oxides. These analyses were carried out at Nuclear Materials Authority laboratories. SiO_2, Al_2O_3, TiO_2 and P_2O_5 were determined colormetrically using Spectrophotometer. Na_2O and K_2O were determined using Flame Photometer. CaO, MgO and Fe_2O_3 (total iron) were determined by means of complex titermetric technique, while special volumetric technique was used for measuring FeO. MnO was measured by Atomic Absorption. The loss of ignition was measured gravimetrically.

Solubility Tests

The inorganic and organic chemical solvent substances required to solubility tests were listed in the following tables (1) and (2).

Table 1. Inorganic chemicals required for solubility tests and their characters.

Required chemicals	Chemical formula	Molarity	Normality	Concentrations
Dilute hydrochloric acid	HCL	0.5	0.5	5.2 %
Concentrate hydrochloric acid	HCL	12	12	37 %
Dilute acetic acid	CH_3COOH	1.84	1.84	11 %
Concentrate sulfuric acid	H_2SO_4	18.4	36.8	98 %
Dilute sulfuric acid	H_2SO_4	0.5	1	5 %
Nitric acid	HNO_3	15	15	68 %

Table 2. Organic solvent used for solubility tests and their characters.

Solvent	Insulating constant	Boiling point	Chemical formula	Density	δH Hydrogen bonding	δP Polar	δD Dispersion
Non polar solvent							
Benzene	2.3	80°C	C_6H_6	0.879 g/ml	2	0	18.4
diethyl ether	4.3	35°C	CH_3CH_2-O-CH_2-CH_3	0.713 g/ml			
Polar solvent							
Ethanol	24.55	79°C	CH_3-CH_2-OH	0.789 g/ml	19.4	8.8	15.8
Water	80	100°C	H-O-H	1.000 g/ml	42.3	16	15.5

Atomic absorption spectroscopy (AAS)

Atomic absorption spectroscopy (AAS) is a spectroanalytical procedure for the quantitative determination of chemical elements (hematite, magnetite and ilmenite) using the absorption of optical radiation (light) by free atoms in the gaseous state.

In analytical chemistry the technique is used for determining the concentration of a particular element (the analyte) in a sample to be analyzed. AAS can be used to determine over 70 different elements in solution or directly in solid samples used in pharmacology, biophysics and toxicology research.

The solubility, TDS, P^H and AAS worked at chemistry laboratory, Faculty of Science, Al-Azhar University.

Microbial Contamination

Inoculation and incubation

The tools that used in this test are:-

Sterile Petri dishes made of glass or plastic, 90mm to 100mm in diameter.

Pipette of nominal capacity 1ml.

Incubator capable of operating at 30°C ± 1°C.

Counting of colonies

Examine the dishes under subdued light

The medium of the incubation: - Plate count agar (PCA)

Composition of Plate count agar (PCA)

Enzymatic digestion of casein	5.0 g
Yeast extract	2.5 g
Glucose, anhydrous ($C_6H_{12}O_6$)	1.0 g
Agar1	9g to 18g
Water	1000ml

By East African Standard (EAS) 68-1 (2006). Methods of microbiological examination, Part 1: Total plate count. This technique carried out at special laboratory.

RESULTS

Since the minerals, this conducted the study non-carcinogenic or toxic and what we were able through tests to prove that minerals under study conformed to international standards for minerals use in medicines and prescribed in **British pharmacopeia (2009)**.

Even though some of the impurities found in the minerals under study and can be controlled by reducing the dose or the quantity added of the minerals on the drugs as stipulated in European Medicines Agency Pre-authorization Evaluation of Medicines for Human Use Doc. Ref. (2007) CPMP/SWP/QWP/4446/00corr.

After all this evidence it can be stated that the minerals under study can be used in the pharmaceutical industries (drugs &/or cosmetics)

Discussion

After crushing and grinding samples, mineralogical analysis has been made of X-ray diffraction on these samples, which are needed to identify the minerals practically through the crystal structure the results were to prove the identity of the minerals.

The results of the X-ray diffraction of these samples are as follows, graphite (graphite with a very little amount of quartz), ilmenite (ilmenite with a small amount of clinochlore), pyrolusite (clean pyrolusite), barite (clean barite), gypsum (clean gypsum), anhydrite (clean anhydrite), magnesite (magnesite with very little amount of dolomite & halite), dolomite (dolomite very little amount of calcite), limestone (clean calcite), fluorite (fluorite with a very little amount of quartz), talc (talc with a very little amount of montmorillonite & kaolinite), microcline (microcline with a very little amount of illite & albite), muscovite (clean muscovite), kaolin (kaolin with a very little amount of montmorillonite & quartz).

And therefore it has been to move to the chemical analysis and of the major oxide, trace element, and rare earth's metals and are required to prove the purity metals, where were the result of the purity of samples as follows, graphite (63.7%), ilmenite (68.6%), pyrolusite (65.7%), barite (64.6%), gypsum (93%), anhydrite (93.5%), magnesite (99.7%), dolomite (98.8%), limestone (100%), fluorite (65.2%), talc (71.7%), microcline (83%), muscovite (92.4%) and kaolinite (98.9%).

Table 3. Uranium and Thorium Analysis for (14) Samples representative Egyptian minerals in pharmaceuticals industry

Samples	Limestone	Graphite	Barite	Fluorite	Magnesite	Dolomite	Gypsum	Anhydrite	Muscovite	Microcline	Kaoline	Pyrollusite	Ilmenite	Talc
U ppm	11	6	10	25	4	5	2	4	36	14	11	2	9	9
Th ppm	18	4	8	14	8	9	3	7	12	20	14	4	11	12

Table 4. XRF Analysis for (14) Samples representative Egyptian minerals in pharmaceuticals industry

Sample No.	Cr	Ni	Cu	Zn	Zr	Rb	Y	Ba	Pb	Sr	Ga	V	Nb
Limestone	10	6	9	7	33	2	8	16	u.d	2	3	u.d	5
Barite	u.d	6	7	4	5	2	u.d	>10000	u.d	u.d	u.d	141	u.d
Fluorite	5	7	9	42	105	7	23	2350	52	3	25	16	16
Magnesite	30	107	13	13	19	u.d	7	38	7	u.d	13	u.d	3
Dolomite	21	11	8	101	46	4	14	52	17	3	12	u.d	8
Gypsum	8	6	8	255	963	u.d	196	30	6	50	4	u.d	145
Anhydrite	20	6	8	9	233	u.d	48	14	u.d	12	4	u.d	35
Muscovite	53	7	21	126	8	1172	11	192	3	u.d	5	7	2
Microcline	19	7	12	9	85	214	32	331	31	4	23	2	14
Kaoline	104	36	19	73	787	84	354	2833	18	29	12	78	137
Talc	696	999	11	32	9	u.d	5	43	9	u.d	10	5	u.d
Pyrollusite	25	26	170	354	14	u.d	u.d	298	39	26	16	25	u.d
Graphite	412	138	38	68	87	15	5	3697	8	136	9	191	4
Ilmenite	275	165	217	68	88	2	5	>10000	4	137	4	1826	4
Chromite	>10000	397	15	103	u.d	2	u.d	846	24	u.d	15	303	u.d

The result of solubility of these samples as follows:

Graphite practically insoluble in all usual solvents, Ilmenite soluble in mineral acids; insoluble in water, Pyrolusite freely soluble in water, practically insoluble in ethanol, Barite practically insoluble in water and in organic solvents. It is very slightly soluble in acids and in solutions of alkali hydroxides, Gypsum very slightly soluble in water, practically insoluble in ethanol, Anhydrite practically insoluble in ethanol, slightly soluble in water more soluble in dilute mineral acids, Magnesite and Dolomite practically insoluble in water It dissolves in dilute acids with effervescence, Limestone practically insoluble in water It is very slightly soluble in acids and in solutions of alkali hydroxides, Fluorite soluble in water, practically insoluble in ethanol, Talc practically insoluble in dilute acids and alkalis hydroxide, organic solvents, ethanol and water, Microcline and Muscovite freely soluble in water, very soluble in boiling water soluble in glycerol practically insoluble in ethanol, Kaolin practically insoluble in water and in organic solvents

Meanings of the terms used in statements of approximate solubilities.

Descriptive term	gram of solute per approximate volume of solvent in milliliters
Very soluble	Less than 1
Freely soluble	From 1 to 10
Soluble	From 10 to 30
Sparingly soluble	From 30 to 100
Slightly soluble	From 100 to 1000
Very slightly soluble	From 1000 to 10 000
Practically insoluble	More than 10 000

The term 'partly soluble' is used to describe a mixture of which only some of the components dissolve.

Table 5. Comparison between solubility of minerals samples and standard reference samples.

No	Name	ASDF Per-DF	Conc.	A: mg/l O: mg/l	Cl	SD	RSD/% Rem
8	Hematite	1.000	A:	12.09	3.677	0.03876	0.321 > CAL
			O:	12.09	3.677	0.03876	0.321 > CAL
9	Magnetite	1.000	A:	9.957	2.884	0.02580	0.259 > CAL
			O:	9.957	2.884	0.02580	0. 259 > CAL
10	Ilmenite	1.000	A:	12.58	3.864	0.02621	0.208 > CAL
			O:	12.58	3.864	0.02621	0. 208 > CAL

Physicochemical Characterization

The therapeutic action is often correlated with the physical and physicochemical properties of the mineral; in other instances, it is related to the ionic composition of the mineral. In common with organic active ingredients, minerals in contact with the human body will pass through one or several of the following phases: liberation, absorption, distribution, metabolism and excretion, which together are referred to by the acronym 'LADME. The type and number of phases will depend on the nature of the mineral, the way of administration (oral, topical, Parenteral), and the kind of formulation (tablets, suspensions, powder, etc.).

Microbiological evaluation

Total viable aerobic count not more than 10^3, 10^2, 10^3 micro-organisms per gram, for Graphite, Talc, kaolin respectively. Determined by plate-count. Where the practical results are 92, 27, 83 by the same succession.

Conclusion

The minerals that collected from Egyptian desert have some desired pharmacopoeial, physicochemical and microbiological properties required for pharmaceutical applications. These minerals are generally have non-toxic ions, vastly available in many regions in Egypt & very low cost than that of imported minerals, Egyptian minerals have the same comparable physicochemical properties to that of commercial brand.

Pharmaceutical characterization

Table 6. Pharmacopoeial Characterization for minerals that used in pharmaceutical industries.

Mineral	Chemical formulae	Method of administration	Therapeutic activity or cosmetic action
Native elements (non metal)			
Graphite	C	Topically Orally	Adsorbent, antimicrobial preservative
Coal	C		
Oxides			
Hematite	Fe_2O_3	Topically	cosmetics and excipients as iron and multi vitamins
Magnetite	Fe_3O_4		
Ilmenite	$FeTiO_3$		
Corundum	Al_2O_3	Parenterally	Discoloring powders and is particularly widely used in antibiotic formulations.
Pyrolusite	MnO_2	Orally	Simple and multivitamins
Rutile	TiO_2	Topically	Dermatological protector, solar protector
Phospherite	P_2O_5	Orally parenterally	Excipient, anti acid & vaccine adjuvant
Sulfide			
Galena	PbS	Topically	Cosmetic
Sulfates			
Barite	$BaSO_4$	Orally	Investigation of the gastro-intestinal tract.
Gypsum	$CaSO_2.2H_2O$	Topically parenterally	Calcium sulfate dihydrate is used in the formulation of tablets and capsules. Calcium sulfate hemihydrates are used in the preparation of plaster of Paris bandage; Anhydrous calcium sulfate is used as adesiccant. .Therapeutically, calcium sulfate is used in dental and craniofacial surgical procedures
Anhydrite	$CaSO_4$		
Alabaster	$CaSO_4$		
Carbonate			
Limestone	$CaCO_3$	Orally, topically	Antacid, antidiarrhoeaics, mineral supplement, abrasive and polishing agent in toothpaste
Calcite	$CaCO_3$		
Magnetite	$MgCO_3$	Orally	Antacid, osmotic oral laxative, mineral supplement
Dolomite	$CaMg(CO_3)_2$		
Halogen			
Halite	NaCl	Orally, parenterally, topically	Homeostatic, mineral supplement, decongestive eye drops, bathroom salts
Fluorite	CaF_2	Topically	Prevention of dental caries.
Silicates			
Asbestos	$Mg_3Si_2O_5(OH)_4$	Topically	Dermatological protector, cosmetic creams, powders and emulsions
Talc	$Mg_3Si_4O_{10}(OH)_2$		
Microcline	$KAlSi_2O_8$	Topically	Cosmetic creams, powders and emulsions
Orthoclase	$KAlSi_3O_8$		
Muscovite	$KAl_3Si_3O_{10}(OH)_2$		
Phlogopite	$K(Mg,Fe)_3AlSi_3O_{10}(OH)_2$		
Quartz	SiO_2		
Kaolin	$Al_2Si_2O_5(OH)_4$	Orally, topically	Gastrointestinal protector, antidiarrhoeaics, dermatological protector, anti-inflammatory and local anesthetic, cosmetic creams, powders and emulsions

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الملخص العربى

دراسات معدنية وكيميائية على بعض معادن الصيدلة فى مصر

للسادة الدكاترة

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تحديد أنواع العناصر الموجودة فى المعادن التي تدخل في صناعة الأدويه و مستحضرات التجميل و تقسيم العناصر من حيث استخداماتها في الأدويه و/ أو مستحضرات التجميل و تحديد الصخور التي تحوى هذه المعادن وتحديد أماكن تواجدها في الصحارى المصرية من خلال عمل خرائط بهذه الأماكن والتى ساعدت فى الحصول على عينات ممثلة من تلك الصخور والمعادن ومن ثم إجراء التحاليل المعدنيه و الكيميائية والبيولوجيه على العينات الممثلة للأنواع المختلفة من الصخور والمعادن للتعرف على مواصفات المعادن والعناصر ولتحديد درجة نقاء المعادن ومدى مطابقتها للمعادن المستخدمه فعلياً فى الأدويه ومستحضرات التجميل والمبينه فى مختلف دساتير الأدويه.

بعد استكمال دراسة هذه النقاط يمكننا الآن أن نقر حقيقه واحده وهى أنه يمكن استخدام المعادن التى انصبت عليها الدراسه و الموجوده فى الصحراء المصريه فى صناعة الأدويه ومستحضرات التجميل.