

**TALC : A VERSATILE PHARMACEUTICAL EXCIPIENT****Jadhav NR^{1*}, Paradkar AR², Salunkhe NH¹, Karade RS¹, Mane GG¹**¹Department of Pharmaceutics, Bharati Vidyapeeth College of pharmacy, Kolhapur, Maharashtra, India.² Institute of Pharmaceutical Innovation, University of Bradford, Bradford, West Yorkshire, United Kingdom. BD7 1DP.Article Received on
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Maharashtra, India.nrjadhav18@rediffmail.com**ABSTRACT**

The present review highlights meticulous account of talc with respect to extraction from mines, purification, pharmaceutical and other applications. Talc is a hydrous magnesium silicate having a chemical composition of $Mg_3Si_4O_{10}(OH)_2$. It has been found in metamorphic belts containing ultramafic rocks. The various techniques have been used for talc mining viz straight forward drill, blast and open pit operations which are followed by crushing with the help of jaw crusher, cone crusher or impact crusher. Talc can be produced by hydration and carbonation of various minerals. Talc demonstrates the high functionality because it has been used as filler, lubricant and glidant in the pharmaceutical formulations as well as in cosmetic formulations as abrasive, absorbent, anticaking agent, opacifying agent

and skin protectant. Now a day, It has been explored as a dissolution retardant in the controlled release products as well as a novel substrate for pellet design due to its physicochemical, physiological inert and inexpensive nature. Due to these attractive features, the wet spherical agglomerates of talc have been used as a substrate for coating and also have been used as a diluent in crystallo-co-agglomeration (CCA). Use of such high functionality excipient gives better products with lower costs, shorter time to market, and extended product lifecycle. India is a country having huge stores of rocks producing talc, hence, it's a need to systematically explore the talc for various novel pharmaceutical applications, so as to assist development of cost effective pharmaceutical formulations.

KEYWORDS: Applications, Mining, Processing, Purification, Talc.

INTRODUCTION

The name 'talc' is derived from the Arabic word 'talk' referring as talc's white color. ^[1] Talc is a hydrous magnesium silicate having a chemical composition of $Mg_3Si_4O_{10}(OH)_2$ or $H_2Mg_3(SiO_3)_4$. Small amounts of Al or Ti can substitute for Si and Fe, while Mg can be substituted with Mn and Al, also a very small amounts of Ca can substitute for Mg. When Mg is substituted with greater amounts of Fe the mineral is known as minnesotaite and when an Al substitute for Mg the mineral is known as pyrophyllite. Talc is usually green, white, gray, brown or colorless, insoluble in water & slightly soluble in dilute mineral acids. It shows a hardness of 1 on the Mohs Hardness scale of 1-10. ^[2] Its silicate layers lie on top of one another without chemical bond but are held together by weak Van der Waals forces which allows them to slip past one another easily. ^[3] This is responsible for talc's extreme softness, greasiness and soapy feel hence termed as "soapstone" and used as a high temperature lubricant. It is sectile (can be cut with a knife) having a specific gravity of 2.5–2.8. ^[4] Steatite means massive talcose rock and soapstone is an impure variety of talc. ^[5] It contains other minerals like calcite, chlorite, dolomite, magnesite, quartz, tremolite or vermiculite. ^[3]

For decades, talc has been widely used in conventional dosage forms like tablets, pills and capsules as a pharmaceutical excipient due to its physicochemical, physiological inert and inexpensive nature. Talc demonstrates the high functionality of multiple excipients because it has been used as filler, lubricant and glidant in the pharmaceutical formulations as well as in cosmetic formulations as anticaking agent, abrasive, absorbent, opacifying agent, bulking agent, skin protectant, and slip modifier. ^[6]

Use of such high functionality excipient gives better products with lower costs, shorter time to market, and extended product lifecycle. ^[7]

However, it is widely used as a dissolution retardant in the development of controlled-release products and as a novel powder coating for extended-release pellet making. To overcome the problem of poor strength, and impart sphericity to granules, Wet Spherical Agglomeration (WSA) of talc was carried out and pellets were explored as a substrate for coating. ^[8] As it is insoluble in aqueous phase, physico-chemically and physiologically inert, it has been used as a diluent in CCA. It has a tendency to agglomerate and also deagglomerate the particles so regulates the dissolution kinetics of hydrophobic pharmaceuticals (phenacetin). ^[9]

Though talc resources are widely distributed in the world, its reserves are small in comparison with other minerals. So worldwide, both the reserves and output of the highly pure white talc are limited. By considering its widespread applications in the pharmaceutical and other fields due to its multifunctional nature, in order to satisfy the excessive demand for highly pure talc it has been thought that the vital importance should be given to mining and extraction of talc from rocks. So the present review is an attempt to take detailed account of talc with respect to extraction from mines, purification, its pharmaceutical and other applications and safety assessment.

TALC STRUCTURE

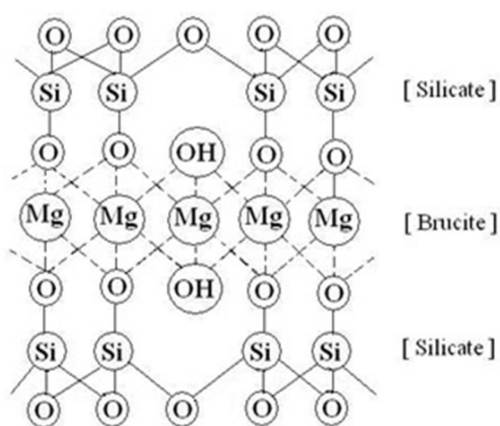


Fig. 1 structure of talc

GEOLOGICAL SOURCE OF TALC

Talc is a metamorphic mineral in metamorphic belts containing ultramafic rocks, such as soapstone and in whiteschist and blueschist metamorphic terrains. Whiteschists include the Franciscan Metamorphic Belt of the western U.S., the western European Alps especially in Italy, some collisional orogens such as the Himalayas, which extends along Pakistan, India, Nepal and Bhutan. In India, Rajasthan contains 50% and Uttarakhand has 32% resources and the remaining 18% resources are in Bihar, Jharkhand, Madhya Pradesh, Maharashtra, Andhra Pradesh, Odisha, Sikkim, Kerala and Tamil Nadu. The cosmetic grade talc has 26% share in total resources followed by paper and textiles 21% and insecticides 14%. Resources of ceramic and paint grades are negligible. Others, Unclassified and unknown grades account for about 38% resources. ^[10] In Western Australia, talc is formed through ultramafic intrusions. The Luzenac Group is the world's largest supplier of mined talc which produces 8% of world production. ^[2]

TYPES OF TALC DEPOSITS

The deposits are formed by hydrothermal activities on earth and are usually classified according to the parent rock present in the deposits.

Talc deposits-

- Derived from Magnesium Carbonates, which found in ancient metamorphosed carbonate sequences. This type is usually the purest form of talc which is mostly white and provides almost 50% of the world's talc production.
- Derived from the metamorphosis of Serpentine into a mixture of Magnesium Carbonates and Talc which forms are known as "Soapstone", which provide 40% of the world's talc production.
- Derived from Alumino-silicate rock, which found mostly in a gray crude ore and alongside many other hydrothermal minerals. It is only about 10% of the world's talc production.
- Derived from magnesium sedimentary deposits and this type is not mined currently and does not bring better economical value. The deposit can be formed by direct transformation of magnesium clay. ^[11]

MINING

Talc is a common component of the gangue mineral associated with the recovery of platinum from ores. Talc deposits are most commonly formed by the hydrothermal or metamorphic alteration of the pre-existing rocks like tremolite, actinolite, and other magnesium minerals. The deposits are worked by open cast by the bench mining techniques or underground mining methods using mechanical excavators which depend on the mode of the occurrence and the type of deposits. Commercial talc is mined in a variety of ways, including straight forward drill, blast and open pit operations. After mining the talc ore is washed which removes dirt in the form of foreign particles and other impurities by sand washing machine and then naturally dried under the sunlight. After drying it is dressed and sorted depending on their talc content and brightness by using techniques like laser and image analysis technology or floatation. Then Talc grains will be collected and analyzed, after that transported to the milling operation. ^[12]

GRINDING

Milling grinding is to obtain super micro talc powder of the right particle size distribution curve. This involves crushing with the jaw crusher, cone crusher, impact crusher and

screened. The crusher can reduce the talc ore into 2mm in a capacity of 1000 tons per hour. [10] The coarse (oversize) material is returned back to the crusher. Secondary grinding is done with pebble mills or roller mills to produce particles having 44 to 149 micrometers (325 to 100 mesh) in size. The product is collected in cyclones and bagged. Dust is controlled by bag house dust collectors. Roller mills use heated air to dry the material as it is being ground. Sometimes, hammer mills or steam or compressed air powered jet mills may be used to produce additional final products. The air classifiers are in closed circuit with the mills and separate the materials according to their size into coarse and fine fractions. The coarse ones are stored as products and fines may be concentrated using a shaking table (tabling process) to separate product containing minerals like nickel, iron etc and then may undergo a one-step floatation process. Then the resultant talc slurry is dewatered and filtered prior to passing through a flash dryer. The flash-dried product is considered as a final powdered product. [13-21]

TALC PROCESSING

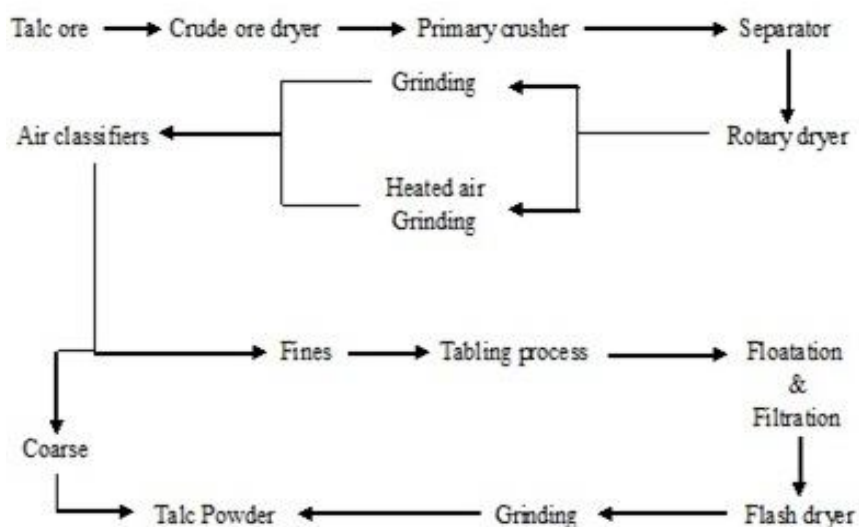


Fig. 2 process flow chart for talc separation from ores

METHOD OF PREPARATION

Talc is obtained from the metamorphism of magnesium minerals such as the Serpentine, Pyroxene, Amphibole, Olivine, in the presence of Carbon Dioxide and Water which is known as Talc Carbonation or Steatization. This produces a suite of rocks known as Talc Carbonates.

1. Mostly the hydration and carbonation of serpentine results in the formation of talc via the following reaction.



2. Talc is also produced by the alteration of Dolomite [$\text{CaMg}(\text{CO}_3)_2$] or of Magnesite (MgO) in the presence of excess dissolved Silica (SiO_2). This involve scarification of the Dolomites via silica-flooding in contact metamorphic aureoles.



3. Talc can be formed from magnesium chlorite and quartz in blueschist and eclogite metamorphism via the following metamorphic reaction.



In this reaction, the ratio of talc and kyanite is dependent on aluminium content, more is aluminous rocks more will be the production of kyanite. It is associated with high pressure, low-temperature minerals such as pungent, garnet, glaucophane within the lower blueschistfacies. ^[11]

PURIFICATION

Talc ore in its natural state is unsuitable for its pharmaceutical and cosmetic applications. Hence upgradation techniques such as floatation, Chlorination & Leaching are needed to improve the chemical purity and color.

Floatation

Mondo Minerals are the major European talc producer to purify talc using a floatation process. In this process, talc is separated from other rock and impurities using air bubbles. The attachment of talc particles with the air bubbles takes place and they float to the surface where they are skimmed along with foam. Mondo Minerals have made attempts firstly, to remove the magnetic impurities using liquid helium-cooled, superconducting electromagnets. ^[22]

Chlorination & leaching

The various techniques like thermogravimetry (TG), X-ray fluorescence (XRF), X-ray diffraction (XRD) and Cie Labcolorimetry has been used for studying the use of chlorine in talc deferritation. Experimentally it is observed that the pyrometallurgical process of chlorination is an efficient method for removing Fe_2O_3 from talc, by volatilizing it as FeCl_3 . Previous leaching of the sample with HCl 10% (w/w) eliminates carbonates, and slightly

iron. Quantitative elimination of iron impurities from untreated and leached samples was carried out by chlorination with chlorine gas 1:1 in nitrogen, at temperatures over 800 °C. Deferritation can remarkably improve mineral coloration. The best bleaching is carried out by using sodium hydrosulphite as 1 kg/ton ore with 10-20% slurry concentration in an acid medium. Acid leaching with conc. HCl had increased the talc content from 67.55 in the crude ore to 91.35% in concentration and its whiteness from 71.3 to 77.45% and decreased the Fe₂O₃ content. ^[23]

Table 1 : Physical properties of talc

Sr. No.	Property	Description
1.	Particle Size Distribution	Two typical grades are > 99% through a 74 µm (200#) or > 99% through a 44 µm (325#).
2.	Solubility	Practically insoluble in water, dilute acids and alkalies, and organic solvents.
3.	Density (Bulk)	Bulk density, 0.5 g/c m ³ ; Tapped Density, 0.8 g/cm ³
4.	Refractive Index	1.54-1.59
5.	Specific Gravity	2.7-2.8.
6.	Hardness (Mohs scale)	1-1.5 depending upon the presence of impurities like calcium silicate and crystalline calcium carbonate.
7.	Hygroscopicity	Talc absorbs a significant amount of moisture at 25 ⁰ C and relative humidity up to 90%

Table 2 : ISO standards for quality (ISO 3262) ^[4]

Type	Talc content min. wt%	Loss on ignition at 1000°C wt %	Solubility in HCl max. wt %
A	95	4 – 6.5	5
B	90	4-9	10
C	70	4-18	30
D	50	4-27	30

ISO : International Organization for Standardization

Table 3 : Gradation of talc as per the Indian Bureau of mines ^[10]

Grade	Quality	Colour	Whiteness	Use
A	First	Pure white to slightly green	90-95%	Pharmaceuticals and cosmetics
B	Second	Pale greenish to white	85-90%	Superior grade paper, textile and ceramics
C	Third	Light greenish to gray	75-85%	Inferior grade paper, paint, rubber
D	Fourth	Dark greenish gray to reddish green	<78%	Insecticide

Table 4 : Pharmacopoeial Specifications of talc ^[24-27]

Sr. No.	Test	Ph Eur 2005 (5.1)	USP 2009	IP2010	BP2011
1	Identification	+	+	+	+
2	Microbial Limit	Topical $10^2/g$ Oral $\leq 10^3/g$	Topical $\leq 100cfu/g$ Oral $\leq 1000cfu/g$	-	Cutaneous $10^2 cfu/g$ Oral $10^3 cfu/g$
3	Loss on ignition	<7%	<7%	-	7%
4	Loss on drying	-	-	$\leq 1\%$	-
5	Acid soluble substances	-	-	<2%	-
6	Water soluble substances	0.2%	0.1%	-	0.2%
7	Acid soluble iron	-	<0.25%	-	0.25%
8	Iron	<0.25%	-	10ppm	-
9	Acid soluble magnesium	17-19.5%	17-19.5%	-	17-19.5%
10	Calcium	<0.9%	<0.9	-	0.90%
11	Chloride	-	-	250ppm	-
12	Lead	<10ppm	0.001%	-	1×10^1
13	Aluminium	<2.0%	<2%	-	2%

TYPES OF TALC POWDER AND LUMP

1. Talc Lump (SiO₂: 52%, MgO: 30%, whiteness: 80%).
2. Chemical grade talcum powder (SiO₂: 60% 1250mesh or SiO₂: 60% 800mesh).
3. Ceramic grade talcum powder (SiO₂: 50-55% 325mesh, SiO₂: 55-60% 325mesh, Talc Powder SiO₂: 60% 400mesh).

4. Cosmetic grade talc powder (Whiteness: 90%-95%, SiO₂: 60%, Mgo: 30%).
5. Pharmaceutical grade talcum powder (Whiteness: 90%, SiO₂: 60% 325mesh)
6. Food grade talcum powder (SiO₂: 60% 325mesh).
7. Paper grade talcum powder (whiteness: 86% min-95% min, SiO₂: 35% min-60% min, Mgo: 30% min).^[28]

Table 5 : US FDA IIG Limits^[29]

Sr. No.	Ingredient	Dosage Form	CAS Number	Unit	Maximum Potency
1	Mistron spray talc	Tablet	-	Pending	-
2	Talc	Tablet	14807966	7SEV7J4R1U	15mg
3	Talc	Gum, chewing	14807966	7SEV7J4R1U	-
4	Talc	Capsule	14807966	7SEV7J4R1U	220.4mg
5	Talc	Capsule, delayed action	14807966	7SEV7J4R1U	70.46mg
6	Talc	Capsule, enteric coated pellets	14807966	7SEV7J4R1U	46.628mg
7	Talc	Capsule, extended release	14807966	7SEV7J4R1U	157.6mg
8	Talc	Capsule, hard gelatin	14807966	7SEV7J4R1U	139.17mg
9	Talc	Capsule, soft gelatin	14807966	7SEV7J4R1U	0.1mg
10	Talc	Capsule, sustained action	14807966	7SEV7J4R1U	122.06mg
11	Talc	Granule, for oral suspension	14807966	7SEV7J4R1U	34mg
12	Talc	Mucilage	14807966	7SEV7J4R1U	1.53mg
13	Talc	Solution, elixir	14807966	7SEV7J4R1U	0.09%
14	Talc	Suspension	14807966	7SEV7J4R1U	-
15	Talc	Syrup	14807966	7SEV7J4R1U	-
16	Talc	Tablet, controlled release	14807966	7SEV7J4R1U	31.61mg
17	Talc	Tablet, delayed action	14807966	7SEV7J4R1U	27.4mg
18	Talc	Tablet, extended release	14807966	7SEV7J4R1U	80mg
19	Talc	Tablet, orally disintegrating	14807966	7SEV7J4R1U	36mg
20	Talc	Tablet, repeat action	14807966	7SEV7J4R1U	73.933mg
21	Talc	Tablet, sustained action	14807966	7SEV7J4R1U	91mg
22	Talc	Lotion	14807966	7SEV7J4R1U	7.28%
23	Talc	Ointment	14807966	7SEV7J4R1U	8.27%
24	Talc	Powder	14807966	7SEV7J4R1U	98%
25	Talc	Shampoo	14807966	7SEV7J4R1U	24%

US FDA : United States Food and Drug Administration, IIG : Inactive Ingredient Guide

CHARACTERIZATION OF TALC

Surface free energy

Surface free energy is critically important in a number of industrial applications including adhesion, coating, printing, de-inking, lubrication and compounding etc. [30-32] The various mineral processing techniques, like floatation, selective flocculation and filtration also depend on the interfacial interactions between solid and liquid. [33] These interactions mainly depend on the interfacial surface free energy between two phases. Talc is a very versatile mineral used in many industrial applications mainly due to its unique surface chemistry and lamellar crystal habit. Hence the characterization of the surface properties and surface free energy components of talc are important in understanding the mechanism of surface based phenomena. Also the knowledge of aspect ratio is of importance as it plays a key role in the final performance of the mineral in many industrial applications such as polymer reinforcement, paper coating and gas barrier among others. [34-38]

Effect of particle shape and roughness on the wettability and floatability

The Scanning Electron Microscope (SEM) is used to determine the surface topography of talc particles in terms of elongation, flatness, roundness and relative width by measuring on the particle projections in two dimensions (2D). Surface roughness values of talc particles have been expressed by the parameters of R_a value on the pelleted surfaces of the particles by employing Surtronic 3⁺ instrument. The wettability characteristics (γ_c) of talc mineral, produced by different mills can be determined by microflotation and the contact angle measurement techniques using the EMDEE Micro FLOT cell and Rame-Hart goniometer respectively. It is observed that elongation and smoothness helps to increase the hydrophobicity, while roundness and roughness decreases hydrophobicity or floatability of the talc. [39]

Rheological behaviour

A wide angle X-ray diffraction technique is used to determine the orientation of talc particles in samples removed from rheometers. The shape of talc particles is similar to discs, so in the flow they orient in a plane perpendicular to the flow direction in different types of rheometers like cone-plate, capillary, and parallel plate rheometer. The level of orientation of particles is represented in terms of orientation factors. The measurement of viscosity & modulus of solution gives rheological behaviour which includes steady state shear viscosity, storage modulus etc. Generally with increasing particle loading and decreasing particle size

the viscosity increases. When the deformation rate is low the stress builds up in an unbounded manner. The stress below which there is no flow indicates the existence of yield values. [40]

Mechanical activation

The mechanical activation of raw talc can be carried out in a high-energy speed rotary mechanoactivator. Such talc is used to study the degree of recovery of Fe_2O_3 by hydrometallurgical method. The variable parameters of the mechanoactivator operation are: rate of rotor revolutions, circle sieve mesh and the current intensity. In dry mechanical activation process various factors like mechanical activation time, mechanoactivator capacity should be studied. The mechanically activated powder is subjected to differential thermal analysis, degree of mechanical activation and specific surface area as well. As the rate of revolution, circle sieve mesh size increases the degree of activation also gets increased. The high-grade talc concentrates with low content of Fe_2O_3 may be obtained by physical-chemical process. Mechanically activated talc effect on the degree of recovery of Fe_2O_3 by hydrometallurgical process also provides a new approach for obtaining high-grade talc concentrate. [41]

Adsorption states at talc surfaces

A preliminary Molecular Dynamics Stimulation (MDS) study of talc shows that due to the absence of hydrogen bonding sites, the hydrophobic talc basal plane is not in close contact with water molecules, thus leaving a 3 Å void space at the basal plane. When the cationic surfactant Dodecyl Trimethyl Ammonium Bromide (DTAB) is added hydrophobic chains of the DTAB preferentially adsorb at the talc basal plane surface through hydrophobic interactions. Also the breakage of Si–O and Mg–O bonds facilitates the formation of strong hydrogen bonds with water dipoles and water wets the hydrophilic edges. The DTAB cationic surfactant adsorbs at the talc edge surface through electrostatic interactions. In case of dextrin molecule the simulation results shows that the hydrophobic moieties in the dextrin molecule plays a significant role in dextrin adsorption at talc surfaces. Whereas, the dextrin molecule is not able to displace the water molecules at the surface edges. [42]

Surface pre-coating

In mineral science, Carboxyl Methyl Cellulose (CMC) (long chain polysaccharide) is polymer depressant for talc particles [42-43] as it reduces the floatability of talc by adsorbing both at the edge and face of talc particles. In flat conformation it adsorbs via hydrophobic

interactions so that hydrophilic hydroxyl and carboxyl groups of CMC extend out from the talc surface. Such conformation improve the hydrophilic character of talc particles leading to a better dispersion in water. ^[43] On washing the talc particles with distilled water it is observed that adsorption is irreversible. Also adsorption leads to an increase in the negative surface charge and hence increase in the wettability. The settling velocity of such pre-coated particles in water can be around 50 % lower than that of the initial talc particles. This increases their stabilization because particle aggregation is hindered by adsorbed CMC layer inducing electrosteric repulsion between the talc particles. The talc floatability is not decisively affected by the molecular weight of CMC. ^[44] However, the use of CMC in solution to help dispersion of talc is not always possible because for use of a complex solution with talc (e.g. electrolytes mixtures for electrochemical co-deposition), the adding of significant quantities of CMC can disturb solution equilibrium and then alter process efficiency.

IMPURITIES

The most common impurity of the talc is tremolite, $2\text{CaO}\cdot 5\text{MgO}\cdot 8\text{SiO}_2\cdot \text{H}_2\text{O}$. The occupational safety and health administration have defined this mineral as an asbestos-mineral and may/may not be present in the commercial talc. Other impurities include chlorite, dolomite, calcite, iron oxide, carbon quartz and MnO_2 . Talc is a natural mineral, so it may contain microorganisms therefore it should be sterilized while using in pharmaceuticals and should be asbestos free.

APPLICATIONS

Pharmaceutical applications

The percentage of talc used in the design of various dosage forms varies. It fulfills all the criteria of the glidant and diluent. For decades, it has been used as a pharmaceutical aid (dusting powder), an excipient and filler for pills, tablets and for dusting tablet molds. It is also used as an anti caking agent and lubricant in tablet making. However, it is widely used as a dissolution retardant in the development of controlled-release products and as a novel powder coating for extended-release pellet making. Moreover, it has been included in the Food and Drug Administration (FDA) inactive ingredients guide (buccal tablets, rectal and topical preparations) and in the non-parenteral medicines licensed in the UK. In vitro studies show that talc possesses the least adsorption capacity as compared to the adsorbents like kaolin, activated charcoal, magnesium trisilicate etc. In the range of 0-50% it has been used

as an additive in the formulation of enteric coated microcapsules prepared by spray drying as it greatly improves the micromeritic and compressibility of the microcapsules meant for the compression. As the percentage of the talc used increases, the crushing strength of tablet also increases due to adsorbent property and it may causes release problems. It has tendency to agglomerate and also deagglomerate the particles so regulates the dissolution kinetics of the pharmaceuticals for the hydrophobic products (phenacetin), talc also improved their solution rate. The adsorption of drug with the poor aqueous solubility on the talc facilitate the drug dissolution rate and desorption will allow the complete release of the drug. Talc facilitates the release of salicylic acid at a faster rate in vitro as compared to the stearate. This shows that the hydrophobic lubricants retard the dissolution of the drugs contained in the compressed tablets by the prolonging the disintegration time and reducing the area of the interface between the drug particle and solvent. Talc may not retard the water penetration due to its hydrophobicity. It provide a large surface area for the adsorption of the drugs from the solution, so maintaining the high concentration gradient for the precipitated drug to redissolve. Talc dust produced during handling may causes various respiratory diseases. Addition of the large quantity of the talc to the tablet would make the resultant tablet friable and unacceptable. It has been useful as an antidote for the antimicrobial ciprofloxacin as 0.5 g of talc has showed adsorption of ciprofloxacin in 1 hr from gastrointestinal tract. ^[45-47] Talc is incorporated in many anti- fungal powders to help killing of bacteria and improve the odor of the body. In many commercial antacids for stomach and indigestion problems talc had been used. The high resistance of acids and chemicals in the stomach make talc a good filler for the tablets. Many ointments used to treat scabies and insect bites contains talc because of its ability to not react with chemicals. The pills are often coated with talc to help keep moisture out of them. ^[11]

As a tablet glidant and lubricant

- The Glidant activity of the talc is dependent upon particle size compatibility between the talc and the other powders in the formulation.
- As the talc particle size decreases its surface area increases and lubricant efficiency in plastic deforming binders/fillers increases but, even the smallest grade talc is not as effective as magnesium stearate.
- Very large talc aggregates greatly improve powder flow but may create problems in the formation of tablets at all.

- The disintegration behavior of direct-compression tablet formulation is improved in the presence of talc, which is independent of particle size.
- In combination with magnesium stearate talc restores disintegration and dissolution properties impaired by magnesium stearate.
- Talc around 2.5 microns in size gives the best performance in tableting.
- Talc particles having size range 2 to 3 microns can be used as both lubricant and gliadant. ^[48]

As a substrate for coating

Talc being physico-chemically and physiologically inert diluent ^[49-50] having the least adsorption capacity, unlike other diluents. ^[51] It has been used in the design of spherical agglomerates. While using talc as a carrier/inert core for drug loading, sphericity and strength of agglomerate are essential parameters deciding its suitability for coating process. To overcome the problem of poor strength, and impart sphericity to granules, Wet Spherical Agglomeration (WSA) of talc was carried out and pellets were explored as a substrate for coating. The talc agglomerates shows excellent micromeritic, and mechanical properties on comparison with sugar spheres. In pan coating, both sugar spheres and talc agglomerates showed comparable drug and polymer layering efficiency and similar types of drug release patterns in in-vitro studies, thus proposing talc agglomerates as inert substrates for coating. Also due to a deformable property of talc agglomerates during compression these are useful in the design of disintegrating heterogeneous matrices, having advantages of pellets and compacts. ^[8] Talc pellets produced by WSA and CCA, get deformed instead of fracture due to slippage of talc particles, which avoid the fracture during compression. The strength of talc pellets was relatively low compared to sugar pellets but the friability studies, suggest that it can withstand the rigorous vigour of attrition in coating operation. Hence, the talc pellets produced by WSA used as an inert substrate for coating. ^[52]

As a diluent in CCA

CCA is applicable for the size enlargement of all low or high doses, and single or more drugs in combination with or without diluent. Diluent must be inexpensive, physico-chemically and physiologically inert. Also it should be insoluble in aqueous phase to avoid losses through continuous phase. As talc fulfills all these requirements it has been selected as a diluent in CCA. It has been used in the CCA of some drugs like bromhexine hydrochloride, ibuprofen so that these shows improved micromeritic, compressional and drug release properties. The

spherical agglomerates obtained can be used as directly compressible agglomerates as tablet intermediates or acts a matrix beads to be encapsulated due to uniform distribution of crystallized drug particles on the surface of diluents. ^{[9],[53-54]}

In food industry

As it is harmless, chemically inert and passes through the body without being digested, it is approved as a carrier for food coloring and as a separating agent in such products as rice, powdered dried foods, seasonings, cheese, sausage skins or table salt.

In plastics and rubber

- 1. Modulus:** Talc increases the modulus of elasticity of polypropylene (PP) compounds and thus the stiffness of structures.
- 2. Color consistency:** PP compounds are dyed with colors, by using talc purified by the floatation process to obtain reproducible color hues.
- 3. Scratch resistance:** Grey talc can reduce the visibility of scratches.
- 4. Production rates:** Talc provides much higher heat conductivity as compared to polymers so that either heating or cooling of compounds is accelerated and productivity is improved.
- 5. Low abrasion:** Pure, chlorite-free talc grades result in extremely low abrasion values and thus useful in compounding and extrusion.
- 6. Nucleation:** The crystallization of polypropylene is efficiently promoted by small amounts of extremely fine talc (e.g. diameter of 2 μm or less) due to setting of nucleation at a higher temperature.
- 7. Rubber reinforcement:** Talc improves the mechanical properties of rubber compounds. It causes a reduction in gas permeability and electrical conductivity, increase resistance to UV radiation and provides good compression resistance.

In paint & coating

Talc in paint and coating is used as a functional component that introduces a number of properties.

In polyester putties

Talc is useful in putty for car and truck bodies in the proportions of up to 60% by weight.

In pleurodesis

When the incidence of pleural effusion occurs means collection of fluid around the lung takes place then pleurodesis is essential. Pleurodesis is carried out by Thoracoscopic (VATS) talc pleurodesis and Bedside talc slurry pleurodesis.

Agricultural use

It is used as a carrier for fertilizer and in the manufacture of insecticides and pesticides.

DRUG EXCIPIENT INTERACTIONS

Different talcs have different effects on the stability of certain drugs depending on its origin. The stability of the aspirin was adversely influenced by the presence of the calcium silicate in the talc rather than the aluminum silicate or red oxide. Thus the rate of the decomposition in the tablet formulation containing aspirin, phenacetin and caffeine minimized when talc was used as a lubricant.

HANDLING PRECAUTIONS

In the UK, the occupational exposure limits for talc are $10\text{mg}/\text{m}^3$ of the total inhalable dust long term (8 hrs TWA) and $1\text{ mg}/\text{m}^3$ of respirable dust long term (8 hrs TWA). Also eye protection, gloves and respirator are recommended.

SAFETY AND EFFECTIVENESS

Talc is not absorbed systemically and hence oral ingestion is non toxic. However, intranasal and intravenous abuse of products containing talc can cause granulomas in the body tissues particularly in the lungs. Contamination of wounds or body cavities with the talc may also cause granulomas; hence dusting of surgical gloves with talc should be avoided. Also talc inhalation produces irritation which on prolonged exposure may cause pneumoconiosis. Some suspicions have been raised about the possibility of talc to cause certain diseases like cancer of the ovaries. This is not widely recognized that talc may cause lung or ovary cancer. [55-56] The studies related to pulmonary issues [57], lung cancer [58], skin cancer and ovarian cancer [59] found that cosmetic grade talc containing no asbestos-like fibres was correlated with tumour formation in rats (animal testing) forced to inhale talc for 6 hrs/day, for 5 days of week up to at least 113 weeks. [57] As per the US FDA talc (magnesium silicate) is generally recognized as safe for use as an anti-caking agent in table salt in concentrations smaller than 2%. [60]

US FDA

In 1994, the US FDA and the International Society of Regulatory Toxicology and Pharmacology (ISRTP) had revealed that no hazards to health occurs from normal use of cosmetic talc.

US NTP

The National Toxicology Program (NTP) in the US considered talc for possible listing in the 12th Report on Carcinogens in 2004, but in October 2005 talc was withdrawn from their review process due to insufficient scientific data. [61]

In 2003, a meta-analysis of data on 11,933 subjects concluded that the available data does not support the existence of a causal relationship between talc exposure and an increased risk of ovarian cancer. [62]

In 2007, another meta-analysis was conducted to find out whether direct genital tract exposure of cosmetic talc from the dusting of contraceptive diaphragms is associated with an increased ovarian cancer risk. [63]

STABILITY AND STORAGE CONDITIONS

stability

Talc is a stable material and hence it can be sterilization by heating at 160⁰C for not less than an hour. It may also be sterilized by exposure to the ethylene oxide or gamma irradiation.

storage

Talc should be stored in well closed container in cool and dry place.

CONCLUSION

Talc deposits are most commonly formed by the hydrothermal or metamorphic alteration of the pre-existing rocks like tremolite, instatite, and other magnesium minerals and hence mining, grinding & purification of talc deposits is required to obtain purified talc powder. Now a days, talc is widely used in pharmaceutical formulation as well as cosmetics hence, the need was felt to review meticulous account of talc with respect to extraction from mines, purification, pharmaceutical and other applications. However as revealed from the available literature, talc is used as filler, lubricant and glidant in the pharmaceutical formulations as well as in cosmetic formulations as abrasive, absorbent, anticaking agent, opacifying agent and skin protectant. Also, talc is used as a dissolution retardant in the controlled release

products as well as novel powder coating because of its physicochemical, physiological inert and inexpensive nature. Due to its high functionality, its use gives novel products with lower costs, shorter time to market, and extended product lifecycle. Till date, not a single excipient exists, which will meet all these attributes. But, at this instance, the reserves and output of the highly pure white talc are limited. Hence, from the literature review, it can be concluded that the future challenge is to develop talc industries with the improvement in the technology for processing micro talc powder.

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