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Soybean Oil: Production Process, Benefits and Uses in Pharmaceutical Dosage Form

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1. Introduction

Vegetable oils are the most important source of fat in the human diet. Derived from an array of vegetable sources, oils are extracted and processed for a variety of food uses. In the demanding and competitive edible fats and oils marketplace, the product evaluation criteria are important for both customers and suppliers.

Soybean oil is very popular with rich value of Omega 3 and Omega 6. Those fatty acids regulate lipid and cholesterol metabolism and prevent narrowing in artery veins. In addition its high content of vitamin B makes digestion easier and by this feature it prevents chronic digestion problem and constipation. For those reasons, refined soybean oil is widely used all over the world.

Production of high quality meal and crude oil is the main objective in soybean processing. For achievement, thorough knowledge of the technical system and disciplined operation are required.

The starting point is reception of soybeans at the processing plant. And, the endpoint is meal delivered to the storage silos and oil delivered to the storage tanks.

First of all accurate weight, representative sample, accurate analyses are important criteria for receiving. Receipts, which need drying and cleaning before transfer to storage can be placed in interim storage. Also 'Tramp Iron Removal' part is important for magnets which should be strategically placed in the product stream to protect equipment from damage. Moreover removal of excessive foreign material should be accomplished before transferring soybeans to long-term or primary storage. Then drying equipments recognize the average moisture of the population.

Next primary or long-term storage facilities should include properly placed sensors to monitor the soybean temperature (Smallwood, 2001).

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Soybean dehulling methods differ primarily in the technique used to attain targeted moisture range. There are three types of dehulling methods; "In Conventional Dehulling" soybean tempering followed by cracking, screening and aspiration. "Hot Dehulling", which involves the use of fluidized bed to achieve the desired moisture equilibrium before cracking. "Esher Wyss Dehulling System", in which the soybeans are first cracked into two pieces prior to the use of a fluidized bed to achieve uniform target moisture content.

The purpose of soybean cracking is to provide pieces of the right size to make the best flakes for oil extraction and to remove the hulls. Following cracking and removal of hulls, screening and aspiration is used to separate the hulls from the meats.

Conditioning is used to soften the meats to optimize flaking. In flaking to expose the cell structure sufficiently for penetration of solvent and removal of oil in extraction process, the conditioned meats are fed through a single pair of smooth-surface rolls. With proper soybean preparation, the solvent drains adequately from the flakes at the conclusion of the extraction. In desolventizing step, the purpose is to remove the residual solvent in the wet flakes from the extractor.

In regard to meal quality, the most critical unit operation in soybean processing is toasting. Both urease and trypsin inhibitor which soybean contains can be adequately deactivated by subjecting the meal to the proper combination of temperature and time.

Following toasting, drying step is used to remove the moisture of meal. Forced air cooling is the preferred method for cooling the meal immediately after drying.

First screening, grinding and screening are the typical unit operations in meal finishing. The meal specifications established by American Feed Manufacturers Association (AFMA) are controlled by screening.

The last step for meal is storage of last product. Temperature, time, moisture, infestation, contamination are critical elements of meal storage quality.

If the oil is exposed to air at high temperature, severe oxidative degradation will occur. Thus, a heat exchanger must be included to cool the crude oil to 65 °C before exposing the oil to air in storage tanks. In addition each crude oil storage tank, the filling line should be extended to near the bottom of the tank to minimize oil aeration and oxidation.

Following step is refinery process of crude soybean oil. The operational steps to convert crude soybean oil to usable finished edible fat and oil products are given below. The starting point is reception of crude soybean oil at the processing plant. And the endpoint is deodorized oil loading to the transfer/transportation tank.

Processing sequence begins by the proper receipt and unloading of crude oil. Transporting container must be free of internal contaminants and protect the crude oil from external contamination. Before storage the crude soybean oil has to be sampled and analyzed.

After receiving, crude soybean oil transferred to the storage tanks. Those tanks must be constructed to provide proper isolation from other oils as contaminants.

Degumming is the first processing step for soybean oil which has high amount of hydratable phosphatides. This step provides producing the lecithin and reducing the phosphatide removal load in neutralization. Following degumming, neutralization (caustic refining) are essential part of processing for removing of fatty acids, phosphatides and other materials including protein meal, glycerol, carbohydrates, resins and metals.

The following step of the process, bleaching is used to reduce color pigments and remove oxidation products and residual soap left neutralizing.

To remove sufficient saturated triglycerides or wax from oil, winterization step is used. The process consist crystallization and filtration.

Last step of processing is deodorization. In deodorization process, removal of volatile components including free fatty acids, glycerol, oxidation products, sterol, herbicides and pesticides is done under high vacuum system.

Nitrogen blanketing of the head space above the oil level if possible, agitation to preclude any separation of the triglyceride components, temperature controlling capability, sampling capability are important properties for deodorized oil storing. And tank washing/cleaning at the proper frequency to preclude the accumulation of old oil films on the interior tank surfaces which would eventually reflux into the fresh oil.

During loading, tanks and oil transfer system cleanliness and washing capability are important parameters; also tanks must be conducted before oil loading is initiated.

As a result, for high quality refined soybean oil, the steps that we mentioned above are very necessary if they are performed carefully.

Refinery processing effects the components of oil. Means; fatty acid composition, free fatty acid value, peroxide value, soap value e.g. are depend on criteria of refining process. During refining, under some circumstances fishy odor, trans fatty acid formation and many contaminations may occur. To prevent those issues, refining process has to be performed professionally and attentively (Farhoosh, et al., 2009).

Most studies on the relationship of diet to heart disease have focused on the theory that high levels of serum lipids are related to intake of dietary fats and oils and the reduction in the quality or change in the kind of dietary fat will lead to a lowering of lipid levels in the blood which in turn may help to stop or to slow the progress of these disease.

Soybean oil is classified as polyunsaturated oil which includes about 15 % saturates, 24 % monounsaturates and 61 % polyunsaturates of which 53.2 % is linoleic acid while the linolenic acid content is about 7.8 %. The nutritional advantages of this composition and it's effects in regulating the plasma lipid and eicosanoids bio - synthesis are reviewed on the basis of results from several human clinical trials and studies. These studies have shown that soybean oil effective in lowering the serum cholesterol and LDL levels, and likely can be used as potential hypocholesterolemic agent if used as a dietary fat and ultimately help prevent atherosclerosis and heart diseases (Kummerow, et al., 2007).

Attention also drawn to the ability of soybean oil to regulate the eicosanoids balance in such a manner that reduce the atherosclerotic and thrombotic tendencies which are the main causes of heart attacks and strokes. These positive findings on the effect of soybean oil on the cardiovascular system are attributed to its unique fatty acid composition. Soybean oil provides the optimum linoleic to linolenic acid ratio which is the key to achieve the desired balance between the various categories of eicosanoids that help in prevention of heart diseases.

Soybean oil is a rich source of vitamin E. Vitamin E is essential to protect the body fat from oxidation and to scavenge the free radicals and therefore helps to prevent their potential effect upon chronic diseases such as coronary heart diseases and cancer (Lu and Liu, 2002).

In regard to human nutrition, the U.S. Food and Nutrition Board , recommends an intake of 8 - 9 mg of alpha - tocopherol equivalents/day for adult . Considering an alpha - tocopherol level of 11 mg/100 g in a typical salad and cooking oil made from soybean oil, a 1 - table - spoon (14 g) serving of such a food would contain 1.5 mg of alpha - tocopherol. Thus a single serving of this product would provide about 15-20 % of an adult's recommended daily intake as established by the U.S. Food and Nutrition Board.

Soybean oil is a rich source of essential fatty acids, both linoleic and linolenic acid. These polyunsaturated fatty acids are important key to prevent cardiovascular diseases by

lowering serum cholesterol through reducing lipoprotein (LDL) synthesis and increasing lipoprotein breakdown , as well as by the effect of linolenic acid. Linolenic acid reduces plaque formation and thrombosis by decreasing platelet aggregation, promoting prostaglandin E3 synthesis.

Attention must be drawn to possible adverse effects arising from over consumption of polyunsaturates. Polyunsaturated fatty acids are especially prone to oxidative rancidity and the products of oxidation may contribute to cardiovascular risk. To unfold their health benefits, they must be protected from oxidation by using antioxidants both in the diet and in supplements. For this purpose, the most commonly used naturally occurring antioxidant is vitamin E. According to some researchers the intake of vitamin E should be increased in line with increased intakes of polyunsaturated acids. They have estimated that the more suitable daily ratio will be 0.6 mg alpha - tocopherol / gram polyunsaturated fatty acids.

Drugs must be properly formulated for administration to patients. Especially, lipophilic or low solubility drugs are a major problem in pharmaceutical formulation design. Emulsions are attractive candidates for improving drug solubility. They are well accepted for their ability to incorporate lipophilic drugs, to reduce side effects of various potent drugs, to increase the bioavailability of drugs, and to prolong the pharmacological effects in comparison to conventional formulations. Emulsions are mixtures consisting of one (or more) immiscible liquid phase(s) dispersed in another. Oil-in-water (O/W) or water-in-oil (W/O) emulsions have been widely used in pharmaceutical formulations. They are also used as carriers for the delivery of water insoluble drugs (Duenas-Laita et al., 2009; Han et al., 2010; Ince et al., 2007; Karasulu et al., 2004, 2007; Zhao et al. 2010). Recently, oil-in-water (O/W) submicron-sized emulsions are commonly used for parenteral administration of lipophilic drugs which are a major problem in pharmaceutical formulation (Prabhakar et al., 2011). In addition, emulsions have the potential to achieve sustained drug release, and for site-specific drug delivery by binding ligands for various cell surface receptors to the particle surface (Nishikawa&Hashida 1999). The oils typically used for pharmaceutical emulsions consist of digestible oils from natural sources such as soybean oil. Soybean oil is very popular because it is cheap, healthful and has a high smoke point. Soybean oil does not contain much saturated fat. Like all other oils from vegetable origin, soybean oil contains no cholesterol. Saturated fat and cholesterol cause heart diseases and mainly found in products from animal origin such as milk, cheese and meat products. Soybean oil contains natural antioxidants which remain in the oil even after extraction. These antioxidants help to prevent the oxidative rancidity. Therefore, soybean oil is not only used in food products but is also used as pharmaceutical excipients to produce a novel, biocompatible formulations which are cost effective, non-irritating, and capable of being sterilized before application (Rowe et al. 2006).

2. Nutritional benefits and usage of soybean oil

The dietary fat consumption for about 70% of the population averages 62,5% of the recommended amount for good health. Soybean seed (Fig. 1.) oil is the one of the most preferred oil for an healthy life. The reasons that people's choice are quality, functionality, being precursors of Omega-3, Omega-6 and Vitamin E, having a low price of soybean oil (Mounts et. al., 1986).

Beyond that, the Chinese have included soy protein in their diets for thousands of years. In other parts of the world, dietary protein has come largely from meat. On the basis of economics, it is much less expensive to produce vegetable protein than animal protein. From

the perspective of ecology, production of vegetable protein is much more favorable than animal sources.



Fig. 1. Soybean seeds

Proper intake of essential fatty acids derived from polyunsaturated fats and oils are critical for human growth and health. About 61% of the fatty acid chains of the soybean triglyceride molecules are polyunsaturated. Soybean oil and protein are vital elements in the world food supply (Fig. 2 and 3).

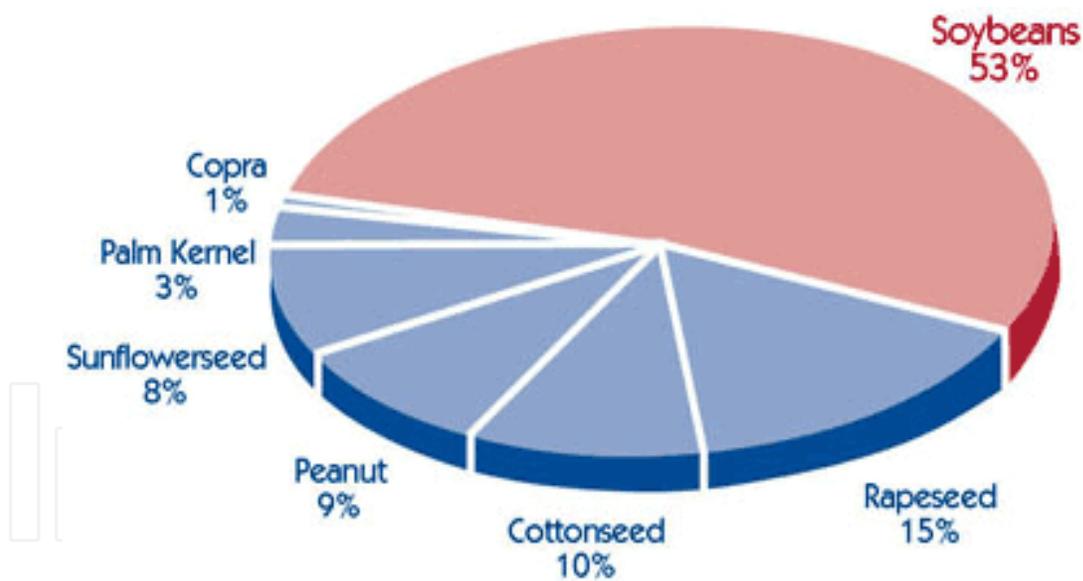


Fig. 2. World Oilseed Production of 2009

Essential fatty acids are required for the human body to produce prostoglandins. Prostoglandins are long-chain fatty acid derivatives synthesized by most cells in the body and affect many of the vital physiological functions. Essential fatty acids are polyunsaturated fatty acids.

Vitamin E (tocopherol) is important for the human body to sustain cardiovascular health. For older males, vitamin E serves as an effective deterrent to prostate cancer. Soybean oil contains more Vitamin E than any other commonly consumed vegetable oil. Tocopherol is a naturel anti-oxidant which serves to retard soybean oil oxidative degradation.

Soybean production, about 24 million metric tons of oil are extracted and largely utilized for human food each year (Fig. 3.). With a fatty acid composition of 61% polyunsaturated and only 15.5% saturated, soybean oil can be utilized in a broad array of products.

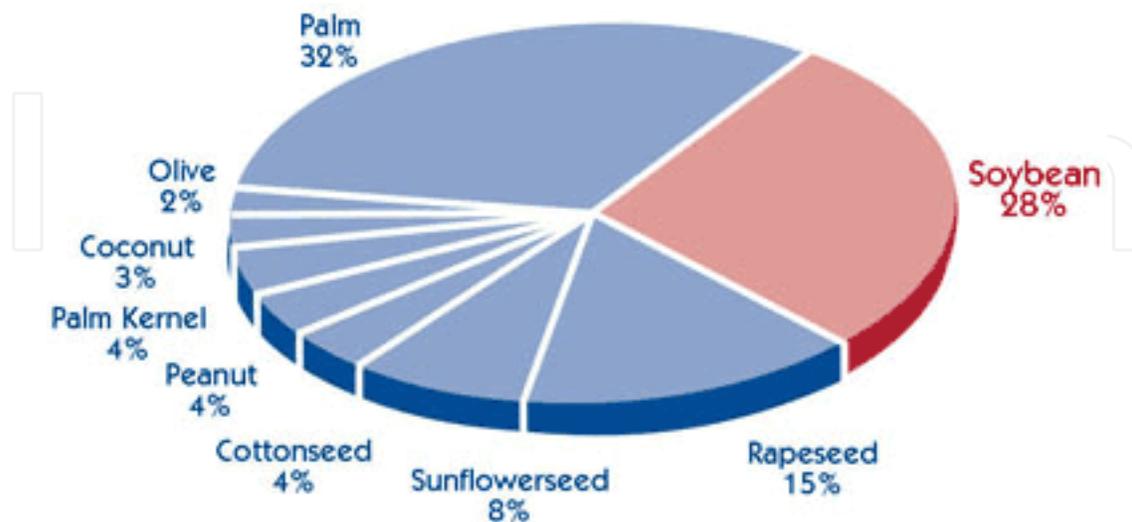


Fig. 3. World Vegetable Oil Consumption of 2009

The neutralized-bleached-deodorized soybean oil is usually used as salad oil, cooking oil, baking fats, confectionary fats, ingredient for margarine and mayonnaise, heavy-duty frying oil if blended with a high stability oil like cottonseed or palm oil. The lightly, lightly too moderately, moderately, moderately too highly and highly-hydrogenated oil is used as frying oil, ingredient for margarine, shortening, confectionery fat and stabilizer applications.

To sum up; soybean oil is rich in polyunsaturated fats, regulates the body temperature, transport fat-soluble vitamins throughout body, rich source of Omega-3 fatty acids and good source of antioxidant Vitamin E.

2.1 Edible oil processing operations

2.1.1 Cold pressed oil

Full pressing is still used on a variety of raw materials for oil extraction particularly when the residual oil left in the meal after pressing is not critical. The very high pressure required to extract the cold pressed oil produces high temperatures which may produce a poorer quality oil and meal (Erickson, 1983).

Today although full pressing is still being used, many full press machines have been converted to pre-pressing or have been replaced with new pre-presses. The modern pre-press machine will remove fifty to sixty percent of the oil contained in the seed, producing a cake that will have the remaining oil removed with solvent extraction. This method of used for high oil content seeds. On the other hand, full pressing is still useful if the high amount of oil is expected from seed.

The operational steps to convert crude vegetable oil to usable finished edible fat and oil products are given in the typical sequence and simply explained in this section. Each sequential step has a specific purpose and is included on the basis of providing the most efficient and cost-effective method for achieving the product quality and yield objectives.

2.1.2 Processes of cold pressing

The whole or de-hulled soybean at field moisture content is fed continuously to the dry extruder. The extruder is set up in appropriate configuration to achieve the desired degree of cooking. Within the extruder barrel, the material is subjected to friction, shear and pressure whereby heat is generated through viscous dissipation of mechanical energy. No external heat source such as steam is required for the process when using dry (autogenous) extruders. The temperature during cold pressing should not exceed 50 °C (Moreau & Kamal-Eldin, 2009). The temperature profile within the extruder barrel can be varied depending upon the intended use of the processed protein meal.



Fig. 4. Cold Pressed Oil Production

Typically, the top temperature at the exit of the extruder barrel is about 150 °C. Lower temperature profiles are used when the meal is intended for use as a functional ingredient in food application. Higher temperature profiles are used when the meal is used directly in feed formulation for various animal species. The average residence time of the material within the extruder is under 30 seconds. The frictional forces within the extruder barrel and the sudden decompression of the material as it exits the extruder cause the rupture of the cell structure and release of oil from the sub-cellular sites.

Soybean exiting the extruder is immediately and continuously conveyed into a continuous horizontal screw press where the oil and meal are separated. The process of extrusion changes the physical characteristics of the soybean from solid particles to an oily meal. The bulk density and compressibility are drastically altered. Hence, a conventional screw press designed to press whole oil seeds will not handle the extruded soybean. The pressing worm and the barrel cage of the press must be re-configured to handle the extruded product. The process of extrusion results in significant increase in the throughput rate of the press over its rated capacity for whole oil seeds. The oil and meal exiting the press are at elevated temperature. They are further processed or cooled to near room temperature before storage. Pressed soybean oil has high value of tocopherol which imparts oxidative stability to the oil (Fig. 4).

2.2 Why should soybean oil have been refined?

Most crude oils and fats consist for more than 95% of mixtures of triacylglycerols. The non-triacylglycerol fraction contains variable amounts of phosphatides, free fatty acids, oxidation products, unsaponifiable matter (tocopherols, sterols, hydrocarbons etc.) and other so-called impurities the quantities of these minor components in crude oils vary with the oil source, extraction process, season and geographical origins. They can have different effects on the nutritional, functional and organoleptic properties of the oil.

The general objective of refining is to remove those components that have an adverse effect on the overall oil quality with the least possible damage to the triacylglycerols. At the same time, minor components with a known positive impact have to be retained as much as possible in the oil (Farhoosh, et al., 2009).

Some components like fatty acids, mono and diacylglycerols and phosphatides are the glyceride origin. Although phosphatides protect the crude oil from oxidation, they need to be removed because of their negative effect on the color, taste and oxidative stability of the oil.

Other minor components can be isolated in the unsaponifiable fraction. The main components of the unsaponifiable fraction (0,3-2%) include sterols, tocopherols, hydrocarbons, pigments and vitamins.

The potential possible impact of some components of the unsaponifiable fraction, on health receives a lot of attention. Tocopherols for example are the most important natural antioxidants of phenolic nature protecting the edible oils from oxidation (Lu & Liu, 2002). On the other side, tocopherols are also biologically active substances with a generally accepted vitamin activity in the human body. Phytosterols are desired because they may reduce blood cholesterol levels.

2.3 Processes of refining

2.3.1 Crude vegetable oil receiving and unloading

The processing sequence begins by the proper receipt and unloading of crude oil. The first significant product vulnerability occurs in the transportation means for the crude oil. The transporting container (tank car, tank truck, barge or vessel) must be free of internal contaminants and protect the crude oil from external contamination (Fig.5).

Upon receipt of the crude oil at the processing plant, the oil is sampled and analyzed before unloading to identify oil type and ascertain edibility. The unloading equipment (fittings, hoses, pumps, pipelines, etc.) must be protected to preclude contamination from various sources including rodents, insects and birds (Smallwood, 2001). Finally, if necessary to heat the crude oil to facilitate unloading, proper control must be exercised to avoid overheating.

2.3.2 Crude vegetable oil storage

Storage of crude oil prior to processing is required to build sufficient inventory for efficient processing runs. The kind of storage tanks used and the storage conditions are important considerations. Storage tanks must be constructed to provide proper isolation from other oils and external contaminations. Each storage tank should be equipped with effective agitation to provide uniform mixing of the crude oil components and homogeneous feed to processing. Storage time should be minimized to avoid and analyzed before the start of each processing run to establish proper processing conditions.

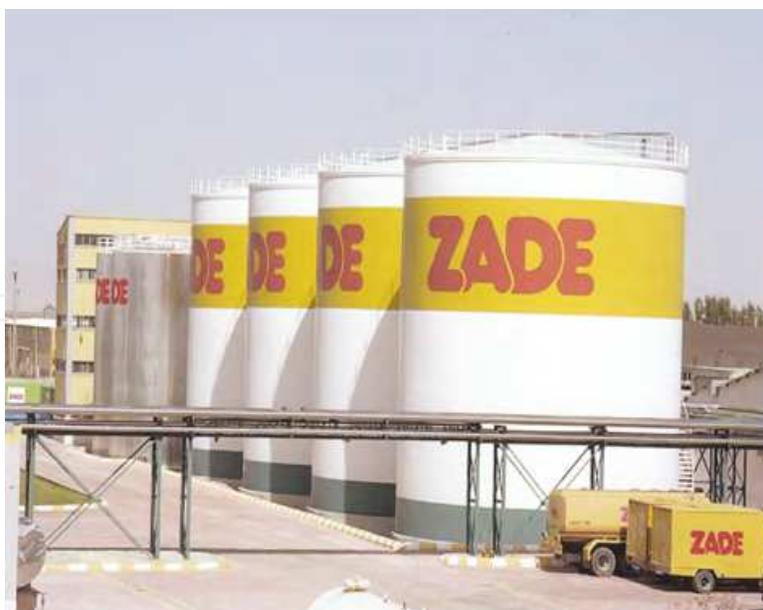


Fig. 5. Crude Vegetable Oil Silos

2.3.3 Degumming

Degumming is frequently the first processing step for crude oils like soybean which contain relatively high amount of hydratable phosphatides which are soluble in triglycerides (Karleskind&Wolff, 1996). Hydratable phosphatides can be removed from oil by adding the proper quantity of water, mixing thoroughly, allowing time for the hydration to occur, and separating by centrifugation. For this process, water is injected into the crude oil feed stream in proper proportion to the quantity of water-hydratable phosphatides. After sufficient hold time in a surge tank, the process stream is fed to centrifuges for separation of the hydrated phosphatides (gums) from the oil stream.

The crude oil feed stream is filtered to remove particulate matter if the subsequent gum recovery is for producing lecithin. Properly designed and operated water degumming process can achieve at least 90% of the ideal. Consequently, achieving the typical trading rule specification of 200 ppm phosphorous maximum is usually not a problem.

Degumming provides the advantages of producing lecithin and reducing the phosphatide removal load in caustic refining. If physical refining is subsequently employed, it is essential to degum oils high in phosphatides for both economic and product quality purposes.

With the very best degumming, some water-hydratable phosphatides are left in the oil. Further hydration of water-hydratable phosphatides occurs in storage due to atmospheric moisture condensation on the exposed interior tank surface. If the storage tanks are not equipped with the mechanical agitation the hydrated phosphatides settle to the bottom of the tank over time. Each individual tank truck, tankcar or barge shipment of degummed oil drawn from a given static storage tank will have a different phosphorous levels. Consequently, degummed oil storage tanks should be equipped with a properly specified and installed mechanical agitator to sustain product consistency.

If emulsions are formed in the degumming process and are still present in the product stream at the inlet of the centrifuge, efficient separation will be difficult (Fig. 6). Depending upon the centrifuge back-pressure setting, the emulsion will be separated as either part of the degummed oil (light phase) or part of the wet gums (heavy phase). If the emulsion is part of the degummed oil phase, the phosphatide level will be high. If the emulsion is part

of the wet gums, the oil loss will be high. Formation of emulsions must be avoided to in the degumming process to achieve high-quality and high-yield oil. Use of hard water and turbulent flow conditions may cause emulsification.



Fig. 6. Degumming Separator

Lab-scale degumming tests can be done to guess proper degumming process. When degummed oil quality problem are encountered, first thoroughly check the actual process to determine any detectable anomalies (Karleskind&Wolff, 1996). If processing condition deviations are found make a proper corrections and determine if the oil quality problem is corrected by the changed conditions. If the cause of the problem is not readily apparent, use the lab test to identify the problem cause. The lab tests are relatively fast and can be controlled. It is a much more efficient method than testing on a plant scale.

2.3.4 Neutralization

The purpose of caustic refining (neutralization) is to remove free fatty acids, phosphatides and other materials including protein meal, glycerol, carbohydrates, resins and metals. In addition, some color reduction (pigment removal) is achieved.

Crude oil, degummed oil or mixtures of crude and degummed oil are fed to the refining process. Caustic soda (sodium hydroxide) is fed in the proper strength and quantity to react with the free fatty acids and phosphatides to form soapstock and hydratable gums.

Having polar and hydrophilic properties, the soapstock produced is effective in removing some of the other impurities from the oil stream. Soapstock and other impurities are separated from the oil by centrifuges.

The processing endpoint for caustic refining varies according to the quality of the crude or degummed oil. It could be free fatty acid, phosphatide or color level. The impurity most difficult to remove in meeting the in-process oil specification determines the refining endpoint.

Caustic soda is not completely selective in reacting with the targets of free fatty acid and phosphatides; therefore, some triglycerides are hydrolyzed and saponified (broken down and converted to soap). Thus, selecting the proper strength caustic soda and the caustic-oil exposure time are key considerations to maximize the yield of refined oil (Smallwood, 2001). Some processors pretreat crude oil with phosphoric acid to hydrate the phosphatides that are not water hydratable. Thus, the caustic soda addition requirement in refining is reduced by the amount which would have been needed to hydrate the gums. Refining loss is slightly improved due to less exposure of triglycerides to caustic soda.

Usually, the most significant cost factor in neutralizing is oil loss. Oil loss occurs in two ways; saponification loss and separation loss. Saponification loss is consequence of caustic soda being in contact with neutral oil. While caustic soda is much more reactive free fatty acid saponification and phosphatide hydration, some reaction occurs with the triglycerides (hydrolysis and subsequent saponification of the free fatty acids). By keeping the caustic soda strength, the contact time and the contact temperature low, saponification of triglycerides can be minimized.

The second occurrence of oil loss is in the separation (Fig. 7) of the refined oil (light phase) from the soapstock (heavy phase) produced in caustic refining. The magnitude of the separation loss is a function of specific gravity difference between the light and the heavy phase, the presence of an emulsion (a third phase), the separation method, the design and condition of the separator, and the temperature of the product stream through a centrifuge. To achieve the lowest separation loss, the process design should reflect minimum product stream passes through a centrifuge.



Fig. 7. Neutralization Separator

The advantage of continuous neutralization is the very short contact time between oil and soda, which reduces the risk of saponification. A good separation between soap and oil phases after neutralization depends largely on the correct execution of phospholipids 'conditioning', as the surfactant properties of phospholipids favor the emulsion. Possibly, similar effects are produced by the presence of considerable quantities of mono and diglycerides and glycerides whose chains are heavily oxidized.

2.3.5 Bleaching

The implications of bleaching are substantial and are often misunderstood or underrated. The common misconception about bleaching is to consider the purpose limited to reducing the color pigment level. Removal of oxidation products, residual soap left from caustic refining and metals along with further reduction of the phosphatide content are the functionally-essential requirements.

Bleaching is known as a mass transfer process that involves the partial removal of the oil-soluble, non-triglyceride components from the oil stream by changing the physical state to a solid separating the solids from the oil stream by filtration. Specifically, the non-triglyceride components in a liquid state are changed to a solid state by adsorption on to the surface of the solid bleaching earth particles added to the oil stream.

To optimize the performance of edible oil bleaching, the process design and the operating variables involved must be selected to drive the equilibrium toward maximum adsorption within the required product quality and operational equipment restraints.

Increasing temperature improves adsorption. The oil temperature for bleaching is limited to the maximum allowable for the amount of air (oxygen) exposure occurring in the process. The air exposure is determined by the vacuum capacity of the bleaching vessel, the mechanical condition of the system (air entry), and operating practices, the maximum allowable temperature is in the range of 104 to 116 °C (220 to 240°F) with a vacuum level of 50 mm Hg (absolute). In the case of bleaching at atmospheric pressure (about 760 mm Hg), the maximum allowable temperature is 65 °C (150 °F).

Time is a primary factor in the context of the probability that the undesirable, non-triglyceride components will come in contact with a bleaching earth surface feature that is capable of adsorption. In the bleaching vessel prior to filtration, the probability of adsorption occurrence is expended in about 20-25 minutes. After about 20-25 minutes, the rate of adsorption becomes asymptotic.

Proper bleaching vessel (Fig. 8) design must include sufficient agitation to keep the bleaching- earth particle in suspension and uniformly dispersed. Vessel design must assure plug flow of the oil column from top inlet to bottom outlet for providing 20-25 minutes of residence time for the total oil stream.

The surface condition of the clay particles is a critical factor in bleaching. Adsorption occurs at points on the clay crystal surface where a sharp edge, striation, or boundary is exposed. Natural clay mined for use as bleaching earth contains other material that can interfere with adsorption (Omar, et al., 2003). Often deposits of clay contain basic compounds such as calcium carbonate that can cover a significant portion of the clay crystal surface features capable of adsorption.

Acid-activated clay has been treated with a mineral acid to react with and dissolve the basic compounds on the surface of the clay particles. The activation significantly improves the performance of the bleaching earth by increasing the exposure of surface features capable of adsorption.

The mechanism of bleaching is adsorption using natural or acid-activated clay. The process is carried out by adding the proper amount of clay to the refined oil stream. Typical bleaching conditions include a minimum of 20-25 minutes contact time between the clay and the oil, a temperature range 104 to 116 °C (220 to 240°F) and a vacuum of 50 mmHg absolute. Subsequently, the spent clay is filtered out of the bleached oil.

Moisture enhances adsorption within a specified range that varies with the type of bleaching earth used. Most vendors can offer guidance on the optimum oil moisture content for the bleaching earth supplied. If this information is not available, laboratory scale bleach test can be performed on oil samples with varying moisture content to determine the optimum level.



Fig. 8. Bleaching Step

Quality of the oil feed to the bleaching process is another critical determinant of bleaching performance. If impurities are present in the oil which covers the clay surface features necessary for adsorption, the bleaching effect mass transfer will be proportionally reduced. Impurities like phosphatides, soap and polymerized oil are especially detrimental to bleaching by coating the clay particle surface features.

From the bleaching earth slurry tank the oil with bleaching earth is pumped through an oil to oil heat exchanger (economizer) to gain heat from the hot oil exiting the bleaching vessel. The design parameters for this oil to oil heat exchange (equipment type and product stream velocity) are critical to preclude fouling and frequent cleaning. From the oil to oil heat exchanger, the product stream passes through the final heat exchanger to for heating by steam to the targeted bleaching temperature.

On exit from the final heat exchanger, the oil-bleaching earth slurry flows to the vacuum bleaching vessel. Typically, the bleaching vessel is installed with the long dimension in the vertical position. Oil enters near the top of the vessel through nozzles to evenly distribute the flow over the top surface of the oil column. In the top of the vessel, a demister pad is installed to condense and reflux oil droplets in the vapor stream pulled from the vessel by the vacuum. To keep the bleaching earth uniformly dispersed in the column of oil in the

vessel, a multi-impeller top-entering mechanical agitator is used. Baffling is installed from the vessel walls between agitator impeller stages to maximize plug flow of the oil column from top inlet to bottom outlet. The baffling minimizes the chance of short circuit flow to assure that the residence time for all of the oil is at least 20-25 minutes in the vessel.

After exiting the bleaching vessel, the oil-bleaching earth slurry passes through the economizer then to a pre-coated filter.

After each bleaching filter cleaning, clean (filtered) bleached oil is pumped to the pre-coat and sufficient diatomaceous earth (filter aid) is added to and mixed with the oil to provide a protective film over the all of the filter media surface area in the clear filter. The filter aid is uniformly deposited on the filter media by completely filling the filter with the oil-diatomaceous earth slurry and re-circulating the stream until complete deposition occurs.

Filter pre-coating as described above offers both product quality and operating economic advantages; oil quality is enhanced by better removal of solids from the product stream, oil recycle on start-up a cleaned filter can be minimized or eliminated and filter media is protected from direct contact with fouling substances like soap, phosphatide and polymerized/oxidized oil. The life of the filter is thus improved for each operating cycle and the number of uses before washing of the media is required.

In recent years, most equipment vendors have replaced mechanical agitation, with steam sparing to maintain bleaching earth dispersion in the vacuum bleaching vessel. The justification for this design change has been on the argument that the moisture addition enhances adsorption. From the author's perspective, careful analysis reflects that the economics of this change are not favorable and that mechanical agitation remains as the preferred solution. It is outside of the scope of this presentation to probe the details of this matter.

Using filtration leaves requires the use of safety filters generally equipped with paper, filtration cardboard or cellulose products. The selection of a filter is based on the type of installation (continuous or discontinuous flow) local factors (cost or labor) and goal (primary or safety filtration). The plugging reduces the filtration flow and that plugging is slower if the flowing speed into the porous wall is low.

Metal cloth or leaf supports the filter cake made of a mix of filtering and bleaching earths that formed the porous wall. The gaps between the metallic cloth mesh is such that a layer of cake has to be spread before starting to filter. This type of filter always allows the passage of traces of earth; thus, a safety net must double it.

A polished filter is provided for the oil stream before entry to bleached oil storage. A bag-type filter is usually preferred. Pressure drop can be continually monitored across the polish filter to detect anomalous bleaching earth content or when it is necessary to routinely replace the filter bags.

Installation of an in-line turbidity monitor can be beneficial to detect to presence of bleaching earth particles and divert/recycle the product stream before ether bleached oil in storage is fouled.

To transport the bleached oil to storage, a transfer pump is required in the scheme unless gravity flow is possible to the storage tanks, which is usually not the case. If closed filtration systems are used, it is not permissible to connect the transfer pump directly to the filter discharge. If that were to be done, a hydraulic pulse would be transmitted back to the filter and disrupt (crack) the filter cake, which would result in bleaching earth particles passing through the filter media and the oil would be fouled. For closed filter systems, it is necessary to discharge the oil from the filter after passing through the economizer into a hydraulic-

impulse break tank that is under atmospheric pressure. If nitrogen is available, the bleached oil in the hydraulic- impulse break tank must be kept under nitrogen blanket to preclude oxidation. In the case that nitrogen is not available, the hot oil from the economizer must be cooled to at least 40°C-65°C before entry to the hydraulic-impulse break tank, the pre-coat tank, or bleached oil storage tanks. Furthermore, for open filtration systems, the bleached oil-spent bleaching earth slurry must be cooled to 40°C-65°C before filtration to preclude oil oxidation at the filter outlet, where atmospheric exposure occurs.

An in-line colorimeter is installed in the oil pipeline to bleached oil storage. The signal from the colorimeter is feed to a control loop for adjusting the feed rate of bleaching earth addition to the slurry tank. With this capability significant economic advantage can be gained from the fact that as the bleaching earth filter cake thickness increases, the adsorption probability is increased, which results in improved bleaching performance. Thus, over the life of the filter cycle, the amount of bleaching earth required to meet the specified endpoint (color in most cases can be continually reduced). At some point in the filter cycle, the amount of bleaching earth addition may drop below the level necessary to sustain adequate cake porosity for maintaining the needed flow rate. To avoid this occurrence, the control system is designed to initiate and ramp up the addition of the sufficient diatomaceous earth (filter aid) to sustain the needed filter cake porosity. Careful economic analysis is needed to assure that the operating parameters selected are advantageous.

The processing endpoint for bleaching is determined by the most difficult of the factors to achieve in meeting the bleached oil specification (color, soap, oxidation products, metal or phosphatide). In theory, properly bleached oil should have a zero peroxide value (Bailey, 1996). In practice, it does because the sample taken for analysis is usually exposed to the atmosphere (air); thus the presence of peroxide will be found typically < 1.0 meq/kg.

With physical refining, caustic refining is by-passed; thus bleaching along with phosphoric acid pretreatment are the only tools available to clean up the oil stream prior to the final processing step of deodorization.

2.3.6 Winterization

The purpose of winterization is; to produce a product higher in unsaturated, to remove sufficient saturated triglycerides or wax from an oil in order that the liquid fraction will remain clear and brilliant at room temperature for aesthetic purposes and isolate the saturated fraction for use in formulating products to achieve specific functionality.

In most cases, the winterization process is a less sophisticated form of a dry fractionation. The oil is cooled slowly and kept at a low temperature for a long time to allow the waxes to crystallize. After stabilization, oil temperature is normally increased to about 15°C to allow easier filtration by lowering the viscosity. In order to facility crystallization and filtration some filter aid is usually added.

There are different types of filters (Fig. 9) that can be used to remove the waxes and filter aid from the oil.

Moreover, crystals appear and create turbidity then a settling prejudicial to the oil's commercial image. This additional treatment is required to obtain oil that will remain clear and shiny, regardless of storage conditions. This process is 2 step processes, containing a cooling that causes crystallization at an elevated melting point and a separation of the formed crystals. A cooling down to 5-6°C (41-43°F) causes the oversaturation desired and a crystal growth (Gomez, et al., 2002). The latter consists in maintaining the mixture at this

low temperature until complete crystallization of the waxes and the formation of crystal sufficiently large not to hinder the second step that is separation. Originally, wax crystals were barely left to naturally decant during the winter storage of oil.

The winterization process is accomplished by cooling oil to a temperature sufficiently low to solidify (crystallize) the saturated triglyceride fraction or wax. After crystal formation is complete, the gently agitated oil is transferred through a filter to separate the fractions (liquid and solid).



Fig. 9. Winterization filters

2.3.7 Deodorization

Deodorization is the final step in the processing sequence of converting crude vegetable oil or fat to an acceptable product for human consumption. In the deodorization process, the remaining impurities are either removed or reduced to a sufficiently low level for the production of acceptable flavor and functional edible oils and fats. While oils and fats do not harbor the growth bacteria and other organisms, one of the benefits of deodorization is to completely sterilize final product (Bockisch, 1998).

With deodorization, relative bland flavor and odor, essentially complete removal of residual herbicide and pesticide residue, low free fatty acid content, removal of oxidation products (zero peroxide content), low moisture content (about 0,05%), color reduction through heat bleaching of the carotene pigments improvements achieved.

Usually the last step of in the actual processing sequence, deodorization is utilized to remove volatile components including free fatty acids, glycerol, oxidation products, sterols, herbicides and pesticides. Heat bleaching of carotene and xanthophylls color pigment is achieved. Normally, a chelant, like citric acid, is injected into the deodorized oil stream for reacting with any residual metals. The metal salts formed are subsequently removed from the oil by filtration.

Deodorization is carried out in batch (Fig. 10), semi-continuous or continuous systems. The deodorization principles are the same regardless of the system used. By heating the oil up to a temperature in the range (230-260°C) under a vacuum of 2 to 10 mm Hg absolute, the non-triglyceride components and steam (vapor steam) are removed from the deodorization vessel by the vacuum system.

As previously mentioned, product sterilization occurs in the deodorization process as the consequence of the high temperature and the injection of live steam in to the product stream. Like bleaching deodorization is a mass transfer process that involves the partial removal of the oil-soluble, non-triglyceride components from the oil stream by changing the physical state. In deodorization, the non-triglyceride components are changed from a liquid to a vapor state with subsequent removal of the vapor by vacuum. Conditions are established to raise the partial pressure of the non-triglyceride components from transformation to the vapor state. Mass transfer is an equilibrium-type phenomenon. The variables involved in the deodorization-process mass-transfer equilibrium (vaporization of the non-triglyceride components) are; temperature, pressure (vacuum level), height (thickness) of the oil column, time (operating rate), stripping steam addition rate, molecular weight (kind) of the oil fed to the process, quality of the oil fed to the process.



Fig. 10. Deodorization step

To optimize the performance of deodorization, process design operating variables involved must be selected to drive the equilibrium toward maximum vaporization of the non-triglyceride components while minimizing the removal of the oil. By increasing temperature, the partial pressure of each component fraction is increased in relation to the molecular weight. Oil temperature in the range of (230-260°C) is common for deodorizing vegetable oils. The temperature at the top of the range is applicable to most of the highly polyunsaturated oils (Brekke, 1980). If the high temperature is not applied during refining fishy odour may occur. For this reason, performance of the deodorization process has to be done attentively.

By reducing the pressure (increasing the vacuum level), the partial pressure required for transformation to the vapor state is reduced relation to the molecular weight of each component fraction.

Deodorization efficiency is inversely proportional to the height of the oil column. The first deodorizer vessels constructed were batch type with the oil column height in the range of 2 to 4 meters high. The time required to deodorize a batch of oil ranged between 1 and 4 hours. For the most part, tray-type deodorizers have replaced batch deodorizers with about one meter of oil depth in each tray. With tray-type deodorizers, the deodorization time is less than 1 hour. Finally thin-film deodorization has been developed with oil film on the packing approaching one-molecule thickness. The deodorization time for thin-film deodorizers is measured in a few minutes.

Live steam is injected at the bottom of the oil column, bottom of each tray, or bottom of the packed thin film column by means of a sparge ring or other nozzle configuration. The quantity of steam added ranges from 1,5 to 3,0% of the oil-feed rate by weight. Steam addition of 2,0% of the oil-feed rate by weight is the most common practice. The purpose of the steam is to provide a highly-volatile vapor stream to strip out the less-volatile non-triglyceride components.

The molecular weight of the triglycerides in the oil feed stock affects the deodorization conditions. Shorter fatty acid chain triglycerides with lower molecular weight are easier to deodorize than longer fatty acid chain triglycerides.

Feed-stock quality has a profound impact on deodorization performance. The capacity (operating rate) of deodorization is largely determined by the amount of non-triglyceride components in the feed-stock. Each deodorizer is designed to handle a specific vapor load. The operating rate cannot exceed the vapor removal capacity of the process. Thus, as the proportion of non-triglyceride fraction of the feed stock increases, the deodorization rates reduced to not exceed the maximum vapor removal capacity.

Deaeration is accomplished by the product stream flowing counter to the injection of live steam in a vessel under vacuum (about 3 mm Hg). Deaerator vessels are designed with either a packed or open column. The product stream enters the deaerator vessel near the top while the live steam (stripping steam) is injected above the bottom oil reservoir. A level control loop is provided to maintain the desired oil level in the deaerator bottom reservoir. In the top of the deaerator, a demister pad is installed to condense and reflux any oil droplets entrained in the vapor stream exiting the vessel. Oil is removed from the deaerator vessel by means of a centrifugal pumped located at an elevation sufficiently below the bottom of the deaerator to maintain a net-positive-suction head. To preclude air entry into the hot, deaerated oil stream, the aerator discharge pump is usually magnetically coupled to the drive motor to eliminate the mechanical seal, or the pump is equipped with a double mechanical seal. From the deaerator, the product stream passes through an oil to oil heat exchanger for additional heating. Various designs are used to achieve this energy conservation. The heat exchange is accomplished by means of a heat recovery tray in which a tube bundle is inserted for the product stream to pass through prior to entry into the top tray of the deodorizer.

In the top tray of the deodorizer, the product is heated to the targeted deodorization temperature by heat transfer from high-pressure steam or a heat transfer fluid circulated through the tube bundle or coils in the tray.

The product stream exits the heating tray and subsequent trays by means of an overflow pipe that provides the flow path to the tray below. In the top heating tray, live steam is

added through a sparger to provide effective oil agitation and achieve uniform heating of the oil.

Beginning in the top heating tray, following in the two deodorizer trays, and culminating in the heat recovery tray, effective heat bleaching of the carotene pigments occurs with oil temperature $>250^{\circ}\text{C}$. Heat bleaching is both a time temperature phenomenon. Thus, a minimum of 20 minutes residence time at the elevated temperature is needed to maximize heat bleaching. Proper deodorization process design includes sufficient holding capacity time in the trays identified above the heat bleached.

From the third tray (second deodorizer tray), the product stream overflows to the heat recovery tray previously described. Through heat transfer to the incoming product stream, some heat reduction is attained in the deodorized oil stream. Live steam is added through a sparger to provide effective oil agitation and achieve uniform heat transfer from the deodorized oil.

Similar to the deaerator, oil is pumped from the deodorizer vessel by means of a centrifugal pump located at an elevation sufficiently below the bottom of the vessel to maintain a net positive suction head. To preclude air entry into the deodorized oil stream, the deodorizer discharge pump is usually magnetically coupled to the drive motor to eliminate the mechanical seal.

The empty deodorizer trays for stock change or for shut down of the operation, each tray is equipped with a bottom discharge pipe to the tray below. There is a valve in each drain pipe to actuate the tray emptying operation. For stock change each tray is emptied in sequence to maintain a complete break of the two feed stocks.

To improve oil quality, a chelating agent is injected into the product steam after the outlet from the deodorizer vessel discharge pump. The use of chelating agents to improve deodorized oil quality is presented in a separate paper.

For deodorized oil, a chelating agent enhances oil stability in two ways. First, if pro-oxidant metals like copper or iron are present, the acid will react to form a metal salt that is subsequently removed by filtration. Second, the residual chelant in the oil has some anti-oxidant attributes. It is common practice to add the chelating agent to deodorized oil on exit from the deodorization process prior to polish filtration.

Citric acid is the most commonly used chelating agent. Citric acid can be purchased in 100% or less concentrations. Whatever concentration is purchased the amount added to the deodorized oil should be equivalent to the recommended amount. To dissolve citric acid, addition of hot water at a temperature near the boiling point is recommended. The amount of water added to the citric acid can not exceed an amount that would result in the moisture content of the deodorized oil being above 0,05%. The temperature of citric acid can not exceed 104°C . Above 104°C , citric acid starts to decompose. Thus, the maximum temperature for the deodorized oil at the point of citric acid addition can not exceed 104°C (Smallwood, 2001).

One of the advantages in using citric acid as a chelating agent is the tolerance for variation in the addition rate. There is a wide variation in the addition rate the impact on the oil quality is relatively minor.

For handling citric acid, two identical make-up/feed tanks are recommended. The tanks should be constructed of 316-grade stainless steel and be equipped with an external heating jacket a mechanical agitator and a graduated sight glass in the sight wall. With this capability while citric acid is fed to the deodorized oil from one tank, a new supply can be prepared in the other tank. The purpose of the side-wall graduated sight glass is to observe

the rate of this appearance for calibrating the metering pump which transfers the citric acid to the deodorized oil stream.

Phosphoric acid is a much better chelant than citric acid for 2 reasons; first of all, it is purchased in a liquid state and, thus, is much easier to handle. Second, phosphoric acid has much better antioxidant attributes than citric acid. Addition of phosphoric acid is much simpler than citric acid.

The transfer line from the feed tank to the injection point must be constructed of 316-grade stainless steel for both citric and phosphoric acid. If not failure will occur and a serious safety hazard will result from the acid leakage.

The deodorized oil is pumped through a polish filter (usually a bag-type filter) to remove any sediment from the oil prior to transfer to storage. Usually, two polish filters are installed in parallel to enable the use of one while the other is out of service for replacing the bags or other type of filter elements.

The deodorized oil is pumped through a polish filter to remove any sediment from the oil prior to transfer to storage. Usually, two polish filters are installed in parallel to enable the use of one while the other is out of service for replacing the bags or other type of filter elements.

On the start-up of the process, the product stream is initially recycled until proper operating conditions are achieved and the product quality is acceptable. Then, the fully deodorized oil stream is diverted to storage.

Vacuum for the deodorization process is obtained by a system comprised of four stages of steam ejectors and two stages of barometric condensers. Some designs utilize vacuum pumps in place of steam ejectors in the last two stages or final stage.

Most deodorizer processes include a vessel and equipment to condense and recover the fatty acid and other less volatile components from the vapor stream. The less volatile components are condensed by circulating the cooled condensate back to the condensing vessel for spray application to the incoming vapor stream. To maintain the needed balance of deodorizer distillate that is recycled for condensing the less volatile vapors, the excess quantity is continually pumped to a storage tank a heat exchanger is used to cool the deodorizer distillate before recycle or transfer to storage. Cooling water is used to cool the distillate. A single pass, tube and shell heat exchanger is the most reliable for distillate cooling. Plate heat exchangers are often used in this service due to superior energy efficiency.

Properly deodorized oil will have free fatty acid content under 0.05% and have no oxidation products as indicated by peroxide value (zero expected). The flavor of deodorized oil is relatively bland (typically weak nutty or buttery).

Deodorization is the final major processing step to produce acceptable quality edible oil products. To meet finished product quality objectives the deodorization process must be operated within prescribed temperature and vacuum limits, have relatively clean interior metal surfaces in contact with the product stream and receive feed stock within acceptable quality limits. Direct exposure of air to the product stream results in both several oxidation of the oil and rapid deposition of oxidized oil on the metal surfaces. Air leakage into the system that does not directly contact the product stream. But contacts the product the-coated surfaces results in rapid deposition of oxidized oil build up of oxidized oil on the deodorization system interior surfaces impacts product quality in two ways. First oxidized oil film on the interior surfaces will slough off into the product stream. Second, build up of

oxidized oil on the entrainment separators and demister pads will result in increase oil loss and decrease vacuum level due to increase pressure drop. Furthermore any air leakage in to the deodorizer system will increase the non condensable load and reduce the system vacuum. Finally oxidize oil build up on heating cooling coil surfaces will decrease the heat transfer efficiency and accordingly increase the system energy input requirements. In conclusion there are three cardinal rules for achieving effective edible oil deodorization; establish and meet proper feed stock quality limits, assure that the deodorizer system is air tight via proper design, installation, maintenance, operating and routine testing and inspect and clean the deodorization system interior surfaces at the proper frequency.

Each edible oil processor should independently determine the proper cleaning frequency according to need. Deodorizer system cleaning on a six month frequency is the industry norm. With an effectively designed and executed cleaning capability, the practice of cleaning too soon instead of waiting too long yields the best product quality and operating expense results. The scope of the deodorizer system cleaning should include all the elements which impact functional performance, product quality and operating cost. If present, routinely clean the following elements of the deodorization system; deareator heat exchanger, deaerator vessel, deodorizer heat exchangers, deodorizer vessel internals, distillate recovery system, system piping from inlet to outlet and barometric condensing system.

Also the computer-based process control has many benefits for vegetable oil refineries. More precise and responsively controls can be applied while using materials like caustic soda, sulfuric acid, bleaching earth etc. Also temperature, pressure catalyst additions and hydrogen gas input can be programmed and controlled. Problems which are occurred in process system are detected easily and solved quickly by using computer-based process control.

2.3.8 Deodorized oil storage

If not transferred directly from deodorization to a tank car for shipment, deodorized oil is held in storage tanks prior to loading for bulk shipment by truck or transferring to package filling (packaging). Effective deodorized oil storage requires the following to assure product quality:

1. Nitrogen blanketing of the head space above the oil level if possible.
2. Agitation to preclude any separation of the triglyceride components.
3. Temperature control capability.
4. Sampling capability
5. Tank washing/cleaning at the proper frequency to preclude the accumulation

Of old oil films on the interior tank surfaces which would eventually reflux into the fresh oil. Nitrogen Blanketing of edible oils is essential for, oxidative and flavor stability, extended storage period and maintenance of nutritive value. Whether refined or not, all oils are sensitive to heat, light and exposure to oxygen. Exposure to above conditions leads to the rancidity in edible oils. Rancid oil has an unpleasant aroma acrid taste, and its nutrient value is greatly diminished. Also, rancid oils are injurious to health. To delay the development of rancid oil, a blanket of nitrogen, an inert gas is applied to the vapor space in storage container immediately just after production and also in the packing containers. This is referred to as Total Nitrogen Blanketing. Care for quality of edible oils during storage is especially important for refined oil products. Major sources of deterioration may be brass sampler, reheating and contamination in pipe line and by absorption of oxygen.

Oil storage tanks (Fig. 11), should be carefully inspected on a quarterly frequency and thoroughly washed at least annually. Failure to maintain clean tanks will result in poor oil and product quality. Means for effective and rapid tank washing should be included in the total system.



Fig. 11. Refined Oil Silos

2.3.9 Deodorized oil loading

The final and perhaps most vulnerable step in edible oil processing for bulk shipment are loading the products in tank cars and trucks. High quality products improperly loaded will result in poor quality products received by the customer (end user). Tank car/truck cleanliness is the starting point in oil loading. Tank car/truck washing capability must be provided to assure consistent, high quality cleaning. Thorough inspection of the tank car/truck must be conducted before oil loading is initiated. The oil transfer system itself (hose, nozzles, pipelines, etc.) must be clean and properly protected. The critical consideration in transferring oil from storage to the point of application is to avoid the introduction of air. Nitrogen sparging is recommended to minimize or eliminate air exposure during loading. Bottom filling of tank car/truck using a loading nozzle extends through the top hatch to the bottom of the tank is advisable. A protective cover around the open top hatch during loading is essential. Finally, security seals properly attached to all access openings to the tank car/truck are mandatory after loading and sampling are completed.

2.4 Uses in pharmaceutical drug delivery systems: Why is soybean oil necessary for pharmaceutical dosage form?

In pharmaceutical preparations, soybean oil emulsions are primarily used as a fat source in total parenteral nutrition (TPN) regimens. Although other oils, such as peanut oil, have been used for this purpose, soybean oil is now preferred because it is associated with fewer adverse reactions (Rowe et al. 2006). An emulsion is a dispersion of two or more immiscible

liquids stabilized by a surfactant or emulsifier coating the droplets and preventing coalescence by reducing interfacial tension or creating a physical repulsion between the droplets. Two common types of emulsions are found in parenteral drug delivery systems. Water in oil emulsions (W/O) is used in sustained release of steroids and vaccines by intramuscular injection. Oil in water (O/W) or lipid emulsions can be administered by a variety of parenteral routes (for example subcutaneous, intramuscular and intra-arterial) but are predominantly injected intravenously in parenteral nutrition applications. Lipid emulsions have been used in parenteral nutrition for more than four decades as a life-saving treatment by the intravenous infusion of fat in patients who cannot orally consume or metabolize food properly. The use of fat or lipid emulsions in parenteral feeding provides an insulin independent energy source and essential fatty acids necessary for metabolism. The emulsion is usually admixed with amino acids, carbohydrates and electrolytes as part of a therapy programme known as total parenteral nutrition. The stability of these lipid emulsions based on soybean oil dispersed with egg lecithin in parenteral nutrition has demonstrated a shelf life of 24 months at room temperature. Consequently, the stability and safety record of these types of lipid emulsions offers an attractive drug delivery system for lipophilic candidates in a drug development programme (Amidon, 1995; Aungst, 1993; McNiff, 1977; Medina 2001).

Emulsions containing soybean oil have also been used as vehicles for the oral and intravenous administration of drugs; drug substances that have been incorporated into such emulsions include vitamins, peptides, proteins, hormones, poorly water-soluble active substances, fluorocarbons and insulin (Chansri, et al. 2006; Ganta et al. 2008; Hwang, et al. 2004; Fukushima, et al. 2000; Nishikawa et al. 1999; Rowe et al. 2006; Tamilvanan, 2009; Terek et al., 2006). In addition, soybean oil has been used in the formulation of many drug delivery systems such as liposomes, microspheres, dry emulsions, self-emulsifying systems, microemulsions, and nanoemulsions and nanocapsules. Soybean oil may also be used in cosmetics and is consumed as edible oil. As soybean oil has emollient properties, it is used as a bath additive in the treatment of dry skin conditions (Constantinides et al., 2008; Karasulu, et al., 2007; Rowe et al. 2006).

An interesting study was performed with a new lipid emulsion based on soybean oil, medium chain triglycerides, olive oil and fish oil (SMOFlipid) for safety, tolerance, metabolic and clinical efficacy in surgical patients. It is concluded that SMOFlipid is clinically safe and well tolerated in postoperative patients. There are indications that SMOFlipid may be associated with a better liver tolerance and a shorter length of hospitalization (Metres, 2006).

The oral route is the preferred route for chronic drug therapy. Numerous potent lipophilic drugs exhibit low oral bioavailability due to their poor aqueous solubility properties. Self-emulsifying drug delivery systems (SEDDS) have been previously described in the literature as homogeneous mixtures of natural or synthetic oils, solid or liquid surfactants, or alternatively, one or more hydrophilic solvents and co-solvents. The principal characteristic of these systems is their ability to form fine oil-in-water (O/W) emulsions or microemulsions upon mild agitation following dilution by aqueous phases. This property renders SEDDS as good candidates for the oral delivery of hydrophobic drugs with adequate solubility in oil or oil/surfactant blends. Lipid-based drug delivery systems are commonly studied for the enhancement of oral bioavailability of hydrophobic and lipophilic drugs (Han et. al., 2010; Zhao et al., 2010).

An injectable microemulsion of arsenic trioxide ($\text{As}_2\text{O}_3\text{-M}$) was prepared for intratumoral injection and the suppressive effect of As_2O_3 -loaded microemulsion on human breast cancer cells MCF-7 was compared with those of a solution of the drug (Karasulu, 2004). Microemulsion was made up of soybean-oil as oil phase, a mixture of Brij 58 and Span 80 as surfactants, and absolute ethanol as co-surfactant and bi-distilled water containing As_2O_3 solution as the aqueous phase. Microemulsion formulation containing of 5×10^{-6} molar (M) As_2O_3 . The formulation was physically stable for 12 months at room temperature when kept in ampule forms, as well as after autoclaving at 110°C for 30 min. It was clearly demonstrated that $\text{As}_2\text{O}_3\text{-M}$ had significant cytotoxic effect on breast cancer cell lines and the cytotoxic effect of $\text{As}_2\text{O}_3\text{-M}$ was significantly more than that of regular As_2O_3 -solutions. Even ~ 3000 times diluted microemulsion formulation loaded with 5×10^{-6} M As_2O_3 showed cytotoxic effect. According to the in-vitro cytotoxicity studies, it can be concluded that when As_2O_3 was incorporated into the microemulsion ($\text{As}_2\text{O}_3\text{-M}$), which is a new drug carrier system, it suppresses tumour cell growth on multiple tumor lines.

The most significant problem of microemulsion systems is the lack of biological tolerance of excipient such as surfactant, cosurfactant and oil. Karasulu et al. (2007) have examined microemulsion of methotrexate (M-MTX) and solution of the drug (Sol-MTX) on a model biological environmental model. In this formulation, microemulsion was made up of soybean-oil, Span 80, Cremophore EL isopropyl alcohol and NaOH solution. For this purpose a gastrointestinal cell culture model, the Caco-2 cell line, was used to investigate the cytotoxic effects of the polymeric carrier and its effect on the cell monolayer integrity. After an incubation of the cells with Sol-MTX for 3 days, the Caco-2 cell proliferation was significantly inhibited in a dose-dependent manner to an extent of 38.11 ± 3.90 % at the highest concentration of $40 \text{ ng}/75\mu\text{L}$. The differences between the viability of cells for M-MTX and Sol-MTX were found to be significantly different when applied to ANOVA according to 2×8 factorial randomized design ($p: 0.016$; for $\alpha: 0.05$, power : 0.695). Therefore, by using M-MTX in the therapy, low cytotoxic effect on normal cells and low side effects may be expected. In the other study, the formulation of microemulsion containing pilocarpin was development using Brij 35P, Span 80 as surfactant and propanol as cosurfactant, and soybean oil as the oil phase (Ince et al. 2007). The test microemulsion was non-irritant in rabbit eyes and a prolonged pharmacodynamic effect was observed in vivo compared to the drug administered as a simple solution or gel.

Lipid emulsions composed of egg phosphatidylcholine, cholesterol and soybean oil were the optimized carriers for All-trans-retinoic acid (ATRA) delivery. The delivery of ATRA by emulsions can reduce the elimination of ATRA from the blood circulation and preferentially accumulate retention of ATRA in the liver can successfully suppress the progression of liver metastasis in mice injected with colon carcinoma cells. These findings indicate that the effective delivery and retention of ATRA in hepatocytes by emulsion is an efficient approach for the treatment of liver metastasis (Chansri, 2006).

Pharmaceutical specifications of soybean oil are listed at Table 1. Soybean oil is a clear, pale-yellow colored, odorless or almost odorless liquid, with a bland taste that solidifies between -10 and -16°C (Rowe et al. 2006).

3. Conclusion

Soybean oil has a variety usage in nutrition such as, salad oil, cooking oil, baking fats, confectionary fats, ingredient for margarine and mayonnaise and also heavy-duty frying oil

if blended with high stability oil like cottonseed or palm oil. Having a high value of Omega-3, Omega-6 and Vitamin E and low value of price makes soybean oil an vital nutriment for daily consume.

Both cold pressing and refining of soybean oil are commonly used and beneficial processing systems. In cold pressing while high temperature have not been used, the deodorization step of refining needs high temperature and pressure to eliminate of impurities comes from extracted raw material. Refining has more steps than cold pressing, like, degumming, neutralization, bleaching, winterizing and deodorizing. Moreover conditions of crude oil receiving and unloading, storage, refined oil storage and loading steps effects the quality and hygiene of last product.

Soybean oil has been used in the pharmaceutical formulations. In conclusion, soybean oil is not only used in food products but is also used as pharmaceutical excipients to produce a novel, biocompatible formulations which are cost effective, non-irritating, and capable of being sterilized before application.

Test	JP 2001	PhEur 2005	USP 28
Identification	-	+	-
Characters	-	+	-
Specific gravity	0.916-0.922	≈ 0.922	0.916-0.922
Refractive index	-	≈ 1.475	1.465-1.475
Heavy metals	-	-	≤ 0.001%
Free fatty acids	-	-	+
Fatty acid composition	-	+	+
Acid value	≤0.2	≤0.5	-
Iodine value	126-140	-	120-141
Saponification value	188-195	-	180-200
Unsaponifiable matter	≤1.0%	≤1.5%	≤1.0%
Cottonseed oil	-	-	+
Peroxide	-	≤10.0 or ≤5.0 ^(a)	+
Alkaline impurities	-	+	-
Brassicasterol	-	≤0.3%	-
Water	-	≤0.1% ^(a)	-

^(a)In soybean oil intended for parenteral use.

Table 1. Pharmacopeial specifications for soybean oil

4. Acknowledgment

The authors would like to thank the management of ZADE Edible Oil Refinery & Cold Pressed Oil Plant for assisting on the preparation of this review.

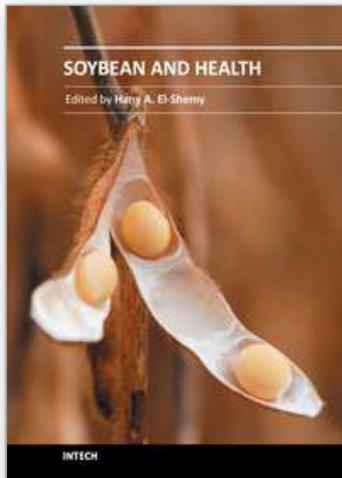
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Soybean and Health

Edited by Prof. Hany El-Shemy

ISBN 978-953-307-535-8

Hard cover, 502 pages

Publisher InTech

Published online 12, September, 2011

Published in print edition September, 2011

Worldwide, soybean seed proteins represent a major source of amino acids for human and animal nutrition. Soybean seeds are an important and economical source of protein in the diet of many developed and developing countries. Soy is a complete protein, and soy-foods are rich in vitamins and minerals. Soybean protein provides all the essential amino acids in the amounts needed for human health. Recent research suggests that soy may also lower risk of prostate, colon and breast cancers as well as osteoporosis and other bone health problems, and alleviate hot flashes associated with menopause. This volume is expected to be useful for student, researchers and public who are interested in soybean.

How to reference

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H. Yesim Karasulu, Ercüment Karasulu, Mevlüt Büyükhelvacıgil, Mustafa Yıldız, Ahmet Ertugrul, Kadir Büyükhelvacıgil, Zeliha Ustün and Nilay Gazel (2011). Soybean Oil: Production Process, Benefits and Uses in Pharmaceutical Dosage Form, Soybean and Health, Prof. Hany El-Shemy (Ed.), ISBN: 978-953-307-535-8, InTech, Available from: <http://www.intechopen.com/books/soybean-and-health/soybean-oil-production-process-benefits-and-uses-in-pharmaceutical-dosage-form>

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