A fresh shot of inspiration

A day packed with interesting speeches from a selection of Alsiano’s suppliers awaited the participants at the Alsiano Pharma & Healthcare Seminar 2008

By Dorthe Andersson, Marketing, Alsiano A/S

Bright sunshine over the Copenhagen waterfront set the perfect frame for the biennial Alsiano Pharma & Healthcare Seminar, which was held on 1 April. More than 50 persons from the Nordic pharmaceutical and nutraceutical industries had signed up to enjoy a day of inspiration and networking. To allow the participants to get the most out of the day, the seminar consisted of a joint section with lectures of common interest to both the pharmaceutical and nutraceutical industry and 2 parallelly held sections – one aimed at the pharmaceutical industry and one aimed at the nutraceutical industry. Below is a brief summary of the different presentations from our suppliers.

Cyclodextrin complexes

Cyclodextrins offer, by their ability to form inclusion complexes, interesting tools for solving various formulation problems. During her presentation, Elham Blouet, Roquette, reviewed the main advantages of using them in pharmaceutical applications and their regulatory status.

Read more about cyclodextrins from Roquette article on page 7.

Microencapsulated ferrous fumarate

Joseph S. Giaimo of Particle Dynamics presented a case-study about how the use of microencapsulated ferrous fumarate has been demonstrated to be an effective treatment for iron deficient anemia, and how technical issues such as stability, discoloration, bioavailability, and poor taste had been successfully overcome by the use of ferrous fumarate in a microencapsulated form.

SEPIFILM IR

Armelle Ungidos from Seppic presented their new product SEPIFILMTM IR, which is an innovative instant release formulation with the polymer Kollicoat IR in granulated form. The main advantage of SEPIFILMTM IR is the solid content in the dispersion (up to 30%). Among other advantages are easy processing and a significant reduction of the spraying time (20%). After lunch, the seminar continued in divided forums – one dealing with raw materials for the pharmaceutical industry, and one dealing with the nutraceutical industry:

AEROSIL® Colloidal Silicon Dioxide

The properties and benefits of the various AEROSIL® pharma grades were presented by Dr Beata-Maria Lortz from Evonik Degussa, who also showed examples of the grades in solid, semisolid and liquid dosage forms. With the different AEROSIL® pharma grades from Evonik Degussa formulators have a wide range of options for improving their products and processes.

Lycoat® in orodispersible films

Xavier Parissaux from Roquette presented a practical case-study with Lycoat®. The presentation...(cont. >>)
Egg based ingredients from BNLfood

An egg is a source of life! As an ingredient, it provides essential lipids and amino acids to humans regardless of age. BNLfood offers a wide range of interesting egg based ingredients for dietetic products such as sport nutrition, baby nutrition, slimming products and products designed for elderly and diabetics.

By Annette Strarup, Area Sales Manager, Alsiano A/S

BNLfood has acquired a solid international reputation within egg science and technology for its range of highly functional egg products (whole egg/albumen/yolk), its portfolio of egg fractions (lysozyme, avidin, ovotransferrin, phospholipids) and its successful transfer of technology to international partners.

The following is an extract of BNLfood's broad line of egg based ingredients for nutrition and food supplements.

Omega-3 fatty acids – Super foods for athletes

Belovo, the egg science and technology division of BNLfood, has developed two Omega-3 rich egg powders from Columbus eggs: whole egg powder and egg yolk powder.

Columbus egg is the brand name for eggs from hens fed with a vegetable and balanced feed consisting of flax seed, among other ingredients. In Columbus eggs, the ratio between Omega-6 and Omega-3 is 1:1. During the evolution of the human diet, the Omega-6/Omega-3 ratio has gone from 1:1 ...

Inulin and oligofructose

The use of inulin and oligofructose as functional food ingredients offers considerable opportunities to improve gut health and to increase the absorption and utilization of calcium present in the diet. At the seminar, Hélène Alexiou of Beneo-Orafti spoke about the various proven health benefits of the two prebiotics and presented some of the latest findings – e.g. the usefulness in the area of weight management (increase satiety).

Egg based ingredients

During the past forty years, BNLfood has acquired a solid international reputation in egg science and technology for its range of highly functional and healthy egg powders (egg albumin powder, whole egg powder) and its portfolio of egg specialities (egg yolk phospholipids, lysozyme and avidin). Jetze Wijnia from BNLfood presented the company’s recent developments in product innovation for applications in health food, nutraceuticals and pharmaceuticals. Read more about BNL’s product range in the article above.

Phosphatidylserine – maintaining optimal cognitive performance

Dr Dori Pelled and Michal Bravman from Enzymotec spoke about their product Sharps PS (phosphatidyl-serine). Preliminary findings support the theory that Soy-PS - enzymatically modified soybean lecitin - has a beneficial impact on cognitive performance in regard to attention, vigilance, memory, and learning. Sharp PS is currently sold in USA and is under regulatory assessment in Europe.

If you missed out on the Alsiano Pharma & Healthcare Seminar and would like to have further information about some of the above mentioned presentations/products you are welcome to contact us.
in ancient time to 20:1 now in modern time. In ordinary eggs, the Omega-6:Omega-3 ratio is 15:1.

The Omega-6:Omega-3 ratio of 1:1 makes Columbus egg powder a good solution for balanced foods (balanced nutrition). Today, dieticians recommend that a well-balanced diet provides 30-35% energy as fat with a large proportion of the dietary fat consisting of monosaturated fatty acids and an even distribution of saturated and polyunsaturated fatty acids (S:M:P = 1:6:1). A ratio between Omega-6 and Omega-3 fatty acids not exceeding 5 to 1 is recommended and achieved through an optimal daily intake of 350-400 mg Omega-3 polyunsaturated fatty acids (Omega-3 LCPs).

The stress originating from growth and/or intense activity places severe demands on nutrition such as antioxidants and fatty acids. A relevant application area for fatty acids is thus nutrition for athletes.

Given its high level of healthy fatty acids, Columbus egg powder is well suited for:

- Sports nutrition
- Healthy bars
- Diabetic foods

The amount of Omega-3 fatty acid in Columbus whole egg (WEP-C) and egg yolk (EYP-C) powders is shown in table 1.

**Egg Yolk Phospholipids and Baby Vit. F for infant nutrition**

Long chain fatty acids (LCPs) are essential for all human cell membranes, and egg yolk phospholipids are ideal carriers for these fatty acids. Egg phospholipids differ from soy lecithin by their high content in long chain unsaturated fatty acids and phosphatidylcholine. They constitute a natural source of essential fatty acids (Vitamin F) and among them, arachidonic acid (AA) and docosahexaenoic acid (DHA), which cover specific needs of humans at various stages of development and lifetime.

The need for infant formulae enriched with DHA and AA for infants not being breast-fed has been recognised by various official bodies including FAO/WHO whose recommendations are that all infant formulae should contain DHA and AA. DHA and AA must come from fats of animal origin. The best choice to fulfil the FAO requirements in one shot is to use egg phospholipids because it brings AA and DHA from natural origin in the right ratio (whilst fish oil provides only DHA) together with the essential choline from the yolk.

Egg phospholipids from BNLfood are available as flakes, in a viscous oil blend and as a free flowing micro-encapsulated powder. Egg phospholipids from Belovo have been given the Novel Food Status (258/97/EC).

Baby Vit. F is made from essential dietary lipids in egg phospholipid finely dispersed micelles.

In Baby Vit. F, the encapsulation of essential oils in 4% egg phospholipids micelles provides a means to closely mimic the characteristic emulsified state of human milk. One portion of Baby Vit. F provides all the essential fatty acids, cholesterol and choline present in 250 ml human milk as designed by nature for the proper development (continues on page 4)

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**Table 1: Columbus whole egg (WEP-C) and egg yolk (EYP-C) powders - contents of omega-3 fatty acids**

<table>
<thead>
<tr>
<th>Egg powder</th>
<th># eggs/kg</th>
<th>LnA (g/kg)</th>
<th>LC-PUFAs (g/kg)</th>
<th>Σ (g/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>WEP-C</td>
<td>80</td>
<td>44</td>
<td>8.8</td>
<td>52.8</td>
</tr>
<tr>
<td>EYP-C</td>
<td>120</td>
<td>66</td>
<td>13.2</td>
<td>79.2</td>
</tr>
</tbody>
</table>
of the infant. In addition, Baby Vit. F ensures that newborn babies get a plentiful supply of prostaglandines with beneficial effects on blood pressure, clotting ability, kidney function and immune system function - see table below.

**Egg ingredients for immune health**

Egg immunoglobulin (IgY), Ovotransferrin (OVT) and Lysozyme (LYS) are three components extracted from the egg albumen (egg white) with immune improving properties. Lysozyme has been seen in applications together with Colostrum (immunoglobulin-rich), but can also be formulated together with immunoglobulins from egg (IgY). Examples of applications: Toothpaste, chewing gum and food supplements.

BNLfood also offers a pharmaceutical grade of Lysozyme: Lysozyme Hydrochloride (Mucoprotein N-Acetylmuramyl hydrolase, hydrochloride, E.C. 3.2.1.17). This protein is purified by ion-exchange chromatography and is also offered for:

- Aerosols for treatment of broncho-pulmonary diseases
- Droplets for nasal tissue protection
- Pharmaceutical creams for burns, Herpes and shingles

**New inspiration guides for finished products**

To inspire and to provide our customers with an overview of our product range, Alsiano has launched the first product guides in a series.

4 product leaflet are now ready for presentation. In the leaflets, the ingredients are divided into applications in order to give inspiration and an overview.

The first 4 inspiration guides deal with:

- Plant extracts
- Tablets
- Creams & lotions
- Nutrition bars

In the coming months, we will launch new product guides covering other application areas within the pharmaceutical, nutraceutical and cosmetics areas.

### Albumin (CSA) - Egg protein for sports nutrition

Albumin or ovalbumin (CSA = Chicken Serum Albumin) is a protein extracted from the egg albumen with a very interesting amino acid profile and is often seen in formulations together with vegetable based proteins in sports nutrition. It is recommended in combination with Remypro rice protein from Beneo-Remy and/or together with Nutralys® pea protein from Roquette in sports nutrition. Also the protein fractions from the yolk - Apoprotein and Apolipoprotein (EYAP and ALP) - can be used in sports nutrition.

**Table 1**

<table>
<thead>
<tr>
<th></th>
<th>LA</th>
<th>GLA</th>
<th>DHLA</th>
<th>AA</th>
<th>ALA</th>
<th>EPA</th>
<th>DPA</th>
<th>DHA</th>
<th>DHLA GLA</th>
<th>DHLA GLA</th>
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<tr>
<td>Human milk (mg/250 ml)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Baby Vit. F (mg/10 g)</td>
<td>875</td>
<td>35</td>
<td>30</td>
<td>65</td>
<td>3</td>
<td>30</td>
<td>30</td>
<td>35</td>
<td>35</td>
<td>35</td>
</tr>
<tr>
<td>FAO/WHO (1994)*</td>
<td>1000</td>
<td>65</td>
<td>(AA)</td>
<td>85</td>
<td>33</td>
<td>33</td>
<td>33</td>
<td>-</td>
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</tbody>
</table>


If you would like to receive a copy of our inspiration guides, please let us know: we can either send them to you or set up a meeting during which we can present them to you.
Montanov™ emulsifiers for ECOCERT certified cosmetic products

Seppic offers a range of emulsifiers of 100% natural origin for straightforward formulation of ECOCERT formulas

By Seppic

The terms of natural and/or organic ingredients become more and more important to the beauty industry. For your natural product, Seppic has a patented range of emulsifier range which is ECOCERT validated.

Amazing emulsifying capacity
Montanov™ has an outstanding emulsifying capacity. Used at low levels – between 0.5 and 3% - Montanov™ emulsifiers significantly reduce the interface tension and can therefore emulsify up to 60% oily phases like vegetable oils, mineral oils, esters and silicones.

In addition, Montanov™ is compatible with the majority of active ingredients and is highly stable at all pH (3-11).

100% vegetable origin
Montanov™ is of 100% vegetable origin and is produced from non-GM raw materials that are solvent and preservative-free. It is an original and patented synthesis of fatty alcohols and alkyl polyglucosides.

Furthermore, Montanov™ has excellent skin compatibility and biodegradability

A broad variety applications
Montanov™ emulsifiers are recommended for all types of applications for the face, body and hair – i.e. skin care, toiletries, hair care, and deodorants.

For instance in skin care, it can be used for dry, oily, mixed, sensitive and mature skins in all types of conventional products, but also for more specific products such as young problem skins, ethnic skins, men skin care, etc. Montanov™ is also well suited to create all types of textures such as sprays, lotions, creams, butters, and waxes with a broad range of skin feeling: light and evanescent, melting or rich. Montanov™ emulsifiers can even be used to formulate emulsions with an intrinsic moisturizing effect linked to the presence of liquid crystals. Thanks to the bi-layers similar to those of the skin formed by the liquid crystals, the skin’s liquid barrier is reinforced and the skin is protected against dehydration.

More than excipients
Montanov™ emulsifiers are excellent liquid crystal promoters. In the oily phase, they prevent coalescence thanks to the formulation of a rigid shell around oil droplets. In the aqueous phase, the liquid crystals extend to form a continuous network of lamellar phases, which provide a dominant elastic character and a very good stability that prevents creaming.

### Ingredients

<table>
<thead>
<tr>
<th>Montanov™</th>
<th>202</th>
<th>82</th>
<th>L</th>
<th>68</th>
<th>S*</th>
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<tbody>
<tr>
<td>INCI name</td>
<td>Arachidyl alcohol &amp; Behenyl alcohol &amp; Arachidyl glucoside</td>
<td>Cetearyl glucoside &amp; Coco glucoside</td>
<td>C14-22 alcohols &amp; C12-20 alkyl glucoside</td>
<td>Cetaneryl alcohol &amp; Cetearyl glucoside</td>
<td>Coconut glucoside &amp; Coconut alcohol</td>
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<td>Emulsifying capacity</td>
<td>+ + +</td>
<td>+ + +</td>
<td>+ + +</td>
<td>+ + +</td>
<td>+ +</td>
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<tr>
<td>Liquid crystals</td>
<td>+ + +</td>
<td>+ +</td>
<td>+ +</td>
<td>+ +</td>
<td>-/-</td>
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<tr>
<td>Consistency of emulsions</td>
<td>Thick lotion to cream</td>
<td>Variable consistency spray to thick cream</td>
<td>Variable consistency spray to thick cream</td>
<td>Fluid to thick cream</td>
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<tr>
<td>Sensory profile</td>
<td>Light texture, matt finish</td>
<td>Rich texture</td>
<td>Light texture</td>
<td>Rich texture</td>
<td>Rich texture</td>
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<tr>
<td>Strong points &amp; specific characteristics</td>
<td>- Whiteness of the emulsion</td>
<td>- Very good resistance to cold (-25°C)</td>
<td>- Emulsion whiteness</td>
<td>- Stabilizer not compulsory (if absence of electrolytes)</td>
<td>- Refattener</td>
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<tr>
<td>Specific compatibilities</td>
<td>- Mineral ingredients (make-up)</td>
<td>- Chemical filters &amp; mineral screens</td>
<td>- Mineral ingredients (make-up)</td>
<td>- Chemical filters &amp; mineral screens</td>
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<tr>
<td>Melting point</td>
<td>70-80°C</td>
<td>55-60°C</td>
<td>66-72°C</td>
<td>61-65°C</td>
<td>56-60°C</td>
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</table>

*Co-emulsifier
Professional wound care – plasters

Platilon® films by Epurex Films meet the demanding requirements of professional wound care

Modern “wound management” focuses on the patient’s well-being. Its objectives are rapid wound healing and inconspicuous plasters that are comfortable to wear.

Innovative plaster systems consist, for instance, of breathable (water vapour permeable) film and adhesive and partly also non-woven fabric, depending on the application. Platilon® films supplied by Epurex Films have been developed to meet the various demanding requirements of professional wound care.

Rapid wound healing
The healing process is shortened due to a “controlled climate” in the wound area. The plaster system allows wetness to escape, while retaining sufficient moisture in the wound. The regulated moisture balance provides an optimized wound climate, thus causing no additional stress to the skin around the wound underneath the plaster. Liquids that penetrate from the outside to the plaster are kept out by the waterproof film.

Wound hygiene
Platilon® films provide a barrier against dirt and microbes – on both sides. Wounds are not only protected against contamination from the outside, but on the other side, too, any exudation is kept back in the plaster to protect clothing, for example, or to prevent potential infection.

Reliable adhesion
The purpose of the plaster is to cover the wound reliably while being skin-friendly. Even in conjunction with skin-friendly adhesives, Platilon® films provide a stable system with dependable adhesion.

The plaster system is moisture-permeable, so the plaster stays in place on sweaty skin during physical exertion. When the plaster is changed, gentle detachment is desired making it possible to remove the complete plaster system, i.e. film plus adhesive, all in one action.

Skin-friendly
Due to the controlled climate, the healthy skin beneath the plaster remains intact. The accelerated wound healing and skin-friendly adhesives are gentle to the skin underneath the sticking area, in particular during lengthy treatment and repeated plaster changes.

Additional care
Plaster systems with integrated non-woven or foam pads can give the wounds additional care or protection. The pad can contain extra wound-healing substances such as a gel. The film prevents the active substances in the non-woven/foam pad from drying out and also against contamination.

About Epurex Films
Epurex Films GmbH & Co. KG is a leading company in the development and production of high performance films. The Bayer MaterialScience company is located in Bomlitz near Hamburg in Northern Germany. Polyurethane and special elastomer films are tailored to customer’s requirements either as blown films or cast films. The company offers a unique combination of development potential, film manufacturing technologies, production capabilities and capacities, material expertise and customer focus. Improvements in development and production are boosted by research into new compositions and technologies. Epurex Films is an ISO 9001:2000 registered company.

The non-woven or foam pad can also act as a spacer or depot for wound fluids.

Properties of Platilon®:
- Permeable to water vapour
- Waterproof
- Barrier against dirt and microbes
- Highly compatible with adhesives, even with sensitive systems such as silicone adhesive
- Conforms to contours
- Skin-friendly
- Plasticizer-free
- Solvent-free

Article 330
KLEPTOSE® native and modified cyclodextrins: Multi-functional excipients for molecular encapsulation

Molecular encapsulation with cyclodextrins and their derivatives offers attractive and alternative tools to overcome different problems encountered in formulation development

By Elham Blouet, Pharmaceutical Project & Development Manager, Roquette

To cover the specific needs of the pharmaceutical and cosmetic industry, Roquette has developed a range of KLEPTOSE® products: β-cyclodextrins, hydroxypropyl β-cyclodextrins and methylated β-cyclodextrins.

Interest in cyclodextrins has sharpened over the past years leading to a strong market demand, and several pharmaceutical and cosmetic products containing β-cyclodextrins or their derivatives have reached the market successfully.

The versatile excipient

Cyclodextrins (CDs), native and modified, have the ability to form inclusion compounds through molecular encapsulation with a wide range of organic molecules. This ability makes the CDs and their derivatives valuable as formulation aids. They are used to increase aqueous solubility of poorly soluble drugs and consequently to avoid the use of organic solvents. Their use is, however, also of great interest for improving physical and chemical stability of drugs (protection against light, oxidation, etc.), for enhancing local tolerance of drugs and for any other applications where inclusion compounds would enable innovative solutions. Medicinal products containing cyclodextrins and their derivatives are world-wide marketed including, among others, oral, parenteral, topical and eye preparations.

Native cyclodextrins

CDs are cyclic oligosaccharides obtained from starch by enzymatic cyclisation using cycloglycosyltransferases. They are composed of α-(1,4) linked glucopyranose subunits. Several unsubstituted or native cyclodextrins exist; the most referenced ones being α-cyclodextrin, β-cyclodextrin and γ-cyclodextrin constituted of 6, 7 or 8 α-(1,4) glucopyranose units respectively. β-cyclodextrin (BCD) is the most accessible and useful one with a significant industrial usage. Roquette’s brand name for BCD is KLEPTOSE®.

KLEPTOSE®

The BCD molecule is a torus shaped ring. Due to the spatial distribution of its hydroxyl groups, the BCD molecule has a polar hydrophilic outside and an apolar hydrophobic cavity. As a consequence of this particular structure, BCD is, when in presence of water, able to encapsulate or entrap guest molecules to form the so-called inclusion compounds.

βCD is a crystalline, homogeneous, non-hygroscopic substance with a low aqueous solubility (approx. 1.85% at room temperature). It is currently considered to be an essentially non-toxic and non-irritant ingredient, authorized for food applications and used in oral and topical pharmaceutical applications. Due to its nephrotoxicity, BCD is not suitable for parenteral applications.

Modified cyclodextrins

The native CDs can be chemically modified by hydroxyalkylation, alkyla-
ROQUETTE® HPB / KLEPTOSE® HP
Roquette has developed a range of substituted HPβCD with different degrees of substitution (DS = number of hydroxypropyl groups per molecule of βCD) as described by the Molar Substitution value (MS = average number of hydroxypropyl groups per anhydroglucose unit). KLEPTOSE® HPβCD derivatives - KLEPTOSE® HP and KLEPTOSE® HP - are suitable for the cosmetic and pharmaceutical industry, including a pyrogen free grade produced under cGMP conditions for parenteral applications.

KLEPTOSE® CRYSMEB EXP
The pioneering product, Roquette’s KLEPTOSE® HPB derivative, has now been successfully marketed and used for several years. KLEPTOSE® CRYSMEB EXP is a second-generation product (under development at lab scale), which has several advantages including the possibility of increased solubilisation power while maintaining a high biological tolerance.

KLEPTOSE® CRYSMEB EXP is a mixture of methyl βCD containing on average 4 methyl groups per native αCD molecule (i.e. a typical MS of 0.57). Due to its high aqueous solubility (20% at 20°C), it dissolves easily in water (unlike βCD), and solubility increases with temperature.

As with the KLEPTOSE® HPB, the KLEPTOSE® CRYSMEB EXP can be used in pharmaceutical applications with different aims:

- to increase water solubility and rate of dissolution of poorly soluble drug
- to increase the rate of transfer of a drug from solution into tissue without damaging the tissue
- to reduce side effects of active ingredients
- to reduce bitterness or unpleasant odour of some drugs.

KLEPTOSE® CRYSMEB EXP can also be used in cosmetics for different aims, in particular for solubilisation or stabilization of ingredients.

Early preliminary toxicological information indicates that this methyl βCD shows potential for the development of injectable products and should be further investigated by formal toxicity studies.

Main applications and benefits
There are many potential applications of CDs and their derivatives in the pharmaceutical and cosmetics field. A non exhaustive list of main applications is given hereafter.

Pharmaceutical field:
- Increase poor aqueous solubility of drugs with subsequently increased dissolution rate and hence improved bioavailability
- Increase physical and chemical stability of drugs (increase shelf-life and reduce time to market)
- Enhance local tolerance after topical or oral administration
- Improve organoleptic properties of drugs (taste and/or odour masking)
- Enhance drug delivery to and through biological membranes
- Prevent drug-drug, drug-excipient interactions and drug-container interaction
- Convert oily/liquid or volatile material into stable/microcrystalline powder
- ...

Cosmetics field:
- Fragrance masking or release
- Delivery of specific substances
- Enhancement of UV filter activity
- Reduction of local irritation
- ...

Key points of the KLEPTOSE® range

<table>
<thead>
<tr>
<th></th>
<th>KLEPTOSE®</th>
<th>KLEPTOSE® HPB (medium MS, approx. 0.65)</th>
<th>KLEPTOSE® HP (high MS, approx. 0.85)</th>
<th>KLEPTOSE® CRYSMEB EXP</th>
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<tbody>
<tr>
<td>Generic name</td>
<td>Betacyclodextrin</td>
<td>Hydroxypropyl betacyclodextrin</td>
<td>Hydroxypropyl betacyclodextrin</td>
<td>2-O-methyl betacyclodextrin</td>
</tr>
<tr>
<td>Grade</td>
<td>• Standard</td>
<td>• Oral</td>
<td>• Oral</td>
<td>Standard</td>
</tr>
<tr>
<td></td>
<td>• DC (direct compression)</td>
<td>• Parenteral (endotoxin controlled)</td>
<td>• Parenteral (endotoxin controlled)</td>
<td></td>
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<tr>
<td></td>
<td>• Specific particle size (200 F, 10)</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>• Specific moisture content (7PC)</td>
<td></td>
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</tr>
<tr>
<td>Applications</td>
<td>Pharmaceutical, cosmetics and nutraceutical</td>
<td>Pharmaceutical and cosmetics</td>
<td>Pharmaceutical and cosmetics</td>
<td>Pharmaceutical and cosmetics</td>
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<tr>
<td>Route of administration</td>
<td>Oral and topical</td>
<td>Oral, topical and parenteral</td>
<td>Oral, topical and parenteral</td>
<td>Oral, topical and parenteral*</td>
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<tr>
<td>Aqueous solubility</td>
<td>1.85% at room temperature</td>
<td>65% at 25°C</td>
<td>65% at 25°C</td>
<td>20% at 20°C</td>
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<td>DMF</td>
<td>US</td>
<td>US and Canada</td>
<td>US and Canada</td>
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</tr>
<tr>
<td>Food use status</td>
<td>ADI 5 mg/kg body weight</td>
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</table>

* Lab scale development for market evaluation
** Early preliminary toxicological studies tend to show the safety of parenteral use of KLEPTOSE® CRYSMEB
Green tea extract – the star within slimming

Green tea extract is a versatile ingredient. Several studies show that green tea extract has a slimming effect. Through our Indian supplier Vidya Herbs, Alsiano supplies green tea extract of high quality.

Green tea is made from the leaves of the tea plant *Camellia sinensis* which is dried without fermentation. The leaves are steamed soon after the harvest to stop enzyme reactions. The active components in green tea are catechins (polyphenol compounds) accounting for most of the health benefits attributed to the consumption of green tea. The most important catechin found in green tea is epigallocatechin-3-gallate (EGCG). Other catechins include epicatechin-3-gallate (ECG) and epigallocatechin (EGC). Green tea also contains the bioactive component caffeine.

**Documented slimming effect**

Five human intervention studies illustrate the slimming effect of green tea\(^1\).\(^5\). The newest study is a study published in Obesity Research in 2005\(^3\). This study concluded that green tea has a slimming effect when subjects otherwise have a low habitual caffeine intake. The evaluation period was 3 months. 104 overweight and moderately obese male and female subjects participated in the study that consisted of a very low-energy diet intervention of 4 weeks followed by a weight-maintenance period of 13 weeks during which the subjects received green tea or placebo. The green tea contained caffeine (104 mg/day) and cathechins (573 mg/day, of which 323 mg was EGCG). The subjects were split into two groups: habitual low caffeine consumers (< 300 mg/day) and high caffeine consumers (> 300 mg/day). Subjects lost 5.9 kg (+/- 1.8 kg) of body weight corresponding to a reduction of 7% of their bodyweight during the diet period.

During the diet period, weight loss was significantly higher among the high caffeine consumers than among the low caffeine consumers (\(p< 0.01\)). However, during the maintenance period, low caffeine consumers treated with green tea extract, continued to lose body weight and fat mass while the high caffeine consumers regained weight. Furthermore, the same group of low caffeine consumers displayed significantly increased resting energy expenditure and a decreased respiratory quotient compared to the high caffeine consumers.

This indicates a raised thermogenesis (the rate at which calories are being burned) and a higher fat oxidation, respectively, during the weight maintenance period.

Two human intervention studies\(^6\),\(^7\) investigated the underlying mechanisms of the slimming effect with focus on thermogenesis and fat oxidation. They found a significant increase in energy expenditure upon consumption of green tea and concluded that green tea activated thermogenesis and increased fat oxidation.

**Other extracts for slimming**

Besides green tea, Vidya Herbs also offers other extracts for slimming:

- Green Coffee Bean extract
- Cocoa extract
- White Bean extract

**References**

The Alsiano Pharma team

It is always nice to be able to put a face on the person you talk to over the telephone or e-mail. So here we are...

Key accounts

Anders Hager
M.Sc. Chem.
Sales manager
E-mail: ahg@alsiano.com
Tel. dir.: +45 8230 0026
Mobile: +45 2618 8545

Pharmaceuticals - cosmetics
health & nutrition

Lene Aarøe Nissen
B. Chem. Eng.
Area sales manager
E-mail: lan@alsiano.com
Tel. dir.: +45 8230 0025
Mobile: +45 2270 1002

Pharmaceuticals - cosmetics
health & nutrition

Annette Strarup
B.Sc. (Hons.) Chem. Eng.
Area sales manager
E-mail: ask@alsiano.com
Tel. dir.: +45 8230 0049
Mobile: +45 2285 1015

Logistics

Christa Børgesen
Key accounts
E-mail: cb@alsiano.com
Tel. dir.: +45 8230 0002

Sales support

Birgitte Falkensteen
Sales assistant
E-mail: bf@alsiano.com
Tel. dir.: +45 8230 0006

Sales support

Malene Rask Harder
Sales assistant
E-mail: mrh@alsiano.com
Tel. dir.: +45 8230 0007

Sales support

Signe Mørck
Sales assistant
E-mail: sm@alsiano.com
Tel. dir.: +45 8230 0042

Pharmaceuticals - Fermentation

Annette Jarlskov
M.Sc. Food Science
Area sales manager
E-mail: aja@alsiano.com
Tel. dir.: +45 8230 0072
Mobile: +45 2270 1017

Fermentation

Otto Andresen
Senior Technical Adviser
E-mail: oan@alsiano.com
Tel. dir.: +45 8230 0017
Mobile: +45 2085 1231

Pharmaceuticals - cosmetics
health & nutrition

Henrik A. Petersen
M.Sc. Pharm.
Area sales manager
E-mail: hap@alsiano.com
Tel. dir.: +45 8230 0009
Mobile: +45 2067 1231

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