The DYNASAN® product range is a family of high-purity monoacid triglycerides. Their chemical nature, raw materials, manufacturing and purification result in products with advantageous properties and impurity profile.

**Characteristics**

DYNASAN® 118 is a monoacid triglyceride based on C18 fatty acid with a high melting point. It is available as a microfine powder or in flaked form particularly suitable for oral solid dosage forms.

**Uses**

- Matrix for lipophilic actives
- Coated formulations for protection of sensitive drug molecules (or APIs) or for taste masking
- Solid Lipid Nanoparticles, Self-Emulsifying Drug Delivery Systems
- Processing by hot melt techniques like granulation and extrusion

**Benefits for Tableting**

- Effective lubricant for tablet production in low concentrations (~0.5%) without the risks of fatty acid soaps
- No influence on drug release up to a concentration of 1%, model drug Acetylsalicylic Acid
- Higher concentrations from 2 to 5% increase the hydrophobic characteristics of tablet matrix and introduce retardation effects into oral dosage forms for sustained release characteristics
- Enhances the tablet fracture stability due to an increased lubricity factor resulting from particle morphology and particle surface

**Particle Size Distribution of DYNASAN® 118 (microfine powder)**

<table>
<thead>
<tr>
<th>Product</th>
<th>Chemical Description</th>
<th>Melting Point °C</th>
<th>Hydroxyl Value mg KOH/g</th>
</tr>
</thead>
<tbody>
<tr>
<td>DYNASAN® 114</td>
<td>Trimyristin</td>
<td>55 - 58</td>
<td>Max. 10</td>
</tr>
<tr>
<td>DYNASAN® 116</td>
<td>Tripalmitin</td>
<td>63 - 68</td>
<td>Max. 10</td>
</tr>
<tr>
<td>DYNASAN® 118</td>
<td>Glyceryl Tristearate</td>
<td>69 - 73</td>
<td>Max. 5</td>
</tr>
</tbody>
</table>

* Additional DYNASAN® Triglycerides from mixed or pure fatty acids are technically feasible; please get in touch with us.

Incompatibilities with metallic salts of fatty acids have been reported, e.g. for the following active ingredients: Acetylsalicylic Acid, Captopril, Besylate, Cephalexin, Clopidogrel Besylate, Erythromycin, Gilbenclamide, Glimepiride, Ibuprofen, Indomethacin, Ketoprofen, Norfloxacine, Oxacinill, Penicillin G, Temazepam

**References**

10) Lubricants in Pharmaceutical Solid Dosage Forms, Jinjiang Li and Yongmei Wu, Lubricants 2014, 2, 21-43
11) Lubricating properties of triacylglycerols related to the release of medicaments. M. Vitková, M. Chalabala, I. Rik, Faculty of Pharmacy, 832-32, Bratislava, Czecho-Slovakia
YOUR FORMULATION CHALLENGES – OUR SOLUTIONS

According to the Biopharmaceutical Classification System (BCS), more than 70% of the APIs used in pharmaceutical preparations are difficult to formulate due to poor solubility and/or permeabilities, and the majority of drug candidates have similar characteristics. Formulating these APIs into stable forms and achieving satisfactory active delivery and dissolution profiles is a key challenge for galenic scientists.

IOI Oleo PHARMA offers a variety of vegetable-derived mono-, di- and triglycerides for a wide range of dosage forms such as tablets, capsules, granules or powders. The lipid nature of our products gives them an inherent compatibility towards these problematic API categories and can help to solve the galenic formulation hurdles. Most of our excipients are multifunctional and suitable for various drug delivery systems. Adopted dosing is a trajectory to accentuate certain characteristics and functionalities depending on the specific formulation task.

Technologies and techniques such as SEDDS, SMEDDS, SNEDDS, SLN, Hot Melt Coating (taste masking), Hot Melt Extrusion or Hot Melt Granulation can be applied to enable delivery or enhance the dissolution profile of poorly soluble drugs.

Application Survey of Solid Dosage Forms

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>Lubricant</th>
<th>Taste Masking</th>
<th>Hot Melt Coating</th>
<th>Hot Melt Extrusion</th>
<th>Hot Melt Granulation</th>
<th>SLN</th>
<th>Implants</th>
</tr>
</thead>
<tbody>
<tr>
<td>DYNASAN® 114</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
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</tr>
<tr>
<td>DYNASAN® 116</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
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<td></td>
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<tr>
<td>DYNASAN® 118</td>
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<td>✔</td>
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<td>✔</td>
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</tr>
<tr>
<td>IMWITOR® 900 (F) P</td>
<td>✔</td>
<td>✔</td>
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<td>✔</td>
<td>✔</td>
<td>✔</td>
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</tr>
<tr>
<td>IMWITOR® 900 K</td>
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<td>✔</td>
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<tr>
<td>WITEPSOL® E 85</td>
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<td>✔</td>
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</tr>
<tr>
<td>SOFTISAN® 154</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td></td>
</tr>
</tbody>
</table>

Identified uses in commercial products and literature

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Application Survey of Solid Dosage Forms

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>Chemical Description</th>
<th>Monograph</th>
<th>Melting Point °C</th>
<th>Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>DYNASAN® 114</td>
<td>Trimyristin</td>
<td>–</td>
<td>59 - 58</td>
<td>Lubricants for tablets &amp; capsules</td>
</tr>
<tr>
<td>DYNASAN® 116</td>
<td>Tripalmitin</td>
<td>–</td>
<td>63 - 68</td>
<td>Lipophilic matrices for fat-soluble active substances</td>
</tr>
<tr>
<td>DYNASAN® 118</td>
<td>Glyceryl Tristearate</td>
<td>USP-NF</td>
<td>69 - 73</td>
<td>Release profile modification in oral solid dosage forms and implants</td>
</tr>
</tbody>
</table>

IMWITOR® 900 (F) P

Glyceryl Monostearate
40-55%, Type I & II

Ph. Eur.
USP-NF
54 - 64

Solid partial glycerides with surface-active properties
Lipophilic matrices for oral solid dosage forms
Granulation, Hot Melt Techniques
Tablet lubricant
Matrix component for SLN
Emulsion stabilizer
Dispersing agent for pigments

WITEPSOL® E 85

Hard Fat
Ph. Eur.
USP-NF
42 - 44

Lipophilic matrix for use in bio-degradable subcutaneous implants

SOFTISAN® 154

Hydrogenated Palm Oil
–
53 - 58

Lipophilic matrix for SLN for controlled drug release

Approved Ingredients:
- Vitamin preparations
- Expectorants (e.g. ACC/NAC)
- Antiacidics (e.g. Hydrochloride)
- Antihehlemites (e.g. Moxidectin)
- Non-steroidal anti-inflammatory drugs (e.g. ASA)
- Non-opioid Analgesics (e.g. Paracetamol)