



IOI OLEOCHEMICAL

PHARMA

DYNASAN[®] 118

TECHNICAL DATA SHEET

USP (current version): Glyceryl Tristearate

DESCRIPTION

DYNASAN® 118 is a triglyceride ester of the selected saturated single fatty acid C₁₈. The fatty acid and glycerol is derived from vegetable sources. DYNASAN® 118 is free from antioxidant and other stabilizers.

APPLICATION

DYNASAN® 118 is used in the pharmaceutical industries in the following application fields:

- in suppositories, ovules and pharmaceutical sticks as crystallisation accelerators to improve congealing processes
- in ointments, creams and lotions for body imparting and structure forming effects
- in hot melt coating processes (taste masking)
- in hot melt extrusion processes (bioavailability enhancement)
- in solid lipid nanoparticles (SLN) procedures
- in tablets as a lubricant showing a very low influence on disintegration (see table below) or as retarding agent if used in higher concentrations (2-5%).

CHEMICAL AND PHYSICAL PROPERTIES

Tests	Values	Typical values	Units	Methods
Melting range	69 – 73	72	°C	Ph. Eur. 2.2.34
Acid value	max. 1.0	0.2	mg KOH/g	Ph. Eur. 2.5.1
Hydroxyl value	max. 5.0	3	mg KOH/g	Ph. Eur. 2.5.3
Triglycerides	min. 90.0	97	%	Ph. Eur. 2.2.30
Peroxide value	max. 3	0.4	meq O/kg	Ph. Eur. 2.5.5
Water	max. 0.1	0.01	%	Ph. Eur. 2.5.12

Above mentioned tests are a selection of relevant parameters and do not represent the complete current sales specification.

DYNASAN® 118 fully complies with the requirements of the current USP monograph “Glyceryl Tristearate”.

When DYNASAN® 118 is rapidly cooled after melting, a glassy, amorphous mass is initially formed. Upon standing, it changes into crystalline modifications showing a volume expansion. The stable β-modification has a very sharp melting point and is of triclinic structure.



Advantages of DYNASAN® 118 vs. typically used tablet lubricants

Broadly used tablet lubricants like Mg-Stearate could cause certain problems, either by itself but mostly due to presence of impurities. Such impurity problems could be:

- reactions with some APIs, causing stability issues
- presence of Mg-Stearate can increase the micro-environmental pH of the formulation creating an alkaline condition and consequently accelerating the hydrolysis of some drugs.
- inducing an oxidation reaction
- metal ion-mediated degradation of some APIs
- reactions with amines: amines are typically prone to reactions with excipients and salt counter-ions*

* *Lubricants 2014, 2, 21-43*

DYNASAN® 118 is a very pure triglyceride, containing none of the above mentioned impurities and due to its chemical structure it does not cause previously described problems.

Solubility

DYNASAN® 118 is slightly soluble in n-hexane, as well as in diethyl ether. It is virtually insoluble in ethanol and water.

PACKAGING UNITS

Microfine powder in paper sacks with a PE inliner of 25 kg net.

HANDLING AND SHELF LIFE

If stored longterm in original tightly closed containers, dry, protected from light and moisture and below 25°C, the shelf life then is at least two years.

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