



IOI OLEOCHEMICAL

PHARMA

IMWITOR[®] 988

TECHNICAL DATA SHEET

Ph. Eur. (current version): Glycerol Monocaprylate, type I
USP (current version): Glyceryl Mono and Dicaprylate

DESCRIPTION

IMWITOR® 988 is a partial ester of caprylic acid and glycerol. Fatty acids and glycerol are derived from vegetable sources.

APPLICATION

IMWITOR® 988 is used in oral, topical, rectal, vaginal und nasal preparations in the amount of 3 – 15 %, depending on the kind and quantity of the active ingredients used.

It acts as a solubilizer for poorly soluble drugs in oral administration forms (i.e. capsules).

IMWITOR® 988 also functions as a penetration enhancer in topical drug forms.

IMWITOR® 988 is surface-active and acts as co-emulsifier in emulsions. In low concentrations it acts as a plasticizer in tablet coatings and as a defoaming agent.

CHEMICAL AND PHYSICAL PROPERTIES

Tests	Values	Typical values	Units	Methods
Acid value	max. 3.0	1.02	mg KOH/g	Ph.Eur. 2.5.1
Saponification value	275 – 300	286	mg KOH/g	Ph. Eur. 2.5.6
Water content	max. 1.0	0.21	%	Ph. Eur. 2.5.12
Monoglycerides	45.0 – 75.0	54	%	Ph. Eur. 2.2.28
Diglycerides	20.0 – 50.0	39	%	Ph. Eur. 2.2.28
Free glycerol	max. 3	0.24	%	Ph. Eur.
Hydroxyl value	315 – 380	345	mg KOH/g	Ph. Eur. 2.5.3

IMWITOR® 988 fully complies with the requirements of the current Ph. Eur. monograph “Glycerol Monocaprylate, type I”.

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

IMWITOR® 988 is a white, crystalline, pasty mass with a slight coconut odour and a bitter taste. Therefore a direct oral use is not recommended.

IMWITOR® 988 melts at about 25°C to form an oily, yellowish liquid.



It is typical for the product that it might occur in different shapes, ranging from a crystalline solid or partly solid, paste or liquid, depending on the monoester content and the ambient temperatures. Due to this and in order to obtain a homogeneous product when only parts of product are taken out of the container, **it is recommended to melt the complete container at approx. 60°C for at least 12 hours**. It is advisable to check from time to time whether the product is already molten or not.

Although it is recommended not to heat over 25°C for a longer time, this shortly applied heating procedure does not affect the quality or the applicational properties.

IMWITOR® 988 contains no unsaturated components and is thus stable against oxidation even at elevated temperatures (f.i. 60°C, 14 d)

Solubility

IMWITOR® 988 is readily soluble in natural fats and oils or MCT (f.i. MIGLYOL® 812 N), diethyl ether, n-hexane, ethanol and dispersible in water (about 10 %).

PACKAGING UNITS

HDPE container 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 three years.

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