

IMWITOR® 742

TECHNICAL DATA SHEET

Ph. Eur. (current version): Glycerol Monocaprylocaprate, type I USP (current version): Glyceryl Mono- and Dicaprylocaprate

DESCRIPTION

IMWITOR® 742 is a blend of mono-, di- and triglycerides, mainly of caprylic and capric acid. Glycerol and fatty acids are derived from vegetable sources.

APPLICATION

IMWITOR® 742 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.

IMWITOR® 742 acts as a solubilizer for poorly soluble drugs in oral administration forms (i.e. capsules) and functions as a penetration enhancer in topical drug forms as well.

IMWITOR® 742 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	0.8	mg KOH/g	Ph. Eur. 2.5.1
Saponification value	250 - 280	267	mg KOH/g	Ph. Eur. 2.5.6
Water content	max. 0.5	0.13	%	Ph. Eur. 2.5.12
Monoglycerides	45.0 - 75.0	53	%	Ph. Eur. 2.2.28
Diglycerides	20.0 - 50.0	35	%	Ph. Eur. 2.2.28
Free glycerol	max. 3.0	0.5	%	Ph. Eur.
Hydroxyl value	315 - 380	364	mg KOH/g	Ph. Eur. 2.5.3
lodine value	max. 1	0.18	g I/100 g	Ph. Eur. 2.5.4

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

IMWITOR® 742 fully complies with the requirements of the current Ph. Eur. monograph "Glycerol Monocaprylocaprate, type I".



The colour of IMWITOR® 742 is white to yellowish and it is typical for the product that it might occur in different shapes, ranging from a crystalline solid or partly solid to liquid or paste, depending on the monoester content and on the ambient temperatures. Due to this and in order to obtain a homogeneous product 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 this shortly applied heating procedure does not affect the quality or the applicational properties, it is generally recommended not to heat above 25°C for a longer time.

IMWITOR® 742 exhibits a slight fatty odour and a scratchy and bitter taste, therefore it is not recommended to be used for direct oral uptake. It melts at about 25°C forming an oily, yellowish liquid.

When considering the use of this raw material, special attention must be taken around the face and eye areas as partial glycerides are surface active and can show irritating effects on sensitive eye mucous tissue.

IMWITOR® 742 contains no unsaturated components and is thus stable against oxidation even at elevated temperatures (f.i. 60°C, 14d).

Solubility

IMWITOR® 742 is practically insoluble in water, very soluble in ethanol (96 per cent) and freely soluble in methylene chloride.

PACKAGING UNITS

HDPE containers of 25 kg net, steel drums with an inner lacquer lining of 190 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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