

**CUTINA<sup>®</sup> GMS V PH****Further Product Name**

Ph. Eur.: "Glycerol monostearate 40-55 (typ II)"

BP: "Glycerol monostearate 40-55 (typ II)"

NF: "Mono- and Di-glycerides"

**General Characterization**

CUTINA<sup>®</sup> GMS V PH is a white to slightly yellowish, hydrophilic wax which is supplied as powder. On account of its consistency giving characteristics it is mainly used for the viscosity adjustment in pharmaceutical O/W emulsions.

**Chemical description**

Glyceryl monostearate

## Characteristic Values

The specifications stated below finally and conclusively describe the properties of the product.

### Quality control data

Data which is used for quality release and is specified for each batch.

Identification A	conforms	Ph. Eur. 2.2.15
Identification B	conforms	Ph. Eur. 2.2.27
Identification C	conforms	Ph. Eur. 2.4.22 method C
Identification D	conforms	Ph. Eur. 0495
Acid value	max 3.0	Ph. Eur. 2.5.1
Saponification value	158 - 177	Ph. Eur. 2.5.6
Iodine value	max 3.0	Ph. Eur. 2.5.4
Free Glycerol	max 6.0	Ph. Eur. 2.2.30
Melting point	54.0 - 64.0°C	Ph. Eur. 2.2.15
Water	max 1.0	Ph. Eur. 2.5.12
Total ash	max 0.1 %	Ph. Eur. 2.4.16
Stearic acid	60.0 - 80.0 %	Ph. Eur. 2.4.22 method C
Palmitic and Stearic acid	min 90.0 %	Ph. Eur. 2.4.22 method C
Monoacylglycerol	40.0 - 55.0 %	Ph. Eur. 2.2.30
Diacylglycerol	30.0 - 45.0 %	Ph. Eur. 2.2.30
Triacylglycerol	5.0 - 15.0 %	Ph. Eur. 2.2.30
Nickel	max 1 ppm	Ph. Eur. 2.4.31
Monoglycerides	47.0 - 57.0 %	USP/NF
Acid value	max 4.0	USP/NF <401>
Hyxdoxyl value	200 - 244	USP/NF <401>
Iodine value	max 10.0	USP/NF <401>
Saponification value	149 - 181	USP/NF <401>
Residue on ignition	max 0.10 %	USP/NF <281>
Arsenic	max 3 ppm	USP/NF <211> method II
Heavy metals	max 0.001 %	USP/NF <231> method II
Organic volatile impurities	conforms	USP/NF <467> method V
Limit of free glycerin	max 7.0 %	USP/NF
Pesticides residue	conforms	Ph. Eur. 2.8.13 table 1
Microbiological status	conforms	Ph. Eur. 5.1.4 category 2 & 3a
Aflatoxines	conforms	Federal Health Gazette Ban V 2000
Heavy metals	conforms	Federal Health Gazette 1985

### Methods of identification

As described in the current Monograph of the Ph. Eur. and USP/NF.

### Methods of analysis

All test and assay methods are as described in the current Monograph of the Ph. Eur. and USP/NF as not otherwise mentioned.

## Storage, Packaging and Shelflife

### Storage Conditions

In sealed original containers, protected from moisture and at temperatures below 30° C CUTINA® GMS V PH remains stable for at least two years.

Rev. 1.0

## Labeling Information & Registrations

### INCI name(s)

Glyceryl Stearate

### Officially listed in / Quality conforms to

Ph. Eur.	Conforms to the current analytical specification in the monograph "Glycerol monostearate 40-55 (typ II)"
BP	Conforms to the current analytical specification in the monograph "Glycerol monostearate 40-55 (typ II)" (copy of the Ph. Eur. Monograph)
USP/NF	Conforms to the current analytical specification of "Mono- and Di-glycerides"
US DMF no. (Typ IV)	#16503
JCIC	Glyceryl Monostearate, Lipophilic (Ingredient Code 102544)
CAS-No.	67701-33-1
EINECS-No.	266-952-6
Residual solvents	Conforms to current ICH Guideline (CPMP/ICH/283/95) & Residual solvents <467>
Minimising animal spongiform encephalopathy agents	Conforms to requirements Ph. Eur. 5.2.8

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