



**IOI OLEOCHEMICAL**

**PHARMA**

# **WITEPSOL<sup>®</sup>**

## **TECHNICAL DATA SHEET**

**Ph. Eur. (current version):**  
**USP (current version):**

**Hard Fat**  
**Hard Fat**

## DESCRIPTION

WITEPSOL® hard fats comprise of fatty acids and glycerol. Fatty acids and glycerol are based on vegetable sources. WITEPSOL® hard fats are white or almost white, brittle to slightly soft and odourless excipients in a pastill shape.

## APPLICATION

WITEPSOL® hard fats are primarily used for production of suppositories and ovules. Due to the fact that pure hard fats are GRAS listed, those WITEPSOL® bases containing no additives can be also used in the following applications:

- capsule fillings (filling base in hard and soft gel caps, acting as a carrier)
- chewing tablets
- SLN (Solid Lipid Nanoparticles) processes
- microencapsulation
- implants



# CHEMICAL AND PHYSICAL PROPERTIES

	<b>Slip melting point</b> [°C] Ph. Eur. 2.2.15	<b>Acid value</b> [mg KOH/g] Ph. Eur. 2.5.1	<b>Hydroxyl value</b> [mg KOH/g] Ph. Eur. 2.5.3	<b>Peroxide value</b> [meqi O/kg] Ph. Eur. 2.5.5	<b>Saponification value</b> [mg KOH/g] Ph. Eur. 2.5.6
WITEPSOL H 5	34.0 – 36.0 [34.9]	max. 0.5 [0.1]	max. 5 [2]	max. 3.0 [0.3]	235 – 245 [241]
WITEPSOL H 12	32.0 – 33.5 [32.8]	max. 0.5 [0.1]	5 – 15 [11]	max. 3.0 [0.2]	240 – 255 [243]
WITEPSOL H 15	33.5 – 35.5 [34.7]	max. 0.5 [0.1]	5 – 15 [13]	max. 3.0 [0.3]	230 – 245 [239]
<b>WITEPSOL H 19</b>	<b>33.5 – 35.5 [34.8]</b>	<b>max. 5 [0.2]</b>	<b>20 – 30 [27]</b>	<b>max. 15 [0.2]</b>	<b>230 – 240 [235]</b>
WITEPSOL H 32	31.0 – 33.0 [31.9]	max. 0.5 [0.1]	max. 3 [2]	max. 3.0 [0.2]	240 – 250 [248]
WITEPSOL H 35	33.5 – 35.5 [34.5]	max. 0.5 [0.1]	max. 3 [1.5]	max. 3.0 [0.2]	240 – 250 [245]
WITEPSOL H 37	36.0 – 38.0 [36.7]	max. 0.5 [0.1]	max. 3 [1.9]	max. 3.0 [0.1]	225 – 245 [237]
WITEPSOL W 25	33.5 – 35.5 [34.2]	max. 0.5 [0.1]	20 – 30 [25]	max. 3.0 [0.5]	225 – 240 [234]
WITEPSOL W 32	32.0 – 33.5 [32.8]	max. 0.5 [0.2]	40 – 50 [45]	max. 3.0 [0.4]	225 – 245 [232]
WITEPSOL W 35	33.5 – 35.5 [34.4]	max. 0.5 [0.2]	40 – 50 [45]	max. 3.0 [0.6]	225 – 235 [230]
WITEPSOL W 45	33.5 – 35.5 [34.3]	max. 0.5 [0.2]	40 – 50 [47]	max. 3.0 [0.3]	225 – 240 [233]
<b>WITEPSOL S 51</b>	<b>30.0 – 32.0 [31.1]</b>	<b>max. 5 [0.3]</b>	<b>55 – 70 [61]</b>	<b>max. 15 [0.5]</b>	<b>215 – 230 [225]</b>
<b>WITEPSOL S 55</b>	<b>ca. 35**</b>	<b>max. 5 [0.8]</b>	<b>50 – 65 [56]</b>	<b>max. 15 [1]</b>	<b>215 – 230 [223]</b>
<b>WITEPSOL S 58</b>	<b>31.5 – 33.0 [32.2]</b>	<b>max. 5 [0.3]</b>	<b>60 – 70 [66]</b>	<b>max. 15 [0.7]</b>	<b>215 – 225 [222]</b>
<b>WITEPSOL E 75</b>	<b>ca. 38**</b>	<b>max. 2 [1.0]</b>	<b>max. 15 [12]</b>	<b>max. 3.0 [0.4]</b>	<b>220 – 230 [226]</b>
WITEPSOL E 76	37.0 – 39.0 [38.0]	max. 0.5 [0.2]	30 – 40 [35]	max. 3.0 [0.3]	220 – 230 [228]
WITEPSOL E 85	42.0 – 44.0 [43.2]	max. 0.5 [0.1]	5 – 15 [13]	max. 3.0 [0.2]	220 – 240 [223]
<b>Monograph requirements</b>					
Ph. Eur.	30 – 45	max. 0.5	max. 50	max. 3.0	210 – 260
USP	27	max. 1.0	max. 70	-	215 – 255
JPE	30	max. 2.0	max. 70	-	210 – 255

**All WITEPSOL® grades containing no additives comply with the current Ph. Eur. monograph “Hard Fat”.**

**Values in brackets [ ] are nominal values.**

**Highlighted WITEPSOL® grades contain certain additives, in particular:**

WITEPSOL® H 19 contains stabilized Glyceryl Ricinoleate

WITEPSOL® E 75 contains Bees Wax

WITEPSOL® S 51 contains Macrogol Cetostearylether + stabilized Glyceryl Ricinoleate

WITEPSOL® S 55 contains Macrogol Cetostearylether + Bees Wax

WITEPSOL® S 58 contains Macrogol Cetostearylether + stabilized Glyceryl Ricinoleate

**The above mentioned hard fats do not comply with the Ph. Eur. Monograph “Hard Fat With Additives”.**



## ADDITIONAL INFORMATION

\*\* Due to the additive bees wax, the slip melting points are hard to reproduce (adhesion at the inner surface of the glas capillary). The solidification points can be determined more precisely.

Solidification point of WITEPSOL® E 75: 34 – 36.5°C [36.0°C]

Solidification point of WITEPSOL® S 55: 28 – 33°C [29.5°C]

We confirm that all other test requirements, indicated in the monograph, will be fulfilled.

### Solubility

WITEPSOL® hard fats are readily soluble in diethylether, toluene and n-hexane and slightly soluble in anhydrous ethanol and methylene chloride. They are practically insoluble in water.

The WITEPSOL® hard fats have been assigned the type IV US DMF no. 420.

## PACKAGING UNITS

Carton boxes with a PE bag of 20 kg net (exception: WITEPSOL H 32 and H 35 of 15 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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