

## FINAVESTAN white oils Certificate

### Absence of Residual Solvents

- FINAVESTAN white mineral oils are certified to be substantially free of any light solvent trace. It results from the severe hydrogenation and stripping treatments applied during their manufacture, as well as from the dedicated storage and handling facilities.
- FINAVESTAN pharmaceutical white oils comply with:
  - The International Committee on Harmonization ICH guidelines on Residual Solvents as outlined in:
    - The European Pharmacopoeia, 6<sup>th</sup> edition, 2008, chapter 5.4
    - The United States of America Pharmacopoeia General, USP 31 General chapter <467>-Residual Solvents.
  - European Council Directive 88/344/EEC
  - VICH Guideline GL 18
- Solvents are not employed for the white oil production itself. The production process makes no use of any of the solvents listed in class 1 and paragraph 4.4. However, solvents are used in the preparation of the feedstock used to produce FINAVESTAN oils. These are:

	Concentration in feedstock	Solvent Class	ICH limit
n-methylpyrrolidone	< 50 ppm	2	530 mg/kg
methylethylketone	< 50 ppm	3	0.5 wt %
methylisobutylketone	< 50 ppm	3	0.5 wt %

If present in the feedstock, the manufacturing process of the FINAVESTAN oils will eliminate any of the solvents listed above.

- FINAVESTAN white mineral oils contain no products listed on the Californian Prop 65 classification as a chemical known to cause cancer or reproductive toxicity.

### Absence of Volatile Organic Compounds (VOC)

- FINAVESTAN white oils are **free of any Volatile Organic Compounds (VOC)**. According to the directive CE 1999/13, "Limitation of emission of volatile compounds due to the use of organic solvents in certain activities and installations", limitation for VOC is established to 0,01 kPa at 20°C. FINAVESTAN white oils volatility are certified to be inferior to 0,01 kPa at 20°C. The measured value is inferior to 0,0013 kPa (<10-2 mm Hg).

### Absence of heavy metals, chlorine and other elements

- FINAVESTAN white mineral oils comply with the following regulations:
  - Lead in food regulations 1979 (SI1254)
  - Arsenic in food regulations 1959 (SI831)
  - Tin in food regulations 1992 (British regulations)
  - Directive 2005/20/CE

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- The following results have been observed for all FINAVESTAN grades (typical values):

Element	Result	Unit	Method
Ag (Silver)	< 1 (DL)	ppm	ICP-MS
Al (Aluminium)	< 1 (DL)	ppm	ICP-MS
As (Arsenic)	< 1 (DL)	ppm	ICP-MS
Ba (Barium)	< 1 (DL)	ppm	ICP-MS
Be (Beryllium)	< 1 (DL)	ppm	ICP-MS
Bi (Bismuth)	< 1 (DL)	ppm	ICP-MS
Cd (Cadmium)	< 1 (DL)	ppm	ICP-MS
Co (Cobalt)	< 1 (DL)	ppm	ICP-MS
Cr (Chromium)	< 1 (DL)	ppm	ICP-MS
Cu (Copper)	< 1 (DL)	ppm	ICP-MS
Fe (Iron)	< 1 (DL)	ppm	ICP-MS
Hg (Mercury)	< 1 (DL)	ppm	ICP-MS
Li (Lithium)	< 1 (DL)	ppm	ICP-MS
Mn (Manganese)	< 1 (DL)	ppm	ICP-MS
Mo (Molybdenum)	< 1 (DL)	ppm	ICP-MS
Ni (Nickel)	< 1 (DL)	ppm	ICP-MS
Pa (Palladium)	< 1 (DL)	ppm	ICP-MS
Pb (Lead)	< 1 (DL)	ppm	ICP-MS
Pt (Platinum)	< 1 (DL)	ppm	ICP-MS
Sb (Antimony)	< 1 (DL)	ppm	ICP-MS
Se (Selenium)	< 1 (DL)	ppm	ICP-MS
Sn (Tin)	< 1 (DL)	ppm	ICP-MS
Ta (Thallium)	< 1 (DL)	ppm	ICP-MS
Te (Tellurium)	< 1 (DL)	ppm	ICP-MS
V (Vanadium)	< 1 (DL)	ppm	ICP-MS
W (Tungsten)	< 1 (DL)	ppm	ICP-MS
Zn (Zinc)	< 1 (DL)	ppm	ICP-MS
Cl (Chlorine)	< 2 (DL)	ppm	Microcoulometry
N (Nitrogen)	< 1 (DL)	ppm	Chimiluminescence
S (Sulfur)	< 1 (DL)	ppm	Microcoulometry

ppm = mg/kg  
DL : detection limit



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