



Main Pharmaceutical Inspector

**CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER**

**Part 1**

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC as amended and Art. 80(5) of Directive 2001/82/EC as amended

**Main Pharmaceutical Inspector**

/the Competent Authority of Poland/

confirms the following:

the manufacturer

**Brenntag Polska Sp. z o.o.**  
21, J. Bema Str., 47-224 Kędzierzyn-Koźle, POLAND

site address

**Brenntag Polska Sp. z o.o.**  
**Biuro i Centrum Logistyczne w Zgierzu**  
5, Kwasowa Str., 95-100 Zgierz, POLAND

is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC and Art. 80(1) of Directive 2001/82/EC transposed in Pharmaceutical Law of 6<sup>th</sup> of September 2001 (Dz. U. z 2008 r. Nr 45 poz. 271, z późn. zm.).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **15-17/02/2011**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive 2003/94/EC, Directive 91/412/EEC and the principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified with the issuing authority.

date: **2011 -05- 12**

Main Pharmaceutical Inspectorate  
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**Zofia Ulz**  
Main Pharmaceutical Inspector

Part 2

Active substances

1 MANUFACTURING OPERATIONS

Storage

Distribution

Names of substances subject to inspection:

- Cineol,
- DHEA Dehydroepiandrosterone,
- Diosmin,
- Camphora racemica Eur PH,
- Boric acid pharm. - granular,
- Boric acid pharm. - powder,
- Salicylic acid,
- Laevo 95 Alpha - pinene,
- Menthol,
- Menthone,
- Ethacridine Lactate,
- Pine sylvestre oil,
- Juniper Berry oil,
- Peppermint Oil,
- Thyme red oil,
- Acetylsalicylic acid,
- Methyl salicylate,
- Calcium carbonate,
- Calcium carbonate + sorbitol,
- Turpentine oil Ph Eur,
- Vitamin pp - Nicotinamide.



date: 2011 -05- 12