ÚSTAV PRO STÁTNÍ KONTROLU VETERINÁRNÍCH BIOPREPARÁTŮ A LÉČIV
INSTITUTE FOR STATE CONTROL OF VETERINARY BIOLOGICALS AND MEDICAMENTS
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Certificate No. / číslo certifikátu: 145/2011/CGMP

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

CERTIFIKÁT SPRÁVNÉ VÝROBNÍ PRAXE

Part I / Část I

Institute for the State Control of Veterinary Biologicals and Medicaments as national competent authority of the Czech Republic issues according to Section 16(2) letter a) item 3 of the Act No. 378/2007 Coll., on Pharmaceuticals and Amendments to Several Related Laws in current wording (hereinafter referred to as "Act on Pharmaceuticals No. 378/2007 Coll.") and in accordance with Art. 80(5) of Directive 2001/82/EC as amended, this certificate that to confirm that manufacturer

Ústav pro státní kontrolu veterinárních biopreparátů a léčiv se sídlem v Brně jako příslušný úřad České republiky vydává podle § 16 odst. 2 písm. a) bod 3. zákona č. 378/2007 Sb., o léčivech a o změnách některých souvisejících zákonů (dále jen zákon č. 378/2007 Sb., o léčivech) a v souladu s článkem 80(5) Směrnice 2001/82/EC, ve znění pozdějších předpisů, tento certifikát, kterým potvrzuje, že výrobce

FAVEA, spol. s r.o.
B. Němcové 580
742 21 Kopřivnice
Czech Republic
IČ/INo: 603 18 287

site address
místo výroby

B. Němcové 580, 742 21 Kopřivnice

has been inspected under the national inspection programme in connection with manufacturing authorisation no. 321/2009/RHV in accordance with Art. 44 of Directive 2001/82/EC transposed in the following national legislation: Act on pharmaceuticals No. 378/2007 Coll.

je kontrolován Ústavem pro státní kontrolu veterinárních biopreparátů a léčiv v pravidelných terminech a je držitelem povolení k výrobě veterinárních léčivých přípravků reg. č. 321/2009/RHV vydaném v souladu s článkem 44 Směrnice 2001/82/EC ve znění pozdějších úprav, který byl transponován do § 63 zákona č. 378/2007 Sb., o léčivech.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 28-29/06/2011, it is considered that it complies for activities listed in Part II of this certificate with the principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EEC transposed to national legislation: Decree No. 229/2008 Coll. These requirements fulfil the GMP recommendations of WHO.

Na základě výsledků inspekce výrobce, kdy poslední inspekce byla provedena 28. - 29. června 2011, Ústav potvrzuje, že výrobce splňuje pro rozsah uvedený v části II tohoto certifikátu požadavky správné výrobní praxe stanovené Směrnicí 91/412/EEC, transponované do vyhlášky č. 229/2008 Sb. Požadavky správné výrobní praxe jsou v souladu s doporučeními WHO.

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.

Tento certifikát odráží aktuální stav výrobního místa v době inspekce uvedené výše a jeho platnost je limitována na tři roky od data této inspekce. Po této době by měla být platnost certifikátu ověřena u autority, která jej vydala.

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

Pravost certifikátu může být ověřena u autority, která jej vydala.

Part II – Scope of the certificate / Část II – rozsah certifikátu

☒ **Veterinary medicinal products / Veterinární léčivé přípravky**	
1 – Manufacturing operations / Výrobní operace	
1.2	**Non-sterile products / Nesterilní přípravky**
	1.2.1 Non-sterile products / Nesterilní přípravky 1.2.1.5 Liquids for external use / Tekuté pro vnější užití 1.2.1.6 Liquids for internal use / Tekuté pro vnitřní užití 1.2.1.8 Other solid dosage forms / Jiné pevné lékové formy 1.2.1.11 Semi-solids / Polotuhé 1.2.1.13 Tablets / Tablety
1.6	**Quality control testing / Kontrola kvality**
	1.6.3 Chemical/Physical / Chemická/fyzikální

Any restrictions or clarifying remarks related to the scope of this certificate: none
Omezení nebo vysvětlení k rozsahu tohoto certifikátu: žádná

Date of issuing/Datum vydání:
01/08/2011

Name and signature of the authorised person of the Competent Authority of the Czech Republic
Jméno a podpis oprávněné osoby

ÚSTAV PRO STÁTNÍ KONTROLU VETERINÁRNÍCH BIOPREPARÁTŮ A LÉČIV - BRNO

Prof. MVDr. Alfred Hera, Csc.
ředitel ÚSKVBL
Prof. Alfred Hera, D.V.M., PhD.
Director of ÚSKVBL

GMP and HACCP

Through carefoully selected suppliers with many years of experiences on pharmaceutical market and on the market with cosmetics, all ESSENS products can showcase their origin of the internationally recognized GMP certificate. Allso all the suppliers are HACPP certificate holders.
Global markets, international production and supply of raw materials and active pharmaceutical ingredients increases the complexity of supply chains, that´s why GMP audits guarantee the highest possible quality and unified global approach.
We bring you the informations, what is GMP and HACCP certificates are and what the certification entails.

GMP is english shortcut for Good Manufacture Practice.

It is a system, that aims to improve the safety of drugs, food, cosmetics, animal feed, etc.
GMP determines the rules of operation to avoid the danger (ex. the emergence of hazardous food) and that the legislation won´t be violated.
After the compliance with strict rules and standards according to rules of international regulation the producer, grower or breeder receive the certificate, which is a necessary to renew regularly.

GMP certification works under the auspices of WHO World Health Organisation.

The reason of the creation was to ensure globally mostly harmless medications. Poor quality of the medicines doesn´t only carries a health risks, but it is also a waste of funds and not only by the consumers, but also by national governments. Poor handling of drugs may contain toxic substances or on the contrary the therapeutic ingredients occures in inadequate quantities, which does not required therapeutic effect. During the production process the quality must be built. A different stages of production are controlled. It is not enough to test the finished product. The aim is that the countries accept only the import and sale of the medicinal products, which have been manufactured in accordance with GMP.

The main risks of non - certified companies are:

- product contamination - it may cause in adverse health effect or even death
- incorrect labeling of packaging - the risk of misuse
- insufficient or too much active ingredient - ineffective action or side effects

The course and certification conditions of GMP:

- all aspects of the production are controlled - the used space , raw materials, education, personal hygiene of employees
- for individual processes are developed the necessary detailed written procedures, which may have some influence for the final product quality.
- for individual process of the production process must be documented proof of the correct procedure for each and every product
- WHO has established the detailed guidelines for GMP, which may be at each states different and which may be fromulated in accordance of self requirements, but always in base of WHO GMP

HACCP is english shortcut for Hazard Analysis and Critical Control Points

It is a system for every food businesses producing, the processing and the food distribution.
The system is allso for the enterprises, which come into the food chains (agriculture, manufacturers of packaging materials, etc.) The main objective of HACCP are the healthy foodstufs. HACCP system´s creation and implementation is a mandatory from the year 2004 and in base of Regulation of the European Parliament and of the Council. The requirements on HACCP system in Czech Republic is governed by bulletin of the Department of Agriculture CZ 2/2010.