SÚKL
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certifikát sp.zn./ certificate Ref.No:sukls232700/2012

CERTIFIKÁT SVP PRO VÝROBCE
Část 1

Vydaný po inspekci v souladu s článkem 111(5) Směrnice 2001/83/EC ve znění pozdějších přepisů a s §13, odst. 2, písm. a bod 3 zákona č. 378/2007 Sb., o léčivech a o změnách některých souvisejících zákonů (zákon o léčivech), ve znění pozdějších předpisů

Příslušný orgán České republiky potvrzuje následující:

Výrobce:
Biomedica, spol. s r.o.
Pekařská 8, 155 00 Praha 5

Adresa místa výroby:
Biomedica, spol s r.o. Praha, divize Hořátev,
Hořátev 104, 289 12 Nymburk

Byl inspektován v souladu s plánem inspekcí v souvislosti s povolením k výrobě č.j. 38013/1/INS/99, poslední změna sp.zn.sukls232700/2012 ze dne 28.01.2013, v souladu s článkem 40 Směrnice 2001/83/EC převedeným do národní legislativy jako:
§ 62 zákona č. 378/2007 Sb., o léčivech a o změnách některých souvisejících zákonů (zákon o léčivech), ve znění pozdějších předpisů

Na základě znalostí získaných během poslední inspekce, která byla provedena dne 10.12.2012, je tento výrobce považován za subjekt splňující
požadavky a návody správné výrobní praxe stanovené směrnicí 2003/94/EC[1].

[1] Tyto požadavky splňují doporučení SZO na SVP.

Tento certifikát odráží stav výrobního místa v čase výše zmíněné inspekce a nemělo by se spoléhat na to, že bude odrážet stav shody po uplynutí více než tří let od data inspekce. Po této době by měl být konzultován vydávající orgán.

Pravost tohoto certifikátu může být ověřena u vydávajícího orgánu.

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 Section 13, paragraph 2, letter a, point 3 of the Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts,
as amended.

The competent authority of the Czech Republic confirms the following:

The manufacturer:
Biomedica, spol. s r.o.
Pekařská 8, 155 00 Praha 5

Site address:
Biomedica, spol s r.o. Praha, divize Hořátev,
Hořátev 104, 289 12 Nymburk

Has been inspected under the national inspection programme in connection with manufacturing authorisation no.38013/1/INS/99, last variation no. sukls232700/2012 issued on 28/01/2013 in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation: Section 62 of the Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts, as amended.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 10/12/2012, it is considered that it complies with
The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC[1].

[1] These requirements fulfil the GMP recommendation of 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 inspection, after which time the issuing authority should be consulted.
The authenticity of this certificate may be verified with the issuing authority.

Část 2

☒ **Humánní léčivé přípravky**

1 VÝROBNÍ OPERACE

1.2 Nesterilní přípravky

1.2.1 Nesterilní přípravky

1.2.1.6 Tekuté pro vnitřní užití
1.2.1.13 Tablety
1.2.1.17 Ostatní nesterilní léčivé přípravky - zásypy

1.5 Pouze balení

1.5.1 Primární balení

1.5.1.8 Ostatní tuhé lékové formy - sáčky

1.5.2 Sekundární balení

1.6 Kontrola jakosti

1.6.3 Chemické/Fyzikální

Jakékoli omezení nebo vysvětlení vztahující se k rozsahu certifikátu:

Datum: 18.02.2013

podpis oprávněné osoby příslušného orgánu České republiky

František Chuchma
vedoucí inspekčního odboru

Státní ústav pro kontrolu léčiv
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Státní ústav pro kontrolu léčiv v Praze .5.

Part 2

☒ **Human Medicinal Products**

1 MANUFACTURING OPERATIONS

1.2 Non-sterile products

1.2.1 Non-sterile products

1.2.1.6 Liquids for internal use
1.2.1.13 Tablets
1.2.1.17 Other non-sterile medicinal product (powders)

1. 5 Packaging only

1.5.1 Primary packing

1.5.1.8 Other solid dosage forms (sachets)

1.5.2 Secondary packing

1.6 Quality control testing

1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of this certificate:

Date:18/02/2013

signature of the authorised person of the competent authority of the Czech Republic

František Chuchma
Head of the Inspection section

State Institute for Drug Control
Šrobárova 48
100 41 Prague 10
Czech Republic
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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.