



Crna Gora



CALIMS

Agencija za lijekove
i medicinska sredstva Crne Gore
Agency for Medicines and
Medical Devices of Montenegro

SERTIFIKAT O PRIMJENI DOBRE PROIZVOĐAČKE PRAKSE

Broj sertifikata: **2050-512**

Dio 1

Na osnovu inspeksijskog nadzora izvršenog u skladu sa Zakonom o lijekovima („Sl.list RCG” br. 80/04 i „Sl.list CG” br.18/08) i Rješenjem o utvrđivanju Dobre proizvođačke prakse za lijekove u medicini i stomatologiji ("Sl.list SCG" br. 40/98 i 31/2000)
Agencija za lijekove i medicinska sredstva Crne Gore potvrđuje da je:

Proizvođač: Galenika Crna Gora d.o.o.

**Adresa: Ulica 8 marta 55a, Podgorica,
Crna Gora**

Inspektovan u skladu sa nacionalnim programom inspektovanja i dozvolom za proizvodnju broj 3020/2690/2 od 23.08.2010.

Na osnovu nalaza inspeksijskog nadzora izvršenog **11.10.2010.** proizvođač primjenjuje smjerice Dobre proizvođačke prakse u proizvodnji lijekova koji se upotrebljavaju u humanoj medicini.

Ovaj sertifikat važi za naznačno mjesto proizvodnje do **11.10.2012.** nakon čega prestaje njegova važnost.

Sertifikat važi uz Dio 2: Lista proizvodnih procesa usaglašeni sa Dobrom proizvođačkom praksom i prestaje da važi izmjenama proizvodnih procesa navedenih u prilogu.

Za kvalitet pojedinih serija proizvoda, proizvedenih tokom navedenih procesa, odgovoran je proizvođač.

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Certificate No: **2050-512**

Section 1

Following an inspection in accordance with Law on medicines („Official Gazette of Montenegro“ No. 80/04 and 18/08) and Decision on determination of Good manufacturing practise for medicinal products („Official Gazette of Serbia and Montenegro“ No. 40/98 i 31/2000)

Agency for medicines and medical devices of Montenegro confirms the following:

The Manufacturer: Galenika Crna Gora d.o.o.

**Site address: 8 marta 55a St., Podgorica,
Montenegro**

Has been inspected under the national inspection programe in connection with Manufacturing Authorisation No. 3020/2690/2 issued on 23.08.2010.

From the knowledge gained during the inspection of this manufacturer, which was conducted on **11.10.2010.** it is considered that it complies with the guidelines on Good Manufacturing Practise for medicinal products for human use.

This certificate is valid for the manufacturing site noted above untill **11.10.2012.**

Certificate is valid only with section 2: List of manufacturing operations compliant with Good Manufacturing Practise and it ceases to be valid with any modifications of manufacturing operations listed.

Quality of each batch, manufactured during the operations listed, is responsibility of the manufacturer.

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Dio 2: Lista proizvodnih procesa usaglašenih sa
Dobrom proizvođačkom praksom

Lijekovi za upotrebu u humanoj medicini

Proizvodnja

Nesterilnih proizvoda

- prašak za oralnu suspenziju

Cefaklor prašak za oralnu suspenziju

(ALFACET® 125mg/5ml, 60ml)

Cefaklor prašak za oralnu suspenziju

(ALFACET® 250mg/5ml, 60ml)

Cefaleksin prašak za oralnu suspenziju

(PALITREX® 250mg/5ml, 100ml)

Kontrola kvaliteta za gore navedene lijekove:

- Kontrola kvaliteta u postupku proizvodnje
(in-proces kontrola)

Autentičnost ovog sertifikata se može potvrditi u
Agenciji za lijekove i medicinska sredstva
Crne Gore.

Section 2: List of manufacturing operations
compliant with Good Manufacturing Practise

Human medicinal products

Manufacturing operations

Non-steril products

Powder for oral suspension

Cefaklor powder for oral suspension

(ALFACET® 125mg/5ml, 60ml)

Cefaklor powder for oral suspension

(ALFACET® 250mg/5ml, 60ml)

Cefaleksin powder for oral suspension

(PALITREX® 250mg/5ml, 100ml)

Quality control for medicinal products listed above

- In process quality control

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

Podgorica, 28.01.2011.

Nadležno lice/ Person in charge



DIREKTOR
The Director
Dr Milorad Drljević

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