Lyfjastofnun
Icelandic Medicines Agency

Certificate No: IS/10/14

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with:
Art. 15 of Directive 2001/20/EC

The competent authority of Iceland confirms the following:
The manufacturer: **Pharmarctica ehf.**
Site address**: Lundsbraut 2, IS-610 Grenivík, Iceland**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. 038 in accordance with Art. 13 of Directive 2001/20/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **25th of September 2014**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/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.

LYFJASTOFNUN

16 December 2014

.....
Sigríður Ólafsdóttir

Address: Lyfjastofnun, Vínlandsleið 14, IS-113
Reykjvaík, Iceland, **Tel:** +354 520 2100, **Fax:** +354 561 2170,
E-mail: lyfjastofnun@lyfjastofnun.is,
Homepage: www.lyfjastofnun.is

Lyfjastofnun
Icelandic Medicines Agency

Certificate No: IS/10/14

Part 2

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS – MEDICINAL PRODUCTS
1.2 Non-sterile products
1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.11 Semi-solids 1.2.1.12 Suppositories
1.5 Packaging
1.5.1 Primary packing 1.5.1.13 Tablets

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

i. Pharmarctica ehf. license in point 1.2 in annex 1 relates only to magistral formula products. All Pharmarctica ehf. magistral formula products are prescription medicines.

ii. All medicinal products that Pharmarctica ehf. is licensed to produce, relating to point 1.4 in annex 1, other than magistral formula products, are accounted for in annex 8.

iii. Point 1.5.1.13 in annex 2 relates to authorization to manually pack tablets in vials for clinical trials.

16 December 2014

Sigríður Ólafsdóttir

LYFJASTOFNUN

Address: Lyfjastofnun, Vínlandsleið 14, IS-113
Reykjvaík, Iceland, **Tel:** +354 520 2100, **Fax:** +354 561 2170,
E-mail: lyfjastofnun@lyfjastofnun.is,
Homepage: www.lyfjastofnun.is

Lyfjastofnun
Icelandic Medicines Agency

Certificate No: IS/09/14

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
Art. 80(5) of Directive 2001/82/EC as amended

The competent authority of Iceland confirms the following:
The manufacturer: **Pharmarctica ehf.**
Site address**: Lundsbraut 2, IS-610 Grenivík, Iceland**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. 038 in accordance with Art. 40 of Directive 2001/83/EC and Art. 44 of Directive 2001/82/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **25th of September 2014**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.
- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/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.

LYFJASTOFNUN

16 December 2014

.....
Sigríður Ólafsdóttir

Address: Lyfjastofnun, Vínlandsleið 14, IS-113
Reykjvaík, Iceland, **Tel:** +354 520 2100, **Fax:** +354 561 2170,
E-mail: lyfjastofnun@lyfjastofnun.is,
Homepage: www.lyfjastofnun.is

Part 2

Human Medicinal Products
Veterinary Medicinal Products

1 MANUFACTURING OPERATIONS – MEDICINAL PRODUCTS
1.2 Non-sterile products
1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.11 Semi-solids 1.2.1.12 Suppositories 1.2.1.13 Tablets
1.4 Other products or processing activity
1.4.1 Manufacture of: 1.4.1.1 Herbal products
1.5 Packaging
1.5.1 Primary packing 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.11 Semi-solids 1.5.1.12 Suppositories 1.5.1.13 Tablets *1.5.2 Secondary packaging*

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

i. Pharmarctica ehf. license in point 1.2 in annex 1 is restricted to magistral formula products. All Pharmarctica ehf. magistral formula products are prescription medicines.

ii. All medicinal products that Pharmarctica ehf. is licencsed to produce, relating to point 1.4 in annex 1, other than magistral formula products, are accounted for in annex 8.

16 December 2014

.....
Sigríður Ólafsdóttir

LYFJASTOFNUN

Address: Lyfjastofnun, Vínlandsleið 14, IS-113
Reykjvaík, Iceland, **Tel:** +354 520 2100, **Fax:** +354 561 2170,
E-mail: lyfjastofnun@lyfjastofnun.is,
Homepage: www.lyfjastofnun.is

Lyfjastofnun
Icelandic Medicines Agency

Framleiðsluleyfi / *Manufacturer´s Authorisation*

1. Númer leyfis / *Authorisation No.*	**038**
2. Handhafi framleiðsluleyfis / *Name of authorisation holder.*	**Pharmarctica ehf.**
3. Framleiðslustaður / *Address of manufacturing site.*	**Pharmarctica ehf.** **Lundsbraut 2.** **IS-610 Grenivík** **Iceland**
4. Lögheimili handhafa framleiðsluleyfis / *Legally registered address of authorisation holder.*	**Lundsbraut 2.** **IS-610 Grenivík** **Iceland**
5. Umfang leyfis og lyfjaform / *Scope of authorisation and dosage forms*	**Viðaukar 1 og 2 / *Annex 1 and 2***
6. Lagagrundvöllur leyfis / *Legal basis for authorisation.*	**Lyfjalög nr. 93/1994, gr. 34 / *The Medicinal Products Act No. 93/1994, art. 34.***
7. Ábyrgur f.h. Lyfjastofnunar / *Responsible officer of IMA.*	**Sigríður Ólafsdóttir**
8. Undirskrift / *Signature*	
9. Gildir frá: / *Valid from:* Gildir til: / *Valid until:*	**16. desember 2014 / *16 December 2014*** **15. desember 2017 / *15 December 2017***
10. Viðaukar / *Annexes attached*	**Viðaukar 1, 2, 4, 5, 6 og 8/ *Annex 1, 2, 4, 5, 6 and 8***

LYFJASTOFNUN

Sækja verður um heimild til Lyfjastofnunar fyrirhugi leyfishafi breytingar á atriðum sem liggja til grundvallar leyfisveitingunni, samanber 5. og 8. gr. reglugerðar nr. 893/2004. / *Any changes to the terms for this authorisation must be applied for according to art. 5 and 8 of regulation No. 893/2004.*

Kemur í stað leyfis frá 31. janúar 2014 / *Replaces license issued 31 January 2013.*

Address: Lyfjastofnun, Vínlandsleið 14, IS- 113 Reykjavík, Iceland, **Tel:** +354 520 2100, **Fax:** +354 561 2170,
E-mail: lyfjastofnun@lyfjastofnun.is,
Homepage: www.lyfjastofnun.is

Lyfjastofnun
Icelandic Medicines Agency

UMFANG LEYFIS / *SCOPE OF AUTHORISATION* **VIÐAUKI 1 / *ANNEX 1***

Framleiðslustaður / *Name and address of the site:*
Pharmarctica ehf., Lundsbraut 2, IS-610 Grenivík, Iceland.

Lyf fyrir menn / *Human Medicinal Products*
Lyf fyrir dýr / *Veterinary Medicinal Products*

Leyfðar framleiðsluaðgerðir / *Authorised Operations*
Framleiðsluaðgerðir (samkvæmt hluta 1) / *Manufacturing Operation (according to part 1)*

Hluti 1 – framleiðsluaðgerðir / *Part 1 – Manufacturing Operations*

1.2 Lyf, ekki sæfð / *Non-sterile products*

1.2.1 Lyf, ekki sæfð (vinnsluaðgerðir fyrir eftirtalin lyfjaform) / *Non-sterile products (processing operations for the following dosage forms)*

1.2.1.5 Vökvar til útvortis notkunar / *Liquids for external use*
1.2.1.6 Vökvar til inntöku / *Liquids for internal use*
1.2.1.11 Krem og smyrsl / *Semi-solids*
1.2.1.12 Stílar / *Suppositories*
1.2.1.13 Töflur / *Tablets*

1.4 Önnur lyf eða framleiðsluaðgerðir / *Other products or manufacturing activity*

1.4.1 Framleiðsla á / *Manufacture of*:
1.4.1.1 Náttúrulyfjum / *Herbal products*

1.5 Pökkun / *Packaging*

1.5.1 Lokapökkun / *Primary packing*
1.5.1.5 Vökvar til útvortis notkunar / *Liquids for external use*
1.5.1.6 Vökvar til inntöku / *Liquids for internal use*
1.5.1.11 Krem og smyrsl / *Semi-solids*
1.5.1.12 Stílar / *Suppositories*
1.5.1.13 Töflur / *Tablets*
1.5.2 Pökkun í ytri umbúðir / *Secondary packaging*

Takmarkanir eða útskýringar tengdar framleiðsluaðgerðum / *Any restrictions or clarifying remarks related to these Manufacturing operations:*

i. Leyfi Pharmarctica ehf. til framleiðslu lyfja skv. lið 1.2 í viðauka 1 nær einungis til forskriftarlyfja lækna. Öll forskriftarlyf Pharmarctica ehf. eru lyfseðilsskyld. / *Pharmartica ehf. license in point 1.2 in annex 1 is restricted to magistral formula products. All Pharmartica ehf. magistral formula products are prescription medicines.*

ii. Lyf sem Pharmarctica ehf. hefur heimild til að framleiða skv. lið 1.4 í viðauka 1, önnur en forskriftarlyf lækna, eru talin upp í viðauka 8. / *All medicinal products that Pharmartica ehf. is licencsed to produce, relating to point 1.4 in annex 1, other than magistral formula products, are accounted for in annex 8.*

16.12.2014

Address: Lyfjastofnun, Vínlandsleið 14, IS- 113
Reykjavík, Iceland, **Tel:** +354 520 2100, **Fax:** +354 561 2170,
E-mail: lyfjastofnun@lyfjastofnun.is,
Homepage: www.lyfjastofnun.is

Lyfjastofnun
Icelandic Medicines Agency

UMFANG LEYFIS / *SCOPE OF AUTHORISATION* — VIÐAUKI 2 / *ANNEX 2*

Framleiðslustaður / *Name and address of the site:*
Pharmarctica ehf., Lundsbraut 2, IS-610 Grenivík, Iceland.

Rannsóknarlyf fyrir menn / *Human Investigational Medicinal Products*

Leyfðar framleiðsluaðgerðir / *Authorised Operations*
Framleiðsluaðgerðir fyrir rannsóknarlyf (samkvæmt hluta 1) / *Manufacturing Operation of Medicinal Products (according to part 1)*

Hluti 1 – framleiðsluaðgerðir fyrir rannsóknarlyf /*Part 1 - Manufacturing Operations of Investigational Medicinal Products*

1.2 Rannsóknarlyf, ekki sæfð / *Non-sterile investigational medicinal products*

1.2.1 Lyf, ekki sæfð (vinnsluaðgerðir fyrir eftirtalin lyfjaform) / *Non-sterile products (processing operations for the following dosage forms)*

1.2.1.5 Vökvar til útvortis notkunar / *Liquids for external use*
1.2.1.6 Vökvar til inntöku / *Liquids for internal use*
1.2.1.11 Krem og smyrsl / *Semi-solids*
1.2.1.12 Stílar / *Suppositories*

1.5 Pökkun / *Packaging*

1.5.1 Lokapökkun / *Primary packing*

1.5.1.5 Vökvar til útvortis notkunar / *Liquids for external use*
1.5.1.6 Vökvar til inntöku / *Liquids for internal use*
1.5.1.11 Krem og smyrsl / *Semi-solids*
1.5.1.12 Stílar / *Suppositories*
1.5.1.13 Töflur / *Tablets*

1.5.2 Pökkun í ytri umbúðir / *Secondary packaging*

Takmarkanir eða útskýringar tengdar framleiðsluaðgerðum / *Any restrictions or clarifying remarks related to these Manufacturing operations:*

i. Liður 1.5.1.13 í viðauka 2 á eingöngu við heimild til handvirkrar pökkunar á töflum í glös fyrir klíniskar rannsóknir. / *Point 1.5.1.13 in annex 2 is restricted to the authorization to manually pack tablets in vials for clinical trials.*

LYFJASTOFNUN

16.12.2014

Address: Lyfjastofnun, Vínlandsleið 14, IS- 113
Reykjavík, Iceland, **Tel:** +354 520 2100, **Fax:** +354 561 2170,
E-mail: lyfjastofnun@lyfjastofnun.is,
Homepage: www.lyfjastofnun.is

Lyfjastofnun
Icelandic Medicines Agency

Rannsóknarstofur með verksamning / *Contract Laboratories* — Viðauki 4 / *ANNEX 4*

Promat Akureyri ehf.
Furuvöllum 1,
600 Akureyri

Auðlindadeild Háskólans á Akureyri
Borgum v/Norðurslóð
600 Akureyri

Síðast breytt 24. júní 2011 / *latest change 24 June 2011*

Ábyrgðarhafi / *Name of Qualified Person* — Viðauki 5 / *ANNEX 5*

Fanney Ásgeirsdóttir, lyfjafræðingur / pharmacist

Síðast breytt: 14. maí 2008 / *latest change 14 May 2008*

Faglegur forstöðumaður / *Name of Responsible Person* — Viðauki 6 / *ANNEX 6*

Fanney Ásgeirsdóttir, faglegur forstöðumaður (skv. 35. gr. Lyfjalaga nr. 93/1994) / *Responsible for professional direction (according to art. 35 of The Medicinal Product Act no. 93/1994)*

Kemur í stað viðauka 6 frá 14. maí 2008 / *replaces annex 6 from 14 May 2008*
Síðast breytt: 3. október 2013/ *latest change 3 October 2013*

Lyf sem fyrirtækið hefur heimild til að framleiða / *Medicinal products included in the manufacturing licence* — Viðauki 8 / *ANNEX 8*

Lyf sem á við lið 1.4.1.1 í viðauka 1: Náttúrulyfið Viggó. / *Product referring to point 1.4.1.1 in annex 1: Herbal Medicine "Viggó"*

LYFJASTOFNUN

16.12.2014

Address: Lyfjastofnun, Vínlandsleið 13, IS-113,
Reykjavík, Iceland, **Tel:** +354 520 2100, **Fax:** +354 561 2170,
E-mail: lyfjastofnun@lyfjastofnun.is,
Homepage: www.lyfjastofnun.is