Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

BASG / AGES MEA
Institut Überwachung
Traiseng. 5, 1200 Wien, Österreich

GMP-ZERTIFIKAT / *CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*

Zertifikat Nr.: / *Certificate No.:* INS-481892-0003-001

Teil 1 / *Part 1*

Ausgestellt auf Basis einer Inspektion in Übereinstimmung mit /
Issued following an inspection in accordance with

☒ **Art. 111(5) of Directive 2001/83/EC**
☐ **Art. 80(5) of Directive 2001/82/EC**
☐ **Art. 15 of Directive 2001/20/EC**

Die zuständige Behörde **Österreichs** bestätigt wie folgt: /
*The competent authority of **Austria** confirms the following:*

Der Betrieb / *The manufacturer*

Indiana Blood Center, Inc.
3450 N. Meridian Street
46208 IN Indianapolis

wurde inspiziert auf Grundlage einer Auflistung in den Zulassungsunterlagen als Hersteller mit Sitz außerhalb des Europäischen Wirtschaftsraumes, auf Basis von /
has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with

☐ **Art. 8(2)/33(2)/19(3)/44(3)* of Regulation (EC) 726/2004***
☒ **Art. 111(4) of Directive 2001/83/EC**
☐ **Art. 80(4) of Directive 2001/82/EC**

umgesetzt in folgende nationale Gesetzgebung / *transposed in the following national legislation:*
‚Verordnung der Bundesministerin für Gesundheit und Frauen betreffend Betriebe, die Arzneimittel herstellen, kontrollieren oder in Verkehr bringen (Arzneimittelbetriebsordnung 2009 - AMBO 2009), BGBl. II Nr. 324/2008'.

Aus der während der Inspektion des betreffenden Herstellers gewonnenen Kenntnis, zuletzt durchgeführt am /
From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on

19.09.2017 , für/*for* 3,5 Tag(e) / *day(s)*

kann angenommen werden, dass /
it is considered that it complies with

☒ den Richtlinien der Guten Herstellungspraxis[1] entsprochen wird, festgehalten in /
The principles and guidelines of Good Manufacturing Practice[1] laid down in

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Zertifikat Nr.: / *Certificate No.:* INS-481892-0003-001

☒ **Directive 2003/94/EC**

☐ **Directive 91/412/EEC**

☐ **der Richtlinie der GMP für Wirkstoffe (Art. 47 of Directive 2001/83/EC und Art. 51 of Directive 2001/82/EC) / *The principles of GMP for active substances (Art. 47 of Directive 2001/83/EC and Art. 51 of Directive 2001/82/EC).***

Dieses Zertifikat spiegelt den Status der Betriebsstätte zum Zeitpunkt der oben genannten Inspektion. Es sollte nicht zur Bestätigung der Übereinstimmung herangezogen werden, wenn seit der genannten Inspektion mehr als drei Jahre vergangen sind. Die Gültigkeitsdauer kann unter Verwendung eines regulatorischen Risikomanagements durch einen Eintrag in das Feld Einschränkungen oder Erklärungen verkürzt oder verlängert werden.

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. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field

Das Zertifikat ist nur bei Vorlage sämtlicher Seiten und beider Teile (1 und 2) gültig.

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

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[1] *These requirements fulfil the GMP recommendations of WHO.*

(*) Nichtzutreffendes streichen / delete that which does not apply

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GMP-ZERTIFIKAT / *CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*

Zertifikat Nr.: / *Certificate No.:* INS-481892-0003-001

Teil 2 / *Part 2*

☒ Humanarzneimittel / *Human Medicinal Products*

☐ Veterinärarzneimittel / *Veterinary Medicinal Products*

Prüfpräparate zur klinischen Prüfung / *Human Investigational Medicinal Products*

☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV

Teil 1 – HERSTELLUNGSTÄTIGKEITEN / *Part 1 – MANUFACTURING OPERATIONS*

1.4 Andere Produkte oder Herstellungstätigkeiten / *Other products or manufacturing activity*

(jede andere relevante Herstellungsaktivität/ Produktart, die oben nicht erwähnt ist, z.B. Sterilisation von Wirkstoffen, Herstellung von biologischen Ausgangsstoffen (sofern durch nationale Vorschriften vorgesehen), pflanzliche oder homöopathische Produkte, Bulk oder vollständige Herstellung usw.)
(any other relevant manufacturing activity/product type that is not covered above e.g. sterilisation of active substances, manufacture of biological active starting materials (when required by national legislation), herbal or homeopathic products, bulk or total manufacturing, etc).

1.4.1 Herstellung von: / *Manufacture of:*

1.4.1.3 Anderen: / *Others:*
Humanplasma zur Fraktionierung / *Human Plasma for Fractionation*

1.6 Qualitätskontrolle / *Quality control testing*

1.6.3 Chemisch/Physikalisch / *Chemical/Physical*
1.6.4 Biologisch / *Biological*

Mögliche Einschränkungen oder Erklärungen bezüglich des vorliegenden Zertifikats /
Any restrictions or clarifying remarks related to the scope of this certificate:
Keine / none

Für das Bundesamt für Sicherheit im Gesundheitswesen /
For the Federal Office for Safety in Health Care

REPUBLIK ÖSTERREICH Bundesamt für Sicherheit im Gesundheitswesen 22 2018

Austrian
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Institute Surveillance
Traiseng. 5, 1200 Vienna, Austria

Octapharma Pharmazeutika Produktions GmbH
Denisia Wurstbauer
Oberlaaer Straße 235
A-1100 Vienna

Date: 08 October 2019
Contact: Karmin Saadat
T: +43 (0)505 55-36213
E-Mail: inspektionen@ages.at
Reference: INS-481892-0004-004

INSPECTION OF THIRD COUNTRY SOURCE PLASMA / RECOVERED PLASMA SITES FOR Octapharma Pharmazeutika Produktions GmbH

Dear Mrs. Wurstbauer,

We refer to the inspection performed for your company at Indiana Blood Center, Inc., 3450 N Meridian Street, 46208 Indianapolis, IN on 19 – 22 September 2017 by the Austrian Agency for Health and Food Safety (AGES).

On the basis of the inspection performed on 19 – 22 September 2017, and subsequent correspondence, we can confirm that your operations relating to the safety and quality of plasma are in general compliance with the requirements of Commission Directives 2004/33/EC and 2005/62/EC implementing Directive 2002/98/EC of the European Parliament and of the Council, the relevant European Pharmacopoeia Monograph(s) and Directive 2003/94/EC.

This letter reflects the status of the plasma collection site at the time of the inspection noted above. The Issuing Authority has established appropriate inspection and control measures for the above named site to deem it compliant until September 2021. This letter should not be relied upon to reflect the compliance status if the above mentioned date has been exceeded, after which the issuing authority should be consulted.

The listing of this site in EMEA/H/PMF/000008/05 will be recommended.

Any matters arising from this inspection will be reviewed at the next inspection.

On behalf of the Austrian Federal Office for Safety in Health Care

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BASG / AGES MEA
Institute Surveillance
Traiseng. 5, 1200 Vienna, Austria

Saadat Karmin
am 8.10.2019

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	Signaturwert	mvaWuIWalfw/omTuPvpgiifpkzPhwd ub/IhDWDmPSDaWz1ofGPo/DvdhrB5 obcsW5nfGmT2udSPktfnoIeDnWB Tohvvz0atewD5AgolrBuTsroi 0//T/tDTrcru5oGrobGPT5frIe/ lGASunwgnAaincSSpcDnpGu2etv WfWuWnkgmPpSIBAApuslp2vc1/Bt2bkwaf0AP2lw

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Institute Surveillance
Traiseng. 5, 1200 Vienna, Austria

Octapharma Pharmazeutika Produktions GmbH
Denisia Wurstbauer
Oberlaaer Straße 235
A-1100 Vienna

Date: 08 October 2019
Contact: Karmin Saadat
T: +43 (0)505 55-36213
E-Mail: inspektionen@ages.at
Reference: INS-482941-0001-004

INSPECTION OF THIRD COUNTRY SOURCE PLASMA / RECOVERED PLASMA SITES FOR Octapharma Pharmazeutika Produktions GmbH

Dear Mrs. Wurstbauer,

We refer to the inspection performed for your company at Indiana Blood Center – Laboratory 3450 N Meridian Street, 46208 Indianapolis, IN on 19 – 22 September 2017 by the Austrian Agency for Health and Food Safety (AGES).

On the basis of the inspection performed on 19 – 22 September 2017, and subsequent correspondence, we can confirm that your operations relating to the safety and quality of plasma are in general compliance with the requirements of Commission Directives 2004/33/EC and 2005/62/EC implementing Directive 2002/98/EC of the European Parliament and of the Council, the relevant European Pharmacopoeia Monograph(s) and Directive 2003/94/EC.

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Any matters arising from this inspection will be reviewed at the next inspection.

On behalf of the Austrian Federal Office for Safety in Health Care

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Traiseng. 5, 1200 Vienna, Austria

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	Signaturwert	cnDb2Guwhpc2d/cs0giAl/aPuvgs/2T DnwmWkgeozobuiaIzArw1ApdDsi m/w/lo0hgkgnTDSznBu1lsPADSWs /dWBmdTWcbl0kecGtS/BPwpDDfv/BBwGiB rPnorhGcbogTkk1mn/zokpfuo Bm2c0S2iaGsmGdzigSdAlDbl fhrPI0sbfb2zsvbmbPcB5IcrPSB

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Institute Surveillance
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Octapharma Pharmazeutika Produktions GmbH
Denisia Wurstbauer
Oberlaaer Straße 235
A-1100 Vienna

Date: 08 October 2019
Contact: Karmin Saadat
T: +43 (0)505 55-36213
E-Mail: inspektionen@ages.at
Reference: INS-482943-0001-004

INSPECTION OF THIRD COUNTRY SOURCE PLASMA / RECOVERED PLASMA SITES FOR Octapharma Pharmazeutika Produktions GmbH

Dear Mrs. Wurstbauer,

We refer to the inspection performed for your company at Indiana Blood Center – 2726 Adams Street Suite 150, 46032 Carmel IN on 19 – 22 September 2017 by the Austrian Agency for Health and Food Safety (AGES).

On the basis of the inspection performed on 19 – 22 September 2017, and subsequent correspondence, we can confirm that your operations relating to the safety and quality of plasma are in general compliance with the requirements of Commission Directives 2004/33/EC and 2005/62/EC implementing Directive 2002/98/EC of the European Parliament and of the Council, the relevant European Pharmacopoeia Monograph(s) and Directive 2003/94/EC.

This letter reflects the status of the plasma collection site at the time of the inspection noted above. The Issuing Authority has established appropriate inspection and control measures for the above named site to deem it compliant until September 2021. This letter should not be relied upon to reflect the compliance status if the above mentioned date has been exceeded, after which the issuing authority should be consulted.

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Any matters arising from this inspection will be reviewed at the next inspection.

On behalf of the Austrian Federal Office for Safety in Health Care

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Traiseng. 5, 1200 Vienna, Austria

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am 8.10.2019

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	Signaturwert	1TaScrIresvdo1shwd/kTDwdul/t0l Tlo2bdAs0gftTTtw/Pt5wBahvSezItmf ti0AbcDdr2lnWtgp2ke0gvac mezSvvcpSoasnB2WSePvmDocpP5iB Gevzknc00bmvWznp5mlzuoom5s W1r2vkcvlpvwnBzpbP1elp0ozTz mzpbdgBIBcflmunPwluahrbDlirzw

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Octapharma Pharmazeutika Produktions GmbH
Denisia Wurstbauer
Oberlaaer Straße 235
A-1100 Vienna

Date: 08 October 2019
Contact: Karmin Saadat
T: +43 (0)505 55-36213
E-Mail: inspektionen@ages.at
Reference: INS-482945-0001-004

INSPECTION OF THIRD COUNTRY SOURCE PLASMA / RECOVERED PLASMA SITES FOR Octapharma Pharmazeutika Produktions GmbH

Dear Mrs. Wurstbauer,

We refer to the inspection performed for your company at Indiana Blood Center – 11005 Allisonville Road, 46038, Fishers IN on 19 – 22 September 2017 by the Austrian Agency for Health and Food Safety (AGES).

On the basis of the inspection performed on 19 – 22 September 2017, and subsequent correspondence, we can confirm that your operations relating to the safety and quality of plasma are in general compliance with the requirements of Commission Directives 2004/33/EC and 2005/62/EC implementing Directive 2002/98/EC of the European Parliament and of the Council, the relevant European Pharmacopoeia Monograph(s) and Directive 2003/94/EC.

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The listing of this site in EMEA/H/PMF/000008/05 will be recommended.

Any matters arising from this inspection will be reviewed at the next inspection.

On behalf of the Austrian Federal Office for Safety in Health Care

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Traiseng. 5, 1200 Vienna, Austria

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	Signaturwert	rBS2armnPlWvo2rrTrnAiiwgdefTAw BwfupklbhftlogrBvib5d Srgit/mTmvSaP2WDATrBhA/SwSoGkS5 vmpT2iD10zGznkDtamhnka/Ggl bGpwIebuvPvi2oIG/Izbms1fuz2u /acatsovSbckSlGrl2u/PprPPgSIp agzk5ltmhrdt/de5DD10ko2SoaPS

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Octapharma Pharmazeutika Produktions GmbH
Denisia Wurstbauer
Oberlaaer Straße 235
A-1100 Vienna

Date: 08 October 2019
Contact: Karmin Saadat
T: +43 (0)505 55-36213
E-Mail: inspektionen@ages.at
Reference: INS-482942-0001-004

INSPECTION OF THIRD COUNTRY SOURCE PLASMA / RECOVERED PLASMA SITES FOR Octapharma Pharmazeutika Produktions GmbH

Dear Mrs. Wurstbauer,

We refer to the inspection performed for your company at Indiana Blood Center – Market Square 2200 Elmwood Avenue Suite D 16, 47904 Lafayette, IN on 19 – 22 September 2017 by the Austrian Agency for Health and Food Safety (AGES).

On the basis of the inspection performed on 19 – 22 September 2017, and subsequent correspondence, we can confirm that your operations relating to the safety and quality of plasma are in general compliance with the requirements of Commission Directives 2004/33/EC and 2005/62/EC implementing Directive 2002/98/EC of the European Parliament and of the Council, the relevant European Pharmacopoeia Monograph(s) and Directive 2003/94/EC.

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The listing of this site in EMEA/H/PMF/000008/05 will be recommended.

Any matters arising from this inspection will be reviewed at the next inspection.

On behalf of the Austrian Federal Office for Safety in Health Care

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Traiseng. 5, 1200 Vienna, Austria

Saadat Karmin
am 8.10.2019

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	Signaturwert	2hlu1vP5aA2/nzcbc01veWI5ugb0go hiPodwriTv/5gcp/pccml/5A5tpt5Tk hlu22w020iwehlkBz1fkGbI1riDinnG 25rlTPDr1olSWabSnPzDrBlnfhPDdG fbrlhhwpgus2frfeccnDlPIr0 ovoDzBm0aubneDpBhlnAh5ibdAPb 2PodarWguvASuz0tlmpAagllDkvmg

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Denisia Wurstbauer
Oberlaaer Straße 235
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Date: 08 October 2019
Contact: Karmin Saadat
T: +43 (0)505 55-36213
E-Mail: inspektionen@ages.at
Reference: INS-482946-0001-004

INSPECTION OF THIRD COUNTRY SOURCE PLASMA / RECOVERED PLASMA SITES FOR Octapharma Pharmazeutika Produktions GmbH

Dear Mrs. Wurstbauer,

We refer to the inspection performed for your company at Indiana Blood Center – 8739 US Highway 31, South Indianapolis, 46227 IN on 19 – 22 September 2017 by the Austrian Agency for Health and Food Safety (AGES).

On the basis of the inspection performed on 19 – 22 September 2017, and subsequent correspondence, we can confirm that your operations relating to the safety and quality of plasma are in general compliance with the requirements of Commission Directives 2004/33/EC and 2005/62/EC implementing Directive 2002/98/EC of the European Parliament and of the Council, the relevant European Pharmacopoeia Monograph(s) and Directive 2003/94/EC.

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	Signaturwert	puAPhA0BgAbhgnuTb1hmoc/gzStmw1 /DlAdlhczTa21vPe5iAbSmPvWckfg nw20odTDsDk1gD5vfvAhTvlAb Snlwcnfclb/gukS0pgolGovBIG slekkaASiiGuuDsm0TrreWceDuwz uv/zvWeeBgSvd5cmni1ows12TcsmBGn/ eW1slfsWvSomfilS10gWIgA

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Institute Surveillance
Traiseng. 5, 1200 Vienna, Austria

Octapharma Pharmazeutika Produktions GmbH
Denisia Wurstbauer
Oberlaaer Straße 235
A-1100 Vienna

Date: 08 October 2019
Contact: Karmin Saadat
T: +43 (0)505 55-36213
E-Mail: inspektionen@ages.at
Reference: INS-482944-0001-004

INSPECTION OF THIRD COUNTRY SOURCE PLASMA / RECOVERED PLASMA SITES FOR Octapharma Pharmazeutika Produktions GmbH

Dear Mrs. Wurstbauer,

We refer to the inspection performed for your company at Indiana Blood Center – 2021 South 3rd Street, Terre Haute 47802 IN on 19 – 22 September 2017 by the Austrian Agency for Health and Food Safety (AGES).

On the basis of the inspection performed on 19 – 22 September 2017, and subsequent correspondence, we can confirm that your operations relating to the safety and quality of plasma are in general compliance with the requirements of Commission Directives 2004/33/EC and 2005/62/EC implementing Directive 2002/98/EC of the European Parliament and of the Council, the relevant European Pharmacopoeia Monograph(s) and Directive 2003/94/EC.

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The listing of this site in EMEA/H/PMF/000008/05 will be recommended.

Any matters arising from this inspection will be reviewed at the next inspection.

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Traiseng. 5, 1200 Vienna, Austria

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	Signaturwert	kAiuulPAv0P2Bli1GmWuvBIDgIaPbha e/fhtecmbupnerwhhbwSgbT1t1hPom s/lWg0fiaz2lw/5Boll1BwzBstegTTd 0/b/tzplh/Sbal2PmlebsufPBl d2ofWocDGznTGlfAfvdBAPv2gupbkg nAff5p0smus/DBv1azAaA5emlp uvde2sTce5nz5/iAtcAkfevWiGfdv