Zertifikat-Nr./Certificate no:
DE_HE_01_GMP_2018_0013

Aktenzeichen/Reference Number:
II 23.2 (Wei) - 18 I 02 (111) - IND 40

BESTÄTIGUNG DER ÜBEREINSTIMMUNG EINES HERSTELLERS MIT GMP

Teil 1

Ausgestellt nach einer Inspektion gemäß

• Art. 111 (5) der Richtlinie 2001/83/EG

Die zuständige deutsche Überwachungsbehörde bestätigt:

Der Hersteller
Jubilant Generics Limited

Anschrift der Betriebsstätte
Jubilant Generics Limited
Village Sikandarpur Bhainswal, Roorkee
Dehradoon Highway,
Bhagwanpur, Roorkee, District Haridwar,
Uttarakhand, 247661
Indien

• wurde im Rahmen der in der Zulassung aufgeführten Hersteller mit Sitz außerhalb des Europäischen Wirtschaftsraumes inspiziert gemäß
- Art. 111 (4) der Richtlinie 2001/83/EG
umgesetzt in deutsches Recht durch:
§ 72a Abs. 1 Arzneimittelgesetz

Aufgrund der aus der letzten Inspektion vom 05. September 2017 gewonnenen Erkenntnisse wird für die oben genannte Betriebsstätte des Herstellers die Übereinstimmung mit den Anforderungen der Guten Herstellungspraxis festgestellt, die sich aus

• den Grundsätzen und Leitlinien der Guten Herstellungspraxis gemäß
- Richtlinie 2003/94/EG

ergeben.

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with

• Art. 111 (5) of Directive 2001/83/EC

The competent authority of GERMANY confirms the following:

PHD Chamber of Commerce and Industry
22 MAR 2018
New Delhi-110001

The manufacturer
Jubilant Generics Limited

Site address
Jubilant Generics Limited
Village Sikandarpur Bhainswal, Roorkee
Dehradoon Highway,
Bhagwanpur, Roorkee, District Haridwar,
Uttarakhand, 247661
India

• has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with
- Art. 111 (4) of Directive 2001/83/EC
transposed in the following national legislation:
Sect 72a para 1 Arzneimittelgesetz (German Drug Law)

From the knowledge gained during the inspection of this manufacturer, the latest of which was conducted on 05 September 2017, it is considered that it complies with the Good Manufacturing Practice requirements referred to in

• the principles and guidelines of Good Manufacturing Practice laid down in
- Directive 2003/94/EC

ATTESTED
Kharak Singh Bisht
Executive
PHD Chamber of Commerce and Industry
New Delhi (INDIA)

भारत सरकार GOVERNMENT OF INDIA

अपोस्टिल / APOSTILLE

(Convention de La Haye du 5 octobre 1961)

Country INDIA

This public document of the type

COMMERCIAL DOCUMENT

is issued to JUBILANT GENERICS LTD.

has been signed by KHARAK SINGH BISHT

with the seal / stamp of EXECUTIVE, PHD CHAMBER OF COMMERCE AND INDUSTRY, NEW DELHI

Certified by

Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS

on 23-Mar-2018 at NEW DELHI, INDIA

with reference no. DLND0010212618

Seal / Stamp

Signature

(ड्रबाब्रत पाल)

(DEBABRATA PAUL)

अनुभाग अधिकारी (ओ.आई.)

Section Officer (O.I.)

सी.पी.वी. प्रभाग/C.P.V. Division

विदेश मंत्रालय, भारत सरकार

Ministry of External Affairs

New Delhi

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Dieses Zertifikat bestätigt 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. Nach Ablauf dieser Zeit sollte mit der zuständigen Behörde Kontakt aufgenommen werden. Das Zertifikat ist nur bei Vorlage sämtlicher Seiten inklusive der Teile 1 und 2 gültig. Die Echtheit dieses Zertifikates kann ggf. durch die ausstellende Behörde bestätigt 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, 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.

PHD Chamber of Commerce and Industry
22 MAR 2018
New Delhi-110001

ATTESTED
Kharak Singh Bisht
Executive
PHD Chamber of Commerce and Industry
New Delhi (INDIA)

029710

Unterschrift: Nicole Weinreich

JUBILANT GENERICS LIMITED INDIA


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on 23-Mar-2018 at NEW DELHI, INDIA
With reference no. DLND0010212718
Seal / Stamp
Signature
(देबव्रत, पाल)
(DEBABRATA PAUL)
अनुभाग अधिकारी (ओ.आई.)
Section Officer (O.I.)
सी.पी.वी. प्रभाग/C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs
New Delhi

Teil 2

• Humanarzneimittel

1 HERSTELLUNGSTÄTIGKEITEN

1.2 Nichtsterile Produkte

1.2.1 Nichtsterile Produkte (Herstellungstätigkeiten für folgende Darreichungsformen)

1.2.1.13 Tabletten

1.6 Qualitätskontrolle

1.6.2 Mikrobiologisch: Prüfung nicht steriler Produkte

1.6.3 Chemisch/Physikalisch

Einschränkungen oder klarstellende Anmerkungen betreffend den Umfang des Zertifikats:

Anmerkungen:

Dieses Zertifikat ist für die Einfuhr in die Europäische Union nur gültig in Verbindung mit der aktuellen Bescheinigung nach § 72a Absatz 1 Satz 1 Nr. 2 AMG, die den Importeuren Aliud Pharma GmbH, Gottlieb-Daimler-Straße 19, 89150 Laichingen, Betriebsstätte: Stadastraße 2-18, 61118 Bad Vilbel und Hemopharm GmbH, Theodor-Heuss-Straße 52, 61118 Bad Vilbel, Betriebsstätte: Stadastraße 2-18, 61118 Bad Vilbel nach der Inspektion gemäß § 72a Absatz 1 Satz 2 Nr. 1 AMG ausgestellt wurde, und nach Bestätigung der aktuellen Gültigkeit anhand des Eintrages in der Datenbank nach § 67a AMG.

Gegenstand der Inspektion:

Oxcarbazepin 150 mg / 300 mg / 600 mg Filmtabletten

Part 2

• Human Medicinal Products

1 MANUFACTURING OPERATIONS

1.2 Non-sterile products

1.2.1 Non-sterile products (processing operations for the following dosage forms)

1.2.1.13 Tablets

1.6 Quality control testing

1.6.2 Microbiological: non-sterility

1.6.3 Chemical/Physical

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

Comments:

This certificate is in case of importation into the European Union only valid in connection with the current confirmation according to para 72a section 1 sentence 1 number 2 Medicinal Products Act, the German Drug Law (Arzneimittelgesetz, AMG), issued to the importing companies Aliud Pharma GmbH, Gottlieb-Daimler-Straße 19, 89150 Laichingen, Betriebsstätte: Stadastraße 2-18, 61118 Bad Vilbel und Hemopharm GmbH, Theodor-Heuss-Straße 52, 61118 Bad Vilbel, Betriebsstätte: Stadastraße 2-18, 61118 Bad Vilbel after the inspection according to para 72a section 1 sentence 2 number 1 Medicinal Products Act, and after confirming the validity of the inputs using the database according to para 67a Medicinal Products Act.

Scope of inspection:

Oxcarbazepine 150 mg / 300 mg / 600 mg film-coated tablets

PHD Chamber of Commerce and Industry
22 MAR 2018
New Delhi-110001

ATTESTED
Kharak Singh Bisht
Executive
PHD Chamber of Commerce and Industry
New Delhi (INDIA)

029710

Unterschrift: Nicole Weinreich

JUBILANT GENERICS LIMITED
INDIA

31. Januar 2018
Im Auftrag

31 January 2018
On behalf

Name und Unterschrift des Bearbeiters der zuständigen Behörde

Name and signature of the authorised person of the Competent Authority

Nicole Weinreich
Regierungspräsidium Darmstadt
Pharmazie
Luisenplatz 2
64283 Darmstadt
Deutschland

Tel.: +49(0)6151 125326

Nicole Weinreich
Regierungspräsidium Darmstadt
Pharmazie
Luisenplatz 2
64283 Darmstadt
Deutschland

Tel.: +49(0)6151 125326

PHD Chamber of Commerce and Industry
22 MAR 2018
New Delhi-110001

ATTESTED
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PHD Chamber of Commerce and Industry
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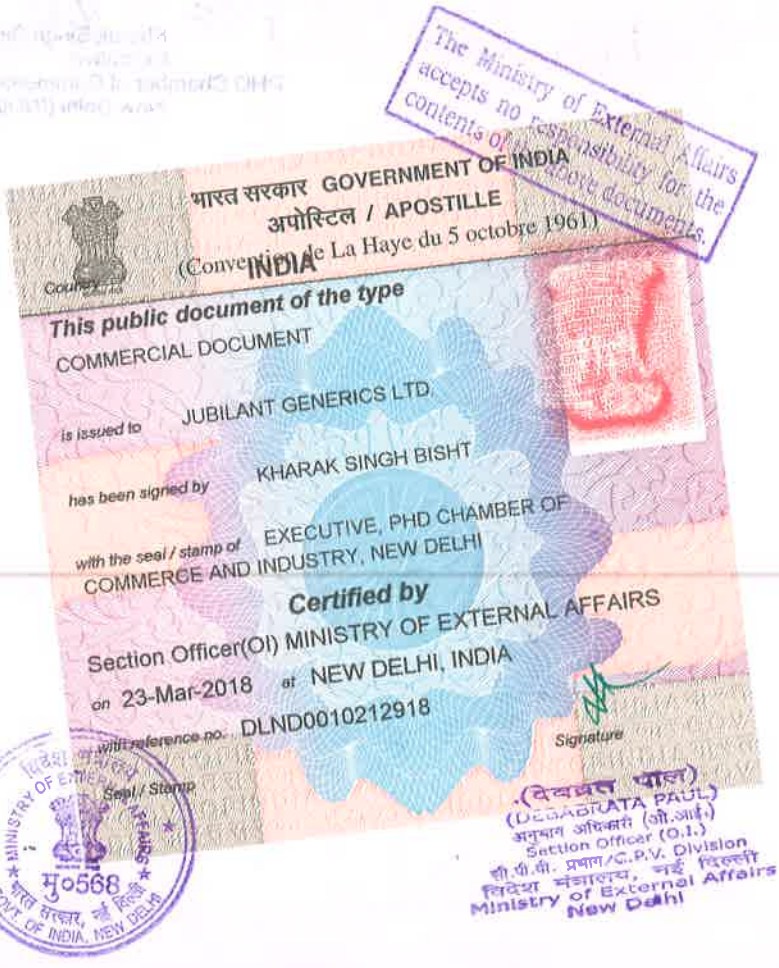
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अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)
INDIA
This public document of the type
COMMERCIAL DOCUMENT
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has been signed by KHARAK SINGH BISHT
with the seal / stamp of EXECUTIVE, PHD CHAMBER OF COMMERCE AND INDUSTRY, NEW DELHI
Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 23-Mar-2018 at NEW DELHI, INDIA
with reference no. DLND0010212918
Seal / Stamp
Signature
मु०568
(देवब्रत पाल)
(DEBABRATA PAUL)
अनुभाग अधिकारी (ओ.आई.)
Section Officer (O.I.)
सी.पी.वी. प्रभाग/C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs
New Delhi

Vania Silva Sepúlveda
Asesor Técnico
Ascend Laboratories SpA

Certificado N°:
DE_HE_01_GMP_2018_0013
Número de Referencia:
II 23.2 (Wei) – 18 I 02 (111) – IND 40

CERTIFICADO DE CUMPLIMIENTO DE BPM DEL FABRICANTE

Parte 1

Emitido seguido de una inspección de acuerdo con

- **Art. 111 (5) de la Directiva 2001/83/EC**

La autoridad competente de ALEMANIA confirma lo siguiente:

El fabricante
Jubilant Generics Limited

Dirección del sitio
Jubilant Generics Limited
Village Sikandarpur Bhainswal, Roorkee
Dehradoon, Roorkee, District Haridwar,
Uttarakhand, 247661
India

- ha sido inspeccionado en relación a la autorización de comercialización de fabricantes listados localizados fuera del Área Económica Europea de acuerdo al
- Art. 111 (4) de la Directiva 2001/83/EC
Transpuesta en la siguiente legislación nacional:
Sect 72a para 1 Arzneimittelgesetz (Ley de Medicamentos de Alemania)

Del conocimiento recabado durante la inspección de este fabricante, la cual la última fue realizada el 05 de Septiembre 2017, se considera en cumplimiento de los requerimientos de Buenas Prácticas de Manufactura referidas a en

- los principios y guías de Buenas Prácticas de Manufactura en
- Directiva 2003/94/EC

Certificate N°:
DE_HE_01_GMP_2018_0013
Número de Referencia:
II 23.2 (Wei) – 18 I 02 (111) – IND 40

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with

- **Art. 111 (5) of Directive 2001/83/EC**

The competent authority of GERMANY confirms the following:

The manufacturer
Jubilant Generics Limited

Site address
Jubilant Generics Limited
Village Sikandarpur Bhainswal, Roorkee
Dehradoon, Roorkee, District Haridwar,
Uttarakhand, 247661
India

PHD Chamber of Commerce and Industry
22 MAR 2018
New Delhi-110001

- has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with
- Art. 111 (4) of Directive 2001/83/EC
transposed in the following national legislation:
Sect 72a para 1 Arzneimittelgesetz (German Drug Law)

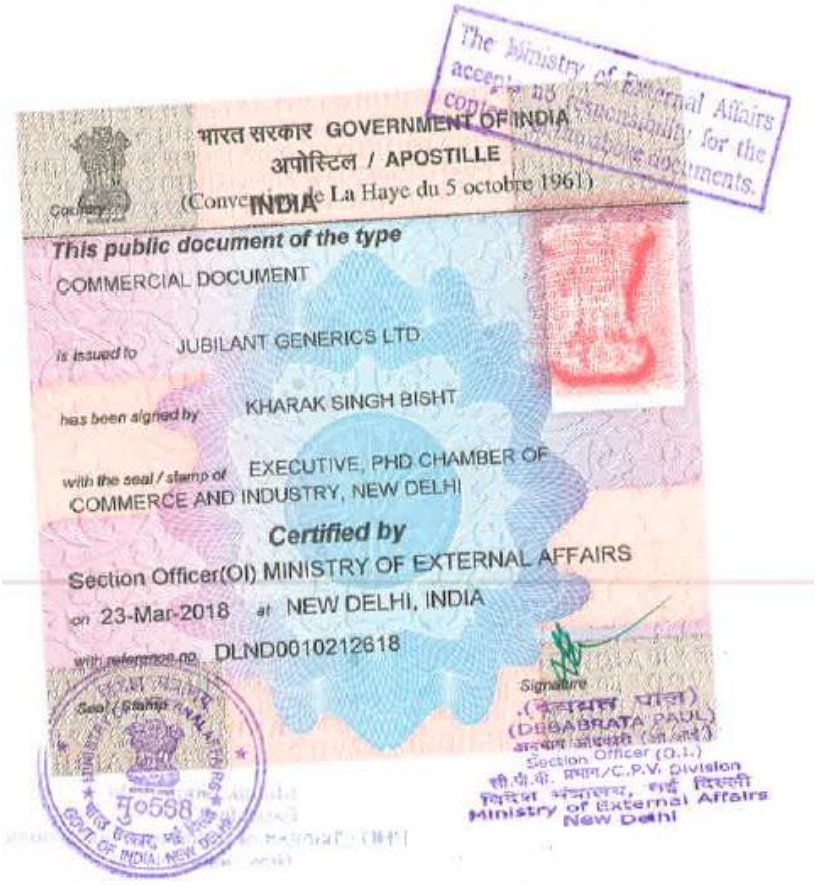
From the knowledge gained during the inspection of this manufacturer, the latest of which was conducted on 05 September 2017, it is considered that it complies with the Good Manufacturing Practice requirements referred to in

- the principles and guidelines of Good Manufacturing Practice laid down in
- Directive 2003/94/EC

029710

ATTESTED
Kharak Singh Bisht
Executive
PHD Chamber of Commerce and Industry
New Delhi (INDIA)

JUBILANT GENERICS LIMITED
INDIA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Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
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Section Officer (O.I.)
C.P.V. Division
Ministry of External Affairs
New Delhi

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Este certificado refleja el estado del sitio de fabricación al momento de la inspección anotada anteriormente y no debe confiarse en este para reflejar el estado de cumplimiento si más de tres años han pasado desde la fecha de la inspección, luego de este tiempo se debe consultar a la autoridad emisora. Este certificado es válido solo si es presentado con todas sus páginas y ambas partes 1 y 2. La autenticidad de este certificado puede ser verificada con la autoridad emisora.

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.

PHD Chamber of Commerce and Industry
22 MAR 2018
New Delhi-110001

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Kharak Singh Bisht
Executive
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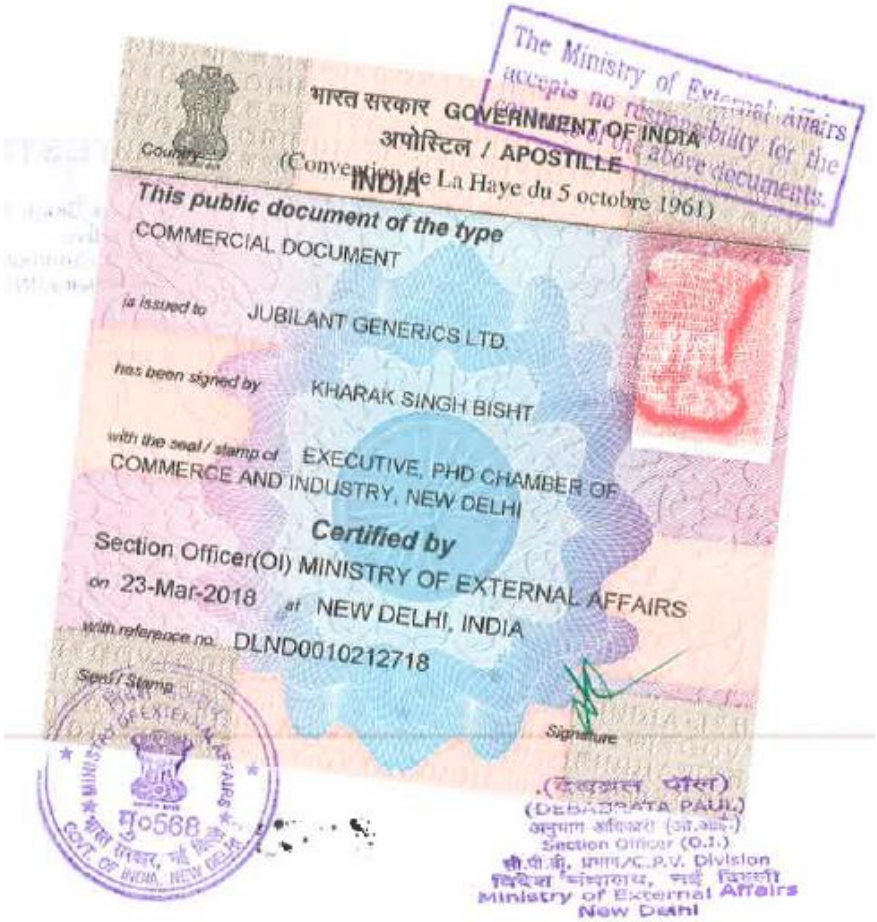
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on 23-Mar-2018 at NEW DELHI, INDIA
With reference no. DLND0010212718
Seal / Stamp
Signature
(DEBADATA PAUL)
Section Officer (O.I.)
Ministry of External Affairs
New Delhi

Parte 2

• Productos Medicinales Humanos

1 OPERACIONES DE FABRICACIÓN

1.2 Productos no estériles

1.2.1 Productos no estériles (operaciones de procesamiento para las siguientes formas de dosis)
1.2.1.13 Tabletas

Cualquier restricción u observación relacionada con el alcance de este certificado:
Comentarios:

Este certificado es en caso de importación en la Unión Europea solo válido en conexión con la confirmación actual de acuerdo con el párrafo 72a sección 1 oración 1 número 2 de la Ley de Medicamentos, la Ley Alemana de Medicamentos (Arzneimittelgesetz, AMG), expedida a las empresas importadoras Allud Pharma GmbH. Gottlieb-Daimler-StraBe 19, 89150 Laichingen, Betriebsstätte: StadastraBe 2-18, 61118 Bad Vilbel und Hemopharm GmbH, Theodor-Heuss-StraBe 52, 61118 Bad Vilbel, Betriebsstätte: StadastraBe 2-18, 61118 Bad Vilbel después de la inspección de acuerdo con párrafo 72a sección 1 oración 2 número 1 de la Ley de Productos Medicinales, y después de confirmar la validez de los insumos utilizando la base de datos de acuerdo con el párrafo 67a de la Ley de Productos Medicinales.

Alcance de la inspección:

Oxcarbazepina 150 mg / 300 mg / 600 mg comprimidos recubiertos con película.

Part 2

• Human Medicinal Products

1 MANUFACTURING OPERATIONS

1.2 Non-sterile products

1.2. 1 Non-sterile products (processing operations for the following dosage forms)
1.2.1.13 Tablets

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

This certificate is in case of importation into the European Union only valid in connection with the current confirmation according to para 72a section 1 sentence 1 number 2 Medicinal Products Act, the German Drug Law (Arzneimittelgesetz, AMG), issued to the importing companies Allud Pharma GmbH. Gottlieb-Daimler-StraBe 19, 89150 Laichingen, Betriebsstätte: StadastraBe 2-18, 61118 Bad Vilbel und Hemopharm GmbH, Theodor-Heuss-StraBe 52, 61118 Bad Vilbel, Betriebsstätte: StadastraBe 2-18, 61118 Bad Vilbel after the inspection according to para 72a section 1 sentence 2 number 1 Medicinal Products Act, and after confirming the validity of the inputs using the database according to para 67a Medicinal Products Act.

Scope of Inspection:

Oxcarbazepine 150 mg / 300 mg / 600 mg film-coated tablets.

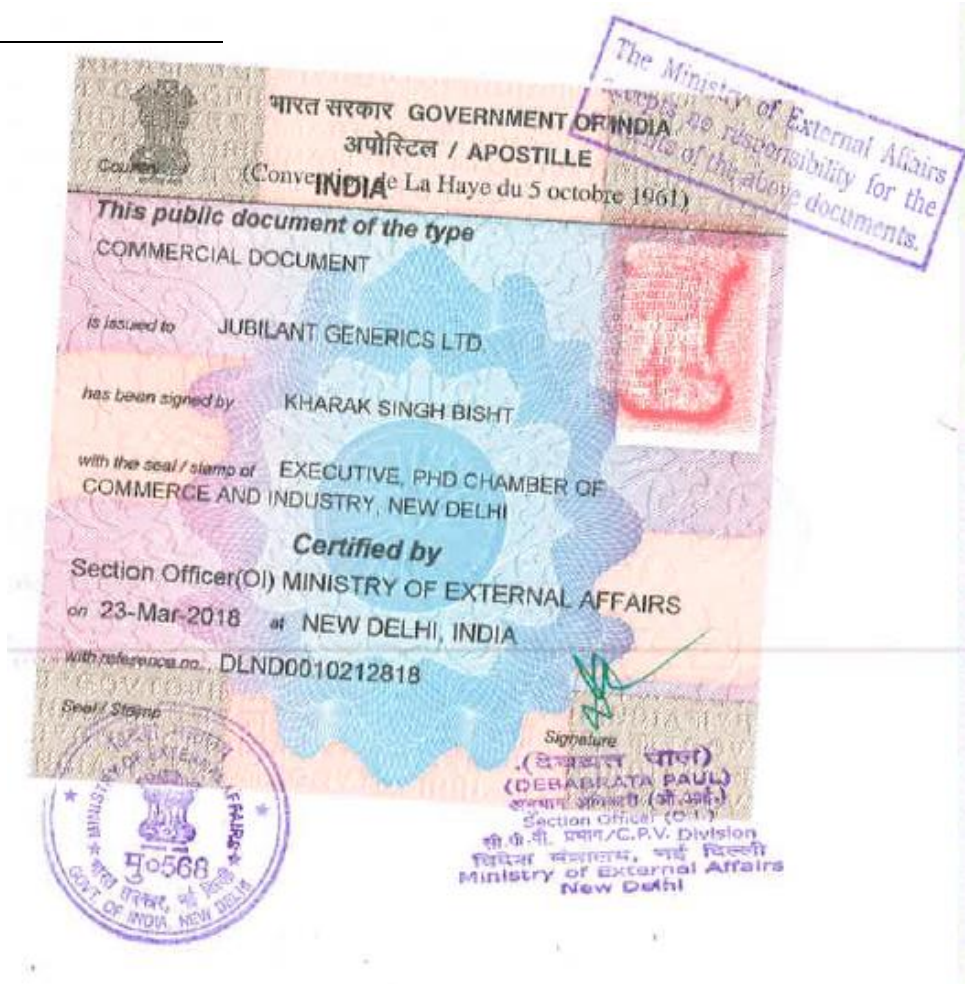
Vania Silva Sepúlveda
Asesor Técnico
Ascend Laboratories SpA

PHD Chamber of Commerce and Industry
22 MAR 2018
New Delhi-110001

ATTESTED
Kharak Singh Bisht
Executive
PHD Chamber of Commerce and Industry
New Delhi (INDIA)

029710

JUBILANT GENERICS LIMITED INDIA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Section Officer (O.I.)
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विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs
New Delhi

31. Enero 2018
En nombre de

Nombre y firma de la persona autorizada de la Autoridad Competente

Nicole Weinreich
Reglerungspräsidium Darmstadt
Pharmazie
Luisenplatz 2
64283 Darmstadt
Deutschland

Tel.: +49(0)6151 125326

31 January 2018
On behalf

Name and signature of the authorised person of the Competent Authority

Nicole Weinreich
Reglerungspräsidium Darmstadt
Pharmazie
Luisenplatz 2
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Deutschland

Tel.: +49(0)6151 125326

PHD Chamber of Commerce and Industry
22 MAR 2018
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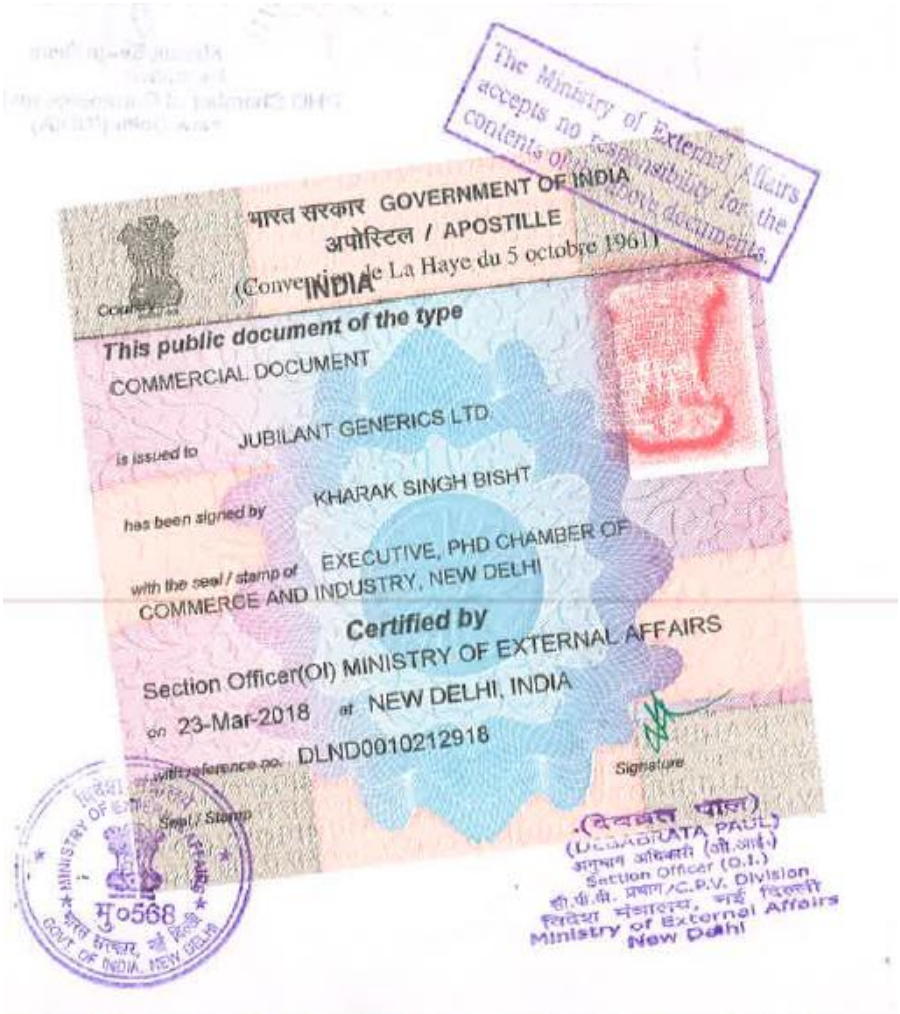
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(देवजता पाल)
(DEVAJATA PAUL)
अनुभाग अधिकारी (ओ.आई.)
Section Officer (O.I.)
सी.पी.वी. प्रभाग/C.P.V. Division
विदेश संचालय, नई दिल्ली
Ministry of External Affairs
New Delhi