MHRA
Regulating Medicines and Medical Devices

MHRA
151 Buckingham Palace Road
London SW1W 9SZ
United Kingdom

mhra.gov.uk

RESTRICTED – COMMERCIAL
Ms Jingman Shi
NCPC HEBEI HUAMIN PHARMACEUTICAL COMPANY LIMITED
NO. 98 HAINAN ROAD
ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE
SHIJIAZHUANG
HEBEI PROVINCE
CN 052165
CHINA

Certificate No: UK GMP 43070 Insp GMP 43070/9869490-0002

MHRA
Regulating Medicines and Medical Devices

Medicines and Healthcare products Regulatory Agency

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 the United Kingdom confirms the following:

The manufacturer	NCPC HEBEI HUAMIN PHARMACEUTICAL COMPANY LIMITED
Site address	NO. 98 HAINAN ROAD ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE SHIJIAZHUANG HEBEI PROVINCE CN 052165 CHINA

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: The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 08/05/2017, 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. 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.

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

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear please contact the issuing authority.

Medicines and Healthcare Products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

1.1 Sterile products

1.1.1 Aseptically prepared (processing operations for the following dosage forms)

1.1.1.6 Other aseptically prepared products
Cephalosporin Powder for Injection filled by sterile API directly

1.2 Non-sterile products

Not Authorised

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

Not Authorised

1.5 Packaging

1.5.2 Secondary packaging

1.6 Quality control testing

1.6.1 Microbiological: sterility
1.6.2 Microbiological: non-sterility
1.6.3 Chemical/physical

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

Not Authorised

2.2 Batch certification of imported medicinal products

Not Authorised

2.3 Other importation activities

Not Authorised

MHRA
Regulating Medicines and Medical Devices

3. MANUFACTURING OPERATIONS

3.1 Manufacture of Active Substance by Chemical Synthesis
Not Authorised

3.2 Processing Activities of Active Substance from Natural Sources
Not Authorised

3.3 Manufacture of Active Substance using Biological Processes
Not Authorised

3.4 Manufacture of sterile active substance
Not Authorised

3.5 General Finishing Steps
Not Authorised

3.6 Quality Control Testing
Not Authorised

4 Other Activities
Not Authorised

MHRA
Regulating Medicines and Medical Devices

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

N/A

1. Building(s)/Area(s)

   The inspection only included module 2D in workshop 101 and supporting areas. Module 2D consists of lines 2D1 and 2D2 which are identical.

2. Room(s)

   N/A

3. Line(s) Equipment(s)

   N/A

4. QC testing

   N/A

5. Medicinal Product(s)/IMP(s)

   N/A

Name of the authorised person of the Competent Authority of the United Kingdom

Norman Gray
GMP Inspector
Norman.Gray@mhra.gsi.gov.uk

Date: 28/07/2017

TRADUCCIÓN OFICIAL No. 147-17, DE UN DOCUMENTO ESCRITO EN INGLÉS, SELLADO CON EL SELLO DEL SUSCRITO TRADUCTOR OFICIAL, HOY OCTUBRE 18, 2017 EN LA CIUDAD DE BOGOTÁ D.C., REPÚBLICA DE COLOMBIA.

MHRA
Regulating Medicines and Medical Devices

MHRA
151 Buckingham Palace Road
Londres, SW1W 9SZ
Reino Unido

RESTRINGIDO – COMERCIAL
Sra. Jingman Shi
NCPC HEBEI HUAMIN PHARMACEUTICAL COMPANY LIMITED
No. 98 HAINAN ROAD
ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE
SHIJIAZHUANG
HEBEI PROVINCE
CN 052165
CHINA

Agencia Reglamentaria de Productos Medicinales y
Para el Cuidado De La Salud

APOSTILLA Y TRAMITES COLOMBIA
Traducción oficial – www.apostillaytramitescolombia.com - 3013535034
Sergio Eleuterio Olaya Mendoza
Traductor e Intérprete Oficial
Resol. No. 2839 Minjusticia 1991

AGENCIA REGLAMENTARIA DE PRODUCTOS MEDICINALES Y PARA EL CUIDADO DE LA SALUD

CERTIFICADO DE CONFORMIDAD GMP DE UN FABRICANTE

PARTE 1

A Continuación se escribe una inspección conforme al Art. 111(5) de la Directiva 2001/83/EC

La autoridad competente del Reino Unido confirma lo siguiente:

El fabricante: NCPC HEBEI HUAMIN PHARMACEUTICAL COMPANY LIMITED
Direccion: No. 98 HAINAN ROAD
ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE
SHIJIAZHUANG
HEBEI PROVINCE
CN 052165
CHINA

Fue inspeccionado en relación con los fabricantes detallados por la autorización de comercialización ubicado fuera del Área Económica Europea conforme al Art. 111(4) de la Directiva 2001/83/EC, transpuesto en la siguiente legislación nacional:
Reglamento para Medicinas Humanas 2012 (SI 2012/1916).

Por el conocimiento adquirido de la inspección de este fabricante, la ultima que se realizó en 08/05/2017, se considera que cumple con los principios y directrices de las Buenas Prácticas de Fabricación establecidas en la directiva 2003/94/EC.

Este Certificado refleja el estado del sitio de fabricación en el momento de la inspección escrita anteriormente y no se debe confiar para reflejar el estado de cumplimiento si han transcurrido más de tres años desde la fecha de esa inspección. Sin embargo, este periodo de validez puede ser reducido o prorrogado usando principios de gestión de riesgos reglamentarios por un ingreso en el campo de comentarios de Restricciones o Aclaraciones.

El certificado es válido únicamente cuando se presenta con todas las páginas y las dos partes: 1 y 2.

La autenticidad de este certificado puede ser verificado en EudraGMDP. Si no aparece favor contactar a la autoridad que expide.

Agencia Reglamentaria de Productos Medicinales y
Para el Cuidado De La Salud

APOSTILLA Y TRAMITES COLOMBIA
Traducción oficial – www.apostillaytramitescolombia.com - 3013535034
Sergio Eleuterio Laterre Mendoza
Traductor e Interprete Oficial
Resol. No. 2837 Minjusticia 1991

Parte 2:
Productos Medicinales Humanos

1. OPERACIONES DE FABRICACIÓN

1.1 Productos esterilizados

1.1.1 Preparados asépticamente (operaciones de procesamiento para las siguientes fórmulas farmacéuticas).

1.1.1.6. Otros productos preparados asépticamente.
Cephalosporin Powder for Injection filled by sterile API directly
(Polvo de Cefalosporina para inyección llenado por API estéril directamente.)

1.2 PRODUCTOS NO ESTERILIZADOS
No autorizado

1.3 PRODUCTOS MEDICINALES BIOLÓGICOS
No autorizado

1.4 OTROS PRODUCTOS O ACTIVIDAD DE FABRICACIÓN
No autorizado

1.5 EMPAQUE UNICAMENTE
1.5.2 Empaque secundario

1.6 PRUEBA DE CONTROL DE CALIDAD

1.6.1 Microbiológico: esterilidad
1.6.2 Microbiológico: no esterilidad
1.6.3 Químico/Físico

2. IMPORTACIÓN DE PRODUCTOS MEDICINALES

2.1 Prueba de Control de calidad de productos medicinales importados
No autorizado

2.2 Certificación de Lote de productos Medicinales Importados
No autorizado

2.3 Otras actividades de importación
No autorizado

Agencia Reglamentaria de Productos Medicinales y
Para el Cuidado De La Salud

APOSTILLA Y TRAMITES COLOMBIA
Traducción oficial – www.apostillaytramitescolombia.com - 3013535034
Sergio Clemente Calorro Mendoza
Traductor e Intérprete Oficial
Resol. No. 2839 Minjusticia 1991

3. OPERACIONES DE FABRICACIÓN

3.1 Fabricación de Sustancia Activa por Síntesis Químico

No autorizado

3.2 Actividades de Procesamiento de Sustancia Activa de Fuentes Naturales

No autorizado

3.3 Fabricación de Sustancia Activa usando Procesos Biológicos

No autorizado

3.4 Fabricación de sustancia activa estéril

No autorizado

3.5 Pasos de Terminación Generales

No autorizado

3.6 Pruebas de Control de Calidad

No autorizado

4 Otras actividades

No autorizado

Agencia Reglamentaria de Productos Medicinales y
Para el Cuidado De La Salud

Traducción oficial – www.apostillaytramitescolombia.com - 3013535034
Sergio Eleuterio Valorre Mendoza
Traductor e Intérprete Oficial
Resol. No. 2819 Minjusticia 1991

MHRA
Regulating Medicines and Medical Devices

Cualquier restricción o comentarios de aclaración relacionados al alcance de este certificado:

N/A

1. Área de Edificación

   La inspección únicamente incluye módulo 2D en taller 101 y áreas de soporte. El Módulo 2D consiste de líneas 2D1 y 2D2 las cuales son idénticas.

2. Salones

   N/A

3. Equipo de Línea(s)

   N/A

4. Pruebas Control de Calidad

   N/A

5. Productos Medicinales /IMP(s)

   N/A

Nombre de la persona autorizada
de la Autoridad Competente del Reino Unido

Norman Gray
Inspector GMP
Norman.Gray@mhra.gsi.gov.uk

Fecha: 28/07/2017

Agencia Reglamentaria de Productos Medicinales y
Para el Cuidado De La Salud

Fin de traducción oficial realizada por Sergio Eleuterio Latorre Mendoza, Cedula No. 17.187.049
Resolución oficial No 2839 de 1991 del Ministerio de Justicia

APOSTILLA Y TRAMITES COLOMBIA
Traducción oficial – www.apostillaytramitescolombia.com - 3013535034
Sergio Eleuterio Latorre Mendoza
Traductor e Intérprete Oficial
Resol. No. 2839 Minjusticia 1991

The validity of time-limited authorisations/registrations to manufacture/import should also be extended until the end of 2021 without the need for further action from the authorisation/registration holder. This automatic extension does not cover changes in the scope of the authorisation/registration (e.g. new premises, new medicinal products).

For new sites/facilities in the EEA that have never been inspected and authorised, a distant assessment may be conducted in order to evaluate if the site could be authorised without a pre-approval inspection. In such cases, it should be indicated that the certificate has been granted on the basis of a distant assessment. Moreover, an on-site inspection should be conducted when circumstances permit. If the outcome of the distant assessment does not permit the granting of the GMP certificate, a clock-stop will be triggered until an on-site inspection is possible.

Sites located outside the EEA

The validity of GMP certificates for manufacturing sites of active substances and/or finished products located outside the EEA should be extended until the end of 2021 without the need for further action from the holder of the certificate, unless the issuing/supervisory authority takes any action that affects the validity of the certificate.

For new sites/facilities in third countries where an inspection is required, and where there is no operational mutual recognition agreement (MRA) or the scope is not covered by the MRA, a distant assessment by an EEA supervisory authority may be conducted. A GMP certificate may be granted depending on the outcome of the assessment. In such cases, it should be indicated that the certificate has been granted on the basis of a distant assessment. Moreover, an on-site inspection should be conducted when circumstances permit. If the outcome of the distant assessment does not permit the granting of the GMP certificate, a clock-stop will be triggered until an on-site inspection is possible.

Important remarks

Pre-approval or routine on-site inspections will resume as soon as COVID-19 restrictions are lifted,[7] according to risk based inspection planning taking into account the date of the last inspection.

It is stressed that the obligation of manufacturers and importers to comply with GMP is not waived. It is incumbent upon manufacturers and importers to continue complying with GMP. Supervisory authorities will remain vigilant to ensure the quality of medicines that are made available to patients in the EEA. Inspections (including distant assessments) may be launched at any time and, in case of non-compliance, appropriate regulatory actions will be triggered.

[7] Resumption of inspections will vary according to timing of the lifting of containment measures taken by each country and other factors such as restoration of transport links.