



石药集团欧意药业有限公司

**CSPC CSPC OUYI PHARMACEUTICAL CO., LTD.**

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地址：中国石家庄市中山西路 99 号 Add: No. 99 Hainan Road, High-tech Industry Zone of Shijiazhuang  
Hebei Province, P.R. China

Registration dossier: **Dexamethasone Sodium Phosphate Injection 4mg/ml, 10ml/ampoule**  
Module 1

### **1.2.2 GMP Certificate**

The copy of Good Manufacturing Practices (GMP) certificate is enclosed in the following pages.

石欧意



170035089-001 1/1 ⑤  
摩尔多瓦 R D C M  
2017/03/01

# 公 证 书

中华人民共和国河北省石家庄市国信公证处



中华人民共和国  
药品GMP证书

CERTIFICATE OF GOOD MANUFACTURING PRACTICES FOR PHARMACEUTICAL PRODUCTS  
PEOPLE'S REPUBLIC OF CHINA

证书编号：CN20160031  
Certificate No. .

企业名称：  
Manufacturer : 石药集团欧意药业有限公司  
CSPCOUYI PHARMACEUTICAL CO.,LTD.

地 址：  
Address : 石家庄经济技术开发区海南路 99 号  
No.99,Hainan Road,High-tech Industry Zone of Shijiazhuang, China

认证范围：  
Scope of Inspection : 小容量注射剂（含非最终灭菌，含激素类，十三车间）  
Small Volume Parenteral Solutions (Including Hormones, Workshop 13)

经审查，符合中华人民共和国《药品生产质量管理规范》要求。  
特发此证。

This is to certify that the above-mentioned manufacturer complies with the requirements of Chinese Good Manufacturing Practices for Pharmaceutical Products.

有效期至 2021 年 03 月 08 日  
This certificate remains valid until 08/03/2021

发证机关：  
Issued By

Date for Issuing 09/03/2016

2016 年 03 月 09 日



国家食品药品监督管理总局制  
CHINA FOOD AND DRUG ADMINISTRATION

# 公 证 书

(2016)冀石国证外民字第 3737 号

申请人：石药集团欧意药业有限公司，住所：石家庄中山西路 276 号。

法定代表人：卢建民，男，一九五八年六月十五日出生，公民身份号码：13230119580615951X。

公证事项：药品 GMP 证书

兹证明国家食品药品监督管理局于二〇一六年三月九日发给石药集团欧意药业有限公司的《药品 GMP 证书》的原件与前面的复印件相符，原件属实。

中华人民共和国河北省石家庄市国信公证处

公证员

岳立坚

Notary: Yue Lijian (Signature)

Public Office of

二〇一六年七月十五日

The People's

July 15, 2016



IV11931770

# NOTARIAL CERTIFICATE

(2016)J.S.G.Z.W.M.Zi.No.3737

Applicant: CSPC Ouyi Pharmaceutical Co., Ltd., address: No. 276 West Zhongshan Road, Shijiazhuang City.

Legal Representative: Lu Jianmin, male, was born on June 15, 1958, ID Card No.: 13230119580615951X.

Issue under Notarization: Certificate of Good Manufacturing Practices for Pharmaceutical Products

This is to certify that the original one of "Certificate of Good Manufacturing Practices for Pharmaceutical Products", which was issued to CSPC Ouyi Pharmaceutical Co., Ltd. by State Food and Drug Administration on March 9, 2016, is in conformity with the foregoing copy, and the original is found to be authentic.

Notary: Yue Lijian <Signature>

Shijiazhuang Guoxin Notary Public Office of

Hebei Province <Seal>

The People's Republic of China

July 15, 2016

IV11931772

NOTARIAL CERTIFICATE



认字第170035089-001号

兹证明前面文书上公证处的印章和公证员岳立坚的签名(印章)属实。



中华人民共和国外交部  
领事司一等秘书  
二〇一七年二月九日

郝志平



The Embassy of the Republic of Moldova  
to the People's Republic of China  
authenticates the preceding signature and stamp  
no. 033  
15 Feb 2017  
Lusy Alexandru, Nino  
Name, surname Secretary  
Position  
The Embassy of the Republic of Moldova  
is not responsible for the content of the document.

