*Finnish Medicines Agency*

CERTIFICATE NUMBER: ***FIMEA/2023/005665***

# CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

## Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Finland confirms the following:
The manufacturer: ***Nanjing King-Friend Biochemical Pharmaceutical Co. Ltd.***
Site address: ***No 16 Xuefu Road, Nanjing High and New Technology Development Zone, Nanjing, 210061, China***
OMS Organisation Id. / OMS Location Id.: ***ORG-100021124*** / ***LOC-100054143***

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.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2024-01-18***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.[3]

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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only 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.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

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

## Part 2

| Human Medicinal Products |
|---|

| 1 MANUFACTURING OPERATIONS | |
|---|---|
| **1.1** | **Sterile products** |
| | *1.1.1 Aseptically prepared (processing operations for the following dosage forms)*<br>1.1.1.2 Lyophilisates<br>1.1.1.4 Small volume liquids |
| **1.3** | **Biological medicinal products (list of product types)** |
| | *1.3.1 Biological medicinal products (list of product types)*<br>1.3.1.6 Human or animal extracted products |
| **1.5** | **Packaging** |
| | *1.5.2 Secondary packaging* |
| **1.6** | **Quality control testing** |
| | *1.6.1 Microbiological: sterility*<br>*1.6.2 Microbiological: non-sterility*<br>*1.6.3 Chemical/Physical*<br>*1.6.4 Biological* |

Any restrictions related to the scope of this certificate:

| Building | Room | Line/equipment | QC testing | Products |
|---|---|---|---|---|
| ***Workshop 1*** | **-** | ***Vial line 1*** | **-** | ***confidential*** |
| ***Workshop 1*** | **-** | ***Prefilled Syringe line 2*** | **-** | ***confidential*** |
| ***Workshop 1*** | **-** | ***Vial line 3*** | **-** | ***confidential*** |
| ***Workshop 2*** | **-** | ***Cartridge line 7*** | **-** | ***confidential*** |
| ***Workshop 2*** | **-** | ***Vial line 9*** | **-** | ***confidential*** |

***2024-02-16***

Name and signature of the authorised person of the Competent Authority of

---

***Confidential***
***Finnish Medicines Agency***
Tel:***Confidential***
Fax:***Confidential***

12/29/2023
CEO YongQun Tang
Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd. (FDF Site)
Nanjing High And New No. 16 Xuefu Road; Technology Development Zone Nanjing, Jiangsu

Dear CEO YongQun Tang :

The U.S. Food and Drug Administration (FDA) conducted an inspection at Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd. (FDF Site), FEI 3010625707, located at Nanjing High And New, No. 16 Xuefu Road; Technology Development Zone, Nanjing, Jiangsu, from 10/30/2023 to 11/10/2023. FDA has determined that the inspection classification of this facility is "voluntary action indicated" ("VAI"). Based on this inspection, this facility is considered to be in a minimally acceptable state of compliance with regards to current good manufacturing practice (CGMP).

A VAI inspection classification indicates that, although investigators found and documented objectionable conditions during the inspection, FDA will not take or recommend regulatory or enforcement action because the objectionable conditions do not meet the threshold for action at this time. Despite this facility inspection classification, FDA recommends that you address any observations noted on the Form FDA 483 issued at the conclusion of the inspection or otherwise conveyed to you following the inspection. If not corrected, the same or similar conditions could lead to a future inspection being classified as "official action indicated" ("OAI").

This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to ensure continued compliance with CGMP.

An inspection classification of VAI for CGMP compliance will not directly negatively impact FDA’s assessment of any pending marketing application referencing this facility. Please note, however, that application approval will depend on a product- and application-specific facility assessment conducted by CDER’s Office of Pharmaceutical Quality. This letter does not address or reflect FDA's decision making with respect to any potential non-CGMP compliance issues.

FDA has concluded that this inspection is "closed" under 21 CFR 20.64(d)(3), and we are enclosing a copy of the narrative portion of the Establishment Inspection Report (EIR). It may reflect redactions made by FDA in accordance with the Freedom of Information Act (FOIA) and 21 CFR part 20. This, however, does not preclude you from requesting additional information under FOIA.

If you have any questions regarding this letter, you may contact Melissa Y Giorgi via telephone at 19496084454 or email at Melissa.Giorgi@FDA.HHS.GOV.

Sincerely,

Melissa Y Giorgi
PROGRAM SUPPORT SPECIALIST
PHARMACEUTICAL QUALITY IV INVESTIGATION BRANCH (PHRM4-IB)

# 药品GMP符合性检查告知书

编号：川监2025034

| | | | |
|---|---|---|---|
| 任务编号 | NS2JD20250115081 | 检查类型 | 常规检查 |
| 被检查单位名称 | 健进制药有限公司 | 药品生产许可证号 | 川 20170441 |
| 检查地址 | 成都高新综合保税区科新路 8 号附 9 号 | | |
| 检查范围及相关车间、生产线 | 冻干粉针剂（抗肿瘤药）（一车间 1 线） | | |
| 检查依据 | 《药品生产质量管理规范（2010 年修订）》及相关附录 | | |
| 检查时间 | 2025 年 05 月 20 日至 2025 年 05 月 22 日 | | |
| 结论 | 符合要求（通过） | | |
| 附件 | 检查缺陷项目表 | | |
| 主送 | 健进制药有限公司 | | |
| 抄送 | 四川省药品监督管理局第一检查分局 | | |

四川省药品监督管理局（盖章）

2025 年 06 月 17 日

# Compliance Notification of GMP Inspection for Pharmaceuticals

No.: Chuan 2025034

| | | | |
|---|---|---|---|
| Task No. | NS2JD20250115081 | Inspection Type | Routine Inspection |
| The name of the inspected entity | Kindos Pharmaceuticals Co., Ltd. | Drug Manufacturing Certificate No. | Chuan 20170441 |
| Inspection Address | No.8-9 Kexin Road, Chengdu Hi-Tech Comprehensive Bonded Zone, Chengdu | | |
| Inspection Scope and Related Workshops/Production Lines | Lyophilized Powder for Injection (Antineoplastic) (Production Line 1 of NO.1 workshop ) | | |
| Inspection Basis | "Good Manufacturing Practice for Pharmaceutical Products ( Revised in 2010)" and related appendices | | |
| Inspection Duration | May 20, 2025 to May 22, 2025 | | |
| Conclusion | Is in compliance with the requirements (Passed) | | |
| Attachment | Inspection Deficiency Item List | | |
| Primary Recipient | Kindos Pharmaceuticals Co., Ltd. | | |
| Copies To | The First Inspection Branch of Sichuan Medical Products Administration | | |

Sichuan Medical Products Administration

June 17, 2025

# Compliance Notification of GMP Inspection for Pharmaceuticals

No.: Chuan 2025070

| | | | |
|---|---|---|---|
| Mission number | 510000-20241230-109539 | Inspection type | license Inspection |
| The name of the inspected entity | Kindos Pharmaceuticals Co., Ltd. | Drug Manufacturing Certificate No. | Chuan 20170441 |
| Inspected Address | No.8-9 Kexin Road, Chengdu Hi-Tech Comprehensive Bonded Zone, Chengdu | | |
| Inspected Scope and Inspected facility | Small Volume Injection (Antineoplastic) (terminal sterilization) Production Line 2 of No. 1 workshop | | |
| Inspection basis | "Good Manufacturing Practice for Pharmaceutical Products (Revised in 2010)" and related appendices | | |
| Inspection Duration | 2025.03.14-2025.03.16 | | |
| Conclusion | It complies with the "Good Manufacturing Practice for Pharmaceutical Products (Revised in 2010)" and relevant appendices Foot. | | |
| Attachment | / | | |
| To | Kindos Pharmaceuticals Co., Ltd. | | |
| Cc | / | | |

Sichuan Medical Products Administration

Apr 18, 2025

# 药品 GMP 符合性检查告知书

编号：川许 2025070

| | | | |
|---|---|---|---|
| 任务编号 | 510000-20241230-109539 | 检查类型 | 许可检查 |
| 被检查单位名称 | 健进制药有限公司 | 药品生产许可证号 | 川 20170441 |
| 检查地址 | 成都高新综合保税区科新路 8 号附 9 号 | | |
| 检查范围及相关车间、生产线 | 小容量注射剂(抗肿瘤药)(最终灭菌)，一车间，2 线。 | | |
| 检查依据 | 《药品生产质量管理规范（2010 年修订）》及相关附录 | | |
| 检查时间 | 2025 年 3 月 14 日-2025 年 3 月 16 日 | | |
| 结论 | 符合《药品生产质量管理规范（2010 年修订）》及相关附录规定。 | | |
| 附件 | / | | |
| 主送 | 健进制药有限公司 | | |
| 抄送 | / | | |

四川省药品监督管理局

2025 年 4 月 18 日

09/28/2024
President Chuan Qin
Kindos Pharmaceuticals Co., Ltd.
Chengdu Hi-Tech Comprehensive No. 8-9 Kexin Road;
Chengdu, Sichuan, 611731 China

Dear President Chuan Qin:

The U.S. Food and Drug Administration (FDA) conducted an inspection at Kindos Pharmaceuticals Co., Ltd., FEI 3008865184, located at Chengdu Hi-Tech Comprehensive, No. 8-9 Kexin Road; Chengdu, Sichuan, 611731 China from 07/11/2024 to 07/19/2024. FDA has determined that the inspection classification of this facility is "voluntary action indicated" ("VAI"). Based on this inspection, this facility is considered to be in a minimally acceptable state of compliance with regards to current good manufacturing practice (CGMP).

A VAI inspection classification indicates that, although investigators found and documented objectionable conditions during the inspection, FDA will not take or recommend regulatory or enforcement action because the objectionable conditions do not meet the threshold for action at this time. Despite this facility inspection classification, FDA recommends that you address any observations noted on the Form FDA 483 issued at the conclusion of the inspection or otherwise conveyed to you following the inspection. If not corrected, the same or similar conditions could lead to a future inspection being classified as "official action indicated" ("OAI").

This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to ensure continued compliance with CGMP.

An inspection classification of VAI for CGMP compliance will not directly negatively impact FDA’s assessment of any pending marketing application referencing this facility. Please note, however, that application approval will depend on a product- and application-specific facility assessment conducted by CDER’s Office of Pharmaceutical Quality. This letter does not address or reflect FDA's decision making with respect to any potential non-CGMP compliance issues.

FDA has concluded that this inspection is "closed" under 21 CFR 20.64(d)(3), and we are enclosing a copy of the narrative portion of the Establishment Inspection Report (EIR). It may reflect redactions made by FDA in accordance with the Freedom of Information Act (FOIA) and 21 CFR part 20. This, however, does not preclude you from requesting additional information under FOIA.

If you have any questions regarding this letter, you may contact Atul J. Agrawal or Rita K. Vick via email at Atul.Agrawal@FDA.HHS.GOV or Rita.Vick@FDA.HHS.GOV, respectively.

Sincerely,
Atul J. Agrawal
DIVISION DIRECTOR
DIVISION OF FOREIGN PHARMACEUTICAL QUALITY INSPECTION (DFPQI)

# Drugs@FDA: FDA-Approved Drugs



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## Search Results for "idarubicin"

Products listed on this page may not be equivalent to one another.

IDAMYCIN

IDAMYCIN PFS

IDARUBICIN HYDROCHLORIDE

- IDARUBICIN HYDROCHLORIDE (IDARUBICIN HYDROCHLORIDE) | NDA #050734 | SOLUTION;INTRAVENOUS | Prescription | PFIZER
- IDARUBICIN HYDROCHLORIDE (IDARUBICIN HYDROCHLORIDE) | ANDA #065036 | SOLUTION;INTRAVENOUS | Prescription | MEITHEAL
- IDARUBICIN HYDROCHLORIDE (IDARUBICIN HYDROCHLORIDE) | ANDA #065037 | POWDER;INTRAVENOUS | Discontinued | TEVA PARENTERAL
- IDARUBICIN HYDROCHLORIDE (IDARUBICIN HYDROCHLORIDE) | ANDA #065275 | SOLUTION;INTRAVENOUS | Prescription | HIKMA
- IDARUBICIN HYDROCHLORIDE (IDARUBICIN HYDROCHLORIDE) | ANDA #065288 | SOLUTION;INTRAVENOUS | Prescription | HIKMA
- IDARUBICIN HYDROCHLORIDE (IDARUBICIN HYDROCHLORIDE) | ANDA #065440 | SOLUTION;INTRAVENOUS | Discontinued | FRESENIUS KABI USA
- IDARUBICIN HYDROCHLORIDE (IDARUBICIN HYDROCHLORIDE) | ANDA #091293 | SOLUTION;INTRAVENOUS | Discontinued | SANDOZ
- IDARUBICIN HYDROCHLORIDE (IDARUBICIN HYDROCHLORIDE) | ANDA #200144 | SOLUTION;INTRAVENOUS | Discontinued | RISING

# Drugs@FDA: FDA-Approved Drugs



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## Search Results for "decitabine"

Products listed on this page may not be equivalent to one another.

DACOGEN

DECITABINE

- DECITABINE (DECITABINE) | ANDA #202969 | INJECTABLE;INTRAVENOUS | Prescription | SANDOZ
- DECITABINE (DECITABINE) | ANDA #203131 | INJECTABLE;INTRAVENOUS | Prescription | DR REDDYS
- DECITABINE (DECITABINE) | ANDA #203475 | INJECTABLE;INTRAVENOUS | Prescription | ACCORD HLTHCARE
- DECITABINE (DECITABINE) | ANDA #204607 | INJECTABLE;INTRAVENOUS | Prescription | PHARMASCIENCE INC
- DECITABINE (DECITABINE) | ANDA #205539 | INJECTABLE;INTRAVENOUS | Prescription | GLAND
- DECITABINE (DECITABINE) | NDA #205582 | POWDER;INTRAVENOUS | Discontinued | SUN PHARM
- DECITABINE (DECITABINE) | ANDA #206033 | INJECTABLE;INTRAVENOUS | Prescription | CHEMI SPA
- DECITABINE (DECITABINE) | ANDA #207100 | INJECTABLE;INTRAVENOUS | Prescription | SAGENT PHARMS INC
- DECITABINE (DECITABINE) | ANDA #208601 | INJECTABLE;INTRAVENOUS | Discontinued | CIPLA
- DECITABINE (DECITABINE) | ANDA #209056 | INJECTABLE;INTRAVENOUS | Prescription | WOCKHARDT BIO AG
- DECITABINE (DECITABINE) | ANDA #210756 | INJECTABLE;INTRAVENOUS | Discontinued | LUPIN
- DECITABINE (DECITABINE) | ANDA #210984 | INJECTABLE;INTRAVENOUS | Discontinued | INGENUS PHARMS LLC
- DECITABINE (DECITABINE) | ANDA #212117 | INJECTABLE;INTRAVENOUS | Prescription | NIVAGEN PHARMS INC
- DECITABINE (DECITABINE) | ANDA #212265 | INJECTABLE;INTRAVENOUS | Prescription | MSN
- DECITABINE (DECITABINE) | ANDA #212826 | INJECTABLE;INTRAVENOUS | Prescription | QILU PHARM HAINAN
- DECITABINE (DECITABINE) | ANDA #212959 | INJECTABLE;INTRAVENOUS | Prescription | MEITHEAL
- DECITABINE (DECITABINE) | ANDA #213472 | INJECTABLE;INTRAVENOUS | Prescription | JIANGSU HANSOH PHARM
- DECITABINE (DECITABINE) | ANDA #214486 | INJECTABLE;INTRAVENOUS | Prescription | ZYDUS PHARMS
- DECITABINE (DECITABINE) | ANDA #214569 | INJECTABLE;INTRAVENOUS | Discontinued | EUGIA PHARMA
- DECITABINE (DECITABINE) | ANDA #215355 | INJECTABLE;INTRAVENOUS | Prescription | HETERO LABS LTD VI
- DECITABINE (DECITABINE) | ANDA #217814 | INJECTABLE;INTRAVENOUS | Prescription | RELIANCE LIFE SCI

INQOVI

ANDA 077356/S-033

**PRIOR APPROVAL SUPPLEMENT**
**APPROVAL**

Meitheal Pharmaceuticals Inc.
8700 W Bryn Mawr Avenue
Ste 600S
Chicago, IL 60631

Attention: Christina Cutler
Manager, Regulatory Affairs

Dear Christina Cutler:

This letter is in reference to your supplemental abbreviated new drug application (sANDA) received for review on October 31, 2024, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Mitoxantrone Injection USP, 20 mg/10 mL, 25 mg/12.5 mL and 30 mg/15 mL (MDV).

Reference is also made to any amendments submitted prior to the issuance of this letter.

The sANDA, submitted as “Prior Approval Supplement," provides for:

> Change in the sterile manufacturing site for the Mitoxantrone Injection, USP, 20 mg/10 mL and 25 mg/12.5 mL, MDV, from Teva Parenteral Medicines, Inc. (Teva) to Kindos Pharmaceuticals Co., Ltd. (Kindos; FEI #3008865184).

We have completed the review of this sANDA, as amended, and it is **approved**.

## COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP’s website as https://www.uspnf.com/.

## REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas.

If you have any questions, contact Sara Harris, Regulatory Business Process Manager, at (301) 796 - 6748 or sara.harris@fda.hhs.gov.

Sincerely yours,

*{See appended electronic signature page}*

*For:*
Hasmukh Patel, Ph.D.
Director
Division of Product Quality Assessment III
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Aijin Shen

Digitally signed by Aijin Shen
Date: 4/25/2025 06:49:29AM
GUID: 508da6ff000285a46513f7be84a4adb5