ALP PHARM BEIJING CO., LTD.
Address: 12-2-620, Jia 69, Fushi Rd., Haidian, Beijing 100049, China
Tel: 86 10 56531161,71,81, Cell: 86 176 1112 9981, 86 135 0139 9361
Email: lisa@alliancepharm.com Website: www.alppharm.com

ALP Pharm Beijing Co., Ltd. is manufacturing these APIs for US FDA and EU:

API Name	*DMF , CEP , GMP status*
Alogliptin Benzoate	027993, DMF fee paid. FDA approved on Oct.30, 2017.
Abiraterone Acetate	028292 All validation was done in mid 2018.
Apixaban	034954/032781, FDA approved in 2019
Argatroban Hydrate	025893, FDA approved.
Bacitracin, non-sterile &injectable	023999, FDA approved, Written Confirmation approved.
Bacitracin Zinc	024000, FDA approved on Apr.14, 2017 and 2018, Written Confirmation approved.
Besifloxacin Hydrochloride	032611. FDA approved
Bivalirudin	024257, FDA approved in 2014,2016, 2019, US DMF32281 approved, Chinese DMF: Y20190000290
Bromfenac Sodium	023031 DMF reviewed, DMF fee paid.Canada DMF 2010-198/**e208529**,ASMF
Captopril	011095, GMP, FDA approved
Cetrorelix acetate	033914, 035171 DMF fee paid, FDA approved in 2019
Cidofovir Dihydrate	023446. 25406 DMF reviewed, DMF fee paid, Canada DMF 2012-031/e208528,ASMF EC 2018-001730-18.
Clevidipine butyrate	029850, DMF reviewed by US FDA. FDA approved
Dasatinib monohydrate	029505 FDA approved in Nov.2018.
Doxapram Hydrochloride	033794. FDA approved in 2017
Doxercalciferol	025148, Canadian DMF,ASMF, , FDA approved on Nov.3, 2015
Empagliflozin	029796, US FDA approved.
Eptifibatide	023786,DMF reviewed, DMF fee paid.FDA approved in 2014,2016, 2019, Canadian DMF,ASMF UK,DMFNL 03347 for Netherland and Germany, UK and Ireland MFD-46708-1-08350-0001，Chinese DMF: Y20180001360
Exenatide	035476.US FDA approved
Febuxostat	025664 Form A, 031339, Form G ASMF, FDA approved on Oct.30, 2017, Written Confirmation approved.
Fulvestrant	033902 reviewed, US FDA approved.
Goserelin Acetate	029713 , US FDA approved
Iopromide	035356, EU GMP and Japan GMP approved. FDA will approve
Lanreotide Acetate	024378 FDA approved in 2014,2016, 2019, DMF029693 DMF fee paid. DE: DK/H/3027/001-003/DC,Greece:3519,34781/27-03-2019, 43067/10-04-2020，National reference number: 46138/24-04-2020, Spain: AA/0046/19,Estonia: 906190,Ireland: 45000001, LV/H/DMF/19/0012, Denmark: 2215-2906/ 2019031558, UK:MFD-46708-2-07263-0001. cz:sukls77844/2019,French:2019-023, ASMF_2016_154 Poland:DRL-RLE.4003.38.2019, Italy:AIN/2019/1385, EUDMF 21042020, At:552212. CZ:14862SINOP0320A02,Written Confirmation approved.
Lapatinib Ditosylate	029712 FDA approved in Nov.2018.
Leuprolide Acetate (Controlled substance in China)	DMF 034847, US FDA approved
Liraglutide	029711 FDA approved in 2019, GMP
Lurasidone Hydrochloride	027584, FDA Approved on Aug.16,2016, DMF fee paid
Mesalamine	024256, CEP approved. Canadian DMF 2015-141/**e208484**, Written Confirmation approved.
Nepafenac	023032, FDA approved Canada DMF 2012-035/**e208526**
Octreotide Acetate	030992 approved in 2014,2016, 2019, GMP, Chinese DMF: Y20180001746, Written Confirmation approved.

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Oseltamivir Phosphate	033907, DMF reviewed, US FDA approved.
Palonosetron Hydrochloride	023209, FDA Approved on Aug.25, 2014, DMF reviewed. Canada DMF 2012-032/e208527, GMP, ASMF has been approved by EU，ASMF UK H 6130 001. Written confirmation approved.
Paricalcitol	021255,Canadian DMF,ASMF, FDA approved, Chinese DMF: Y20190000760
Plecanatide	035439.FDA approved.
Polymyxin B Sulphate	023997, FDA approved on Apr.14, 2017 and 2018, Written Confirmation approved.
Pregabalin	022223, US FDA approved
Rivaroxaban	034436, US FDA approved
Semaglutide	DMF 035875, US FDA approved
Stiripentol	035817.
Tamsulosin Hydrochloride	023741, DMF reviewed, DMF fee paid, Canada DMF2013-014/ e208383, FDA approved on July 16, 2016 and Oct.16, 2018, EU GMP inspection was conducted May 15 to 17, 2017 and approved EU GMP on Nov.3, 2017
Teduglutide	035438.FDA approved
Tranexamic Acid	US DMF 022277fee was paid and reviewed. FDA Approved in 2011. 2013, on Aug.16,2016, Canada DMF 2009-178/ e206757, Chinese GMP, TGA D17-218386. TGA DMF (17-0073, (E17-6585)), ASMF for 21 countries in EU(German: 3843, UK MHRA: MFD-46708-1-09308-0001, Hungary: OGYEI/42647-2/2016, Italy SIS Code : 4857 Belgium ID 226016), Swiss:D56015. Spain AA/0161/18,Austria551758, Singapore 015:1130, New ZealandTT60-1267-11-1. Malaysia BPFK DMF No.20160048G, **Uganda** N393, Russian ND001118-100615, 001079-300415
Zoledronic Acid, monohydrate	023847, GMP, ASMF DMFNL 3409, US FDA approved on July13, 2016, Written Confirmation approved.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

Office of Process and Facilities
Division of Inspectional Assessment
10903 New Hampshire Avenue
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FAX: (301) 842-8742

August 1, 2016

Ms. Lisa Xu
General Manager
ALP Pharm Beijing Co. Ltd.
12-2-620, Jia 69, Fushi Rd.
Haidian District
Beijing - 100049
China

Reference: FEI 3007284956

Dear Ms. Lisa Xu:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at ALP Pharm Beijing Co. Ltd., API Distributor and DMF Holder, in Beijing, China by Investigators Marijo B. Kambere and Uttaniti Limchumroon, and Senior Consumer Safety Officer Chiang Syin during the period of May 30 - June 01, 2016, in support of DMF 22277.

Based on the profile class covered during the inspection, we are classifying your facility as acceptable. This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to assure continued compliance with current good manufacturing practices (CGMP).

Please be advised that all manufacturers must register annually as required by 21 C.F.R. § 207.40. Information on how to register is available at http://www.fda.gov/cder/drls/registration_listing.htm.

Additionally, we enclose a copy of the establishment inspection report (EIR). Releasing this EIR to you is part of FDA's effort to make its regulatory process and activities more transparent to the regulated industry. It is being provided to you for information purposes only and may reflect some redactions made by the Agency in accordance with the Freedom of Information Act and 21 C.F.R. Part 20. Copies provided to other requestors may have additional redactions of trade secret and confidential commercial information.

If you have any questions regarding this letter, you may contact me at the above address or number.

Sincerely,

Vidya Pai

Dr. Vidya Pai
Facility Reviewer
Division of Inspectional Assessment

Enclosure: EIR

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Introduction of ALP Pharm Beijing Co., Ltd.

US FDA approved.

US FDA inspected ALP Pharm Beijing Co Ltd on May 30th, May 31st and June 1st, 2016 without advance notice and approved the EIR on Aug.1, 2016. For the regulatory work done by ALP, all times of the US FDA inspections from 2004 to now have passed successfully for our exclusive contract manufacturers.

- **Responsibility is the success of ALP which brings the most profit.**

ALP takes full responsibility to all the APIs supplied by ALP. For example, when Aurobindo and Akorn decided to return the two APIs to ALP, ALP accepted their reasonable reasons, wired the payment to clients immediately, and arranged the Chinese shipping company to pick up the returned APIs from the clients' warehouses to Beijing China, although the manufacturers refused to accept the returned APIs and did not return the payment to ALP till now.

- **ALP Pharm started to manufacture the APIs in the contracted cGMP facilities since 2007.**

Most APIs have been inspected and approved by US FDA, EU authorities or EU QP (Qualified Person). ALP Pharm has put much investment on the comprehensive work ranging from APIs process improvement, test method improvement, some special reactors for synthetic process, some analytical instruments, process validation and cleaning validation work, regulatory filing, document preparations, mock audit, interaction with regulatory agencies etc. ALP PHARM holds these API's cGMP technology, exclusive sales and DMFs.

ALP Pharm authorizes the API manufacturers to produce the targeted APIs for ALP Pharm exclusively, makes the decision of every batch manufacturing, testing, releasing, storage and sales. The manufacturers can not sell the DMF grade APIs to any company in or for regulated market.

ALP PHARM 's APIs US FDA inspection and EU authorities inspection:

FDA/EU authority Inspecting

- **Core Management Team**

ALP Pharm's rapid business growth has been based on the knowledge and integrity of its core management team, technical and regulatory executives in China, USA, Canada, and EU countries.

Each of our local Chinese members and US members has more than 10 years of cGMP compliance work experience in FDA approved pharmaceuticals companies.

They are working hand in hand to ensure that all documentation meets the necessary requirements of our customers in North America, Canada and Europe, Russia, Australia, New Zealand, Singapore, Japan etc as well as the end buyers in other areas who are applying or have applied ANDAs, NDAs, MAAs, DCPs.

- **Foundation on Sep.26, 2006:**

ALP Pharm Beijing Co., Ltd. was founded in Sep. 26, 2006 after Ms Lisa Xu worked for Beijing Representative Office of The AlliancePharm US, LLC(a New Jersey company in USA) from 2002 to July 2006 on cGMP consulting work for Chinese Pharmaceutical Companies and helped several of them filed the DMFs and passed US FDA and EU EDQM inspections.

- **Contact: ALP PHARM BEIJING CO., LTD.**

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