10627

AstraZeneca
阿斯利康

检验报告

品名：百法达 10μg
[艾塞那肽注射液 0.25mg/ml，2.4ml/支]
本品按进口药品注册标准 JX20080117 检验

产品批号：20E005
生产日期：2019-12
有效期至：2022-11

检验项目	标准规定	检验结果
细菌内毒素	每 1ml 中含内毒素的量应小于 50 EU	符合规定
无菌	应符合美国和欧洲药典的规定(无生长)	符合规定
剂量准确度	应为 30μl~50μl	38μl
可见异物	应符合规定	符合规定

注射笔批号：AZ200012

生产厂：

Baxter Pharmaceutical Solutions LLC, 927 South Curry Pike, Bloomington, Indiana, USA-47403

包装厂：

Enestia Belgium nv, Klocknerstraat 1, Hamont-Achel, Belgium – B3930

上述测试按照中国药典或等同分析方法检验，检验结果符合中国进口药品注册标准 JX20080117.

特此申明，上述信息真实可靠. 本批产品的所有生产过程，包括在相关工厂进行的包装/贴签/质量控制均符合当地监管机构以及进口国家上市许可监管机构的 GMP 规范. 该批产品生产，包装及分析记录经审核符合 GMP 规范。

广东医药有限公司 (3) 质量管理专用章

阿斯利康（中国）
上海市张江高科技园区亮景路199号 201203
电话：021 6030 2288 传真：021 5011 5836
www.astrazeneca.com.cn

AstraZeneca China
199 Liangjing Road, Shanghai 201203, China
T: 021 6030 2288 F: 021 5011 5836
www.astrazeneca.com.cn

AstraZeneca

UK Manufacturing
Silk Road Business Park
Charter Way
Macclesfield
Cheshire SK10 2NA
England
Tel. +44 (0) 1625 582828
Fax.+44 (0) 1625 422266

CERTIFICATE OF ANALYSIS

Byetta 10ug(0.25mg/ml,2.4ml/EA)

Batch Number:	20E005
Date of Manufacture:	Dec-2019
Date of Expiry:	Nov-2022
Importing Country:	China

TEST/PROCEDURE	ACCEPTANCE CRITERIA	RESULT
Description	Clear, colourless and essentially free of visible particulates	Complies
Assay	95.0 - 105.0 % of label claim	99.4 % of label claim
Bioassay	70 - 130 %	91 %
Identity, HPLC	Retention time compares favourably with that of the reference standard.	Complies
Identity, Mass Spectrometry	4185.6 - 4187.6 D	4186.2 D
Purity, Product Related Impurities		
[3-39]AC2993	<= 0.50 %	0.13 %
[Asu9]AC2993	<= 0.50 %	0.13 %
Largest Unspecified Impurity (Excluding [Double-coupled Pro38] AC2993 peak)	<= 1.00 %	0.19 %
Total Impurities	<= 4.0 %	1.2 %
Purity, Oligomer	<= 0.80 %	0.19 %
Colour and Clarity		
Clarity	Complies to the PhEur	Complies
Colour	Complies to the PhEur	Complies
pH	4.2 - 4.8	4.6
Osmolality	260 - 340 mOsm/kg	309 mOsm/kg
Bacterial Endotoxins	< 50 EU/mL	<1 EU/mL

Report: 1377813

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Importing Country:	China

Comments:

Manufacturer:
Baxter Pharmaceutical Solutions LLC, 927 South Curry Pike, Bloomington, Indiana (IN), USA-4740

Packing site:
Enestia Belgium nv, Klocknerstraat 1, Hamont-Achel, Belgium - B3930

The results comply to China imported registered drugs quality standard JX20080117 acceptance criteria and analytical methods or equivalent analytical methods described in the Chinese Pharmacopoeia.

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Bulk pen lot AZ200012

Released by : Karen Bateman QA Group Manager

Qualified Person according to the requirements of Directive 2001/83/EC

Released On : 10-Jul-2020

(This electronic signature is the legally binding equivalent of a hand written signature)

正 本

中华人民共和国
The People's Republic of China

进口药品注册证
IMPORTED DRUG LICENSE

注册证号：H20140822
LICENSE NO.

根据《中华人民共和国药品管理法》和
In accordance with The Drug Administration Law of P.R.of China and The Provisions
《药品注册管理办法》的规定，兹批准下述
for Drug Registration, the following drug produced by the following company has been
公司的下述药品注册。允许进口使用。
approved and registered. The importation has been authorized thereby.

公司名称：AstraZeneca AB
Company

地 址：SE-151 85 Sodertalje , Sweden
Address

国 家：瑞典 Sweden
Country

药品名称：艾塞那肽注射液
Generic Name Exenatide Injection

商品名：百泌达
Trade Name BYETTA

主要成份：艾塞那肽
Active Ingredients

剂 型：注射剂
Dosage Form

规 格：10μg (0.25mg/ml, 2.4ml/支)
Strength

包装规格：1支/盒，3支/盒
Package Size

药品有效期：36个月
Shelf Life

生产厂：Baxter Pharmaceutical Solutions LLC
Manufacturer

地 址：927 South Curry Pike , Bloomington , Indiana 47403, USA.
Address

国 家：美国 U. S. A.
Country

备 注：1. 本证有效期至 2023 年 12月 31日。
Remarks Valid Until Dec. 20, 2023

2. 注册标准：进口药品注册标准JX20080117
Specifications

3. 包装厂名称：Erestia Belgium nv ，包装厂地址：Kloknerstraat 1, Hamont -Achel, B-3930, Belgium

4. 原《进口药品注册证》作废。

华润广东医药有限公司 质量管理专用章

国家药品监督管理局
National Medical Products Administration

2018 年 12 月 21 日
进口药品注册
Dec. 2018

H20141304