

 北京生物制品研究所有限责任公司 BEIJING INSTITUTE OF BIOLOGICAL PRODUCTS CO., LTD.	Documentation	Date
	CoV-Re-20-ARG-B-05	December 2020
Product	SARS-CoV-2 Vaccine (Vero Cell), Inactivated	
Title	Module 1- Administrative and Regional Information	

Module 1

Administrative and Regional Information

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Module 1 Administrative Information- Legal

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Module 1 Administrative information- legal

1.1 Index (Module 1 to 5)

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5.2 Tabular Listing of All Clinical Studies

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1.2 Application form

1.2.1 Commercial name of the vaccine

There is no commercial name of the vaccine.

1.2.2 Generic name of the Vaccine

SARS-CoV-2 Vaccine (Vero Cell), Inactivated

1.2.3 Concentration

6.5U/0.5mL/dose/syringe (or vial)

1.2.4 Pharmaceutical form

Injection

1.2.5 Technical director/ health manager

Provide by local agent.

1.2.6 Legal representative in the country (Manufacturer)

Name: Wang Hui

Position: General Manager

Address: No. 6&9 Bo'xing 2nd Road, Economic-Technological Development Area, Beijing, P.R. China

Tel: +86 10 8722 0568

Fax: +86 10 8722 0568

Email: wh6247@126.com

1.2.7 Holder of the vaccine at the international level

Name: Beijing Institute of Biological Products Co., Ltd.

Address: No. 6&9 Bo'xing 2nd Road, Economic-Technological Development Area, Beijing, P.R. China

Tel: +86 10 8722 0568

Fax: +86 10 8722 0568

Email: ychen97@126.com

1.2.8 Manufacturer of the active ingredient(s)

Name: Beijing Institute of Biological Products Co., Ltd.



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Address: No. 6&9 Bo'xing 2nd Road, Economic-Technological Development Area, Beijing, P.R. China

Tel: +86 10 8722 0568

Fax: +86 10 8722 0568

Email: ychen97@126.com

1.2.9 Manufacturer of the finished product

Name: Beijing Institute of Biological Products Co., Ltd.

Address: No. 6&9 Bo'xing 2nd Road, Economic-Technological Development Area, Beijing, P.R. China

Tel: +86 10 8722 0568

Fax: +86 10 8722 0568

Email: ychen97@126.com

1.2.10 Other laboratories that participate in the manufacturing process

Refer to Module 1, 1. List of contact manufacturers and laboratories

1.2.11 Responsible for the release of finished product batches

Name: Li Na

Title: Manager of QA Department (Qualified Person)

1.2.12 Commercial presentation of the vaccine

6.5U/0.5mL/dose/syringe (or vial)

1.2.13 Route of administration

This vaccine will be administered by a healthcare professional of national health authorities and CDC in accordance with the national immunization program and strategies.

Method of Administration: The recommended administration is through intramuscular route, the injection into a muscle will be preferably performed in the upper part of the arm.

Immunization Program and Dosage: Two dose regimen at an interval of 2~4 weeks, each dose is 0.5mL.

1.2.14 Storage or conservation conditions



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Store and transport in a refrigerated (2°C -8°C) condition, protect from light. Do not freeze.

1.2.15 Qualitative-quantitative formula per dose unit

1.2.15.1 Qualitative declaration

The SARS-CoV-2 Vaccine (Vero Cell), inactivated is formulated with SARS-CoV-2 strain which is inoculated on the Vero cells for culturing, virus harvesting, β -propiolactone-inactivation, concentration and purification, then adsorbed with aluminum adjuvant to form the liquid vaccine. The product is a semi-transparent suspension with slightly white color, could be layered by precipitation, and the precipitation can be easily dispersed by shaking.

Active composition: SARS-CoV-2 (inactivated)

Excipients: Disodium hydrogen phosphate, Sodium chloride, Sodium dihydrogen phosphate, Aluminum hydroxide adjuvant

1.2.15.2 Quantitative declaration

Each pre-filled syringe (or vial) contains 0.5mL of product for each administration by intramuscular injection, each dose contains 6.5U of inactivated SARS-CoV-2 antigen, 0.225 mg Aluminum hydroxide adjuvant and quantum sufficit of sodium chloride, disodium hydrogen phosphate and sodium dihydrogen phosphate.

1.2.16 Legal documents of the product

Legalization of required documents will be arranged after confirmation.

1.2.16.1 Provision for the appointment of the technical director / technical professional responsible for the product.

Provide by local agent.

1.2.16.2 Authorization of the Representative or Letter of Representation.

Will supply this authorization letter as per the template provided by local agent.

1.2.16.3 Certificate of Pharmaceutical Product (CPP).

Refer to Module 1, 2. Commitment Letter for CPP

1.2.16.4 Certificate of Good Manufacturing Practices (GMP)

Refer to Module 1, 3. Commitment Letter for GMP Certificate

1.2.16.5 Manufacturer's declaration

Refer to Module 1, 4. Manufacturer's Declaration.



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1.3 Summary of product characteristics, labeling and package leaflet

1.3.1 Summary of product characteristics

Refer to Module 1, 5. Summary of product characteristics

1.3.2 Label, brochures and information for health professionals

1.3.2.1 Label of the primary container

Refer to Module 1, 6. Label of the primary container

1.3.2.2 Secondary container label

Refer to Module 1, 7. Secondary container label

1.3.2.3 Prospectus

Refer to Module 1, 8. Leaflet

1.3.2.4 Final marketing packaging

Refer to Module 1, 6. Label of the primary container, 7. Secondary container label and 8. Leaflet

1.3.2.5 Information for health professionals

Refer to Module 1, 8. Leaflet

1.3.3 Samples and information projects

We will provide samples as requirement.

1.3.3.1 Summary protocol for production and batch control

Related information will be provided after the batch No. and quantity of samples are confirmed.

1.4 List of countries where the product has been previous registered

SARS-CoV-2 Vaccine (Vero Cell), Inactivated manufactured by Beijing Institute of Biological Products Co., Ltd. has been previous registered in United Arab Emirates and Bahrain in December 2020.

1.5 Information about the experts

Refer to Module 1, 9. Declaration of expert responsibility and 9. Experts on quality, nonclinical and clinical for summary of their academic records and work experience.



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1.6 Risk assessment for the environment

Refer to Module 1, 10. Non-genetical modified organism for the information of risk assessment for the environment.



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List of Contact Manufacturers and Laboratories

No.	Name	Services Type	Test Items	Contact Information (Address, Contactor, Tel)
1	Beijing Pharmaceutical Packaging Material Testing Institute	Testing	Plunger rubber cap: volatile sulphide	No. 13, Shuiche Hutong, Xijiekou, Xicheng District, Beijing Contractor: YUAN Chunmei Tel: +8610 50950470
			Needle cover: volatile sulphide	
			Rubber stopper (film coated): volatile sulphide	
			Middle-borosilicate glass vials (film coated): identification, the amount of leaching antimony, the amount of leaching arsenic, the amount of leaching plumbum, the amount of leaching cadmium, acid resistance and alkali resistance	
			Aluminum Foil Caps: mechanical characterization test	
2	National Institutes for Food and Drug Control	Testing	Master Vero cell bank, working Vero cell bank, end of production cells (EOPC)	29 Huatuo Road, Daxing District, Beijing Contractor: MENG Shufang Tel: +8610 67095414



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3	Beijing Hontest Technology Development Co., Ltd	Testing	Sodium bicarbonate:	Floor 7 th , Building 6, Yard 58, Jinghai Fifth Road, Beijing Economic and Technological Development Area, Beijing Contractor: CAO Yanming Tel: +8610 56381659
			Chloride, ammonium salt, sulfate, loss on drying, iron salt, heavy metals, arsenic salt	
			Glucose (monohydrate):	
			Chloride, sulfate, loss on drying, ignited residue, iron salt, heavy metals, arsenic salt	
			Sodium hydroxide: sulfate, iron salt, heavy metals, chloride, aluminum salt and iron salt	
			M199: Loss on drying	
			Sodium dihydrogen phosphate (dihydrate):	
			Water-insoluble matter, chloride, sulfate, ammonium salt, iron salt, heavy metals, arsenic salt, ammonia precipitation, potassium salt	
			Disodium hydrogen phosphate (dodecahydrate):	
			Chloride, sulfate, water-insoluble matter, loss on drying, iron salt, heavy metals, arsenic salt	
			Sodium chloride:	
			Sulfate, loss on drying, iron salt, heavy metals, arsenic salt	
			Sodium dihydrogen phosphate (monohydrate):	
			Sulfate, heavy metals, chloride, loss on drying, arsenic salt	



Commitment Letter for CPP

In November 2018, NMPA issued GYJYG[2018]43 "Provisions on The Administration of Certificate of a Pharmaceutical Product (CPP)". This Provisions Article 2 clearly states that the CPP is applicable to the export of approved and marketed drug of the Marketing Authorization Holder and drug manufacturer within the territory of the People's Republic of China. As the SARS-CoV-2 Vaccine (Vero Cell), Inactivated has not been obtained the Drug Registration Certificate, and formal approved marketing in China, so we cannot apply for this CPP now.

After obtaining the Drug Registration Certificate in China, our company will immediately start the CPP application process to get the CPP as soon as possible and submit it to the Argentina health department.

Authorized signatory:



Name: Li Na

Title: Manager of QA Department

Date: December 30th 2020

Beijing Institute of Biological Products Co., Ltd.



Beijing Institute of Biological
Products Co., Ltd.

Commitment Letter for GMP Certificate

We, Beijing Institute of Biological Products Co., Ltd. hereby declared that the SARS-CoV-2 Vaccine (Vero Cell), Inactivated are produced and filled in the production facilities (including filling and packaging) of Beijing Institute of Biological Products Co., Ltd. and also declared that the production process is in compliance with GMP and WHO international standards and according to the relevant national bio safety requirements. The samples have been qualified by NIFDC.

Please be informed that the newly revised “Pharmaceutical Administration Law of the People’s Republic of China” has cancelled drug GMP certification from December 1st 2019, no longer accepts GMP certification applications and issues drug GMP certificates. New drugs that have been applied for listing after December 1st 2019 can obtained the “Drug Production License” and “Drug Registration Certificate” after passing the on-site inspection by the National Medical Products Administration and the GMP inspection by the Beijing Medical Products Administration.

We have more than 100 years experiences of vaccine production, are maintaining all international standards in term of production, packaging and transportation. Refer to Appendix for “Drug Production License”. Once obtained the “Drug Registration Certificate”, we will provide them to Argentina Health Authority.

Authorized signatory:



Name: Li Na

Title: Manager of QA Department

Date: December 30th 2020

Beijing Institute of Biological Products Co., Ltd.



Beijing Institute of Biological
Products Co., Ltd.

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Appendix- Copy of Drug Production License



药品生产许可证

企业名称: 北京生物制品研究所有限责任公司

社会信用代码: 91110302MA007H95X1

注册地址: 北京市北京经济技术开发区(大兴)路9号院4号楼2层205室

法定代表人: 王辉

企业负责人: 王辉

质量负责人: 王辉

生产地址和许可范围: 北京市顺义区(国家经济技术开发区)4号、10号生物制品

许可证书编号: 京20160276

分类码: HBS

日常监督管理机构: 北京市药品监督管理局

投诉举报电话: 12331

发证机关: 北京市药品监督管理局

签发人: 张洪





有效期至: 2021年11月20日

国家药品监督管理局监制



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PEOPLE'S REPUBLIC OF CHINA DRUG PRODUCTION LICENSE

Name: Beijing Institute Biological Products Co., Ltd.
Social Credit Code: 91110302MA007H95X1
Registered Address: Room 205, 2nd floor No.4 Unit, No. 9 Bo'xing 2nd road, Economic-Technological Development Area, Beijing, P.R. China
Legal Representative: Wang Hui
Enterprise Principal: Wang Hui
Quality Principal: Wang Hui
Production Address and Production Scope: No.4, Sanjianfang Nanli, Chaoyang District, Beijing, P.R. China: Preventive biological products***
 No.6&9 Bo'xing 2nd road, Economic-Technological Development Area, Beijing, P.R. China: Preventive biological products, Therapeutic biological products, Low-volume injections, Low-volume injections (Sodium sulfite)***

Certificate No: (Jing) 20160276
Classification Code: HbS
Daily supervision and management organization: Beijing Medical Products Administration
Complaint Reporting Tel: 12331
Issuing Authority: Beijing Medical Products Administration
Issued person: Liang Hong

Issued By: Beijing Medical Products Administration (stamp)
 Issued Date: 13th June, 2020

Valid to: until 21st November, 2021

PRINTED BY NATIONAL MEDICAL PRODUCTS ADMINISTRATION



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变更记录

事项:

同意该企业《药品生产许可证》企业名称由北京北研生物制品有限公司变更为北京生物制品研究所有限责任公司,其他内容不变。

(盖章)

2018年 12 月 19 日

事项:

同意该企业《药品生产许可证》法定代表人由魏树强变更为王辉,企业负责人由魏树强变更为王辉,发证日期由2018年12月19日变更为2020-05-13,日常监管机构由北京市食品药品监督管理局经济技术开发区分局变更为北京市药品监督管理局,其他内容不变。

(盖章)

2020年 05 月 13 日

事项:

经资料审核和现场检查,同意该企业《药品生产许可证》北京市北京经济技术开发区博兴二路6.9号地址项下增加新型冠状病毒疫苗(新型冠状病毒灭活疫苗(Vero细胞))生产范围。

(盖章)

2020年 06 月 13 日

事项:

(盖章)

年 月



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Change record

Items:

Agree to change the enterprise Drug Production License information name of enterprise from Beijing Bio-Institute Biological Products Co., Ltd. to Beijing Institute of Biological Products Co., Ltd. and other contents shall not be changed.

(Stamp)

Beijing Food and Drug Administration

December 19th 2018

Items:

Agree to change the enterprise Drug Production License information Legal representative from Wei Shuyuan to Wang Hui, change the Enterprise principle from Wei Shuyuan to Wang Hui, change the Issued date from December 1st 2018 to May 13th 2020, change the Daily supervision and management organization from Beijing Food and Drug Administration Economic and Technological Development Zone Branch to Beijing Medical Products Administration, and other contents shall not be changed.

(Stamp)

Beijing Medical Products Administration

May 13th 2020

Items:

According to the documents review and on-site inspection, we agree to add the Production scope information "Preventive biological products: SARS-CoV-2 Vaccine



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(Vero Cell), Inactivated” in the Production address “No. 6&9 Bo’xing 2nd Road, Economic-Technological Development Area, Beijing, P.R.China” in the enterprise Drug Production License.

(Stamp)

Beijing Medical Products Administration

June 13 2020



Declaration

We, Beijing Institute of Biological Products Co., Ltd. hereby declared that all pertinent information of SARS-CoV-2 Vaccine (Vero Cell), Inactivated provided for the evaluation is truthful.

Authorized signatory:



Name: Li Na

Title: Manager of QA Department

December 30th 2020

Beijing Institute of Biological Products Co., Ltd.



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Summary of Product Characteristics

1. Name of the Medicinal Product

SARS-CoV-2 Vaccine (Vero Cell), Inactivated

1.1 Strength

6.5U/0.5mL/dose/syringe (or vial)

1.2 Pharmaceutical form

Injection

2. Qualitative and Quantitative Composition

2.1 Qualitative declaration

The SARS-CoV-2 Vaccine (Vero Cell), inactivated is formulated with SARS-CoV-2 strain which is inoculated on the Vero cells for culturing, virus harvesting, β -propiolactone-inactivation, concentration and purification, then adsorbed with aluminum adjuvant to form the liquid vaccine. The product is a semi-transparent suspension with slightly white color, could be layered by precipitation, and the precipitation can be easily dispersed by shaking.

Active composition: SARS-CoV-2 (inactivated)

Excipients: Disodium hydrogen phosphate, Sodium chloride, Sodium dihydrogen phosphate, Aluminum hydroxide adjuvant

2.2 Quantitative declaration

Each pre-filled syringe (or vial) contains 0.5mL of product for each administration by intramuscular injection, each dose contains 6.5U of inactivated SARS-CoV-2 antigen, 0.225 mg Aluminum hydroxide adjuvant and quantum sufficit of sodium chloride, disodium hydrogen phosphate and sodium dihydrogen phosphate.

3. Pharmaceutical Form

6.5U/0.5mL/dose/syringe (or vial), Injection

The product is a semi-transparent suspension with slightly white color, could be layered by precipitation, and the precipitation can be easily dispersed by shaking.

4. Clinical Particulars

4.1 Therapeutic indication

The antibodies against the SARS-CoV-2 can be produced after vaccination, to prevent



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the COVID-19 disease.

This product is used for people aged 18 years old and above, particularly for medical personnel and those in close contact with the virus.

4.2 Posology and method of administration

This vaccine will be administered by a healthcare professional of national health authorities and CDC in accordance with the national immunization program and strategies.

Method of Administration: The recommended administration is through intramuscular route, the injection into a muscle will be preferably performed in the upper part of the arm.

Immunization Program and Dosage: Two dose regimen at an interval of 2~4 weeks, each dose is 0.5mL.

4.3 Contraindication

This vaccine is strictly prohibited in the following cases:

- (1) Individuals who are allergic to any component (active, excipients) of this product, or those who have allergic reactions with this vaccine before.
- (2) Individuals who have serious chronic disease or history of hypersensitivity.
- (3) Vaccination should be postponed if individuals have fever or during the acute phase of disease.

4.4 Special Warning and Precaution for use

- (1) Intravascular injection is strictly prohibited.
- (2) Drugs and equipment such as epinephrine should be available for emergency treatment in the event of an occasional severe allergic reaction. The vaccinee should be watched for at least 30 minutes after vaccination.
- (3) This vaccine should be used with caution if:
 - ① have blood disorders such as decrease in platelets (thrombocytopenia) or clotting disorders because of the risk of bleeding which may occur during intramuscular administration of the vaccine.
 - ② are taking a treatment that suppresses your immune defences or if you present with immune deficiency, the immune response to the vaccine may be reduced. In such cases it is recommended to postpone vaccination until the end of the treatment or to make sure the subject is well protected. If you have chronic immune deficiency, this

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vaccine may also be recommended even though the underlying disease may cause a limited immune response.

③ you have uncontrolled epilepsy and other progressive neurological disorders.

(4) Like all vaccines, this product may not have 100% preventive effect for vaccinee.

(5) Do not use disinfectant to contact the vaccine when the protective cap is pulled off and injection.

(6) This vaccine should be used immediately after opening.

(7) The vaccine should be thoroughly mixed before use. Do not use if any abnormalities are observed such as clots, foreign objects, unclear label, out of expiry and cracks in the syringe (or vial), etc.

(8) Keep away from reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

(1) The clinical trial results of this vaccine in combination with other routine vaccines have not yet been provided.

(2) If any drugs are being taken or recently taken, including over-the-counter (OTC), please inform the physician in time.

4.6 Fertility, pregnancy and lactation

It is not known whether the vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. The vaccine should only be given to a pregnant woman if clearly needed.

4.7 Effect on ability to drive and machine

N/A

4.8 Undesirable effects

a. Summary of the safety profile

The occurrence rate for ADRs (CIOMS recommendation) can be presented as:

(1) Very common(>10%): Pain at the injection site;

(2) Common (1%-10%): Transient fever, fatigue, headache, diarrhea, redness, swelling, itching, and hardening at the injection site;

(3) Uncommon(< 1%): Skin rash at the injection site; nausea and vomiting, itching at the non-injection site, muscle pain, arthralgia, drowsiness, dizziness, etc.



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(4) No vaccine-related serious adverse reaction was observed.

b. Tabulated summary of adverse reactions

Adverse reactions	Symptoms
Very common	Pain at the injection site
Common	Transient fever, fatigue, headache, diarrhea; redness, swelling, itching, and hardening at the injection site
Uncommon	Skin rash at the injection site; nausea and vomiting, itching at the non-injection site, muscle pain, arthralgia, drowsiness, dizziness, etc.
Serious adverse reaction	So far, no vaccine-related serious adverse reaction was observed

c. Description of selected adverse reactions

Participants were monitored after each vaccination for 30 minutes for immediate reactions. Solicited injection site and systemic reactions were recorded in a diary card for 7 consecutive days after each vaccination. Participants were monitored for 28 days for unsolicited adverse events and for 12 months post-vaccination for visits to an emergency room, unexpected visits to an office physician, and serious adverse events. Unsolicited adverse event information was obtained either by telephone interview or at an interim clinic visit. The most frequently reported solicited injection site and systemic reactions within 7 days following vaccination in adults aged 18 years and elder were injection site pain. Fever, fatigue, headache, and diarrhea were also common.

d. Paediatric population

The clinical trials to evaluate the safety and immunogenicity in population aged between 3 years and 17 years old are ongoing.

e. Other special population(s)

N/A

4.9 Overdose

N/A

5. Pharmacological properties

5.1 Pharmacodynamics properties

a. Pharmacotherapeutic group and ATC code:



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N/A

b. Mechanism of action (if known)

The vaccine induces the production of neutralizing antibodies against SARS-CoV-2 virus.

c. Pharmacodynamic effects.

Refer to “d. Clinical efficacy and safety”

d. Clinical efficacy and safety

Immunogenicity is evaluated in a randomized, double-blind, placebo-controlled, phase I/II trials that enrolled children (3 through 12 years of age), adolescents (13 through 17 years of age), and adults (18 through 59 years of age, and >60 years of age) in China, assessed as the neutralizing antibody responses against infectious SARS-CoV-2. Humoral responses against SARS-CoV-2 were induced in all vaccine recipients on day 14 after the second dose. Two-dose schedule with 4µg vaccine on days 0 and 21 achieved higher neutralizing antibody titers in population aged 18 years and above.

The clinical trial results showed that the SARS-CoV-2 Vaccine (Vero cell), Inactivated has good safety in all age groups and dosage groups.

5.2 Pharmacokinetics properties

N/A

5.3 Preclinical safety data

BIBP has completed the preclinical studies using various kinds of animal models (monkey, rat, mouse, rabbit, and guinea pig) and the acquired results have demonstrated the vaccine's remarkable performances in immunogenicity studies and toxicity studies on animal models. Furthermore, the vaccine's complete protection in non-human primate rhesus macaques against SARS-CoV-2 challenge has manifested its superior efficacy during the research. Overall, under the experimental conditions, no obvious abnormal reactions were observed.

6. Pharmaceutical particulars

6.1 List of excipients

Disodium hydrogen phosphate, Sodium chloride, Sodium dihydrogen phosphate, Aluminum hydroxide adjuvant.

6.2 Incompatibilities



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We used acidic solution, alkaline solution, polar solution and solution of simulating chemical liquid to carry out the extraction test of the pre-filled packaging material, and passed the toxicological evaluation of the extraction results, and screened the possible extracts. The possible extracts were detected in the performance investigation during the subsequent acceleration and long-term stability. Currently, no potentially harmful extracts were found in the samples within 60 days of 25 °C and for 6 months.

6.3 Shelf life

24 months (Tentatively)

6.4 Special precaution for storage

Store and transport in a refrigerated (2°C -8°C) condition, protect from light. Do not freeze.

6.5 Nature and content of container

This is a liquid vaccine, and the inner packaging is a prefilled syringe assembly or vial.

Pre-filled syringes are convenient devices for the delivery of parenteral medications. They are small which makes them easy to carry and are dependable for delivering a precise dose of the vaccine. The pre-filled syringe (1-mL) is composed of the needle cover, needle-bearing glass tube, plunger rubber cap and plunger stick.

Middle-borosilicate glass vial is a kind of simple structured, unbreakable, and low-cost material which is comprehensively used for vaccine product. The vial (2mL) is composed of film-coated middle-borosilicate glass vials, aluminium foil cap and film-coated rubber stopper.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorization holder

Name: Beijing Institute of Biological Products Co., Ltd.

Add: No. 6&9 Bo'xing 2nd Road, Economic-Technological Development Area, Beijing, 100176, China

Tel: +86 10 8722 0568

Fax: +86 10 8722 0568



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Title	Module 1- Administrative Information- Legal	

Post Code: 100176

Website: <http://www.bjbpi.com>

8. Marketing authorization number(s)

TBD

9. Date of first authorization/renewal of the authorization

TBD

10. Date of revision of the text

Oct. 13th, 2020

Authorized signatory:



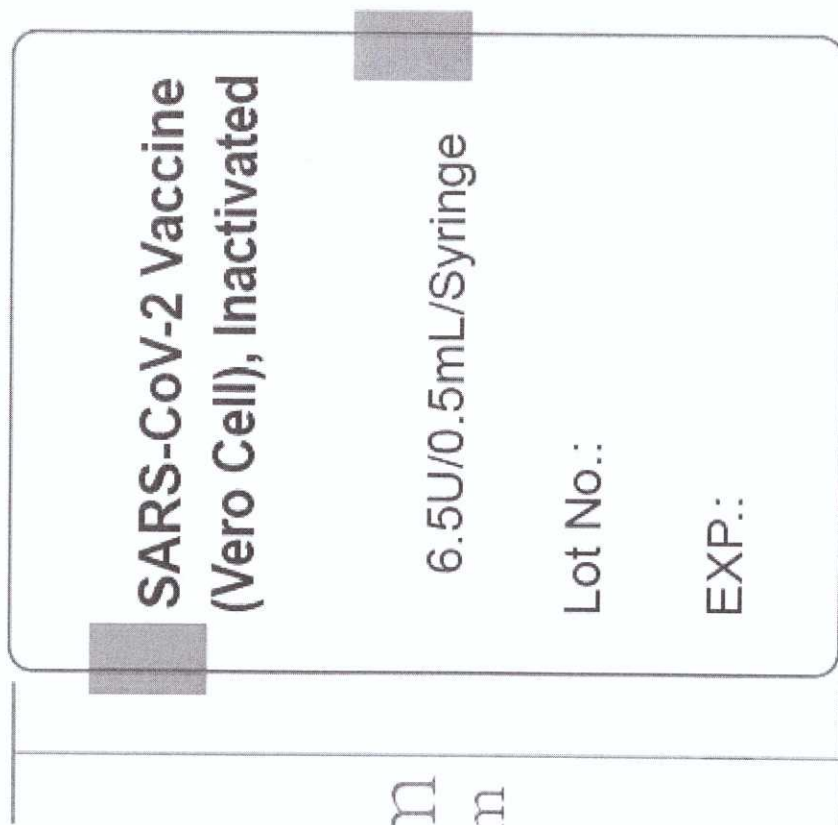
Name: Li Na

Title: Manager of QA Department

December 30th 2020

Beijing Institute of Biological Products Co., Ltd.





 Pantone 7480c

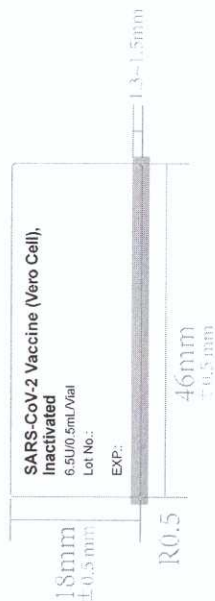
 K100

R1

27mm
± 0.5 mm



1:2

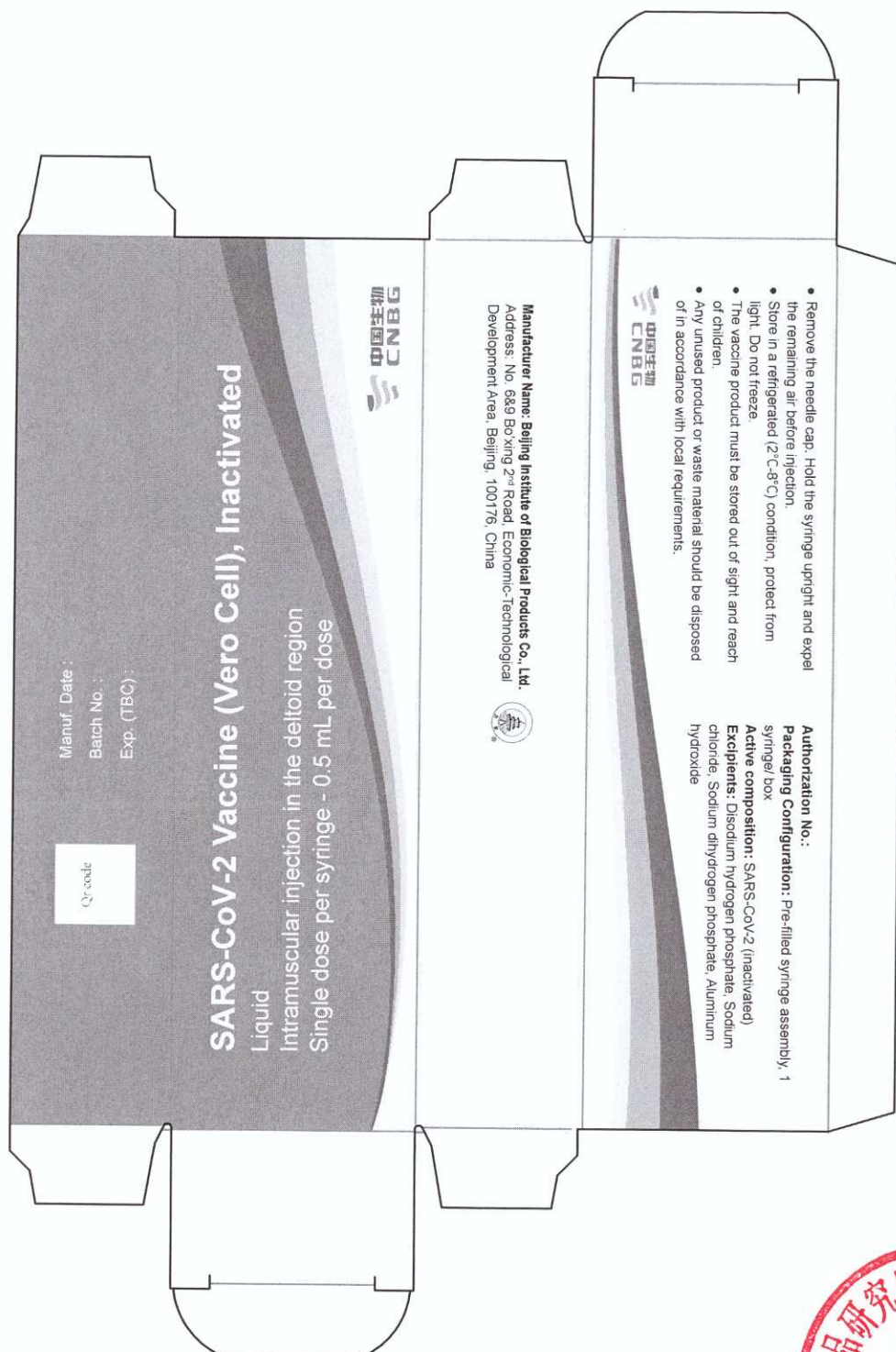


Pantone 7480c

K100



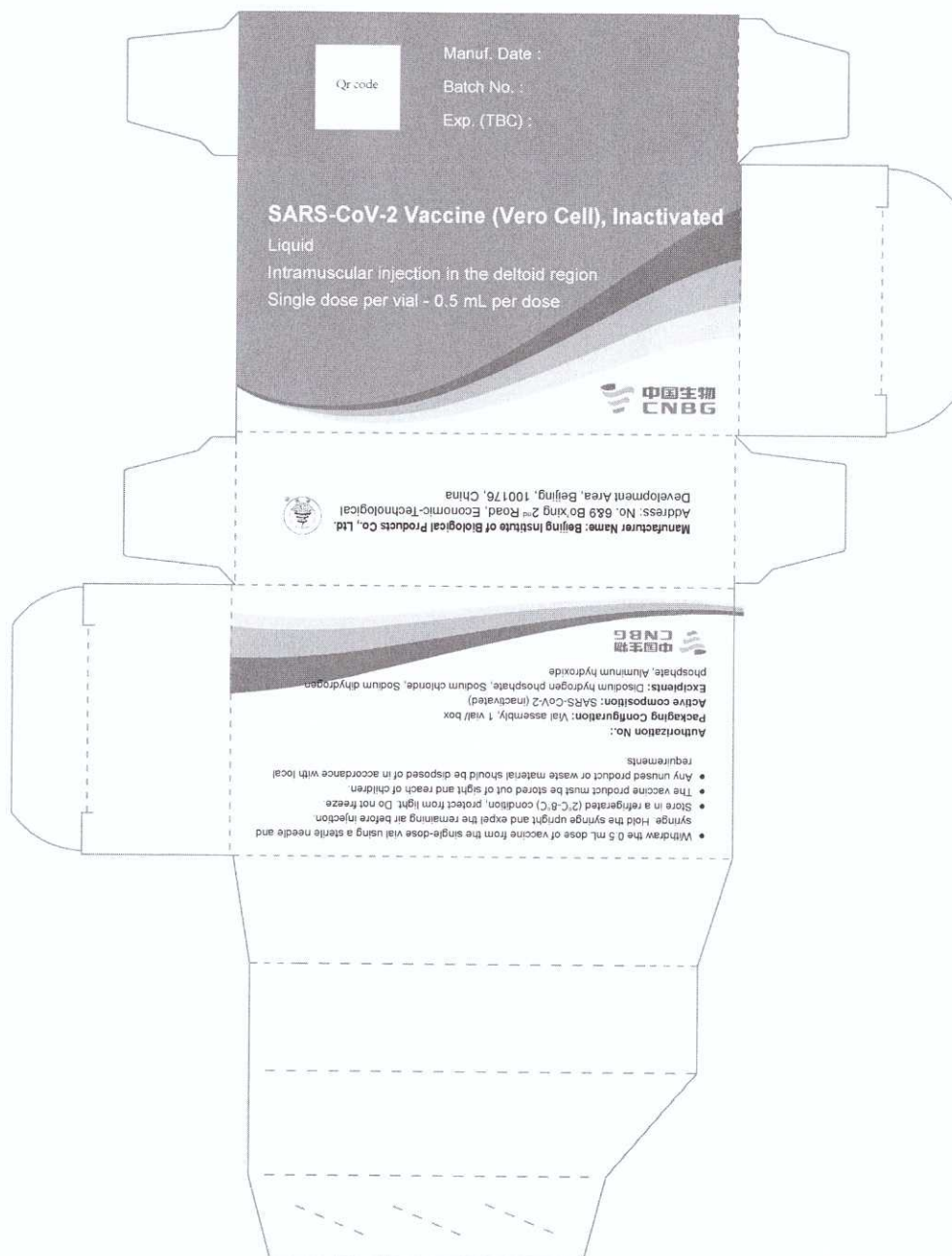
客户名称 Customer name	北京生物制品研究所有限责任公司	产品规格 Product Size	46*18 mm	图 纸 修 改 记 录 Drawing modification record					3				建档日期 Date	20.11.18	客户确认 Customer confirmation
产品名称 Product name	西林瓶标签 (英文)	包装规格 Packaging Size	10000 Pcs/roll	2								工程师 Engineer	Alex Wang	20.11.18	
产品编号 Product number	K0158	公差 Tolerance	±0.5 mm	1								设计 Designer	led Zhang	20.11.18	
材料 Material		备注 Remarks			修改日期 modification date	修改人 Modifier		修改内容 Modification content				销售 Sale			
8	7	6	5	4	3	2	Engineering Drawing								



Pre-filled syringe assembly, 1 syringe/ box

135x37x25mm





Vial assembly, 1 vial/ box

72x39x22mm



Front

130*250mm

Back



SARS-CoV-2 Vaccine (Vero Cell), Inactivated

Please read the instructions carefully and use under the guidance of a physician

Drug Name

SARS-CoV-2 Vaccine (Vero Cell), Inactivated

Composition and Appearance

The SARS-CoV-2 Vaccine (Vero Cell), inactivated is formulated with SARS-CoV-2 strain which is inoculated on the Vero cells for culturing, virus harvesting, β -propiolactone-inactivation, concentration and purification, then adsorbed with aluminium adjuvant to form the liquid vaccine. The product is a semi-transparent suspension with slightly white color, which could be layered by precipitation, and the precipitation can be easily dispersed by shaking

Active composition: SARS-CoV-2 (inactivated)

Excipients: Disodium hydrogen phosphate, Sodium chloride, Sodium dihydrogen phosphate, Aluminum hydroxide adjuvant

Vaccinee

This product is used for people aged 18 years old and above, particularly for medical personnel and those in close contact with the virus.

Functions

The antibodies against the SARS-CoV-2 can be produced after vaccination, to prevent the COVID-19 disease.

Dosage

Each pre-filled syringe contains 0.5mL of product for each administration by intramuscular injection, each dose contains 6.5U of inactivated SARS-CoV-2 antigen.

Immunization Program

This vaccine will be administered by a healthcare professional of national health authorities and CDC in accordance with the national immunization program and strategies.
Method of Administration: The recommended administration is through intramuscular route, the injection into a muscle will be preferably performed in the upper part of the arm.

Immunization Program and Dosage: Two dose regimen at an interval of 2~4 weeks, each dose is 0.5mL.

Adverse Reactions

The occurrence rate for ADRs (CIOMS recommendation) can be presented as:

- (1) Very common: Pain at the injection site;
- (2) Common: Transient fever, fatigue, headache, diarrhea; redness, swelling, itching, and hardening at the injection site;
- (3) Uncommon: Skin rash at the injection site; nausea and vomiting, itching at the non-injection site, muscle pain, arthralgia, drowsiness, dizziness, etc.
- (4) No vaccine-related serious adverse reaction was observed.

If there are any adverse reactions not mentioned above during the use of this vaccine, please inform the physician in time.

Contraindications

This vaccine is strictly prohibited in the following cases:

- (1) Individuals who are allergic to any component (active, excipients) of this product, or those who have allergic reactions with this vaccine before.
- (2) Individuals who have serious chronic disease or history of hypersensitivity.
- (3) Vaccination should be postponed if individuals have fever or during the acute phase of disease.

Special Warnings And Precautions For Use

- (1) Intravascular injection is strictly prohibited.
- (2) Drugs and equipment such as epinephrine should be available for emergency treatment

in the event of an occasional severe allergic reaction. The vaccinee should be watched for at least 30 minutes after vaccination.

(3) This vaccine should be used with caution if:

① have blood disorders such as decrease in platelets (thrombocytopenia) or clotting disorders because of the risk of bleeding which may occur during intramuscular administration of the vaccine.

② are taking a treatment that suppresses your immune defences or if you present with immune deficiency, the immune response to the vaccine may be reduced. In such cases it is recommended to postpone vaccination until the end of the treatment or to make sure the subject is well protected. If you have chronic immune deficiency, this vaccine may also be recommended even though the underlying disease may cause a limited immune response.

③ you have uncontrolled epilepsy and other progressive neurological disorders.

(4) Like all vaccines, this product may not have 100% preventive effect for vaccinee.

(5) Do not use disinfectant to contact the vaccine when the protective cap is pulled off and injection.

(6) This vaccine should be used immediately after opening.

(7) The vaccine should be thoroughly mixed before use. Do not use if any abnormalities are observed such as clots, foreign objects, unclear label, out of expiry and cracks in the syringe, etc.

(8) Keep away from reach of children.

Drug Interaction

(1) The clinical trial results of this vaccine in combination with other routine vaccines have not yet been provided.

(2) If any drugs are being taken or recently taken, including over-the-counter (OTC), please inform the physician in time.

Storage Store and transport in a refrigerated (2°C-8°C) condition, protect from light. Do not freeze.

Packaging Configuration Pre-filled syringe assembly, 1 syringe/ box.

EXP. 24 months (Tentatively)

Executed Standard Technical Guidance for inactivated SARS-CoV-2 Vaccine (Vero Cell) Manufacturing and Testing.

Manufacturer

Company Name: Beijing Institute of Biological Products Co., Ltd.
Add: No. 689 Bo'xing 2nd Road, Economic-Technological Development Area, Beijing, 100176, China

Tel: +86 10 8722 0568

Fax: +86 10 8722 0568

Post Code: 100176

Website: <http://www.bjbpi.com>



Front

135*124mm

Back



SARS-CoV-2 Vaccine (Vero Cell), Inactivated

Please read the instructions carefully and use under the guidance of a physician

Drug Name
SARS-CoV-2 Vaccine (Vero Cell), inactivated

Composition and Appearance

The SARS-CoV-2 Vaccine (Vero Cell), inactivated is formulated with SARS-CoV-2 strain which is inoculated on the Vero cells for culturing, virus harvesting, β -propiolactone-inactivation, concentration and purification, then adsorbed with aluminum adjuvant to form the liquid vaccine. The product is a semi-transparent suspension with slightly white color, could be layered by precipitation, and the precipitation can be easily dispersed by shaking.

Active composition: SARS-CoV-2 (inactivated)

Excipients: Disodium hydrogen phosphate, Sodium chloride, Sodium dihydrogen phosphate, Aluminum hydroxide adjuvant

Vaccine

This product is used for people aged 18 years old and above, particularly for medical personnel and those in close contact with the virus.

Functions

The antibodies against the SARS-CoV-2 can be produced after vaccination, to prevent the COVID-19 disease.

Dosage

Each vial contains 0.5mL of product for each administration by intramuscular injection, each dose contains 6.5U of inactivated SARS-CoV-2 antigen.

Immunization Program

This vaccine will be administered by a healthcare professional of national health authorities and CDC in accordance with the national immunization program and strategies.
Method of Administration: The recommended administration is through intramuscular route, the injection into a muscle will be preferably performed in the upper part of the arm.

Immunization Program and Dosage: Two dose regimen at an interval of 2-4 weeks, each dose is 0.5mL.

Adverse Reactions

The occurrence rate for ADRs (CIOMS recommendation) can be presented as

- (1) Very common: Pain at the injection site;
 - (2) Common: Transient fever, fatigue, headache, diarrhea; redness, swelling, itching, and hardening at the injection site;
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- If there are any adverse reactions not mentioned above during the use of this vaccine, please inform the physician in time.

Contraindications

This vaccine is strictly prohibited in the following cases:

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- (2) Individuals who have serious chronic disease or history of hypersensitivity.
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③ you have uncontrolled epilepsy and other progressive neurological disorders.

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(5) Do not use disinfectant to contact the vaccine when the protective cap is pulled off and injection.

(6) This vaccine should be used immediately after opening.

(7) The vaccine should be thoroughly mixed before use. Do not use if any abnormalities are observed such as clots, foreign objects, unclear label, out of expiry and cracks in the syringe, etc.

(8) Keep away from reach of children.

Drug Interaction

- (1) The clinical trial results of this vaccine in combination with other routine vaccines have not yet been provided.
- (2) If any drugs are being taken or recently taken, including over-the-counter (OTC), please inform the physician in time.

Storage Store and transport in a refrigerated (2°C-8°C) condition, protect from light. Do not freeze.

Packaging Configuration 1 vial/ box.

EXP. 24 months (tentatively)

Executed Standard Technical Guidance for inactivated SARS-CoV-2 Vaccine (Vero Cell) Manufacturing and Testing.

Manufacturer

Company Name: Beijing Institute of Biological Products Co., Ltd.

Address: No. 688 Bo xing 2nd Road, Economic-technological Development Area, Beijing, 100176, China

Tel: +86 10 8722 0568

Fax: +86 10 8722 0568

Post Code: 100176

Website: <http://www.bjbp.com>



Declaration of experts' responsibility

We, BIBP (Beijing Institute of Biological Products Co., Ltd.) is hereby declared that the following experts are responsible for evaluating the product from the point of view of quality, nonclinical and clinical.

Expert on quality: Wang Hui, Li Na, Zhu Xiujuan;

Expert on nonclinical: Zhao Yuxiu;

Expert on clinical: Ma Rui, Zhao Yuxiu.

The Resume of these experts are attached.

Authorized signatory:



Name: Li Na

Title: Manager of QA Department

Date: December 30th 2020

Beijing Institute of Biological Products Co., Ltd.



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Title	Module 1- Administrative Information- Legal	

Expert on clinical

Name	Ma Rui	Gender	Male	Date of birth (38 years old)	October 1981
Ethnicity	Han	Place of origin	Baoding Hebei Province	Birthplace	Baoding Hebei Province
Time of joining the CPC	December 2018	Time to start working	August 2009	State of health	Well
Technical post	Assistant Investigator		Major strengths	Adverse reaction: Familiar with management and assessment Specification: Familiar with establishment, revision and evaluation. Hepatitis B Vaccine: Master process and control	
Education background	Full-time education	Master of Medicine		Graduated from (including major)	Beijing Institute of Biological Products Co., Ltd. Pathogenic biology
	On-the-job education	/		Graduated from (including major)	/
Present post		Assistant Manager of Medical Affairs Department, Beijing Institute of Biological Products Co., Ltd.			
Resume	From September 2001 to June 2006 Study in Hebei North University Medical laboratory science department, Medical laboratory science major. From September 2006 to June 2009 Study in Beijing Institute of Biological Products Co., Ltd. Pathogenic biology major From August 2009 to November 2013 Beijing Institute of Biological Products Co., Ltd. Vaccine research Office 2 Research of Hepatitis B Vaccine process and test method, draft the application documents. From December 2013 to March 2018 (Secondment) China Pharmacopoeia Committee Biological Product Standard Department Establishment, revision and evaluation of the product national specification as the				

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Title	Module 1- Administrative Information- Legal	

	From April 2018 to May 2019	product responsible person. Beijing Institute of Biological Products Co., Ltd. Quality Assurance Department Adverse reaction management and assessment, critical quality task management, regulation management
	May 2019 till now	Beijing Institute of Biological Products Co., Ltd. Medical Affairs Department Deputy Manager



 北京生物制品研究所有限责任公司 BEIJING INSTITUTE OF BIOLOGICAL PRODUCTS CO., LTD.	Documentation	Date
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Product	SARS-CoV-2 Vaccine (Vero Cell), Inactivated	
Title	Module 1- Administrative Information- Legal	

Name	Zhao Yuxiu	Gender	Female	Date of birth (40 years old)	March 1980	
Ethnicity	Han	Place of origin	Hebei Province	Birthplace	Qingyuan Hebei Province	
Time of joining the CPC	/	Time to start working	August 2007	State of health	Well	
Technical post	Assistant Investigator		Major strengths	Immunology, viral vaccine		
Education background	Full-time education		Master of Science	Graduated from (including major)	Beijing Institute of Biological Products Co., Ltd. Immunology	
	On-the-job education		/	Graduated from (including major)	/	
Present post		Assistant Manager of Research management Department, Beijing Institute of Biological Products Co., Ltd.				
Resume	From August 2007 to October 2014			Beijing Institute of Biological Products Co., Ltd. Vaccine Office 4Researcher		
	From July 2011 to October 2014			Beijing Institute of Biological Products Co., Ltd. Quality Assurance Department Validation Management		
	From October 2014 to March 2016			Beijing Institute of Biological Products Co., Ltd. Vaccine research Office 2 Assistant Manager		
	From March 2016 to December 2016			Beijing Institute of Biological Products Co., Ltd. Vaccine research Office 2 Deputy Manager		
	(From September 2016 to December 2016			Beijing Institute of Biological Products Co., Ltd. Vaccine Office 5Deputy Manager)		
	From December 2016 to December 2018			Beijing Institute of Biological Products Co., Ltd. Vaccine research Office 2 Deputy Manager		
	(From December 2016 to May 2017			Beijing Institute of Biological Products Co., Ltd. Vaccine Office 5Deputy Manager)		

 北京生物制品研究所有限责任公司 BEIJING INSTITUTE OF BIOLOGICAL PRODUCTS CO., LTD.	Documentation	Date
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Title	Module 1- Administrative Information- Legal	

	From December 2018 to August 2020	Beijing Institute of Biological Products Co., Ltd. Vaccine research Office 2 Deputy Manager
	From August 2020 till now	Beijing Institute of Biological Products Co., Ltd. Research management Department Deputy Manager

Authorized signatory:



Name: Li Na

Title: Manager of QA Department

December 30th 2020

Beijing Institute of Biological Products Co., Ltd.



 北京生物制品研究所有限责任公司 BEIJING INSTITUTE OF BIOLOGICAL PRODUCTS CO., LTD.	Documentation	Date
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Product	SARS-CoV-2 Vaccine (Vero Cell), Inactivated	
Title	Module 1- Administrative Information- Legal	

Expert on nonclinical

Name	Zhao Yuxiu	Gender	Female	Date of birth (40 years old)	March 1980	
Ethnicity	Han	Place of origin	Hebei Province	Birthplace	Qingyuan Hebei Province	
Time of joining the CPC	/	Time to start working	August 2007	State of health	Well	
Technical post	Assistant Investigator		Major strengths	Immunology, viral vaccine		
Education background	Full-time education	Master of Science		Graduated from (including major)	Beijing Institute of Biological Products Co., Ltd. Immunology	
	On-the-job education	/		Graduated from (including major)	/	
Present post		Deputy Manager of Research management Department, Beijing Institute of Biological Products Co., Ltd.				
Resume	From August 2007 to October 2014			Beijing Institute of Biological Products Co., Ltd. Vaccine Office 4Researcher		
	From July 2011 to October 2014			Beijing Institute of Biological Products Co., Ltd. Quality Assurance Department Validation Management		
	From October 2014 to March 2016			Beijing Institute of Biological Products Co., Ltd. Vaccine research Office 2 Assistant Manager		
	From March 2016 to December 2016			Beijing Institute of Biological Products Co., Ltd. Vaccine research Office 2 Deputy Manager		
	(From September 2016 to December 2016			Beijing Institute of Biological Products Co., Ltd. Vaccine Office 5Deputy Manager)		
	From December 2016 to December 2018			Beijing Institute of Biological Products Co., Ltd. Vaccine research Office 2 Deputy Manager		
	(From December 2016 to May 2017			Beijing Institute of Biological Products Co., Ltd. Vaccine Office 5Deputy Manager)		
	From December 2018 to August 2020			Beijing Institute of Biological Products Co., Ltd. Vaccine research Office 2 Deputy Manager		
	From August 2020 till now			Beijing Institute of Biological Products Co., Ltd. Research management Department Deputy Manager		

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Authorized signatory:



Name: Li Na

Title: Manager of QA Department

December 30th 2020

Beijing Institute of Biological Products Co., Ltd



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Quality responsible person

Name	Wang Hui	Gender	Female	Date of birth (57 years old)	April 1963	
Ethnicity	Han	Place of origin	Lanzhou, Gansu	Birthplace	Lanzhou City	
Time of joining the CPC	September 1993	Time to start working	December 1985	State of health	Well	
Technical post	Investigator		Major strengths	Research & development, production and quality management		
Education background	Full-time education	Bachelor of Medicine		Graduated from (including major)	Medical Profession, Department of Medicine, Lanzhou Medical College	
	On-the-job education	/		Graduated from (including major)	/	
Present post		General Manager, Beijing Institute of Biological Products Co., Ltd.				
Resume	From September 1980 to August 1985 From August 1985 to December 1985 From December 1985 to June 1997 From June 1997 to April 2002 From April 2002 to September 2003 From October 2003 to January 2004 From January 2004 to February 2009 From February 2009 to March 2014 From March 2014 to December 2016 From December 2016 to December 2018 From December 2018 to April 2020 Medical Profession, Department of Medicine, Lanzhou Medical College To be assigned to work Vaccine Office 1, Lanzhou Institute of Biological Products Deputy Director (Work as Chair), Integrated Utilization Department, Lanzhou Institute of Biological Products Deputy Director, Science and Technology Development Department, Lanzhou Institute of Biological Products Vaccine Office 4, Beijing Institute of Biological Products Co., Ltd. Director, Vaccine Office 4, Beijing Institute of Biological Products Co., Ltd. General Manager Assistant, Beijing Institute of Biological Products Co., Ltd. (From August 2009 to March 2014: Manager of Quality Assurance Department) Deputy General Manager, Beijing Institute of Biological Products Co., Ltd. Deputy General Manager, Beijing Institute of Biological Products Co., Ltd. (From December 2016 to April 2017: Deputy General Manager, Beijing Institute of Biological Products Co., Ltd.) Deputy General Manager, Beijing Institute of Biological Products Co., Ltd. (Since					

 北京生物制品研究所有限责任公司 BEIJING INSTITUTE OF BIOLOGICAL PRODUCTS CO., LTD.	Documentation	Date
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Title	Module 1- Administrative Information- Legal	

	From April 2020 till now December 2019: take charge of the business work in Beijing Institute of Biological Products Co., Ltd. and perform duties as a legal person) General Manager & Executive Director, Beijing Institute of Biological Products Co., Ltd.
--	--



 北京生物制品研究所有限责任公司 BEIJING INSTITUTE OF BIOLOGICAL PRODUCTS CO., LTD.	Documentation	Date
	CoV-Re-20-ARG-B-05	December 2020
Product	SARS-CoV-2 Vaccine (Vero Cell), Inactivated	
Title	Module 1- Administrative Information- Legal	

QA Expert

Name	Li Na	Gender	Female	Date of birth (36 years old)	March 1984	
Ethnicity	Han	Place of origin	Shanxi Province	Birthplace	Tianshui, Gansu Province	
Time of joining the CPC	June 11, 2006	Time to start working	July 16, 2012	State of health	Well	
Technical post	Intermediate engineer		Major strengths	Microbiology		
Education background	Full-time education	Master of Science		Graduated from (including major)	Faculty of Life Science and Technology, Kunming University of Science and Technology Microbiology	
	On-the-job education	/		Graduated from (including major)	/	
Present post		Assistant Manager of Quality Assurance Department, Beijing Institute of Biological Products Co., Ltd.				
Resume	From July 2012 to April 2016 Beijing Institute of Biological Products Co., Ltd. Quality Control Department Employee From April 2016 to December 2018 Beijing Institute of Biological Products Co., Ltd. Quality Control Department Assistant Manager From December 2018 to February 2020 Beijing Institute of Biological Products Co., Ltd. Quality Control Department Assistant Manager From February 2020 till now Beijing Institute of Biological Products Co., Ltd. Manager of Quality Assurance Department					



 北京生物制品研究所有限责任公司 BEIJING INSTITUTE OF BIOLOGICAL PRODUCTS CO., LTD.	Documentation	Date
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Title	Module 1- Administrative Information- Legal	

QC Experts

Name	Zhu Xiujuan	Gender	Female	Date of birth (30 years old)	December 1989	
Ethnicity	Han	Place of origin	Henan Province	Birthplace	Shangqiu Henan Province	
Time of joining the CPC	May 2012	Time to start working	August 2016	State of health	Well	
Technical post	Medical biological engineer		Major strengths	Quality management, PQ		
Education background	Full-time education	Master		Graduated from (including major)	National Institutes for Food and Drug Control, immunology	
	On-the-job education	/		Graduated from (including major)	/	
Present post		Deputy Manager of Quality Control Department, Beijing Institute of Biological Products Co., Ltd.				
Resume	From August 2016 to March 2017			Beijing Institute of Biological Products Co., Ltd. Quality Assurance Department PQ management		
	From April 2017 to August 2017			Beijing Institute of Biological Products Co., Ltd. Quality Assurance Department QMS operation management		
	From September 2017 to June 2018			Beijing Institute of Biological Products Co., Ltd. Quality Assurance Department On-site supervision, control and releaser		
	From July 2018 to December 2018			Beijing Institute of Biological Products Co., Ltd. Quality Assurance Department Product quality supervision manager		
	From January 2019 to August 2020			Beijing Institute of Biological Products Co., Ltd. Quality Assurance Department Product quality supervision manager		
	From August 2020 till now			Beijing Institute of Biological Products Co., Ltd. Quality Control Department Deputy Manager		

 北京生物制品研究所有限责任公司 BEIJING INSTITUTE OF BIOLOGICAL PRODUCTS CO., LTD.	Documentation	Date
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Title	Module 1- Administrative Information- Legal	

Authorized signatory:



Name: Li Na

Title: Manager of QA Department

December 30th 2020

Beijing Institute of Biological Products Co., Ltd.



 北京生物制品研究所有限责任公司 BEIJING INSTITUTE OF BIOLOGICAL PRODUCTS CO., LTD.	Documentation	Date
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Non-genetical modified organism

Catalogue

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10.1.7 Conclusion of Environmental Management and Monitoring Plan

(1) Environmental management

After the project is put into operation, it is necessary to improve the environmental management organization and personnel of this project on the basis of the original enterprise environmental management organization, and a dedicated person is responsible for the environmental protection work of this project. Standardize the daily management and accounting records of project wastewater, exhaust gas, equipment noise, solid waste and hazardous waste.

(2) Environmental Monitoring Plan

According to the characteristics of the project, in addition to the conventional pollutant monitoring, the environmental monitoring plan also includes the verification of the purification and inactivation effects of pathogenic microorganisms in the exhaust gas, wastewater and solid waste involved in the project. Routine monitoring data should be entrusted to a qualified environmental monitoring unit on a regular basis, and the inactivation monitoring of pathogenic microorganisms should be carried out by the enterprise itself or by a department with relevant monitoring qualifications, and the data of each monitoring should be archived for inspection by relevant departments.

(3) Total Pollutant Discharge

The total pollutant indexes of the project are nitrogen oxide: 0.28 t/a, SO₂: 0.006 t/a, particulate matter: 0.002 t/a, chemical oxygen demand: 0.949 t/a, ammonia nitrogen: 0.175 t/a. The indexes to be replaced are nitrogen oxide: 0.56 t/a, SO₂: 0.012 t/a, particulate matter: 0.004 t/a, chemical oxygen demand: 0.949 t/a, ammonia nitrogen: 0.175 t/a.

10.1.8 Comprehensive conclusions

This project uses the BIBP's existing facility to be constructed after partial expansion.

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The production involves inoculation and culture of the second type of pathogenic microorganisms, which has certain biological safety risks. The project sets up a high-level biosafety protection zone (P3), and the construction of the facility meets the requirements of "General Requirements for Biosafety in Vaccine Production Facility" (Health Office Science and Education Letter No.483 [2020]), "Technical Specification for Biosafety Laboratory Building" (GB50346-2011) and "Design Specification for Clean facility in Pharmaceutical Industry" (GB50457-2019). After being put into production, it can effectively alleviate and control the COVID-19 situation in China and even in the world, provide protection for national health and safety and make contributions to human health.

This project meets the requirements of the National and Beijing industrial policies and relevant regional planning and meets the constraint conditions of "three lines and one single". The pollution prevention and control measures to be taken are effective, economically and technically feasible, with small emissions of various pollutants and little impact on regional environmental quality. The construction unit has effectively implemented the various environmental protection measures and biosafety management and control requirements proposed in this evaluation, established a strict biosafety management system, and earnestly implemented the environmental protection "three simultaneous" system to ensure that all pollutants meet the discharge standards. From the perspective, the project is feasible.

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December 30th 2020

Beijing Institute of Biological Products Co., Ltd.





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