

 BEIJING INSTITUTE OF BIOLOGICAL PRODUCTS CO.,LTD.	Document No.		EF-SOP-04-03-00-010-002		
	Title		Certificate of Analysis		
	Version No.	01	Revision No.	03	1 / 1

Certificate of Analysis

Name	SARS-CoV-2 Vaccine (Vero Cell), Inactivated	Lot No.	2021020178
Product No.	P12400	CoA No.	P12400-21-0334
Dosage	Liquid	Size	0.5 mL/vial
Test Date	2021/3/2	Report Date	2021/3/18
Storage	Should be stored and transported at a temperature ranging between +2°C and +8°C, protected from light, avoid freezing.	Series No.	nCOVSN2100200
Test Method	STP-01-05-135 Quality Standard for SARS-CoV-2 Vaccine (Vero Cell), Inactivated Version No.: 05 SOP-04-04-01-034 Testing SOP for SARS-CoV-2 Vaccine (Vero Cell), Inactivated Version No.: 04.05		
Test Items	Specification		Result
Appearance	Semi-transparent suspension with slightly white color could be layered by precipitation, and the precipitation can be easily dispersed by shaking.		Conform
Filling Amount	≥ 0.5 mL		Conform
pH	6.8~7.6		Conform
Identification	The substrate solution should be oxidized by enzymes to form a blue complex. After adding the elimination agent, the color of the substrates changed from blue to yellow.		Conform
In-vitro Relative Potency (ELISA)	0.5-2.0		Conform
Sterility Test	Free of bacteria and fungi		Conform
Endotoxin Test	< 10 EU/dose		Conform
Abnormal Toxicity	No abnormal reactions 30min after injection of mice and guinea pigs. During the 7 days of observation period, animals survived without abnormal reactions, and each animal gained weight at the end of the observation period.		Conform
Osmolarity	250 ~ 340 mOsmol/kg		Conform
Aluminum Hydroxide Content	0.30 ~ 0.60 mg/mL		Conform
Conclusion	Pass		
Comments	/		
Prepared by: Yu Wang	Reviewed by: Ling Ding	Review Date: 2021/3/18	
QC Deputy	Xiujuan Zhu	Review Date: 2021/3/18	
QC Supervisor	Yujie Sun	Approve Date: 2021/3/18	
Approved by (QA)	Yang Yang	Expiration Date: 2023/2/27	
This batch of products conforms to GMP requirements and drug registration and quality standard requirements.			
QP	Li Na	2021/3/20	