National Institutes for Food and Drug Control

Certificate of Analysis

Number of Report: SH202101481

Name of the sample: COVID-19 Vaccine (Vero Cell), Inactivated

Manufacturer/Origin: Sinovac Life Sciences Co., Ltd.

Objective of testing: Subcontracted testing

Accordance of testing: Arranged Specifications

Explanation

1. If an objection is raised on this report by the Clint, manufacturer or the sample provider, please raise to the center in written form within 7 days of receiving, no overdue objection is accepted.

2. The data and conclusion issued in this report is based on the testing results of the tested items of the received sample.

3. This report shall not be altered or emendated.

4. The report is invalid without a stamp of National Institutes for Food and Drug Control.

5. This report shall not be used for advertising, evaluation and commercial promotion without written consent by National Institutes for Food and Drug Control.

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Certificate of analysis
National Institute for Food and Drug Control

Number of Report: SH202101481

Name of the sample	COVID-19 Vaccine (Vero cell), Inactivated	Number of the Sample	SH0404202100794
Manufacturer/Origin	Sinovac Life Sciences Co., Ltd.	Batch number	C202102006
Sample provider	Sinovac Life Sciences Co., Ltd.	Strength	0.5mL/vial (syringe), 1 human dose is 0.5 mL, contains 600 SU of SARS-CoV-2 antigen
Objective of testing	Subcontracted testing	Dosage form/Type	Injection
Testing Items	Full testing	Packing specification	/
Date of receiving	2021.02.19	Valid until	2024.02.07
Number of sample	80	Number of Sealing	/
Accordance of testing	Arranged Specifications		

Testing item	Specifications	Testing result
Identification	It shall be proved to contain SARS-CoV-2 antigen	Conforms
Appearance	Opalescent suspension, stratified precipitate may form which can be dispersed by shaking. No clumps shall be found upon shaking.	Conforms
Extractable volume	Not less than the indicated volume	Conforms
pH	6.8-7.8	7.3
Aluminum content (mg/mL)	0.3-0.6	0.5
Osmolality (mOsmol/kg)	250-400	290
Post-dissociation antigen content	Not less than 60% of the indicated content	91
Sterility	No growth of microorganisms shall be observed.	Conforms
Abnormal toxicity (Guinea Pig)	Guinea pigs shall all survive, no abnormal reaction shall be observed, the weight of individual guinea pig shall increase in the end of the test.	Conforms
Abnormal toxicity (Mouse)	Mice shall all survive, no abnormal reaction shall be observed, the weight of individual guinea pig shall increase in the end of the test.	Conforms

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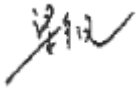
Bacterial Endotoxin (EU/dose) Not higher than 5 <5 The space below is blank			
Remarks: The subcontracted test is based on mutual consent. The test on sample is perform according to the agreement on the contract. The purpose of applying the testing is for emergency use.			
Testing conclusion	When tested as per arranged specifications, the results comply with the requirements.		
Authorized person		Date of issue	2021.03.11

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中国食品药品检定研究院

检验报告

报告编号：SH202101481

检品名称：新型冠状病毒灭活疫苗（Vero细胞）

生产单位/产地：北京科兴中维生物技术有限公司

检验目的：合同检验

检验依据：约定标准

说　　明

一、委托方、生产方或供样方如对本报告有异议，请于收到报告之日起7日内以书面形式提出，逾期不予受理。

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三、本报告不得涂改、增删。

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中国食品药品检定研究院检验报告

报告编号：SH202101481　　共2页，第1页

检品名称	新型冠状病毒灭活疫苗（Vero细胞）	检品编号	SH0404202100794
生产单位/产地	北京科兴中维生物技术有限公司	批　　号	C202102006
供样单位	北京科兴中维生物技术有限公司	规　　格	每支（瓶）0.5ml。每1次人用剂量为0.5ml，含新型冠状病毒抗原600SU。
检验目的	合同检验	剂型/型号	注射剂
检验项目	全检	包装规格	/
收样日期	2021年2月19日	有效期至	2024 02 07
检品数量	80瓶	签封数量	/
检验依据	约定标准		

检验项目	标准规定	检验结果
鉴别试验	应含有新冠病毒抗原	符合规定
外观	应为乳白色混悬液体，可因沉淀而分层，易摇散，不应有摇不散的块状物	符合规定
装量	应不低于标示量	符合规定
pH值	应为6.8～7.8	7.3
铝含量（mg/ml）	应为0.3～0.6	0.5
渗透压摩尔浓度（mOsmol/kg）	应为250～400	290
解离后抗原含量（%）	应不低于标示量的60	91
无菌检查	应无菌生长	符合规定
异常毒性检查（豚鼠）	豚鼠应全部健存，且无异常反应，到期时每只豚鼠体重应增加	符合规定
异常毒性检查（小鼠）	小鼠应全部健存，且无异常反应，到期时每只小鼠体重应增加	符合规定

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中国食品药品检定研究院检验报告

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检验项目	标准规定	检验结果
细菌内毒素检查（EU/剂）	应不高于5	＜5

以下空白

备注：合同检验是在双方自愿基础上，按照合同约定开展的样品检验。企业申请检验目的为应急接种。

检验结论	本品按约定标准检验，结果符合规定。		
授权签字人		签发日期	2021年3月11日