National Medical Products Administration

Drug License

Acceptance No.:CXSS2100014GUO License No.: 2021S00156

Product Name	Non-Proprietary: COVID-19 Vaccine (Vero Cell), Inactivated English / Latin Name: COVID-19 Vaccine (Vero Cell), Inactivated		
Brand Name	CoronaVac		
Main ingredients	Each 1mL contains 1200SU of SARS-CoV-2 viral antigen		
Dosage Form	Injection	Item for application	Drug Registration (Domestic production)
Specification	Each package contains 0.5 mL. Single human dose is 0.5 mL containing 600SU of SARS-CoV-2 viral antigen.	Category	Prophylactic biological product
Registered Drug Standard No.	YBS00152021	Product Validity Period	Tentatively approved as 24 months
Package	0.5mL/syringe; Pre-filled syringe; 1 syringe/box	Prescription drug/OTC	Prescription drug
Review Conclusion	According to *Drug Administration Law of the People's Republic of China*, Vaccine Administration Law of the People's Republic of China and *Approval Procedures for Drug Conditional Approval Application (Trial Implementation)* and the relevant provisions, the COVID-19 Vaccine (Vero Cell), Inactivated which is accepted for review on February 3rd, 2021, complies with the relevant requirements for drug registration. It is recommended that the product be conditional approved for marketing for people age 18 and above to prevent the COVID-19 disease caused by SARS-CoV-2.		
Marketing Authorization Holder	Name: Sinovac life Sciences Co., Ltd. Address: Building 1, No. 21, Tianfu Street, Daxing Biomedicine Industrial Base of Zhongguancun Science Park, Daxing District, Beijing, P.R.China		
Manufacturer	Name: Sinovac life Sciences Co., Ltd. Address: Building 1, No. 21, Tianfu Street, Daxing Biomedicine Industrial Base of Zhongguancun Science Park, Daxing District, Beijing, P.R.China		
Drug Approval No.	GuoYaoZhunZi S20210002	Valid till	February 4th, 2022
Attachment	Quality specification, Package insert and Label		
Sent to	Sinovac life Sciences Co., Ltd.		
Copy Sent to	National Institutes for Food and Drug Control Chinese Pharmacopoeia Commission Center for Drug Evaluation, NMPA Center for Food and Drug Inspection of NMPA Center for Information, NMPA Department for Drug Administration, NMPA Production process is only sent to the applicant.		
Remarks	1. This product is conditional approved for marketing with a valid period of Drug Approval No. one year. 2. This is a correction dated February 9th, 2021. The original approval date was February 5th, 2021, and the original approval document and the attachments shall be abolished.		

(Stamp)

February 9th , 2021

国家药品监督管理局

药品注册证书

受 理 号：CXSS2100014国　　证书编号：2021S00156

药品名称	药品通用名称：新型冠状病毒灭活疫苗（Vero细胞） 英文名/拉丁名：COVID-19 Vaccine (Vero Cell), Inactivated		
商品名称	克尔来福/CoronaVac		
主要成分	每ml本品含新型冠状病毒抗原1200SU		
剂　型	注射剂	**申请事项**	药品注册（境内生产）
规　格	每支0.5 ml，每1次人用剂量为0.5ml，含新型冠状病毒抗原600SU。	**注册分类**	预防用生物制品
药品注册标准编号	YBS00152021	**药品有效期**	暂定24个月
包装规格	0.5mL：预充式注射器：每盒1支	**处方药/非处方药**	处方药
审批结论	见附页。		
上市许可持有人	名　　称：北京科兴中维生物技术有限公司 地　　址：北京市大兴区中关村科技园大兴生物医药产业基地天富街21号1号楼		
生产企业	名　　称：北京科兴中维生物技术有限公司 地　　址：北京市大兴区中关村科技园大兴生物医药产业基地天富街21号		
药品批准文号	国药准字S20210002	**药品批准文号有效期**	至2022年02月04日
附件	生产工艺、质量标准、说明书、标签		
主送	北京科兴中维生物技术有限公司		
抄送	中国食品药品检定研究院，国家药典委员会，国家药品监督管理局药品审评中心，国家药品监督管理局药品审核查验中心，国家药品监督管理局信息中心，国家药品监督管理局药品监管司，其中生产工艺仅送注册申请人（主送单位）。		
备注	1. 本品附条件批准上市，批准文号有效期一年。 2. 此件为更正件，更正日期为2021年02月09日。原批准日期为2021年02月05日，原批件、附件废止。		

2021年02月09日

国家药品监督管理局 药品注册专用章

No. 2003756

National Medical Products Administration

Drug License

Acceptance No.:CXSS2100015GUO License No.: 2021S00157

Product Name	Non-Proprietary: COVID-19 Vaccine (Vero Cell), Inactivated English / Latin Name: COVID-19 Vaccine (Vero Cell), Inactivated		
Brand Name	CoronaVac		
Main ingredients	Each 1mL contains 1200SU of SARS-CoV-2 viral antigen		
Dosage Form	Injection	Item for application	Drug Registration (Domestic production)
Specification	Each vial contains 0.5 mL. Single human dose is 0.5 mL containing 600SU of SARS-CoV-2 viral antigen.	Category	Prophylactic biological product
Registered Drug Standard No.	YBS00152021	Product Validity Period	Tentatively approved as 24 months
Package	0.5mL/vial; Vial; 1 vial/box	Prescription drug/OTC	Prescription drug
Review Conclusion	According to *Drug Administration Law of the People's Republic of China*, Vaccine Administration Law of the People's Republic of China and *Approval Procedures for Drug Conditional Approval Application (Trial Implementation)* and the relevant provisions, the COVID-19 Vaccine (Vero Cell), Inactivated which is accepted for review on February 3rd, 2021, complies with the relevant requirements for drug registration. It is recommended that the product be conditional approved for marketing for people age 18 and above to prevent the COVID-19 disease caused by SARS-CoV-2.		
Marketing Authorization Holder	Name: Sinovac life Sciences Co., Ltd. Address: Building 1, No. 21, Tianfu Street, Daxing Biomedicine Industrial Base of Zhongguancun Science Park, Daxing District, Beijing, P.R.China		
Manufacturer	Name: Sinovac life Sciences Co., Ltd. Address: Building 1, No. 21, Tianfu Street, Daxing Biomedicine Industrial Base of Zhongguancun Science Park, Daxing District, Beijing, P.R.China		
Drug Approval No.	GuoYaoZhunZi S20210003	Valid till	February 4th, 2022
Attachment	Quality specification, Package insert and Label		
Sent to	Sinovac life Sciences Co., Ltd.		
Copy Sent to	National Institutes for Food and Drug Control Chinese Pharmacopoeia Commission Center for Drug Evaluation, NMPA Center for Food and Drug Inspection of NMPA Center for Information, NMPA Department for Drug Administration, NMPA Production process is only sent to the applicant.		
Remarks	1. This product is conditional approved for marketing with a valid period of Drug Approval No. one year. 2. This is a correction dated February 9th, 2021. The original approval date was February 5th, 2021, and the original approval document and the attachments shall be abolished.		

(Stamp)

February 9th , 2021

国家药品监督管理局

药品注册证书

受 理 号：CXSS2100015　　证书编号：2021S00157

药品名称	药品通用名称：新型冠状病毒灭活疫苗（Vero细胞） 英文名/拉丁名：COVID-19 Vaccine (Vero Cell), Inactivated		
商品名称	克尔来福/CoronaVac		
主要成分	每ml本品含新型冠状病毒抗原1200SU		
剂　型	注射剂	**申请事项**	药品注册（境内生产）
规　格	每瓶0.5ml，每1次人用剂量为0.5ml，含新型冠状病毒抗原600SU。	**注册分类**	预防用生物制品
药品注册标准编号	YBS00152021	**药品有效期**	暂定24个月
包装规格	0.5ml：西林瓶：每盒1瓶	**处方药/非处方药**	处方药
审批结论	见附页。		
上市许可持有人	名　　称：北京科兴中维生物技术有限公司 地　　址：北京市大兴区中关村科技园大兴生物医药产业基地天富街21号1号楼		
生产企业	名　　称：北京科兴中维生物技术有限公司 地　　址：北京市大兴区中关村科技园大兴生物医药产业基地天富街21号		
药品批准文号	国药准字S20210003	**药品批准文号有效期**	至2022年02月04日
附件	生产工艺，质量标准，说明书，标签		
主送	北京科兴中维生物技术有限公司		
抄送	国家药品监督管理局药品审评中心，中国食品药品检定研究院，国家药典委员会，国家药品监督管理局药品监管司，国家药品监督管理局信息中心，国家药品监督管理局食品药品审核查验中心，其中生产工艺仅送注册申请人（主送单位）。		
备注	1. 本品附条件批准上市，批准文号有效期一年。 2. 此件为更正件，更正日期为2021年02月09日。原批准日期为2021年02月05日，原批件、附件废止。		

2021年02月09日

药品注册专用章

No. 2003753