

Government of Nepal Ministry of Health and Population Department of Drug Administration

Regarding the permission for Emergency Use Authorization of Covid-19 vaccine

It is to notify to all concerned that the conditional permission has been granted for Emergency Use Authorization of COVISHIELD vaccine against COVID-19 in Nepal as per the departmental decision dated 15th Jan 2021.

Name of the Product	ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) (COVISHIELD, also known as SARS-CoV-2 AZD 1222, Oxford/AstraZeneca Vaccine)	
Name of manufacturer	Serum Institute of India Pvt Ltd., India	
Dosage form	Solution for injection Presentation: Multi-dose Glass vial (10 dose- 5 ml) Route of Administration: Intramuscular	
Composition	Each dose of 0.5 ml of vaccine contains	
	Active Ingredients	Quantity
	Replication- Deficient Chimpanzee Adenovirus particles encoding SARS-CoV- 2 spike (S) glycoprotein*	5 x 10 ¹⁰ virus particles
	Inactive Ingredient	Quantity
	L- Histidine and L- Histidine Hydrochloride	10 mM
	Sodium Chloride	35 mM
	Magnesium Chloride	1 mM
	Polysorbate 80	0.1% (w/v)
	Sucrose	7.5% (w/v)
	Ethanol	0.5% (w/v)
	EDTA Disodium Salt	0.1 mM
	Water for injection	q.s. to 0.5 ml
	* Produced in genetically human embryonic kidney (HEK) 293 cells.	
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Director General