



**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 the conditional permission has been granted for Emergency Use Authorization of **Whole-virion inactivated SARS CoV-2 Vaccine (BBV152) (COVAXIN™) vaccine** manufactured by Bharat Biotech International Limited, Hyderabad, Telangana, India against COVID-19 in Nepal as per the departmental decision dated 19<sup>th</sup> Mar 2021.

<b>Name of the Product</b>	Whole Virion Inactivated Corona Virus Vaccine, (BBV152) COVAXIN™	
<b>Dosage form</b>	Suspension for injection Presentation: Single-dose Glass vial (0.5 ml) Route of Administration: Intramuscular	
<b>Composition</b>	Each dose of 0.5 ml of vaccine contains:	
	<b>Active Ingredients</b>	<b>Quantity</b>
	Whole Virion, Inactivated Corona Virus antigen	6mcg
	<b>Inactive Ingredient</b>	<b>Quantity</b>
	Aluminum Hydroxide gel equivalent to Al <sup>+++</sup>	250 mcg
	TLR 7/8 Agonist	15 mcg
	2-Phenoxyethanol (2PE) I.P.	2.5 mg
	Phosphate Buffered Saline	q.s to 0.5 mL
<b>Indication</b>	For active immunization against Corona Virus Disease (COVID-19) for age ≥18 years when administered in two doses interval of day 0 & day 28.	
<b>Shelf life with storage condition:</b>	6 months when stored at 2 to 8 °C	

*[Signature]*  
19<sup>th</sup> March 2021  
**Director General**



नेपाल सरकार  
स्वास्थ्य तथा जनसंख्या मन्त्रालय  
औषधि व्यवस्था विभाग

कोभिड-१९ खोपको आपतकालीन प्रयोग अनुमति प्रदान गरिएको सम्बन्धमा

नेपालमा कोभिड-१९ विरुद्धको खोपको आपतकालीन प्रयोगका लागि मिति २०७७/१२/०६ को विभागीय निर्णयानुसार उत्पादक Bharat Biotech International Limited, Hyderabad, Telangana, India को **Whole-virion inactivated SARS CoV-2 Vaccine (BBV152) (COVAXIN™)** खोप आपतकालीन प्रयोगका लागि सशर्त अनुमति प्रदान गरिएको व्यहोरा सम्बन्धित सबैको जानकारीका लागि अनुरोध छ ।

तपश्चिल

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17/11/2021  
महानिदेशक