JUAN DAVID ROJAS

CONGOPE
Consorcio de Gobiernos Autónomos Provinciales del Ecuador

DE-2021-0031-OF
Quito, 8 de marzo del 2021

03557

MINISTERIO DE SALUD PUBLICA
SECRETARIA GENERAL
RECIBIDO
MAR 8'21 PM 3:39
Fecha: ..... Hora: .....
Nombre: Edwin Cancero
Anexos: 14 Tomi

Doctor
Rodolfo Enrique Farfán Jaime
Ministro de Salud Pública del Ecuador
En su despacho.-

De mi consideración:

Con fecha 1 de febrero de 2021, mediante oficio N° 001-CONGOPE-COMAGA-2021, se solicitó al señor Presidente de la República Lic. Lenin Moreno, por parte de quienes conformamos el Consorcio de Gobiernos Provinciales del Ecuador la adquisición de vacunas contra el covid 19 destinada para la población rural, lo que permitirá apoyar al plan nacional de vacunación.

Por lo expuesto solicitamos a usted la autorización correspondiente para inmediatamente los GAD Provinciales proceder con la compra de las vacunas.

Al respecto para su conocimiento me permito remitir adjunto la propuesta de abastecimiento de vacunas para el covid de AZTRAZENECA, del laboratorio Betapharma.

En espera de una respuesta oportuna, reitero mi consideración y estima.

Atentamente,

Dr. Edwin Miño Arcos
Director Ejecutivo

Anexo: Oficio N° 001-CONGOPE-COMAGA-2021
Oficio N° PC-2021-0014-Of.
Propuesta Laboratorio Betapharma
Información de vacunas Procedente de India

Wilson E8-166 y Av. 6 de Diciembre
(593) 02-3801-750
congope@congope.gob.ec

Documento ingresado por correo electrónico
03-02-2021
CORRESP-5FEB'21-10:50
PRESIDENCIA-
PR-RD-2021-00611-E

CONGOPE

COMAGA
Consorcio de Municipios Amazónicos y Galápagos

ASAMBLEA NACIONAL
No. de trámite:
401402
Fecha recepción: 2021-02-05 10:34
No. de referencia:

Fecha documento: 2021-02-05
Remitente:
Pablo Anibal Jurado Moreno
pjurado@congope.gob.ec
Institu. Remitente:
CONSORCIO DE GOBIERNOS AUTÓNOMOS PROVINCIALES DEL ECUADOR - CONGOPE
Revise el estado de su documento con el usuario 1001295011 en:
http://dts.asambleanacional.gob.ec

Oficio No 001- CONGOPE - COMAGA - 2021
Quito, 01 de Febrero de 2021

Licenciado
Lenin Moreno
PRESIDENTE CONSTITUCIONAL DE LA REPÚBLICA DEL ECUAI
En su despacho. -

Ingeniero
César Solorzano
PRESIDENTE DE LA ASAMBLEA NACIONAL (S)

Economista
Mauricio Pozo Crespo
MINISTRO DE ECONOMIA Y FINANZAS

Doctor
Juan Carlos Zevallos López
MINISTRO DE SALUD
En sus despachos.-

MINISTERIO DE SALUD PUBLICA
SECRETARIA GENERAL
RECIBIDO
Fecha: FEB 5'21 - 11:25 Hora:
Nombre: Elena Cancero
Anexos: s/n

De nuestras consideraciones:

Reciban un atento y cordial saludo de quienes conformamos el Consorcio de Gobiernos Autónomos Provinciales del Ecuador- **CONGOPE,** y el Consorcio de Municipios Amazónicos y Galápagos -**COMAGA**; a su vez aprovechamos la oportunidad para desearles éxitos en tan delicadas funciones.

Considerando que la salud de la ciudadanía es prioritaria, en Asamblea Extraordinaria de Prefectos/as del país, realizada el pasado 27 de enero del 2021, se tomó la decisión de solicitar a usted Señor Presidente, se pueda adquirir, con los recursos adeudados por parte del Gobierno Nacional a los GAD Provinciales y al Consorcio de Municipalidades de la Amazonía y Galápagos, COMAGA, una provisión de vacunas contra la Covid19, **destinada para la población rural**, lo que permitirá apoyar al plan nacional de vacunación.

MINISTERIO DE ECONOMIA Y FINANZAS
DIRECCIÓN DE CERTIFICACIÓN Y DOCUMENTACIÓN
02/03/21
S/A

Señor Presidente, como es de conocimiento público, la empresa farmacéutica Pfizer y BioNtech no podrá entregar las vacunas a todos los países Latinoamericanos y en especial al Ecuador, en los plazos previstos, debido a un retraso en la producción, y la solicitud de la presidenta de la Unión Europea Ursula von der Leyen, para que cumpla primero con la provisión de vacunas a Europa, en este sentido consideramos pertinente:

1. Iniciar el proceso de aprobación de las vacunas SputnikV de Rusia y de las empresas Sinopharm, Sinovac Biotech de China.

2. Autorizar la compra de vacunas por parte de los Gobiernos Autónomos Descentralizados.

3. Los recursos asignados a la compra de vacunas ser lo realizará mediante el pago de una parte de la deuda que mantiene el Gobierno Nacional a los GAD Provinciales y los GAD Municipales Amazónicos.

4. En el marco del cronograma y protocolo establecido por parte del Ministerio de Salud, se establecerá la vacunación de la población del sector rural, para lo cual los Gobiernos Autónomos Provinciales, apoyarán en la logística que requiera.

Con la seguridad de contar con una respuesta positiva a esta propuesta, en miras de aportar a contribuir por el bienestar de la población rural del país.

Atentamente,

PABLO ANIBAL
JURADO MORENO

Abg. Pablo Jurado Moreno
Presidente CONGOPE

TELMO ANDRES
BONILLA ABRIL

Ing. Andrés Bonilla
PRESIDENTE DEL COMAGA

PC-2021-0014-Of.
Quito, 4 de marzo de 2021

Economista
Mauricio Pozo Crespo
Ministro de Economía y Finanzas

Ingeniero
Xavier Vidal
Gerente BdE (subrogante)
En sus despachos.-

De nuestra consideración:

Reciban un atento y cordial saludo de quienes conformamos el Consorcio de Gobiernos Autónomos Provinciales del Ecuador- **CONGOPE,** a su vez aprovechamos la oportunidad para desearles éxitos en tan delicadas funciones.

Mediante Oficio.No001- CONGOPE-COMAGA- 2021, del 1ero de febrero del 2021, se informó la predisposición de las Prefecturas del país de asignar recursos que permita la compra de vacunas por parte del Gobierno Nacional, a través del Ministerio de Salud. Por medio de la presente ratificamos nuestro compromiso de realizar la compra con los recursos adeudados por parte del Gobierno Nacional a los GAD Provinciales, así como los $250.000,00 dólares (doscientos cincuenta mil dólares), asignados a los 23 GAD Provinciales, provenientes de la distribución de utilidades del BdE en el año 2019.

Esta asignación de recursos permitirá una provisión de vacunas contra la Covid19, **destinada para la población rural**, lo que permitirá apoyar al plan nacional de vacunación, para lo cual se requiere:

1. Iniciar el proceso de aprobación de las vacunas SputnikV de Rusia y de las empresas Sinopharm, Sinovac Biotech de China.
2. Autorizar la compra de vacunas por parte de los Gobiernos Autónomos Descentralizados.
3. En el marco del cronograma y protocolo establecido por parte del Ministerio de Salud, se establecerá la vacunación de la población del sector rural, para lo cual los Gobiernos Autónomos Provinciales, apoyarán en la logística que requiera.

Con la seguridad de contar con una respuesta positiva a esta propuesta, en miras de aportar a contribuir por el bienestar de la población rural del país.

Atentamente;

Abg. Pablo Jurado Moreno
Presidente CONGOPE

Dr. Edwin MiñoArcos
Director Ejecutivo de CONGOPE

ETAPHARMA

Quito, 3 de marzo de 2021

ASUNTO: PROPUESTA DE ABASTECIMIENTO DE VACUNA PARA EL COVID DE AZTRAZENECA

Señor

Dr. Edwin Miño
DIRECTOR EJECUTIVO DE CONGOPE

Ciudad

Respetada Autoridad

Yo, Roberto Aldana representante legal de Laboratorio Betapharma S.A., manifiesto que me encuentro en disposición de ofertar a **DIRECTOR EJECUTIVO DE CONGOPE** siguiente producto:

PRODUCTO	VACUNA – AZD1222 para COVID 19. AstraZeneca
DOSIFICACION	Primera dosis de 0.5ml. Segunda dosis de 0.5ml.
EMPAQUE	Estuche de 10 viales de 5 ml.
FORMA FARMACEUTICA	Vial de 5mL Contiene 10 dosis de 0.5mL
ORIGEN	Plantas de Fabricación Autorizadas en Todo el Mundo.
ALMACENAMIENTO Y TRANSPORTE	La Vacuna debe almacenarse en refrigeración NEVERA (2 a 8)Grados C° . El transporte de ser en cadena de Frio
CANTIDAD	100.000 Viales (1'000.000 dosis)
ENTREGA	AEROPUERTO - NACIONALIZADA
FACTURACION	BETAPHARMA S.A. (Factura Nacional)

Conscientes de las múltiples complicaciones que atraviesan los Gobiernos del mundo por acceder a tan necesarias vacunas. Teniendo en cuenta la autorización emitida por el Señor Presidente de la Republica y la aprobación de la vacuna por ARCSA, pongo a disposición al **DIRECTOR EJECUTIVO DE CONGOPE**, el contingente operativo y comercial de mi representada para acelerar la importación inicial de 1 millones de dosis de AztraZeneca, al tenor de las siguientes condiciones de abastecimiento y comerciales:

Av. Manuel Córdova Galarza Oe4 - 175 (Vía a la Mitad del Mundo)
Telfs.: (593-2) 2491658 • 099 760 0982 • Quito - Ecuador

CANTIDAD OFERTADA	1 millones de dosis (100 mil viales conteniendo 10 dosis cada uno)
CONDICIONES DE PAGO	Carta de crédito.
CONDICIONES DE RESPALDO	Póliza de fiel cumplimiento del contrato.
PLAZO DE ENTREGA	Envío parcial permitido. De acuerdo a planificación enviada por el fabricante. (Depende fecha orden de compra.)
INCOTERM	CIP – Aeropuerto de la ciudad de Guayaquil o Quito.
ALMACENAMIENTO	La institución, debe garantizar el cumplimiento de BPADT (Buenas Prácticas de Almacenamiento y de Transporte) de los Cuartos al frío de 2 a 8 grados C° y de transporte, de cada entidad en donde vaya a ser almacenado el producto.
PRECIO DE CADA DOSIS	6,50 USD Dólares Americanos
POBLACIÓN BENEFICIARIA	medio millón de ciudadanos vacunados.

Adicionalmente y en caso de que su distinguida autoridad lo considere pertinente, nuestra empresa está en capacidad de ofertar la importación de más dosis de la vacuna para inmunizar a más personas, de conformidad a los acuerdos que se pudiesen alcanzar.

Lo expuesto queda supeditado a la aceptación de la carta oficial de intención de compra, misma que enviamos adjunto a esta comunicación.

Cordialmente,

Ing. Roberto Aldana Celis
GERENTE GENERAL

Av. Manuel Córdova Galarza Oe4 - 175 (Vía a la Mitad del Mundo)
Telfs.: (593-2) 2491658 • 099 760 0982 • Quito - Ecuador

सत्यमेव जयते

File No. BIO/MA/20/000103

From:

The Drugs Controller General, India
Directorate General of Health Services

FDA Bhawan, Kotla Road,
New Delhi- 110002, India.
Dated: 03-JAN-2021

To

M/s Bharat Biotech International Ltd.,
Genome Valley, Shameerpet,
Hyderabad, India -500 078.

Subject: Application for permission to manufacture of Whole-virion Inactivated SARS-CoV-2 Vaccine (BBV152C) for restricted use in emergency situation in Form CT-23 as per the provisions of New Drugs and Clinical Trials Rules, 2019 under Drugs & Cosmetics Act, 1940- regarding.

Reference: SUGAM application no. BIO/CT21/FF/2020/22922 dated 07-Dec-2020.

Sir,

Please find enclosed herewith permission no. MF/BIO/21/000002 dated 03-Jan-2021 in Form CT-23 to manufacture of Whole-virion Inactivated SARS-CoV-2 Vaccine (BBV152C) for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode as per the provisions of New Drugs and Clinical Trial Rules, 2019 under Drugs & Cosmetics Act, 1940.

Yours faithfully,

VENUGOPAL GIRDHARILAL SOMANI

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
DN: c=IN, o=MINISTRY OF HOME AFFAIRS, ou=CDSCO DGHS, postalCode=411401, st=Maharashtra, [illegible]
cn=VENUGOPAL GIRDHARILAL SOMANI
Date: 2021.01.03 17:43:16 +05'30'

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licensing Authority

Copy to:

1. The Deputy Drugs Controller (India), CDSCO Zonal office, CDSCO Bhavan, Beside T.B. & Demonstration Centre, S.R. Nagar, Hyderabad - 500038, India.
2. The Drugs Controller Telangana, Directorate of Drug Control Administration, Drug Control Bhavan, Vengal Rao Nagar, Hyderabad-500 038, India.

F. No.: BIO/MA/20/000103
Permission no.: MF/BIO/21/000002 dated 03-JAN-2021

FORM CT-23
(*See rules 81, 82, 83 and 84*)

PERMISSION TO MANUFACTURE PHARMACEUTICAL FORMULATION OF NEW DRUG FOR SALE OR FOR DISTRIBUTION

The Central Licensing Authority hereby grant permission to M/s Bharat Biotech International Limited, Sy. No. 230, 231 & 235, Genome Valley, Shameerpet Mandal, Medchal-Malkajgiri District, Telangana State- 500078. Telephone No.: nil, Fax: nil, E-Mail:dra@bharatbiotech.com, Telephone No.: nil, Fax: nil, E-Mail:dra@bharatbiotech.com to manufacture for sale of pharmaceutical formulation manufactured by a manufacturer specified below.

2. Details of manufacturer and its manufacturing site under this license:

S. No	Name and address of manufacturer (full name and address with telephone and e-mail address of manufacturer).	Name and address of manufacturing site (full name and address with telephone and e-mail address of manufacturing site).
1.	Bharat Biotech International Limited, Sy. No. 230, 231 & 235, Genome Valley, Shameerpet Mandal, Medchal-Malkajgiri District,Telangana State- 500078. Telephone No.: nil, Fax: nil, E-Mail:dra@bharatbiotech.com	Bharat Biotech International Limited, Sy. No. 230, 231 & 235, Genome Valley, Shameerpet Mandal, Medchal-Malkajgiri District,Telangana State- 500078. Telephone No.: nil, Fax: nil, E-Mail:dra@bharatbiotech.com **Component** — **Manufacturing facility** Drug substance — • Facility PS2, Building S Drug Product — • Building A, Facility PA1

3. Details of pharmaceutical formulation:

Name of the New drug to be manufactured:	Whole Virion Inactivated Corona Virus Vaccine, [BBV152B]
Dosage form:	Suspension for injection Presentation: single dose glass vial (0.5ml) Route of Administration: Intramuscular
Composition:	Each dose of 0.5ml contains: **Active Ingredients** — **Quantity** Whole Virion, Inactivated Corona Virus antigen (Strain: NIV-2020-770) — 6 mcg **Inactive Ingredients** — **Quantity** Aluminium Hydroxide gel equivalent to Al+++ — 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 * Produced in Vero cells.
Indication:	For active immunization against Corona Virus Disease (COVID-19) for age ≥18 years when administered in two doses interval of day 0 & day 28.
Shelf life with storage condition:	6 months when stored at 2 to 8 °C.

4. This is subject to the conditions prescribed in Chapter X of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act,1940.
5. This permission is for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode.
6. The firm should provide the protocol for rolling out for the restricted use of the vaccine in emergency situation.
7. The firm should provide the updated prescribing information/ Package Insert and Summary of Product Characteristics (SmPC) for Whole Virion Inactivated Corona Virus Vaccine (BBV152B) and also disseminate the necessary information, instructions and educational materials through their website.
8. The firm should submit updated safety, efficacy & immunogenicity data from the ongoing Phase I, II & III clinical trials till the completion of trials as per requirement of New Drugs & Clinical Trials, 2019.
9. The firm should submit safety data including the data on AEFI and AESI, with due analysis, every 15 days for the first two months & monthly thereafter and also as per requirement of New Drugs & Clinical Trials, 2019.
10. The firm should submit Risk management plan.
11. The firm should submit ongoing stability of commercial scale batches (real time and accelerated) of drug substance & drug product.
12. The permission is subject to condition of satisfactory evaluation & lot release by CDL, Kasauli. Further, each batch/lot of Whole Virion Inactivated Corona Virus Vaccine, (BBV152B) shall be released from Central Drugs Laboratory, Kasauli.

VENUGOPAL GIRDHARILA L SOMANI

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licensing Authority

Place: New Delhi
Date: 03-Jan-2021

Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O
New Delhi-110002

File No: BIO/MA/20/000103

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan, Kotla Road,
New Delhi- 110002.
Dated: 8/1/2021

To,

M/s Bharat Biotech International Ltd.,
Genome Valley, Shameerpet,
Hyderabad, India -500 078.

Subject: Request for amend the Form CT-23 for permission to manufacture Whole Virion, Inactivated Corona Virus Vaccine (BBV152) for sale and distribution – regarding.

References:

1. Your letter vide no. BBIL/RA/20/006 dated 05.01.2021 submitted to this office vide diary no. 120 dated 06.01.2021.
2. Permission granted by this Directorate in Form CT-23 vide no. MF/BIO/21/000002 dated 03.01.2021.

Sir/Madam,

With reference to the subject cited above and based on the submission of information/documents to this office, the name of product code of Whole Virion, Inactivated Corona Virus Vaccine mentioned in the cover letter and permission is hereby amended to read as **"BBV152"** instead of **BBV152C** or **BBV152B** respectively.

Further, as per the license issued in Form 28D, 2.5ml, 5ml & 10 ml vial presentations, are also permitted subject to condition mentioned in permission, license & communication in this regard including the provisions of New Drugs and & Clinical trials Rules, 2019 under Drugs and Cosmetics Act, 1940.

Yours faithfully,

V.G.S

(Dr. V. G. Somani)
Drugs Controller General (India)

Copy to:

1. The Deputy Drugs Controller (India), CDSCO Zonal office, CDSCO Bhavan, Beside T.B. & Demonstration Centre, S.R. Nagar, Hyderabad - 500038, India.
2. The Director, CDL, Kasauli, HP

DCA

DRUGS CONTROL ADMINISTRATION
GOVERNMENT OF TELANGANA

L. Dis. No. 519374/TS/2020

Dated: 19/12/2020

APPROVAL OF GRANT OF ADDITIONAL PRODUCT TO M/S. BHARAT BIOTECH INTERNATIONAL LIMITED, SY.NO. 230, 231 AND 235, GENOME VALLEY, TURKAPALLY, SHAMIRPET MANDAL, MEDCHAL- MALKAJGIRI DISTRICT, TELANGANA STATE, INDIA UNDER THEIR DRUG MANUFACTURING LICENCE IN FORM-28D BEARING NO.03/HD/AP/98/V/R, DATED: 14.10.1998 VALID UPTO 31.12.2021.

NAME OFTHE PRODUCT

1.	**Whole Virion, Inactivated Corona Virus Vaccine**	
	Presentation : 0.5 mL (Single dose) Vial, 2.5 mL (Multi dose) Vial, 5.0 mL (Multi dose) Vial, 10.0 mL Vial (Multi dose) ~~and 0.5 mL (Single dose) PFS~~	
	Route of Administration : Intramuscular	
	Composition: Each dose of 0.5 mL contains:	
	Whole Virion, Inactivated Corona Virus antigen Strain: NIV-2020-770 (6 mcg)	
	Aluminium Hydroxide Gel equivalent to Al^{+++}	250 mcg
	TLR7/8 Agonist	15 mcg
	2-Phenoxyethanol IP	2.5 mg
	Phosphate Buffered Saline	q.s. to 0.5 mL

1.	**Whole Virion, Inactivated Corona Virus Vaccine (For Export Purpose)**	
	Brand Name: COVAXIN ™	
	Presentation : 0.5 mL (Single dose) Vial, 2.5 mL (Multi dose) Vial, 5.0 mL (Multi dose) Vial, 10.0 mL Vial (Multi dose) and ~~0.5 mL (Single dose) PFS~~	
	Route of Administration : Intramuscular	
	Composition: Each dose of 0.5 mL contains:	
	Whole Virion, Inactivated Corona Virus antigen Strain: NIV-2020-770 (6 mcg)	
	Aluminium Hydroxide Gel equivalent to Al^{+++}	250 mcg
	TLR7/8 Agonist	15 mcg
	2-Phenoxyethanol BP	2.5 mg
	Phosphate Buffered Saline	q.s. to 0.5 mL

DRUGS CONTROL ADMINISTRATION HYDERABAD JD(FAC)

Signature :
Designation :
* Licensing Authority :

Dr. Y. NAVEEN KUMAR
M.Pharm.,Ph.D
Joint Director (Enforcement)
Licensing & Controlling Authority (FAC)
Drugs Control Administration
Government of Telangana
Hyderabad-500 038, TS

Dated: 19/12/2020

// CENTRAL LICENCE APPROVING AUTHORITY //

Drugs Controller General (India)
Directorate General of Health Services
Ministry of Health & Family Welfare
FDA Bhawan, Kotla Road
New Delhi-110002

24 DEC 2020

Bharat Biotech Announces Phase 3 Results of COVAXIN®: India's First COVID-19 Vaccine Demonstrates Interim Clinical Efficacy of 81%

- Data from 25,800 participants, received vaccine or placebo in a 1:1 ratio showed that the vaccine candidate was well tolerated.
- COVAXIN® demonstrated 81% interim efficacy in preventing COVID-19 in those without prior infection after the second dose.
- Clinical trial to continue through to final analysis at 130 confirmed cases in order to gather further data and to evaluate the efficacy of COVAXIN in additional secondary study endpoints.

Hyderabad, India, 03, March, 2021: Bharat Biotech, a global leader in vaccine innovation, developing vaccines for infectious diseases, today announced the first interim analysis of its BBV152 (COVAXIN®). The whole virion inactivated COVID-19 vaccine candidate demonstrated an interim vaccine efficacy of 81% in its Phase 3 clinical trial. The trials involved 25,800 subjects, the largest ever conducted in India, in partnership with the Indian Council of Medical Research.

"Today is an important milestone in vaccine discovery, for science and our fight against coronavirus. With today's results from our Phase 3 clinical trials, we have now reported data on our COVID-19 vaccine from Phase 1, 2, and 3 trials involving around 27,000 participants. COVAXIN® demonstrates high clinical efficacy trend against COVID-19 but also significant immunogenicity against the rapidly emerging variants," said **Dr. Krishna Ella, Chairman & Managing Director, Bharat Biotech**.

BBV152 contains a whole virion inactivated SARS-CoV-2 vaccine, which is produced in Vero cells. It is stable at 2 to 8°C (refrigerated) and is shipped in a ready-to-use liquid formulation that permits distribution using existing vaccine supply chain channels. BBV152 has a 28-day open vial policy as a unique product characteristic, thus reducing vaccine wastage by approximately 10-30%.

BBV152 is based on an established manufacturing platform with a better safety profile when compared to other vaccine platforms. The inclusion of the Algel-IMDG adjuvant enhances T-cell immune responses to COVID-19, leading to long-term protection.

"I want to thank every one of the participants, who volunteered to participate in this vital clinical trial, our partners, principal investigators across 25 study sites, and our team at Bharat Biotech who dedicated their time to this vaccine discovery," said **Mrs. Suchitra Ella, Joint Managing Director, Bharat Biotech**. "We could not have achieved this public-private partnership milestone without the relentless commitment of those involved."

Interim Phase 3 Results: 81% Efficacy

The Phase 3 study enrolled 25,800 participants between 18-98 years of age, including 2,433 over the age of 60 and 4,500 with comorbidities. The primary endpoint of Phase 3 clinical trial is based on the first occurrence of PCR-confirmed symptomatic (mild, moderate, or severe) COVID-19 with onset at least 14 days after the second study vaccination in serologically negative (to SARS-CoV-2) adult participants at baseline.

The first interim analysis is based on 43 cases, of which 36 cases of COVID-19 were observed in the placebo group versus 7 cases observed in the BBV152 (COVAXIN®) group, resulting in a point estimate of vaccine efficacy of 80.6%.

The interim analysis included a preliminary review of the safety database, which showed that severe, serious, and medically attended adverse events occurred at low levels and were balanced between vaccine and placebo groups. The trial's conduct and monitoring are as per Good Clinical Practice guidelines and have been outsourced to IQVIA.

Analysis from the National Institute of Virology indicates that vaccine-induced antibodies can neutralize the UK variant strains and other heterologous strains, which has been published in bioRxiv.
https://doi.org/10.1101/2021.01.26.426986

Bharat Biotech expects to share further details of the trial results as additional data become available. An additional interim analysis is planned for 87 cases, and the final analysis is planned for 130 cases. All data from the second interim and final analyses will be shared via pre-publication servers as well as submitted to a peer-reviewed journal for publication.

More than 40 countries globally have expressed their interest in COVAXIN®. These countries are highly satisfied with the safe, inactivated vaccine technology and robust data package for safety and immunogenicity.

About Bharat Biotech

Bharat Biotech has established an excellent track record of innovation with more than 145 global patents, a wide product portfolio of more than 16 vaccines, 4 bio-therapeutics, registrations in more than 123 countries, and the World Health Organization (WHO) Pre-qualifications. Located in Genome Valley in Hyderabad, India, a hub for the global biotech

industry, Bharat Biotech has built a world-class vaccine & bio-therapeutics, research & product development, Bio-Safety Level 3 manufacturing, and vaccine supply and distribution.

Having delivered more than 4 billion doses of vaccines worldwide, Bharat Biotech continues to lead innovation and has developed vaccines for influenza H1N1, Rotavirus, Japanese Encephalitis, Rabies, Chikungunya, Zika, and the world's first tetanus-toxoid conjugated vaccine for Typhoid. Bharat's commitment to global social innovation programs and public-private partnerships resulted in introducing path-breaking WHO pre-qualified vaccines BIOPOLIO®, ROTAVAC®, and Typbar TCV® combatting polio, rotavirus, typhoid infections, respectively. The acquisition of the rabies vaccine facility, Chiron Behring, from GlaxoSmithKline (GSK) has positioned Bharat Biotech as the world's largest rabies vaccine manufacturer. To learn more about Bharat Biotech, visit www.bharatbiotech.com

To learn more about Bharat Biotech visit www.bharatbiotech.com

Media contact for Bharat Biotech:
Sheela Panicker | +91 9849809594 | enright@enrightpr.com
Shilpa Suryawanshi | +91 9833738595 | shilpa.suryawanshi@perfectrelations.com

BHARAT BIOTECH	ARTWORK APPROVAL	
Product: **COVAXIN™**	Name of the artwork: **Package Insert**	Market: CGS/Institutional
Artwork code:	Change control No:	Item code:
DCGI/NOC/Diary NO.		

For use only of a Registered Medical Practitioner or Hospital or Laboratory

Whole-Virion, Inactivated Corona Virus Vaccine

COVAXIN™

1. NAME AND DESCRIPTION OF THE MEDICINAL PRODUCT:

COVAXIN™ (Whole-Virion Inactivated Corona Virus Vaccine) is a white translucent liquid free from particulate matter containing 6 mcg of Whole-Virion, Inactivated Corona Virus Antigen (strain NIV-2020-770).

COVAXIN™ can be administered to the individuals ages ≥ 18 years.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each dose of 0.5mL contains:

Active Ingredient	Quantity
Whole-Virion, Inactivated Corona Virus Antigen (Strain: NIV-2020-770)	6 µg
Inactive Ingredients	
Aluminium Hydroxide Gel equivalent to Al3	0.25 mg
TLR7/8 Agonist	15 µg
2-Phenoxyethanol IP	2.5 mg
Phosphate Buffered Saline	q.s. to 0.5 mL

3. PHARMACEUTICAL FORM:

Sterile liquid for injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic indication

Whole-Virion, Inactivated Corona Virus Vaccine is indicated for active immunization against SARS-CoV-2 Virus infection for age ≥18years. This vaccine is permitted for restricted use in Emergency situation in Clinical Trial mode, under the provisions of New Drugs and Clinical Trials Rules, 2019, under Drugs & Cosmetics Act 1940.

4.2 Posology and method of administration.

Whole-Virion, Inactivated Corona Virus Vaccine should be administered as two doses on Day 0 and Day 28.

Method of administration: Intramuscular injection (IM).

Once opened, multi-dose vials should be used as soon as possible and within 6 hours when kept at between 2-8°C.

4.3 Contraindications

- Hypersensitivity to any constituents of the vaccine.
- Pregnant and lactating mothers.
- During fever or severe infection.
- Individuals below 18 years.

4.4 Special warnings and precautions for use

- Do not administer intravenously, intradermally, or subcutaneously.
- Like all other vaccines, supervision and appropriate medical treatment should always be available to treat any anaphylactic reactions following immunization.
- The vaccinee should remain under medical supervision for at least 30 minutes after vaccination.

Before use, Whole-Virion, Inactivated Corona Virus Vaccine should be shaken well to obtain a uniform, whitish translucent suspension. Vial should be visually checked for the presence of any particulate matter or other coloration, if any, prior to its administration. If in doubt, do not use the contents of the vial. Whole-Virion, Inactivated Corona Virus Vaccine should not be mixed with other vaccines.

4.5 Interaction with other medicinal products.

Chloroquine and Corticosteroids as they may impair the antibody response.

4.6 Pregnancy and Lactation

Safety and effectiveness has not been established in pregnant women and in nursing mothers.

4.7 Effects on ability to drive and use machines

No studies on the effect of Whole-Virion, Inactivated Corona Virus Vaccine on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Clinical Trial Experience

Safety of the Whole-Virion, Inactivated Corona Virus Vaccine vaccine was established in the on going Phase 1 and Phase 2 studies.

Phase 1 clinical trial was conducted in India in 375 adult healthy volunteers which is still on going. The most common local adverse event reported was Injection site Pain. The most common systemic adverse events reported were headache, followed by fatigue, fever, body ache, abdominal pain, nausea, and vomiting. The other less common adverse events were dizziness/giddiness, tremor, sweating, cold, cough, and injection site swelling. No vaccine related serious adverse events (SAE) were reported.

A Phase 2 clinical trial was conducted in India in 380 adolescents and adult healthy volunteers which is still on going. Similar adverse events were reported in the phase 2 clinical trial. No vaccine related serious adverse events (SAE) were reported.

A Phase 3 efficacy study is on-going in 25800 participants and administered with 1st dose of vaccination with Whole-Virion, Inactivated Corona Virus Vaccine no vaccine related adverse events were observed.

4.9 Immune Response

COVID-19 disease is caused due to SARS-CoV-2 virus infection.

In Phase 1 clinical trial a total of 375 healthy participants were enrolled across the three groups and received three vaccine formulations, BBV152A (3µg with Algel-IMDG (Aluminium hydroxide gel- Imidazo quinoline gallamide (IMDG); a TLR 7/8 agonist), BBV152B (6µg with Algel-IMDG), and BBV152C (6µg with Algel). None of the participants had detectable neutralizing antibodies at baseline analyzed by MNT_{90}. The proportion of participants seroconverted post 2 weeks after 2nd dose was 87.9%, 91.9%, and 82.8% in the BBV152A, B, and C, groups, respectively.

In Phase 2 clinical trial a total of 380 healthy participants were enrolled among two groups and received two vaccine formulations, BBV152 A and BBV152B. None of the participants had detectable neutralizing antibodies at baseline analyzed by MNT_{90}. The proportion seroconverted participants of Group 1 and Group 2, post 4 weeks of 2nd dose was 88.0% and 96.6% respectively.

4.10 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

COVID-19 disease is caused due to SARS-CoV-2 virus infection. Whole-Virion, Inactivated Corona Virus Vaccine is a whole virion inactivated SARS-CoV-2 virus vaccine, has been studied in Phase 1 and 2 clinical studies for safety and immunogenicity and found to be safe and immunogenic. Whole-Virion, Inactivated Corona Virus Vaccine has been shown to prevent COVID-19 following 2 doses given 4 weeks apart. The duration of protection against COVID-19 is currently unknown.

5.2 Pharmacokinetic properties

Evaluation of pharmacokinetic properties is not required for vaccines.

5.3 Preclinical safety data

All the formulations were tested for immunogenicity in mice, rats, and rabbits. Mice, rats, and rabbits were vaccinated on days 0, 7, and 14 (n+1 doses). Further these formulations are tested for immunogenicity, safety, and protective efficacy in Syrian Hamster challenge model and Non-Human Primates (*Rhesus macaque*) challenge model. The Hamsters were vaccinated on Days 0, 14, and 35 (n+1 doses), the live SARS-CoV-2 virus was challenged through intranasal route on Day 50. Likewise, the Rhesus macaques were vaccinated on Days 0 and 14, and live SARS-CoV-2 virus was challenged through intranasal and intratracheal routes on Day 28. All the formulations were found to be safe, immunogenic, and provided effective protection to both upper and lower respiratory tract.

6.PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Aluminium hydroxide gel
- TLR7/8 Agonist
- 2-Phenoxyethanol
- Phosphate Buffered Saline

6.2 Incompatibilities

The product should not be mixed with any other medicinal products or active immunizing agents.

6.3 Shelf life

The expiry date of Whole-Virion, Inactivated Corona Virus Vaccine is indicated on the label and carton of the product. Do not use the product after the expiration date shown on the label and carton of the product.

6.4 Special precautions for storage

Store at +2° to +8 °C, do not freeze. Discard if frozen.

Shake well before use. Keep out of reach of children. Protect from light.

7. PRESENTATION

Whole-Virion, Inactivated Corona Virus Vaccine is presented in USP type 1 glass.

Single dose vial - 0.5mL

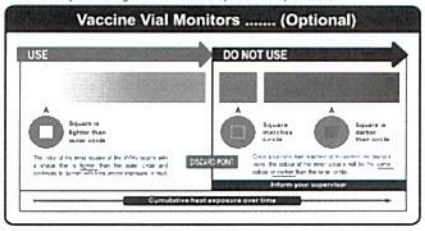
Multi dose vial - 5.0mL (10 dose)

Multi dose vial - 10.0mL (20 dose)

8. The Vaccine Vial Monitor (Optional)

Presentation available with or without vaccine vial monitor

Vaccine Vial Monitors (VVM7) dot is on the seal of the Whole-Virion, Inactivated Corona Virus Vaccine vials supplied through Bharat Biotech. VVM7 are supplied by TEMPTIME Corporation, USA. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.



The interpretation of the VVM7 is simple. Focus on the central square, its colour will change progressively. As long as the colour of this square is lighter than the colour of the ring, the vaccine can be used. As soon as the colour of the central square is the same colour as the ring or of a darker colour than the ring, the vial should be discarded.

Revision date: January 2021

Manufactured & Marketed by

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Front

Back

Date: 16-01-2021	COVAXIN™ (Whole-Virion, Inactivated Corona Virus Vaccine) Package Insert artwork for CGS							Colours CMYK/Pantone
Specs	Text/colour/design dimension(WxH)	NVZ area	Presentation/ Composition	Material/ Sticker/GSM	Text	Clinical data	Text	90% Black C
	65 x 195 mm Fold (V-3/65 x 24.5)		0.5mL, 5mL, 10mL	News Print (45±10)				
Approval	HOD/designee PKD	HOD/ designee	HOD/ designee	HOD/ designee	Marketing (Domestic/	HOD/ designee	QAO-	