

DUPLICATE

GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH  
MINISTRY OF HEALTH & FAMILY WELFARE  
DIRECTORATE GENERAL OF DRUG ADMINISTRATION  
AUSHAD BHAVAN, MOHAKHALI, DHAKA-1212, BANGLADESH  
CERTIFICATE OF REGISTRATION

We hereby declare that **Imovax Polio, Poliomyelitis vaccine (Inactivated)** manufactured by **Sanofi Pasteur, Parc Industriel d'Incarville 27100 Val de Reuil France**, Marketing Authorization Holder (MAH) **M/S. Sanofi Pasteur, 14 Espace Henry Vallee, 69007 Lyon, France** and represented by **M/s. Sanofi Bangladesh Limited, Station Road, Tongi, Gazipur-1710, Bangladesh** is registered with Directorate General of Drug Administration and Licensing Authority (Drugs) under Reg. No. **102-3978-05**. The drug as described below is allowed to be imported into Bangladesh under **The Drugs Act, 1940 (XXIII of 1940), The Drug (control) Ordinance, 1982** and The Drug (Control) (Amendment) Act, 2006 subjected to the provision of import policy published by Government from time to time.


**Name of the Product** : **Imovax Polio, Poliomyelitis vaccine (Inactivated)**  
**Dosage Form** : **Suspension for Injection**  
**Packing** : **0.5ml of Suspension, in Pre-filled syringe (glass), 1 dose**

**Composition: (Amount(s) per unit dose):** Each 0.5ml dose of Imovax Polio contains-

<u>Name of ingredients</u>	<u>Specification</u>	<u>Quantity</u>
<b><u>Active Ingredient:</u></b>		
<b>Inactivated Poliovirus type 1</b>	Ph. Eur.	40 antigen D units
<b>Inactivated Poliovirus type 2</b>	Ph. Eur.	8 antigen D units
<b>Inactivated Poliovirus type 3</b>	Ph. Eur.	32 antigen D units
<b><u>Excipients:</u></b>		
<b>2 phenoxylethanol</b>	Ph. Eur.	2-3 µl
<b>Formaldehyde</b>	Ph. Eur.	2-20 µg
<b>Medium 199, Water for injection</b>		Up to 0.5 ml
<b>Hydrochloride acid or sodium hydroxide for pH adjustment</b>		

Registration Date: 27-01-2005  
Validity: 24-01-2020

*Instructions  
To be dispensed only by or  
on the prescription of a  
registered physician.*

  
**Major General Md. Mustafizur Rahman**  
Director General  
06 MAY 2019  
Directorate General of Drug Administration  
&  
Licensing Authority (Drugs)  
Government of the People's Republic of Bangladesh

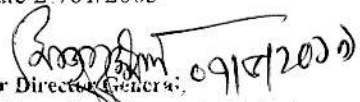
**Conditions:**

- (1) Labeling should be done in accordance with the provision of the Drugs Act and Rules which require that the name and address of the manufacturer, batch number, manufacturing date, expire date, M.R.P. (Maximum Retail Price) D.A.R. No. (Drug Administration Reg. Number) etc. should be displayed on the label or container and also on the outer cover containing the container.
- (2) The registration will be valid for 5 (five) years from its date of issue unless it is revoked, suspended or cancelled earlier.
- (3) The certificate will be treated as cancelled if any violation of conditions and the name or the formula of this product is changed or modified qualitatively or quantitatively without approval of the Licensing Authority.

Memo. No. DA /15-5/102/97/684

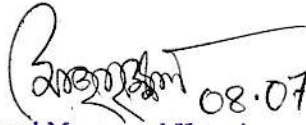
c.c. to: M/S. Sanofi Bangladesh Limited  
Station Road, Tongi, Gazipur  
Contact: 6/2/A, Segun Bagicha, Dhaka-1000, Bangladesh.

Date 27/01/2005

  
For Director General,  
Directorate General of Drug Administration



This Registration shall remain valid  
up to 24-01-2025 unless it is  
suspended Cancelled or revoked earlier.

 08.07.2019

**Mohammad Mozammel Hossain**  
Assistant Director  
Directorate General of Drug Administration  
&  
Licensing Authority (Drugs)  
Government of the People's Republic of Bangladesh