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 **Typhim Vi, 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. **102-3177-97**. 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 : **Typhim Vi**
Dosage Form : Injtable Preparation
Packing :
1. 0.5 ml single dose pre-filled syringe
2. 0.5 ml in single dose syringe (glass) box of 20
3. 10ml (20 doses) in vial (glass)
4. 25ml (50 doses) in vial (glass)
5. 5ml (10 doses) in vial (glass)
Sub cutaneous or intramuscular route

Composition : For one vaccinating dose:

	Name of ingredients	Specification	Quantity
A.	**Active Ingredient**		
	Purified Vi capsular polysaccharide of salmonella Typhi (Ty 2 strain)	Frence Pharmacopoeia	0.025mg
B.	**Excipients:**		
	Phenol	Eur. Ph.	Max. 1.250 mg
	Sodium Chloride	Eur. Ph.	4.150 mg
	Diabasic sodium phosphate, $2H_2O$	Eur. Ph.	0.065mg
	Monobasic sodium phosphate, $2H_2O$	Eur. Ph.	0.023mg
C.	**Diluent:**	Eur. Ph.	
	Water for injections	Eur. Ph.	Up to 0.5 ml

Registration Date: 29-10-1997
Validity: 28-10-2022

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

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

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) DAR 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 /15-5/102/97/5144

Date 29/10/1997

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

MINISTRY OF HEALTH & FAMILY WELFARE ★ DIRECTORATE GENERAL OF DRUG ADMINISTRATION ★ GOVT. OF BANGLADESH ★ DHAKA

For Director General,
Directorate General of Drug Administration