GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH
MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
AUSHAD BHABAN, MOHAKHALI, DHAKA-1212
www.dgda.gov.bd

CERTIFICATE OF REGISTRATION

We hereby declare that **Tetraxim Suspension for injection in Prefilled Syringe** 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. 102-6688-2020.....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	:	**Tetraxim**
Dosage Form	:	**Suspension for Injection in Prefilled Syringe**
Packing	:	**1 x 1's 0.5m1 Prefilled Syringe**

Composition: Each 0.5m1 contains:

	Name of ingredients	**Specification**	**Quantity**
A.	Diphtheria toxoid	Ph. Eur.	≥30 IU
	Tetanus toxoid	Ph. Eur.	≥40 IU
	Bordetella pertussis antigens:		
	Pertussis Toxoid	Ph. Eur.	25µg
	Filamentous haemagglutinin	Ph. Eur.	25µg
	Poliomyelitis virus (inactivated)		
	Type 1 (Mahoney strain)	Ph. Eur.	40 DU†
	Type 2 (MEF-1 Strain)	Ph. Eur.	8 DU†
	Type 3 (Saukett strain)	Ph. Eur.	32 DU†
	*DU: antigen D unit		
	†or eq. antigenic quantity determined by a suitable immunochemical method		
B.	**Excipient(s)**		
	Aluminium hydroxide, hydrated, for adsorption	Ph. Eur.	0.3mg Al
	Phenoxyethanol	Ph. Eur.	2.5µL
	Ethanol anhydrous	Ph. Eur.	2.5µL
	Formaldehyde solution	Ph. Eur.	10 µg
	Medium 199 Hanks 10 x C without phenol red	Ph. Eur.	0.05mL
	Water for Injections	Ph. Eur.	q.s to 0.5ml

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

Major General Md Mahbubur Rahman
Director General
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh
11 OCT 2020

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/ 338

Date .13../.10../2020

c.c. to: M/S. Sanofi Bangladesh Limited
6/2/A, Segun Bagicha, Dhaka-1000, Bangladesh.

MINISTRY OF HEALTH & FAMILY WELFARE * DIRECTORATE GENERAL OF DRUG ADMINISTRATION * GOVT. OF THE PEOPLE'S REPUBLIC OF BANGLADESH * DHAKA

11.10.20
For Director General
Directorate General of Drug Administration