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

# CERTIFICATE OF REGISTRATION

We hereby declare that **Stamaril Prefilled Syring,** 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. **102-4650-011**. 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** : **Stamaril**
**Dosage Form** : **Powder and Solvent for suspension for injection in Prefilled Syringe**
**Packing** : 1 x 1's Powder in vial & 0.5m1 solvent in Prefilled Syringe

**Composition:** (0.5m1) contains: 0.5m1 Solvent in prefilled syringe

| | Name of ingredients | Specification | Quantity |
|---|---|---|---|
| A | **Active Ingredient:** | | |
| | **Yellow fever Virus l7 D-204 Strain (Live attenuated)** | Ph. Eur. | ≥1000 $LD_{50}$ units |
| | **Excipients:** | | |
| B | **freeze-vaccine conatins:** | | |
| | Lactose | Ph. Eur. | 15.950 mg |
| | Sorbitol | Ph. Eur. | 7.975mg |
| | L-histidine HCI | Ph. Eur. | 0.833mg |
| | L-alanine | Ph. Eur. | 0.362m9 |
| | Sodium Chloride | Ph. Eur. | 1.630 mg |
| | Potassium Chloride | Ph. Eur. | 0.054mg |
| | Disodium Phosphate dihydrate | Ph. Eur. | 0.298mg |
| | Potassium dihydrogen phosphate | Ph. Eur. | 0.063mg |
| | Calcium Chloride | Ph. Eur. | 0.039mg |
| | Magnesium Sulphate | Ph. Eur. | 0.029mg |
| | Nitrogen | Ph. Eur. | q.s |
| C | **Reconstitution Solvent Contains:** | | |
| | Sodium Chloride | Ph. Eur. | 2.0mg |
| | Water for Injection | Ph. Eur. | q.s to 0.5m1 |

Registration Date: 16-05-2011
Validity: 15-05-2021

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

**Major General Md. Mostafizur 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 /15-5/102/97/5947 Date 16/05/2011

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

09/12/2019

**For Director General,**
**Directorate General of Drug Administration**

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