## GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH

## MINISTRY OF HEALTH & FAMILY WELFARE DIRECTORATE OF DRUG ADMINISTRATION

105-106, MOTIJHEEL COMMERCIAL AREA, DHAKA-1000

## CERTIFICATE OF REGISTRATION

We hereby declare that Favirab Solution for Injection manufactured by M/S. Aventis Pasteur SA, 2, avenue pont Pasteur, F-69007 Iyon, France and represented by M/s. Sanofi-aventis Bangladesh Limited, 6/2/A, Segun Bagielia, Dhaka-1000, Bangladesh is registered with Directorate of Drug Administration and Licensing Authority (Drugs) under Reg. No. 102-9262-08 The drug as described below is allowed to be imported into Bangladesh under The Drugs Act 1940 (XXIII of 1940), The Drugs (Control) Ordinance, 1982 and The Drug (Control) (Amendment) Act, 2006 subjected to the provision of import policy published by the Government from time to time.

Name of the Product

Favirab, Solution for Injection

**Dosage Form** 

**Solution for Injection** 

Pack Size

5ml Vialx1 or 10

Composition: Each ml contains:

	Name of ingredients	<b>Specification</b>	Quantity
A.	Active ingredient		
	F (ab') 2 Fragment of equine antirabes immune globulin	Ph. Eur	200-400IU
	Excipients:		
В.	Sodium Chloride Polysorbate 80 Water for Injection Hydrochloric acid or Sodium hydroxide for PH adjustment	Ph. Eur Ph. Eur Ph. Eur	9µg 50µg Up to 1ml

on the prescription of a registered physician.

Brigadier General Sarkar M A Matin Director 0 2 NOV 2008

Directorate 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, expiry date, M.R.P. (Maximum Retail Price), DAR No. (Drug Administration Reg. Number) etc. should be displayed on the label of the 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 the conditions and the name or the formula of this product is changed or modified qualitatively or quantitatively without due approval of the Licensing Authority.

Memo No. DA /

Date: 05/

DHAKA

c.c. to: M/S. Sanofi-aventis Bangladesh Limited,

6/2/A, Segun Bagicha,

Dhaka-1000, Bangladesh Station Road, Tongi, Gatipur-1710

**Directorate of Drug Administration** 

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

Molabella Md. Salahuddin Assistant Director For Director General Directorate General of Drug Administration

Licensing Authority (Drugs)

Government of the Prople's Republic of Bangladesh

1. 1