

GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH
MINISTRY OF HEALTH & FAMILY WELFARE

DRUGS ADMINISTRATION
105/106, MOTIJHEEL COMMERCIAL AREA, DHAKA-1000

CERTIFICATION OF REGISTRATION
(FOR THE IMPORT OF NEW AND UNINTRODUCED DRUGS AND MEDICINE)



We hereby declare that Act-HIB manufactured by ~~PASTEUR MERIEUX CONNAUGHT~~, 58, Avenue Leclerc-69007 Lyon, FRANCE and represented by ~~Rhône-Poulenc Rorer~~ Bangladesh Ltd. registered with the Directorate of Drugs Administration under the Ministry of Health & Family Welfare under Registration No. ~~102-3173-97~~..... The drug as described below is allowed to be imported into Bangladesh under Drugs Act 1940 (XXIII of 1940) and Drug (Control) Ordinance 1982 subject to the provision of import policy published by the government from time to time.

Name of Preparation : Act-HIB
Form : Injectable preparation
Packing : 1 Vial 1 Dose + 1 Syringe Diluent, 1 Box x 10 vials, 1 Box x 10 ampoule.
Composition : For one vaccinating dose :

a. <u>INGREDIENT</u>	<u>SPECIFICATION</u>	<u>QUANTITY</u>
Haemophilus influenzae type b Polysaccharide conjugate to tetanus protein	INN	10 µg
b. <u>EXCIPIENTS</u> :		
Tris (hydroxymethyl aminomethane)	Company monograph	0.6 mg
Sucrose	Eur. Ph.	42.5 mg
Sodium chloride	Eur. Ph.	2.0 mg
c. <u>DILUENT</u> :		
Water for injections	Eur. Ph.	up to 0.5 ml

This Certificate shall remain valid for five years from its date of issue unless it is revoked, suspended or cancelled earlier.

M. A. Hadek 29.10.97
Muhammad Abdul Malek
Director (in charge)

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

Directorate of Drugs Administration & Licensing Authority (Drugs)

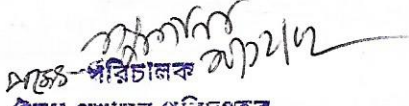
Conditions: (1) Labelling should contain name and address of the manufacturer, batch number, manufacturing date, expiry date, M.R.P. (maximum retail price), DAR No. (Drug Administration Registration Number), (where applicable) etc. should be displayed on the label or container and also on the outer cover containing the container (2) The registration will be valid for 5 (five) years unless it will be canceled earlier. (3) The certificate will be treated as canceled in any violation of the conditions and the name of the formula of this product changed or modified qualitatively or quantitatively without due approval of the Licensing Authority.

Memo No. DA/15-5/102/97/5140

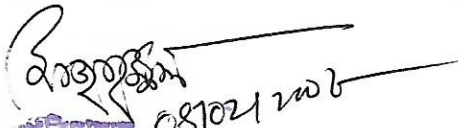
Date...10.11.97..

c.c. to 1. ~~Rhone Poulenc Rorer~~ registration Sangfi-aventis Bangladesh Ltd. Tongi, Gazipur. 29.10.97
For Licensing Authority (Drugs) Drugs Administration.
cc, 6/2/A, Sagon Dhaka. Bogicha.

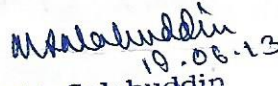
This Registration shall remain valid:
upto 28-10-2007 unless it is suspended,
cancelled or revoked earlier.


পক্ষে-পরিচালক
ঔষধ প্রশাসন পরিদপ্তর
এবং
লাইসেন্সিং কর্তৃপক্ষ (ড্রাগস)
জনপ্রজাতন্ত্রী বাংলাদেশ সরকার

This Registration shall remain valid:
upto 28-10-2012 unless it is suspended,
cancelled or revoked earlier.


পক্ষে-পরিচালক ০৪১০২১২০৬
ঔষধ প্রশাসন পরিদপ্তর
এবং
লাইসেন্সিং কর্তৃপক্ষ (ড্রাগস)
জনপ্রজাতন্ত্রী বাংলাদেশ সরকার

This Registration shall remain valid
up to 28-10-2017 unless it is suspended
Cancelled or revoked earlier.


Md. Salahuddin
19.08.13
Assistant Director
For Director General
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh