



DEPARTMENT OF FOOD SAFETY AND DRUGS CONTROL ADMINISTRATION
GOVERNMENT OF TAMILNADU
359, Anna Salai, Chennai - 600 006, Tamil Nadu.

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

Certificate No: **K Dis. No: 16284/D1/4/2018, Dated: 25.01.2019**

On the basis of the inspection carried out on 26.12.2018, 27.12.2018 and 28.12.2018 we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

1 Name and address of site: M/s. Human Biologicals Institute,
(A Division of M/s. Indian Immunologicals Limited).,
Kozhipannai, Pudumund (Post), Dr. Basavaiah
Nagar, Udthagamandalam – 643 007.

2 Manufacturer's licence number: Form 28D Bearing No: 15, Dated: 11.01.2000.

3 Table 1:

| Dosage form(s) | Category(ies) | Activity(ies) |
|-----------------------|---------------|---------------|
| (Vide List Attached) | - | Manufacturer |
| Vaccines | | |

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until 31.12.2021 It becomes invalid if the activities and/or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Name and function of responsible person:

K.Sivabalan, B.Pharm.,

Director of Drugs Control

Tamil Nadu Drugs Control

Chennai - 600 004

Email: tndcad@gmail.com

Telephone No. 91-44-2433 5068



Explanatory notes

- 1) This certificate, which is in the format recommended by WHO, certifies the status of the Site listed in point 1 of the certificate.
- 2) The certification number should be traceable within the regulatory authority issuing the certificate.
- 3) Where the regulatory authority issues a licence for the site this number should be specified. Record "not applicable" in case where there is no legal framework for the issuing of a licence.
- 4) The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.
- 5) The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials. Good manufacturing practices and inspection, Volume 2, 1999. World Health Organization, Geneva and subsequent updates.

LIST OF ALREADY PERMITTED ITEMS IN FORM 28D BEARING NO. 15, DATED 11.01.2000 OF M/S. HUMAN BIOLOGICALS INSTITUTE (A DIVISION OF M/S. INDIAN IMMUNOLOGICALS LIMITED), KOZHIPANNAI, PUDUMUND POST, DR. BASAVAI AH NAGAR, UDHAGAMANDALAM – 643 007, ARE INCLUDED UNDER WHO GMP CERTIFICATE WHICH IS VALID UPTO 31.12.2021

K.Dis.No. 16284/D1/4/2018

Dated: 25.01.2019

1. **Rabies Vaccine, Human I.P.**

(Purified Vero Cell Rabies Vaccine)

(FOR EXPORTS; Labeling to be done in different languages as per requirement of country of supply for Exports)

Abhayrab®

Purified lyophilized Rabies antigen derived from Rabies virus (L. Pasteur 2061/Vero Strain propagated in Vero Cells) Inactivated

Potency: ≥ 2.5 I.U per vial

Stabilizer: Maltose and Human Albumin...q.s.

Preservative: Thiomersal 0.015% w/v

Pack size: 0.5 ml on reconstitution with accompanying 1 ampoule of 0.5 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.

Dosage: 0.5 ml single immunizing dose for Intramuscular Injection or 0.1 ml dose per site for Intradermal Injection.

2. **Rabies Vaccine, Human I.P.**

(Purified Vero Cell Rabies Vaccine)

(FOR DOMESTIC and EXPORTS; Labeling to be done in different languages as per requirement of country of supply for Exports)

Purified lyophilized Rabies antigen derived from Rabies virus (L. Pasteur 2061/Vero Strain propagated in Vero Cells) Inactivated

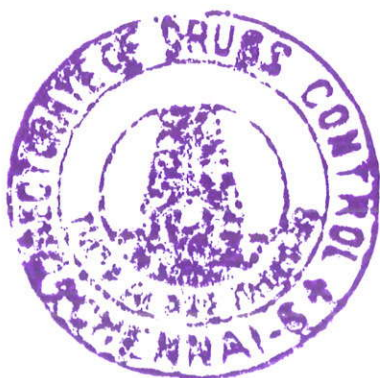
Potency: ≥ 2.5 I.U per vial

Stabilizer: Maltose and Human Albumin...q.s.

Preservative: Thiomersal 0.015% w/v

Pack size: 0.5 ml on reconstitution with accompanying 1 ampoule of 0.5 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.

Dosage: 0.5 ml single immunizing dose for Intramuscular Injection or 0.1 ml dose per site for Intradermal Injection.



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Director of Drugs Control
Chennai-600 006
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LIST OF ALREADY PERMITTED ITEMS IN FORM 28D BEARING NO. 15, DATED 11.01.2000 OF M/S. HUMAN BIOLOGICALS INSTITUTE (A DIVISION OF M/S. INDIAN IMMUNOLOGICALS LIMITED), KOZHIPPANAI, PUDUMUND POST, DR. BASAVAI AH NAGAR, UDHAGAMANDALAM – 643 007, ARE INCLUDED UNDER WHO GMP CERTIFICATE WHICH IS VALID UPTO 31.12.2021

K.Dis.No. 16284/D1/4/2018

Dated: 25.01.2019

3. **Rabies Vaccine, Human I.P.**

(Purified Vero Cell Rabies Vaccine)

(FOR EXPORTS; Labeling to be done in different languages as per requirement of country of supply for Exports)

Abhayrab®

Purified lyophilized Rabies antigen derived from Rabies virus (L. Pasteur 2061/Vero Strain propagated in Vero Cells) Inactivated

Potency: ≥ 2.5 I.U per vial

Stabilizer: Maltose and Human Albumin...q.s.

Preservative: Thiomersal 0.015% w/v

Pack size: 0.5 ml on reconstitution with accompanying 1 ampoule of 0.5 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.

Dosage: 0.5 ml single immunizing dose for Intramuscular Injection

4. **Rabies Vaccine, Human I.P.**

(Purified Vero Cell Rabies Vaccine)

(FOR DOMESTIC and EXPORTS; Labeling to be done in different languages as per requirement of country of supply for Exports)

Purified lyophilized Rabies antigen derived from Rabies virus (L. Pasteur 2061/Vero Strain propagated in Vero Cells) Inactivated

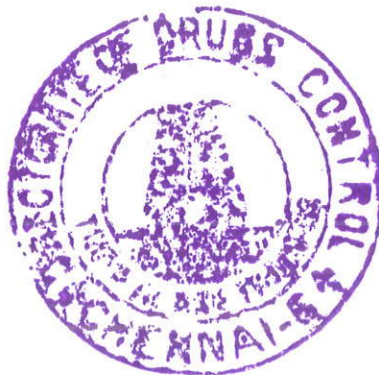
Potency: ≥ 2.5 I.U per vial

Stabilizer: Maltose and Human Albumin...q.s.

Preservative: Thiomersal 0.015% w/v

Pack size: 0.5 ml on reconstitution with accompanying 1 ampoule of 0.5 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.

Dosage: 0.5 ml single immunizing dose for Intramuscular Injection



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Director of Drugs Control
Chennai-600 006

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K.Dis.No. 16284/D1/4/2018

Dated: 25.01.2019

5. **Rabies Vaccine B.P. 'Rab'**

Rabies Vaccine for Human Use Prepared in Cell Cultures (Purified Vero Cell Rabies Vaccine)
(EXPORTS: Labeling to be done in different languages as per requirement of country of supply for Exports)

Abhayrab®

Purified lyophilized Rabies antigen derived from Rabies virus (L. Pasteur 2061/Vero Strain propagated in Vero Cells) Inactivated

Potency: ≥ 2.5 I.U per vial

Stabilizer: Maltose and Human Albumin...q.s.

Preservative: Thiomersal 0.01% w/v

Pack size: 0.5 ml on reconstitution with accompanying 1 ampoule of 0.5 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. B.P.

Dosage: 0.5 ml single immunizing dose for Intramuscular Injection or 0.1 ml dose per site for Intradermal Injection.

6. **Rabies Vaccine B.P. 'Rab'**

Rabies Vaccine for Human Use Prepared in Cell Cultures (Purified Vero Cell Rabies Vaccine)
(EXPORTS: Labeling to be done in different languages as per requirement of country of supply for Exports)

Abhayrab®

Purified lyophilized Rabies antigen derived from Rabies virus (L. Pasteur 2061/Vero Strain propagated in Vero Cells) Inactivated

Potency: ≥ 2.5 I.U per vial

Stabilizer: Maltose and Human Albumin...q.s.

Preservative: Thiomersal 0.01% w/v

Pack size: 0.5 ml on reconstitution with accompanying 1 ampoule of 0.5 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.

Dosage: 0.5 ml single immunizing dose for Intramuscular Injection or 0.1 ml dose per site for Intradermal Injection.



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**Director of Drugs Control
Chennai-600 006**

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K.Dis.No. 16284/D1/4/2018

Dated: 25.01.2019

7. Rabies Vaccine, Human I.P.

(Purified Vero Cell Rabies Vaccine)

(FOR EXPORTS; Labeling to be done in different languages as per requirement of country of supply for Exports)

Abhayrab®

Purified lyophilized Rabies antigen derived from Rabies virus (L. Pasteur 2061/Vero Strain propagated in Vero Cells) Inactivated

Potency: ≥ 2.5 I.U per vial

Stabilizer: Maltose and Human Albumin...q.s.

Preservative: Thiomersal 0.015% w/v

Pack size: 1.0 ml on reconstitution with accompanying 1 ampoule of 1.0 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.

Dosage: 0.5 ml out of 1 ml diluent will be used for single IM dose (0.5 ml) while 1 ml diluent will be used for 10 intradermal injections of 0.1 ml per site.

8. Rabies Vaccine, Human I.P.

(Purified Vero Cell Rabies Vaccine)

(FOR DOMESTIC and EXPORTS; Labeling to be done in different languages as per requirement of country of supply for Exports)

Purified lyophilized Rabies antigen derived from Rabies virus (L. Pasteur 2061/Vero Strain propagated in Vero Cells) Inactivated

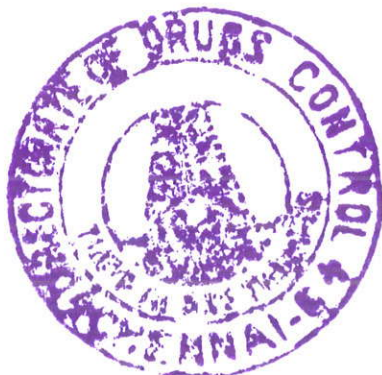
Potency: ≥ 2.5 I.U per vial

Stabilizer: Maltose and Human Albumin...q.s.

Preservative: Thiomersal 0.015%w/v

Pack size: 1.0 ml on reconstitution with accompanying 1 ampoule of 1.0 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.

Dosage: 0.5 ml out of 1 ml diluent will be used for single IM dose (0.5 ml) while 1 ml diluent will be used for 10 intradermal injections of 0.1 ml per site



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**Director of Drugs Control
Chennai-600 006**

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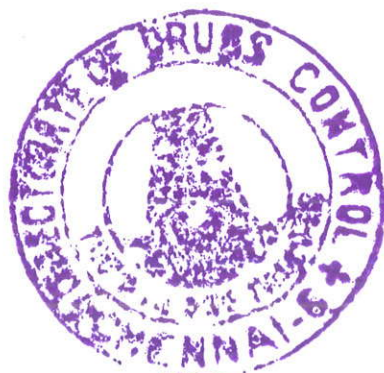
Dated: 25.01.2019

9. Rabies Vaccine B.P. 'Rab'

Rabies Vaccine for Human Use Prepared in Cell Cultures (Purified Vero Cell Rabies Vaccine)
(EXPORTS: Labeling to be done in different languages as per requirement of country of supply for Exports)
Abhayrab®
Purified lyophilized Rabies antigen derived from Rabies virus (L. Pasteur 2061/Vero Strain propagated in Vero Cells) Inactivated
Potency: ≥ 2.5 I.U. per vial
Stabilizer: Maltose and Human Albumin...q.s.
Preservative: Thiomersal 0.01% w/v
Pack size: 1.0 ml on reconstitution with accompanying 1 ampoule of 1.0 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. B.P.
Dosage: 1.0 ml single immunizing dose for Intramuscular Injection or 0.1 ml dose per site for Intradermal Injection

10. Rabies Vaccine B.P. 'Rab'

Rabies Vaccine for Human Use Prepared in Cell Cultures (Purified Vero Cell Rabies Vaccine)
(EXPORTS: Labeling to be done in different languages as per requirement of country of supply for Exports)
Abhayrab®
Purified lyophilized Rabies antigen derived from Rabies virus (L. Pasteur 2061/Vero Strain propagated in Vero Cells) Inactivated
Potency: ≥ 2.5 I.U. per vial
Stabilizer: Maltose and Human Albumin...q.s.
Preservative: Thiomersal 0.01% w/v
Pack size: 1.0 ml on reconstitution with accompanying 1 ampoule of 1.0 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.
Dosage: 1.0 ml single immunizing dose for Intramuscular Injection or 0.1 ml dose per site for Intradermal Injection



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Director of Drugs Control
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11. Rabies Vaccine, Human I.P.

(Purified Vero Cell Rabies Vaccine)

(FOR DOMESTIC and EXPORTS; Labeling to be done in different languages as per requirement of country of supply for Exports)

Pack size: 0.5 ml on reconstitution with accompanying 1 ampoule of 0.5 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.

Each combo-pack for Trade supplies contains

- a) 1 vial of **Rabies Vaccine, Human I.P.**
(Purified Vero Cell Rabies Vaccine)

Purified lyophilized Rabies antigen derived from Rabies virus (L. Pasteur 2061/Vero Strain propagated in Vero Cells) Inactivated

Potency: ≥ 2.5 I.U. per vial

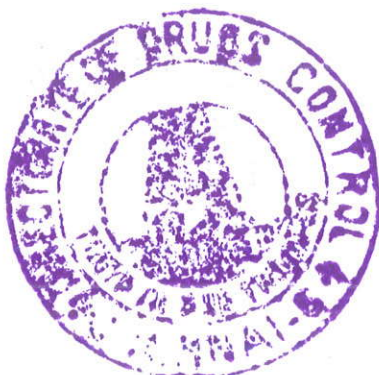
Stabilizer: Maltose and Human Albumin...q.s.

Preservative: Thiomersal 0.015% w/v

Pack size: 0.5 ml on reconstitution with accompanying 1 ampoule of 0.5 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.

Dosage: 0.5 ml single immunizing dose for Intramuscular Injection or 0.1 ml dose per site for Intradermal Injection.

- b) 1 ampoule of 0.5 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.
c) 1 no. of sterile disposable syringe with needle for Intramuscular Injection
d) 1 no. of Vaccination Card
e) 1 no. of Literature
f) 1 no. of Alcohol Swab



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Director of Drugs Control
Chennai-600 006

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K.Dis.No. 16284/D1/4/2018

Dated: 25.01.2019

12. Rabies Vaccine, Human I.P.

(Purified Vero Cell Rabies Vaccine)

(FOR DOMESTIC and EXPORTS; Labeling to be done in different languages as per requirement of country of supply for Exports)

Pack size: 0.5 ml on reconstitution with accompanying 1 ampoule of 0.5 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.

Each combo-pack for Trade supplies contains

- a) 1 vial of **Rabies Vaccine, Human I.P.**
(Purified Vero Cell Rabies Vaccine)

Purified lyophilized Rabies antigen derived from Rabies virus (L. Pasteur 2061/Vero Strain propagated in Vero Cells) Inactivated

Potency: ≥ 2.5 I.U. per vial

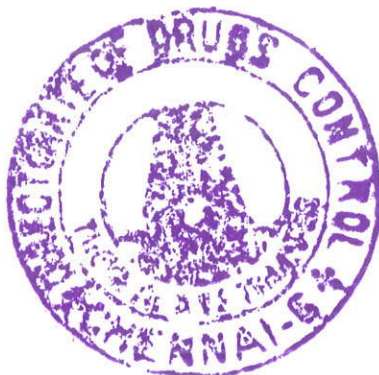
Stabilizer: Maltose and Human Albumin...q.s.

Preservative: Thiomersal 0.015% w/v

Pack size: 0.5 ml on reconstitution with accompanying 1 ampoule of 0.5 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.

Dosage: 0.5 ml single immunizing dose for Intramuscular Injection

- b) 1 ampoule of 0.5 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.
c) 1 no. of sterile disposable syringe with needle for Intramuscular Injection
d) 1 no. of Vaccination Card
e) 1 no. of Literature



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**Director of Drugs Control
Chennai-600 006**

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K.Dis.No. 16284/D1/4/2018

Dated: 25.01.2019

13. Rabies Vaccine, Human I.P.

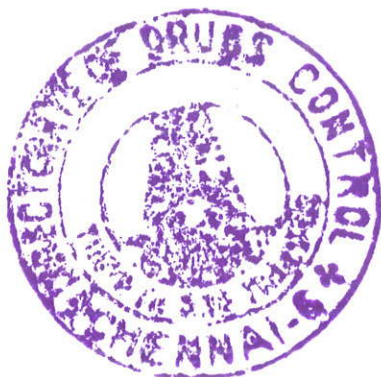
(Purified Vero Cell Rabies Vaccine)

(FOR DOMESTIC and EXPORTS; Labeling to be done in different languages as per requirement of country of supply for Exports)

Pack size: 0.5 ml on reconstitution with accompanying 1 ampoule of 0.5 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.

Each combo-pack for Trade supplies contains

- a) 1 vial of **Rabies Vaccine, Human I.P.**
(Purified Vero Cell Rabies Vaccine)
Purified lyophilized Rabies antigen derived from Rabies virus (L. Pasteur 2061/Vero Strain propagated in Vero Cells) Inactivated
Potency: ≥ 2.5 I.U. per vial
Stabilizer: Maltose and Human Albumin...q.s.
Preservative: Thiomersal 0.015% w/v
Pack size: 0.5 ml on reconstitution with accompanying 1 ampoule of 0.5 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.
Dosage: 0.5 ml single immunizing dose for Intramuscular Injection
- b) 1 ampoule of 0.5 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.
- c) 1 no. of sterile disposable syringe with needle for Intramuscular Injection
- d) 1 no. of Vaccination Card
- e) 1 no. of Literature
- f) 1 no. of Alcohol Swab



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**Director of Drugs Control
Chennai-600 006**

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25/1/19

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K.Dis.No. 16284/D1/4/2018

Dated: 25.01.2019

14. Rabies Vaccine B.P. 'Rab'

Rabies Vaccine for Human Use Prepared in Cell Cultures (Purified Vero Cell Rabies Vaccine)
(EXPORTS: Labeling to be done in different languages as per requirement of country of supply for Exports)

Abhayrab®

Pack size: 0.5 ml on reconstitution with accompanying 1 ampoule of 0.5 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. B.P.

Each combo-pack contains

- a) 1 vial of **Rabies Vaccine B.P. 'Rab'**
Abhayrab®

Purified lyophilized Rabies antigen derived from Rabies virus (L. Pasteur 2061/Vero Strain propagated in Vero Cells) Inactivated

Potency: ≥ 2.5 I.U per vial

Stabilizer: Maltose and Human Albumin...q.s.

Preservative: Thiomersal 0.01% w/v

Pack size: 0.5 ml on reconstitution with accompanying 1 ampoule of 0.5 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. B.P.

Dosage: 0.5 ml single immunizing dose for Intramuscular Injection or 0.1 ml dose per site for Intradermal Injection.

- b) 1 ampoule of 0.5 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. B.P.
c) 1 no. of sterile disposable syringe with needle for Intramuscular Injection
d) 1 no. of Vaccination Card
e) 1 no. of Literature
f) 1 no. of Alcohol Swab



**Director of Drugs Control
Chennai-600 006**

25/1/19

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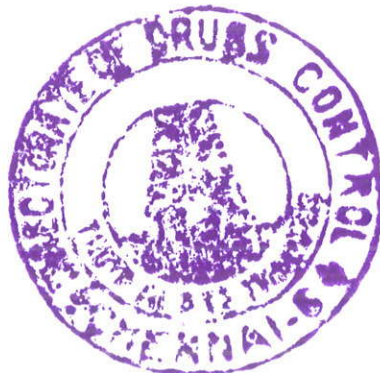
15. Rabies Vaccine B.P. 'Rab'

Rabies Vaccine for Human Use Prepared in Cell Cultures (Purified Vero Cell Rabies Vaccine)
(EXPORTS: Labeling to be done in different languages as per requirement of country of supply for Exports)
Abhayrab®

Pack size: 0.5 ml on reconstitution with accompanying 1 ampoule of 0.5 ml diluent for reconstitution:
0.9% w/v Sodium Chloride Inj. I.P.

Each combo-pack contains

- a) 1 vial of **Rabies Vaccine B.P. 'Rab' Abhayrab®**
Purified lyophilized Rabies antigen derived from Rabies virus (L. Pasteur 2061/Vero Strain propagated in Vero Cells) Inactivated
Potency: ≥ 2.5 I.U per vial
Stabilizer: Maltose and Human Albumin...q.s.
Preservative: Thiomersal 0.01% w/v
Pack size: 0.5 ml on reconstitution with accompanying 1 ampoule of 0.5 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.
Dosage: 0.5 ml single immunizing dose for Intramuscular Injection or 0.1 ml dose per site for Intradermal Injection.
- b) 1 ampoule of 0.5 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.
- c) 1 no. of sterile disposable syringe with needle for Intramuscular Injection
- d) 1 no. of Vaccination Card
- e) 1 no. of Literature
- f) 1 no. of Alcohol Swab



Santhosh
Director of Drugs Control
Chennai-600 006

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K.Dis.No. 16284/D1/4/2018

Dated: 25.01.2019

16. Rabies Vaccine, Human I.P.

(Purified Vero Cell Rabies Vaccine)

(FOR DOMESTIC and EXPORTS; Labeling to be done in different languages as per requirement of country of supply for Exports)

Pack size: 1.0 ml on reconstitution with accompanying 1 ampoule of 1.0 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.

Each combo-pack for Trade supplies contains

- a) 1 vial of **Rabies Vaccine, Human I.P.**
(Purified Vero Cell Rabies Vaccine)

Purified lyophilized Rabies antigen derived from Rabies virus (L. Pasteur 2061/Vero Strain propagated in Vero Cells) Inactivated

Potency: ≥ 2.5 I.U. per vial

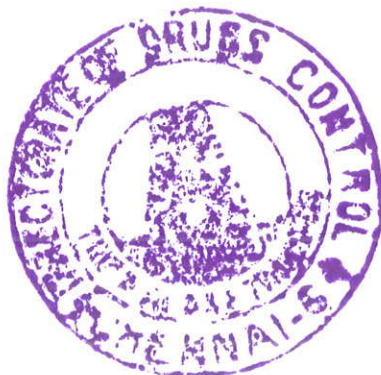
Stabilizer: Maltose and Human Albumin...q.s.

Preservative: Thiomersal 0.015% w/v

Pack size: 1.0 ml on reconstitution with accompanying 1 ampoule of 1.0 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.

Dosage: 0.5 ml out of 1 ml diluent will be used for single IM dose (0.5 ml) while 1 ml diluent will be used for 10 intradermal injections of 0.1 ml per site

- b) 1 ampoule of 1.0 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.
c) 1 no. of sterile disposable syringe with needle for Intramuscular Injection
d) 1 no. of Vaccination Card
e) 1 no. of Literature
f) 1 no. of Alcohol Swab



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**Director of Drugs Control
Chennai-600 006**

25/1/19

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25/1/19

LIST OF ALREADY PERMITTED ITEMS IN FORM 28D BEARING NO. 15, DATED 11.01.2000 OF M/S. HUMAN BIOLOGICALS INSTITUTE (A DIVISION OF M/S. INDIAN IMMUNOLOGICALS LIMITED), KOZHIPPANAI, PUDUMUND POST, DR. BASAVIAH NAGAR, UDHAGAMANDALAM – 643 007, ARE INCLUDED UNDER WHO GMP CERTIFICATE WHICH IS VALID UPTO 31.12.2021

K.Dis.No. 16284/D1/4/2018

Dated: 25.01.2019

17. Rabies Vaccine B.P. 'Rab'

Rabies Vaccine for Human Use Prepared in Cell Cultures (Purified Vero Cell Rabies Vaccine)
(EXPORTS: Labeling to be done in different languages as per requirement of country of supply for Exports)
Abhayrab[®]

Pack size: 1.0 ml on reconstitution with accompanying 1 ampoule of 1.0 ml diluent for reconstitution:
0.9% w/v Sodium Chloride Inj. B.P.

Each combo-pack contains

- a) 1 vial of **Rabies Vaccine B.P. 'Rab'**
Abhayrab[®]

Purified lyophilized Rabies antigen derived from Rabies virus (L. Pasteur 2061/Vero Strain propagated in Vero Cells) Inactivated

Potency: ≥ 2.5 I.U per vial

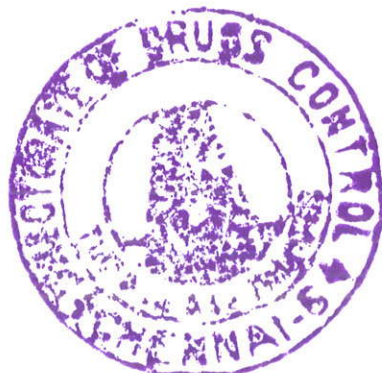
Stabilizer: Maltose and Human Albumin...q.s.

Preservative: Thiomersal 0.01% w/v

Pack size: 1.0 ml on reconstitution with accompanying 1 ampoule of 1.0 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. B.P.

Dosage: 1.0 ml single immunizing dose for Intramuscular Injection or 0.1 ml dose per site for Intradermal Injection.

- b) 1 ampoule of 1.0 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. B.P.
c) 1 no. of sterile disposable syringe with needle for Intramuscular Injection
d) 1 no. of Vaccination Card
e) 1 no. of Literature
f) 1 no. of Alcohol Swab



Can. A. 25/1

**Director of Drugs Control
Chennai-600 006**

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25/1/19*

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25/1/19*

LIST OF ALREADY PERMITTED ITEMS IN FORM 28D BEARING NO. 15, DATED 11.01.2000 OF M/S. HUMAN BIOLOGICALS INSTITUTE (A DIVISION OF M/S. INDIAN IMMUNOLOGICALS LIMITED), KOZHIPANNAI, PUDUMUND POST, DR. BASAVIAH NAGAR, UDHAGAMANDALAM – 643 007, ARE INCLUDED UNDER WHO GMP CERTIFICATE WHICH IS VALID UPTO 31.12.2021

K.Dis.No. 16284/D1/4/2018

Dated: 25.01.2019

18. Rabies Vaccine B.P. 'Rab'

Rabies Vaccine for Human Use Prepared in Cell Cultures (Purified Vero Cell Rabies Vaccine)
(EXPORTS: Labeling to be done in different languages as per requirement of country of supply for Exports)
Abhayrab®

Pack size: 1.0 ml on reconstitution with accompanying 1 ampoule of 1.0 ml diluent for reconstitution:
0.9% w/v Sodium Chloride Inj. I.P.

Each combo-pack contains

- a) 1 vial of **Rabies Vaccine B.P. 'Rab'**
Abhayrab®

Purified lyophilized Rabies antigen derived from Rabies virus (L. Pasteur 2061/Vero Strain propagated in Vero Cells) Inactivated

Potency: ≥ 2.5 I.U per vial

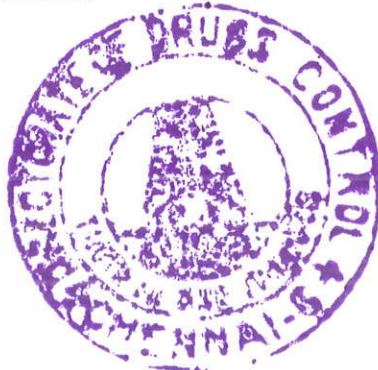
Stabilizer: Maltose and Human Albumin...q.s.

Preservative: Thiomersal 0.01% w/v

Pack size: 1.0 ml on reconstitution with accompanying 1 ampoule of 1.0 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.

Dosage: 1.0 ml single immunizing dose for Intramuscular Injection or 0.1 ml dose per site for Intradermal Injection.

- b) 1 ampoule of 1.0 ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. I.P.
c) 1 no. of sterile disposable syringe with needle for Intramuscular Injection
d) 1 no. of Vaccination Card
g) 1 no. of Literature
h) 1 no. of Alcohol Swab



(Handwritten signature)
Director of Drugs Control
Chennai-600 006

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25/1/19 *(Handwritten initials)*
25/1/19

LIST OF ALREADY PERMITTED ITEMS IN FORM 28D BEARING NO. 15, DATED 11.01.2000 OF M/S. HUMAN BIOLOGICALS INSTITUTE (A DIVISION OF M/S. INDIAN IMMUNOLOGICALS LIMITED), KOZHIPPANAI, PUDUMUND POST, DR. BASAVIAH NAGAR, UDHAGAMANDALAM – 643 007, ARE INCLUDED UNDER WHO GMP CERTIFICATE WHICH IS VALID UPTO 31.12.2021

K.Dis.No. 16284/D1/4/2018

Dated: 25.01.2019

19. Names (s) of drug (s): Purified Rabies Bulk Antigen (for Domestic)

Potency of formulated rabies vaccine: ≥ 2.5 IU/dose when stored in container.
Presentation: HDPE, 4L, STORAGE Bottle.

20. Names (s) of drug (s): Purified Rabies Bulk Antigen (for Export)

Potency of formulated rabies vaccine: ≥ 2.5 IU/dose when stored in container.
Presentation: HDPE, 4L, STORAGE Bottle.

21. Rabies Vaccine, Human I.P. (Purified Vero Cell Rabies Vaccine)

(For Domestic and Exports: Labeling to be done in different languages as per requirement of country of supply for Exports)

Purified lyophilized Rabies antigen derived from Rabies Virus (L.Pasteur 2061/Vero Strain propagated in Vero Cells) Inactivated

Potency: ≥ 2.5 I.U per vial

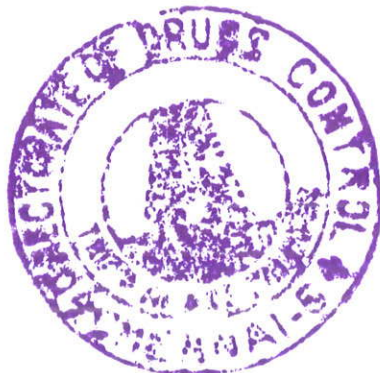
Stabilizer: Maltose and Human Albumin...qs

Preservative: Thiomersal 0.015%w/v

Pack Size: 1.0 mL on reconstitution with accompanying 1 ampoule of 1.0 mL diluent for reconstitution 0.9% w/v Sodium Chloride Inj. I.P.

Dosage: 1.0 mL single immunizing dose for Intramuscular Injection or 0.1 ml dose per site for Intradermal Injection.

Route of Administration: Intramuscular / Intradermal.



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Director of Drugs Control
Chennai-600 006

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25/1/19