NEEDS FOR ANTI-VENOM AND ANTI-RABIES SERA IN INDIA

BY

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ANTI-VENOM
MAP SHOWING THE GLOBAL DISTRIBUTION OF SNAKE BITE MORBIDITY
Snake envenoming is a common medical emergency encountered in the tropics. India estimates in the region of 200,000 bites and 15-20,000 snake bite deaths per year, originally made in the last century, are still quoted. No reliable national statistics are available. In 1981, a thousand deaths were reported in Maharashtra State. In the Burdwan district of West Bengal 29,489 people were bitten in one year with 1,301 deaths. It is estimated that between 35,000 and 50,000 people die of snake bite each year among India’s population of 980 million.

(Guidelines for the clinical management of Snake bites in the South-East Asia Region, WHO, 2005)
**TREATMENT**:

Anti-snake venom (ASV) is a specific antidote to snake venom actions. ASV is most prestigious and valued, India is the pioneer in the preparation of ASV, still there is no satisfactory data available regarding total amount of ASV required to reverse the clinical effects of venom in a particular case. However, the clinical features and outcomes are not as simple as predicted, because every bite does not result in complete envenomation.
ASV PRODUCTION AND AVAILABILITY:

Production of anti-venom in India is not adequate. In India, polyvalent ASV is available which contain antibody against cobra, russell’s viper, common krait and saw-scaled viper.

In India commercially produced ASV is relatively cheap as compared to Western countries. One vial of ASV costs Rs. 350-500 (8-12 US$). Majority of snake bite victims are reported to government hospitals because ASV is given free of cost.
ASV MANUFACTURING PROCESS

HYPERIMMUNISED EQUINE PLASMA

POOL & DILUTE WITH WFI TO ~2.5% PROTEIN

PEPSIN DIGESTION

PEPSIN (1:10,000) → 0.1% W/V
pH → 3.4 to 3.8
TEMPERATURE → 20 to 25°C
DURATION → 120 MIN.

STOP PEPSIN DIGESTION

AMM. SULPHATE → 13.5% W/V
TOLUENE → 0.2% W/V
pH → 4.4 to 4.8
TEMPERATURE → 56 to 58°C
DURATION → 30 MIN.

PRECIPITATION, HEATING
HOLDING & COOLING

FILTRATION

FILTRATE CONTAINING Fab

PRECIPITATE DISCARD

CONCENTRATION & DIAFILTRATION ON 30 KD ULTRAFILTRATION CARTRIDGE

ULTRAFILTRATE DISCARD

DESALTED & CONCENTRATED SERUM

SAMPLE FOR TESTING

Q.C. APPROVAL

BATCH FORMULATION

Q.C. APPROVAL
LIST OF ANTIVENOM MANUFACTURERS IN INDIA

1. Central Research Institute of Kasauli, HP*
2. Haffkine Biopharmaceutical Co., Mumbai, MS*
3. Serum Institute of India Ltd., Pune, MS*
4. VINS Bioproducts Ltd., Andhra Pradesh
5. Kings Institute of Preventive Medicines, Chennai*
6. Bharat Serums & Vaccines Ltd., Mumbai

* Approximately 5 lakh vials are produced annually.
ANTI-RABIES SERA

INTRODUCTION:
Rabies is practically a 100% fatal disease. In India about 30,000 persons contract rabies every year, more than two million people are exposed to animals, and about a million are administered anti-rabies vaccines, according to a report of the National Institute of Communicable Diseases, New Delhi. About 95 per cent of the bites are inflicted by stray dogs.

Recent WHO sponsored Indian Rabies Survey (2003-2004) provided an annual estimate of 20,000 human rabies deaths.
Anti-rabies Serum (ARS) of equine origin is indigenously produced mainly at Central Research Institute, Kasauli, Himachal Pradesh with an annual production of 120 liters. However, this is short of an estimated need of 1,500 liters.

The total supplies made by CRI, Kasauli are 41,295 ml between JAN. to OCT 2005 indicating shortages.
# RABIES IMMUNOGLOBULINS (RIGs) IN INDIA (MEDICAL)

## A. EQUINE (ERIGs)

<table>
<thead>
<tr>
<th>BRAND</th>
<th>PRODUCT</th>
<th>PHARMACEUTICAL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Anti-Rabies Serum (ARS)</strong></td>
<td>Purified equine RIGs, 5 ml vial (300 IU/ml) 1500 IU potency</td>
<td>Central Research Institute, Kasauli, HP</td>
</tr>
<tr>
<td><strong>2. CARIG</strong></td>
<td>Purified Equine RIGs’, 4 ml vial (300 IU/ml, 1200 IU potency)</td>
<td>Cadila Health Care Ltd., Ahmedabad</td>
</tr>
<tr>
<td><strong>3. Equirab</strong></td>
<td>Purified Equine RIGs, 5 ml vial (300 IU/ml 1500 IU potency)</td>
<td>Bharat Serums and Vaccines Limited, Mumbai</td>
</tr>
<tr>
<td><strong>4. Anti-Rabies Serum (ARS)</strong></td>
<td>Purified equine RIGs, 5 ml vial (300 IU/ml 1500 IU potency)</td>
<td>Haffkine Institute, Mumbai</td>
</tr>
<tr>
<td><strong>5. Anti-Rabies Serum (ARS)</strong></td>
<td>Purified equine RIGs, 5 ml vial (300 IU/ml 1500 IU potency)</td>
<td>Serum Institute of India Ltd., Pune</td>
</tr>
</tbody>
</table>
### B. HUMAN (HRIGs)

<table>
<thead>
<tr>
<th>BRAND</th>
<th>PRODUCT</th>
<th>PHARMACEUTICAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Berirab – P</td>
<td>Human Rabies Immunoglobulins, 150 IU/ml; 2ml (300 IU) ampoule and 5 ml (750 IU) ampoule.</td>
<td>Aventis Behring, Cadila Health Care</td>
</tr>
<tr>
<td>2. Imogamrab</td>
<td>Human Rabies Immunoglobulins, 150 IU/ml; 2ml (300 IU) ampoule and 5 ml (750 IU) ampoule.</td>
<td>Aventis Pasteur, France. Ranbaxy Pharma</td>
</tr>
<tr>
<td>3. Rabglob</td>
<td>Human Rabies Immunoglobulins, 150 IU/ml; 2ml (300 IU) ampoule and 5 ml (750 IU) ampoule.</td>
<td>Bharat Serums and Vaccines Limited, Mumbai.</td>
</tr>
<tr>
<td>4. Kamrab</td>
<td>Human Rabies Immunoglobulins, 150 IU/ml; 2ml (300 IU) ampoule and 5 ml (750 IU) ampoule.</td>
<td>Medlife, Thane.</td>
</tr>
</tbody>
</table>
Survey done by NICD, Delhi (2000) from 4 of its centers from urban communities revealed an incidence of animal bites of 2.1/1000 population/year

<table>
<thead>
<tr>
<th>City</th>
<th>Population Surveyed</th>
<th>Number of animal bites cases in last six months</th>
<th>6 month incidence per 1000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangalore</td>
<td>88469</td>
<td>85</td>
<td>0.96</td>
</tr>
<tr>
<td>Calicut</td>
<td>79169</td>
<td>20</td>
<td>0.25</td>
</tr>
<tr>
<td>Coonoor</td>
<td>43577</td>
<td>70</td>
<td>1.61</td>
</tr>
<tr>
<td>Rajamundry</td>
<td>71358</td>
<td>117</td>
<td>1.64</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>282573</strong></td>
<td><strong>292</strong></td>
<td><strong>1.03</strong></td>
</tr>
</tbody>
</table>

*Note: Estimated animal bites in India/year is 2.28 million*

THE IMMEDIATE REQUIREMENTS IN INDIA ARE:

• to increase the annual production of ARS.
• to intensify education programmes for doctors regarding post exposure treatment and proper use of vaccines and sera.
• to improve the facilities for better management of hydrophobia.
• to initiate surveillance on the control of rabies and trials of the newer anti-rabies vaccines.
Thank You