



## Development of new purified vero cell rabies vaccine (Rabivax-S) at the Serum Institute of India Pvt.Ltd.

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### Abstract

**Introduction:** TRabies is a 100% vaccine-preventable disease. Rabies disease still causes human deaths in the endemic areas in Asia and Africa. A cheap, rabies vaccine for humans that could be used in mass vaccination campaigns would be a valuable weapon against rabies. Serum institute of India Pvt. Ltd. has developed a new purified vero cell inactivated and lyophilized rabies vaccine (Rabivax-S) which is now a WHO prequalified rabies vaccine.

**Methodology, Theoretical Orientation & Findings:** Large scale production of Vero ATCC CCL81 cells were seeded in cell cube system. Then cells are infected with Pitman Moore (PM 3218) strain of rabies virus. After 48-72 hrs, infected cells are washed. The multiple harvests are collected from one cell cube system and clarified by filtration. Clarified harvest is concentrated using tangential flow filtration system. Inactivation of rabies virus is done using beta-propiolactone (BPL). Next step of purification is done by affinity column chromatography in order to remove BSA and host cell DNA and diafiltration to remove high salt concentration. Purified rabies antigen is prepared by adding stabilizer to diafiltered antigen and finally filtered by 0.22 micron filtration and stored in ethyl vinyl acetate bags. A number of purified rabies antigen bags are blended to achieve set antigen content in final bulk. The liquid vaccine is filled in 1 ml USP type 1 clear and tubular vial and lyophilized. With the lyophilized vial of rabies vaccine 1.0 ml of sterile water for injection is supplied as a diluents.

**Conclusion & Significance:** Study gives well developed new purified vero cell rabies vaccine (Rabivax-S), following all the GMP requirements. Animal study has demonstrated no toxicity issue. We evaluated its safety, toxicity and immunogenicity in post-exposure prophylaxis in clinical trials by IM and ID routes. This vaccine is good option among the available modern WHO prequalified rabies vaccine. Filling, lyophilization and packaging of final product.

### Biography:

Ashish Sahai has over 29 years of rich experience in the Biotechnological industry and Research Institute. He has experience in Research and Development, Quality Control, Quality Assurance,

Production of Vaccines. He has acquired experience in protein purification, molecular sieve chromatography, ion exchange chromatography, electrophoresis, affinity chromatography, polymerase chain reaction, hybridoma technology. He has specialization in downstream processing of viruses using affinity chromatography.