

## SII invents first ever heat stable Rotavirus vaccine

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### SII's Rotasiil receives patent from United States Patent and Trademark Office



In a landmark development, the world's largest vaccine manufacturer by number of doses produced and sold globally (more than 1.5 billion doses last year), Serum Institute of India (SII) and the National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health (USA), joined hands to create the first-ever heat-stable Rotavirus vaccine in the world.

Albert Z. Kapikian, M.D., a pioneering virologist at NIAID defined the mode of transmission of Rotavirus, identified the viral proteins critical for triggering an immune response, and formulated a vaccine that targeted several important Rotavirus strains. In 2005, NIAID and Serum Institute of India Pvt. Ltd. (SIPL) joined hands for the development of a Rotavirus Vaccine. The collaboration, through a license agreement, aimed at finding a solution that was not just affordable, but would reduce the operational difficulties faced by the poor countries for vaccine distribution and administration. Both parties were cognizant of the fact that the single biggest challenge faced by the distribution channel was the ability to maintain the vaccine under refrigeration. Costs associated with the maintenance of a cold chain can be in the region of 200 Million Dollars a year, which clearly adds to the cost of vaccination.

SII worked to develop a heat stable formulation to overcome this problem and Rotasiil®, is today the only Rotavirus vaccine to have the ability to withstand extreme temperatures. It can be stored at temperatures up to 25°C throughout its shelf life of 30 months, which makes Rotasiil® completely unique from other vaccines that require refrigeration for storage and transportation. The vaccine will revolutionize healthcare for children across the globe due to its potency, longevity and ability to endure severe changes in temperature, thereby reducing wastage and storage costs.

Introduction of the Rotasiil® vaccine, with its long shelf life and lack of need for refrigeration, is a timely boon for millions affected by Rotavirus. SII and NIAID's joint endeavor in creating the heat-stable Rotasiil® vaccine effectively fills the need, reducing costs and relieving bottlenecks in the vaccine supply-chain.

This breakthrough invention has also been awarded a patent for being the first-of-its-kind thermostable Rotavirus vaccine by

United States Patent and Trademark Office (USPTO).

In addition to the patent, Rotasiil® has also been assigned the VVM 250 label, which had to be specially developed for Rotasiil for its high heat stability. Accepted by the World Health Organization (WHO), the VVM250 label on Rotasiil® helps immunization managers across the world to store it at room temperature, while allowing excursion in temperatures during storage and transportation up to 39°C.

Speaking about this development, Mr. Adar Poonawalla, CEO of SII said, "Providing a healthy life to their children is the dream of every parent, and the thermo stabilizing of the Rotasiil® vaccine is one step towards that direction. Among all the barriers that led to decreasing of vaccine potency, heat-instability ranks highest causing the vaccine to become ineffective and therefore increasing wastage. Rotasiil® will help reduce misapplication, wastefulness, cost for logistics, increase availability and therefore, help millions more, lead a healthier life."

Adding to the above, Dr. Rajeev Dhere, Executive Director of SII said, "The enhanced penetration and increased longevity of the Rotasiil® vaccine will not only lead to more infants being protected but will also reduce the number of clinic visits and associated medical costs. Receiving a Patents for Humanity award, by the United States Patent and Trade Office is extremely prestigious for everyone associated with it, especially those of us at SII. In addition to the patent awarded, the development of the VVM label indicator is no less than a breakthrough achievement in our fight to eradicate this severe health hazard."

SII and NIAID, jointly developed the heat-stable Rotasiil® and received two prestigious awards in 2018. The Deal of Distinction award was given by Licensing Executive society of US and Canada (LES) for development of ROTASIIL®, a low-cost, temperature tolerant Rotavirus vaccine for developing countries in the category of Industry-University-Government Interface (IUGI) Sector. The Patent for Humanity award was given by the United States Patent and Trademark Office.

The Government of India is already using ROTASIIL in the Universal Immunization Programme. ROTASIIL is also available in India's private market. It is also exported to several countries.