

Name: Ms. Shalini Tewari

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Designation: Scientist Grade- III

Department: Quality Management Unit

Educational Qualification: M. Sc. (Biochemistry)

Year of Joining: 1995



Professional Experience: Contributed in setting up Quality Control laboratories for Recombinant Products and Vaccine Laboratories of the Institute. More than 26 years in Quality Control testing of Biologicals- Identity, Potency, Purity, Safety, Physical quality, as per specification and requirement in the QC testing as per the Pharmacopoeia monographs of finished drug product of Biologicals using reference standard of highest metrological traceability. Contributed in development of monographs for recombinant Human insulin, and various insulin analogs for Indian Pharmacopoeia. Received trainings in Laboratory Quality Management system and Internal Audit as per ISO/IEC 17025: 2005 and ISO/IEC 17025: 2017 technical requirements for testing and calibration, Occupational Health and safety standard 18001: 2007, HPLC with special reference to Quality Control testing of rh- insulin, Quality assurance & Quality Control, Biosafety aspects, (Biosafety Level- BSL-2), Quality Control aspect of Oral Polio Vaccine & Measles Vaccine. During the COVID-19 pandemic, development of country's first high throughput laboratory and management related to testing of the COVID-19 suspected Clinical Samples received at NIB through ICMR from various hospitals and Quarantine centres located different districts of Delhi- NCR, Uttar Pradesh (Aligarh, Baghpat, Bijnor, Bulandshehar, Gautambudh Nagar, Ghaziabad, Hapur, Meerut, Mujaffarnagar, Muradnagar & Saharanpur), Ladakh, Madhya Pradesh (Bhopal & Indore) and Rajasthan (Jodhpur).

Publications:

1. Cold chain monitoring of OPV at transit levels in India: correlation of VVM and potency status. R Jain, A K Sahu, S Tewari, N Malik, S Singh, S Khare, R Bhatia. Biologicals. 2003 Dec;31(4):237-44.
2. Establishment of the first international standard for PEGylated granulocyte colony stimulating factor (PEG-G-CSF): report of an international collaborative study. Meenu Wadhwa, Chris Bird, Thomas Dougall, Peter Rigsby, Adrian Bristow, Robin Thorpe, participants of the study. J Immunol Methods. 2015 Jan; 416:17-28.
3. Trend Analysis of Potency and Stability of Measles Vaccine in India, Manjula Kiran, Shalini Tewari, Jaipal Meena, Farha Hasan, Pragnya Shree Rath, Rashmi Srivastava, Gurminder Bindra, Subhash Chand, Harit Kasana, Neeraj Malik, Gul Raj Soni and Surinder Singh, International Journal of Current Research 2015, 7, (12), 24053-24056.
4. Evaluation of BCG Vaccine in Excessive Dermal Reactivity Test, Harit Kasana, Suchitra, Gunjan Sikarwar, Lavanyam Pathania, Shalini Tewari, Manjula Kiran, Neeraj Malik, G.R Soni and Surinder Singh, International Journal of Biomedical and Advance Research 2015, 6(11): 761-764.
5. Collaborative Study for the Establishment of First National Human Insulin Reference Standard, Gaurav Pratap Singh Jadaun, Renu Jain, Shalini Tewari,

- Tara Chand, Vandana Saklani, Shruti Dixit, Sudha V Gopinath, J P Prasad, Surinder Singh and Participants of the Study, *Inventi Rapid: Pharm Analysis & Quality Assurance*, 2016(1):1-4, 2015.
6. Comparative evaluation for safety & potency of inactivated Cell Culture Rabies Vaccines from four Indian manufacturers, Subhash Chand, Gurminder Bindra, Saurabh Vaishnav, Anupama Pandey, Ayush Karol, Faraz Sheikh, Jaipal Meena, Shalini Tewari, Manjula Kiran, Neeraj Malik, Shikha Yadav, G.R. Soni and Surinder Singh, *International Journal of Biomedical and Advance Research* 2016; 7(1): 012-016.
 7. Quality Evaluation of Rubella Vaccine used in India, Manjula Kiran, Shalini Tewari, Jaipal Meena, Farha Hasan, Ajay Kumar Ade, Gurminder Bindra, Subhash Chand, Neeraj Malik, Gul Raj Soni and Surinder Singh, *International Journal of Biomedical and Advance Research* 2016; 7(1): 027-030.
 8. Evaluation of Mirasol pathogen reduction system by artificially contaminating platelet concentrates with *Staphylococcus epidermidis*: A pilot study from India, Kabita Chatterjee, Shamsuz Zaman, Rahul Chaurasia, Surinder Singh, Shawn D. Keil, Shalini Tewari, Akanksha Bisht, Nitin Agarwal, Diptiranjan Rout, Subhash Chand, Kallol Saha, *Asian Journal of Transfusion Science*, 2016;10:127-31
 9. Sumit Malhotra, Manju Rahi, Payal Das, Rini Chaturvedi, Jyoti Chhibber-Goel, Anup Anvikar, Hari Shankar, C. P. Yadav, Jaipal Meena, Shalini Tewari, Sudha V. Gopinath, Reba Chhabra and Amit Sharma. Epidemiological profiles and associated risk factors of SARS-CoV-2 positive patients based on a high-throughput testing facility in India. *Open Biol.* (2021) 11: 200288