



राष्ट्रीय औषधीय शिक्षा एवं अनुसंधान संस्थान, अमदाबाद
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NATIONAL INSTITUTE OF PHARMACEUTICAL
EDUCATION AND RESEARCH (NIPER) - AHMEDABAD
(DEPT. OF PHARMACEUTICALS, MINISTRY OF CHEMICALS AND FERTILIZERS, GOI)

To,
Jury & Panel Members,

Sun Pharma Science Foundation Research Awards

Subject: **Endorsement of Research Work Submitted by Dr. Rakesh K. Tekade for Sun Pharma Science Foundation Research Awards**

Date: 08-09-2021

I introduce myself as **Prof. Kiran Kalia**, Director, **NIPER- Ahmedabad**.

I certify that the work entitled "Method and its Composition for encapsulation, stabilization, and delivery of siRNA in Anionic polymeric nanoplex: An *In vitro-In vivo* Assessment" was executed at NIPER-Ahmedabad under Principal Investigator Dr. Rakesh K. Tekade. He has been very productive with all his research projects, including this one. This project so far has generated **#1 Patent# 201921019898 (Date:20/05/2019)** and **#3 research papers** in reputed journals, including **NATURE: Scientific Reports, Molecular Pharmaceutics, and Int. J. Pharmaceutics**.

About the work – I state that the RNA interference technology that is using small interfering RNA (siRNA) as one of the potent therapeutics to knock down the abnormal gene to treat a disease at the cellular and molecular levels (#Gene therapy & Gene fixing). This technology is rapidly aging to be a futuristic and alternative treatment strategy. The clinical fraternity has still not realized the full benefit from this technology due to some limitations. Despite their high potency, specificity, and therapeutic potential, the full-fledged utility of siRNA is predominantly limited to *in vitro* setup.

To date, Onpattro is the only USFDA approved siRNA-based product available in the clinic. The lack of a reliable *in vivo* siRNA delivery system remains a foremost obstacle towards the clinical translation of siRNA therapeutics.

To address these problems, Dr. Tekade at NIPER-Ahmedabad has developed and tested a unique, simple, and clinically applicable dendrimer-templated polymeric technology involving a USFDA approved biopolymer (albumin) for *in vitro* as well as *in vivo* delivery of siRNA. There was a big disconnect between the *in vitro* success and *in vivo* failure of siRNA-directed gene therapy as per the literature. To fill this gap, Dr. Tekade has rightly developed this technology and has been tested using HDAC4-siRNA as a model therapeutics. At the same time, the application can also be extended to other gene therapeutics, including microRNA (miRNA), plasmids oligonucleotides, etc.

The developed approach is simple, clinically translatable, rightly resolves the issue of serum instability, avoids *in vivo* RNase-degradation, and mediates cytosolic delivery of siRNA following the endosomal escape process. The successful *in vitro* and *in vivo* delivery of siRNA and targeted gene knockdown potential were demonstrated by HDAC4 inhibition in *vitro* diabetic nephropathy (DN) podocyte model as well as *in vivo* DN C57BL/6 mice model.

I uprise Jury members that the siRNA delivery system (also known as Transfecting reagents) has a vast market (1000 million US\$; expected to rise to 1500 million US\$ by 2025). This work by Dr. Tekade reports the development of a cost-effective as well as a simple mix-and-deliver type transfecting reagent to offer a viable *in vivo* applicable alternative to marketed Lipofectamine 2000™ to fill the gap in existing transfection technology (**Patent: # 201921019898; Date:20/05/2019**)

The output from this project is an example for my team at NIPER-Ahmedabad and all emerging researchers across India. The current progress of this project outcome is because of his hardship, critical understanding of the problem, and persistent effort.

I am delighted with the scientific honors of Dr. Rakesh K. Tekade. Backed by his accomplishments and services to the Pharma community, **I recommend Dr. Rakesh K. Tekade for the Sun Pharma Science Foundation Research Awards** with absolute confidence.

If you need any other information regarding his application, please do not hesitate to contact my office: director@niperahm.ac.in or write me at: kirankalia@gmail.com

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