Executive Summary

Name: Prof. Vandana B. Patravale

Current designation: Senior Professor of Pharmaceutics, Department of Pharmaceutical Sciences and Technology, Institute of Chemical Technology, Nathalal Parekh Marg, Matunga, Mumbai-400019, Maharashtra, India

1. Title of the Project

Development of drug-eluting coatings for self-expandable peripheral stent for the treatment of in-stent restenosis

2. Date of Start of the Project

Date awarded: October 01, 2021.

3. Aims and Objectives

Aim: To develop self-expandable peripheral stent for the treatment of in-stent restenosis.

Objectives:

1. Development of mTOR inhibitor- biodegradable polymer coating on self -expandable peripheral stents for prolonged release.
2. Development of nanoparticles-based coating on self expandable peripheral stents for release of mTOR inhibitor for over a year
3. Patenting and technology transfer

4. Significant achievements (not more than 500 words to include List of patents, publications, prototype, deployment etc.)

In the third year, we have accomplished the following:

1. The prototype of the nanoparticles-coated peripheral stent has been developed. A representation of this prototype is illustrated in Figure 1. Notably, we achieved a high drug loading on the stent, which resulted in a reduced polymeric load on the stent with uniform coating, and a coating time of less than 5 minutes.

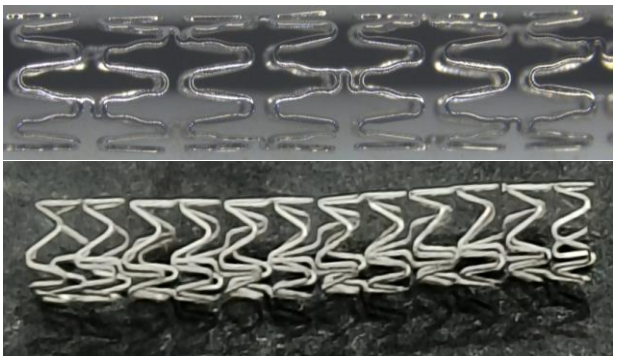

Figure 1. A. Bare metal stent and B. Nanoparticles coated stent

2. Published two research articles in an Elsevier journal based on research outcomes from the past year, with impact factors of 4.5 and 5.3.
    I. S.A. Jadhav, A.J. Raval, A.B. Jariwala, C.B. Engineer, V.B. Patravale, Sirolimus micro/nano particles coated drug-eluting stents using QbD paradigm: Potential approach for the amelioration of arterial diseases, Journal of Drug Delivery Science and Technology 95 (2024) 105629. https://doi.org/10.1016/j.jddst.2024.105629.
    II. S.A. Jadhav, A.J. Raval, A.B. Jariwala, C.B. Engineer, J. Tailor, V.B. Patravale, *In vitro* drug release profiling of Sirolimus polymeric microparticles coated long-acting stents, International Journal of Pharmaceutics (2024) 124572. https://doi.org/10.1016/j.ijpharm.2024.124572.

3. *In vitro* cell line studies, including safety, efficacy, and quantitative cellular uptake, have been completed.
4. A collaborative institute has been identified for *in vivo* cell line studies to achieve other milestones of the project, and the animal study protocol has been finalized.

5. Concluding remarks

The project is going as per the time line. *In vitro* cell line studies demonstrated excellent safety and efficacy the developed nanoparticles. A collaborative institute has been identified for *in vivo* cell line studies to achieve other milestones of the project, and the animal study protocol has been finalized. We are currently facing difficulties in managing and securing funding for *in vivo* studies.