

Patient Information Sheet & Patient Consent Form

“A randomized controlled trial to study the immunogenicity and safety of Curvic[®] in vaccinated population for COVID-19”

Trial ID: SSV-SF-01/2021

Version 1, dated 09th Mar 2021

Sr. No	Amendment No	Date
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Principal Investigator

Dr. Yogita Gaikwad, MD

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Sponsor**Shreepad Shree Vallabh SSV Phytopharmaceuticals**

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I, _____, exercising my free power of choice, hereby give my consent to be included as a subject in the study of, **“A randomized controlled trial to study the immunogenecity and safety of Curvic® in vaccinated population for COVID-19.”**

I have been informed to my satisfaction by the attending Doctor; the purpose of the study; laboratory investigations which I will be expected to undergo. I have also been informed about the nature of the drug treatment.

I have been given the opportunity by the attending doctor to question on all aspects of the study and have understood the advice and information given as a result.

I have already informed the doctor about the medications I was consuming & also about the drug studies I have participated in the last 6 months.

I agree to fully cooperate with the supervising doctor, and to inform him/her immediately in case I suffer from any unusual manifestations during the study.

I understand that the information related to my participation in the study including the medical records will remain confidential except when they will be required to be provided by the law.

I hereby give permission to the doctor's in charge of this study to release the information regarding or obtained as a result of my participation in this study to SSV Phytopharmaceuticals Pvt Ltd.; including its agents and contracts; national and international regulatory bodies and Governmental agencies and to allow them to inspect all my medical records.

I am also aware of my right to opt out of the study at any time during the course of the study without having to give the reasons for doing so.

Signature/Thumb Impression of the patient

Date:

Signature of witness

Date:

(Relation with the Patient)

Signature of the physician

Date: