



SHRI CHHATRAPATI SAMBHAJI SHIKSHAN SANSTHA'S
SITABAI THITE COLLEGE OF PHARMACY

Approved by, PCI, DTE,

Affiliated to Savitribai Phule Pune University (ID No. PU/PN/Pharma/174/2001)



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Ex.Member of Parliament (Baramati)
Founder President

REPORT ON “Certification Course on Pharmacovigilance and Clinical Research”

Activity Name: - Certification Course on Pharmacovigilance and Clinical Research

Date: - 17/07/2018 to 13/10/2018

Time: -9:30 am to 12:30 pm

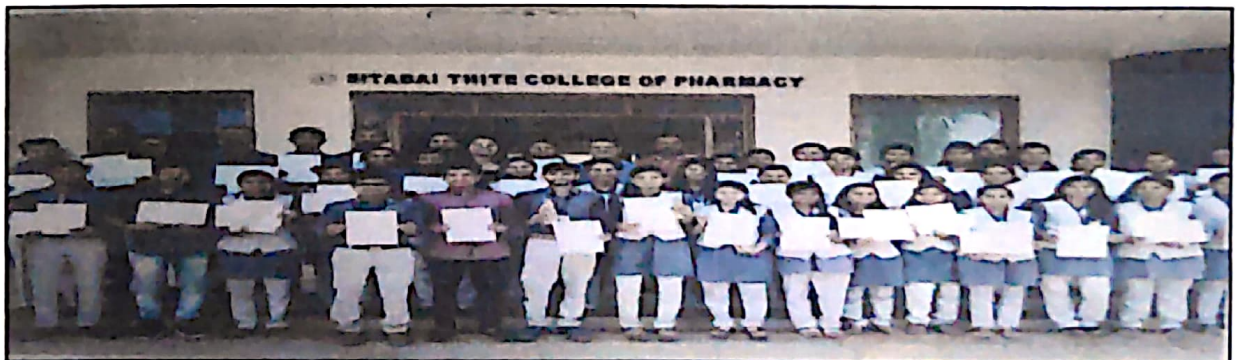
Organized for (student class):- Final Year

Details of Speaker (Name/Affiliation): -Mr. Nilesh Gadekar, Mrs. Archana Gawade

Coordinator Name: Ms. Bhagyashree Talole

Description of Activity (Detail, Attendance, etc.):

- Certification course was conducted offline from July 17 to October 13, 2018.
- Topics covered: - **Clinical Research, Phases of Clinical trial, Introduction to PV, History of GCP, ICH-GCP Guidelines, Schedule Y, ICMR Guidelines, Signal Management, Pharmacovigilance Data Management and Case Processing, McDRA Dictionary, ADR Reporting System, Institutional Ethics committee, ICH Guidelines for Drug Safety, Periodic Safety update Report, Good Pharmacovigilance Practice, Clinical Trial Design, Conduct of Study, Introduction to Clinical Data Management, Data Safety Monitoring Board, Training Program for Development of Interview Skills.**
- Total 52 students actively participated in the session and found the session to be of great value addition.



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'Nurturing Pharmacy Professionals Through Value Based Education'



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