SRI MUTHUKUMARAN MEDICAL COLLEGE
HOSPITAL AND RESEARCH INSTITUTE
(Affiliated to the Tamil Nadu Dr.M.G.R. Medical University)
Chikkarayapuram, Near Mangadu, Chennai - 600069
Ph: 044 - 66344044, 66344000 Fax: 66344055, 66344050
E-Mail : smmchri2009@gmail.com, smmchri@yahoo.com
Website : www.smmchri.res.in

PHARMACOVIGILANCE COMMITTEE

STANDARD OPERATING PROCEDURE

Purpose:

The Pharmacovigilance Committee serves the predominant function of ensuring the safety and efficacy of pharmaceutical products marketed or under development. This SOP outlines the responsibilities, procedures, and guidelines for the operation of the Pharmacovigilance Committee.

Responsibilities:

- The Pharmacovigilance Committee is responsible for overseeing the safety profile of pharmaceutical products.
- Reviewing and evaluating adverse event reports and other safety-related information to assess the potential risks associated with pharmaceutical products.
- Recommending appropriate risk minimization measures and regulatory actions based on safety data analysis.
- Collaborating with relevant stakeholders, including regulatory authorities, healthcare professionals, and marketing authorization holders, to address safety concerns and implement risk management strategies.
- The Pharmacovigilance Committee shall prepare periodic safety reports summarizing adverse event data, signal detection activities, and risk management initiatives.
- Reports shall be submitted to relevant regulatory authorities in accordance with regulatory requirements.
- The Pharmacovigilance Committee shall ensure that all relevant personnel receive appropriate training on pharmacovigilance principles, regulations, and procedures.

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- Awareness programs shall be organized to promote a culture of safety and vigilance within the organization.
- All pharmacovigilance activities, including adverse event reports, meeting minutes, and safety assessments, shall be appropriately documented and maintained in accordance with applicable regulations and company policies.
- Records shall be kept confidential and accessible only to authorized personnel
- Submission of Adverse Drug Reaction Forms from all departments.
- Supervision of use of Antibiotics in Clinical side.

Meetings:

- The Pharmacovigilance Committee shall meet regularly, at least twice in a yearto review safety data and discuss pharmacovigilance-related matters.
- An agenda shall be circulated prior to each meeting, outlining the topics to be discussed and any materials to be reviewed.
- Minutes of the meeting shall be documented, including decisions made, action points, and follow-up activities.

COMMITTEE MEMBERS:

S.NO	NAME OF THE FACULTY	DESIGNATION	POSITION HELD
1.	Dr.Jayanthi.R	Dean	Chairperson
2.	Dr.P.Durairajan	Professor & HOD,Pharmacology	Co-Chairperson
3.	Dr.M.Rajesh	Professor, Pharmacology	Member Secretary/ coordinator
4.	Dr.M.Shamini	Senior Resident, Pharmacology	Member
5.	Dr. Sowmya	Professor, MicroBiology	Member
6..	Dr.Swetha	Associate Professor, Community Medicine	Member

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7.	Dr.Alagammai	Assistant Professor,Dermatology	Member
8.	Mrs.Thangamariyammal	Nursing Superintendent	Member

DOCUMENTATION AND RECORD KEEPING

MAINTENANCE RECORDS

Maintain accurate and up-to-date records of all activities.

REVIEW AND REVISION

Periodically review the SOP to ensure its relevance and effectiveness.

Revise the SOP as needed to accommodate changes

APPROVAL

This SOP is approved by the Dean and will be reviewed annually or as required.

Smitha M.

IQAC COORDINATOR

DEAN

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