EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
http://www.ejbps.com

ISSN 2349-8870
Coden USA: EJBPBO
Volume: 13
Issue: 3
Year: 2026

ENSURING DRUG SAFETY: A REVIEW OF PHARMACOVIGILANCE PRACTICES

[1*]Dr. Tripuramallu Rajithasree, [2]Vitrouth Akshitha, [3]Thudi Deekshitha Reddy, [4]Aiyesha Ahsan, [5]Dr. Chandrasekhara Rao Baru

*[1]Assistant Professor, Department of Pharmacy Practice, Chilkur Balaji College of Pharmacy, RVS Nagar, Aziz Nagar, Hyderabad, 500075.
[2,3,4]Student, Department of Pharmacy Practice, Chilkur Balaji College of Pharmacy, RVS Nagar, Aziz Nagar, Hyderabad, 500075.
[2]Principal, Department of Pharmaceutics, Chilkur Balaji College of Pharmacy, RVS Nagar, Aziz Nagar, Hyderabad, 500075.

***Corresponding Author: Dr. Tripuramallu Rajithasree**
Assistant Professor, Department of Pharmacy Practice, Chilkur Balaji College of Pharmacy, RVS Nagar, Aziz Nagar, Hyderabad, 500075.

DOI: https://doi.org/10.5281/zenodo.18796112

How to cite this Article: [1*]Dr. Tripuramallu Rajithasree, [2]Vitrouth Akshitha, [3]Thudi Deekshitha Reddy, [4]Aiyesha Ahsan, [5]Dr. Chandrasekhara Rao Baru. (2026). Ensuring Drug Safety: A Review Of Pharmacovigilance Practices. European Journal of Biomedical and Pharmaceutical Sciences, 13(3), 59–64.

Article Received on 30/01/2026 **Article Revised on 19/02/2026** **Article Published on 01/03/2026**

ABSTRACT
Pharmacovigilance (PV) is an essential aspect of contemporary healthcare systems that concentrates on identifying, evaluating, comprehending, and preventing adverse drug reactions (ADRs) as well as other issues related to medications. As drug therapies grow more complex and the utilization of medicines becomes widespread, maintaining drug safety during the entire product life cycle has emerged as a significant public health concern. Past incidents involving drug-related harm, such as the toxicity of sulfanilamide and birth defects caused by thalidomide, have underscored the need for organized systems to monitor drug safety. This review highlights the global and Indian progress in pharmacovigilance, pointing out important milestones, regulatory frameworks, and national initiatives like the Pharmacovigilance Programme of India (PvPI). The article examines the scope, significance, and goals of pharmacovigilance, different types of ADRs, mechanisms for reporting ADRs, assessment scales, and the critical role of healthcare professionals, especially pharmacists, in reporting ADRs. It also addresses methods to enhance ADR reporting and the incorporation of digital tools into pharmacovigilance. Ongoing monitoring, efficient reporting systems, and cooperative efforts among healthcare professionals and regulatory bodies are crucial for improving patient safety, reducing drug-related risks, and promoting the rational use of medicines.

KEYWORDS: Pharmacovigilance; Adverse Drug Reactions; Drug Safety; ADR Reporting; PvPI; WHO-UMC; Pharmacist Role; Post-Marketing Surveillance; Risk–Benefit Assessment.

INTROCUCTION
The Greek word phannacon, referring to a drug or medical substance, and the Latin word Vigilare, which stands for "to keep watch", are part of the etymology making up the term "pharmacovigilance."1. "The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problem, particularly long- and short-term adverse effects of medicines," defines pharmacovigilance, according to the World Health Organization. Adverse drug reactions, or ADRs, defined as an unwanted and harmful response to a medication, including lack of efficacy when used for prophylaxis, analysis, or therapy, or to modify physiological function, are a major focus of pharmacovigilance. The Federal Food, Drug, and Cosmetic Act was established in 1938, after sulfanilamide elixir, which contains diethyl glycol as the solvent, was linked to more than 100 deaths in the United States, founding the first governmental organisation dedicated to pharmacovigilance. It has become increasingly challenging to maintain public trust while optimising medicine safety. At each step of a product's lifecycle, from development to post-market, the active estimation and management of drug risk are

required by pharmaceutical and biotechnology businesses. ADRs, or adverse drug reactions, are of special importance to PV since these can occur at levels that are normally utilised for illness diagnosis, treatment, prevention or physiological function alteration to guarantee maximum benefits and minimum dangers, continuous monitoring is necessary regarding the pharmacological effects, side effects, contraindications, and overtly adverse effects that may result in a significant degree of morbidity, and under certain circumstances even mortality. No amount of caution and care throughout the pre-clinical and clinical testing phases can ensure the absolute safety of a drug when it is marketed and prescribed to huge populations both inside and outside of the country. Less common side effects and ADRs often are not known at the time a medication hits the market because several thousand individuals generally participate in clinical trials. Post-marketing PV uses technologies such as data mining and investigation of case reports to uncover the links between medicines and ADRs. It is the responsibility of the drug regulatory bodies to ensure a dependable PV system for monitoring ADRs, both in the early stages of drug development and later in the life of a marketed product. Pharmacovigilance underpins the safe and appropriate use of drugs by

a. Promoting the identification of previously unknown ADRs and interactions,
   along with a growth in the frequency of known ADR s.
   Detecting the risk factors that may lead to ADRs, an d
b. Quantitative evaluation of benefit/risk factors and ex changing data to improve medication prescription an d regulation.[1]

HISTORICAL BACKGROUNDS

The first time this approach was used was in the early 1980s in the field of drug safety during pregnancy. The question of a possible relation between valproic acid and spina bifida aperta was investigated by Robert after a cluster of case reports in France from the Birth Defects Monitoring system in the Rhone-Alpes region (East France). Robert compared exposure to valproic acid in 146 women with infants suffering from spina bifida aperta and in 6616 other mothers with infants suffering from different malformations. They found a strong, significant association, with an odds ratio of 20 and a P value <0.00001. This approach, called ‘case–control study’ in the original paper, was really the first performed case–noncase study. Following this first signal, further studies confirmed the teratogenicity of valproic acid in the first trimester of pregnancy.

The second historical example was the investigation of a possible higher risk of serum-sickness-like syndrome related to cefaclor. Following the report of a number of cases in the early 1990s, Stricker and Tijssen conducted a ‘nested case–control study’ in the WHO Collaborating Centre for International Drug Monitoring Database, including reports from the USA, UK, Sweden, Canada, and Germany for the period 1968–1987. They defined an ADR reporting odds ratio (ROR) as the ratio of the odds of the number of ADR reports of serum sickness in relation to cefaclor and amoxicillin or cephalexin and the odds of other reports on the same drugs. With this case–noncase approach, they were able to identify that cefaclor had a significantly higher risk for serum-sickness-like syndrome compared with the two other antibiotics.[2]

The sequential pharmacovigilance developments with special reference to India

- In 1747, James Lind developed the first known clinical trials by James Lind, proving the usefulness of lemon juice in preventing scurvy.
- In 1937, to was the Death of more than 100 children due to the toxicity of sulfanilamide.
- In 1950, to developed aplastic anemia was developed due to chloramphenicol toxicity.
- In 1961 to developed World worldwide tragedy developed due to thalidomide toxicity.
- In 1963, to developed 16th World Health Organization recognized the significance of rapid action on Adverse Drug Reactions (ADRs).
- In 1968 to developed WHO research project was developed for international drug monitoring on a pilot scale.
- In 1996, to develop Global standards, level clinical trials were initiated in India.
- In 1997 to India developed an attachment with the WHO Adverse Drug Reaction Monitoring Program.
- In 1998, to develop the Initiation of pharmacovigilance in India.
- In 2002, to developed 67th National Pharmacovigilance Center was established in India.
- In 2004 -05 to India developed and launched the National Pharmacovigilance Program.
- In 2005, to develop the Accomplishment of structured clinical trials in India.
- In 2009 -10, to development Pharmacovigilance Program (PvPI) started.
- 2010 – Pharmacovigilance Programme of India (PvPI) launched by the Ministry of Health and Family Welfare.
- 2011 – National Coordination Centre (NCC) established at AIIMS.
- 2014 – Expansion of ADR Monitoring Centres (AMCs) across government and private hospitals.
- 2017 – NCC shifted from AIIMS to the Indian Pharmacopoeia Commission (IPC), Ghaziabad.
- 2018 – Launch of the Materiovigilance Programme of India (MvPI) for medical devices.
- 2019-Integration of PVPI with national public health programmes– Strengthening of spontaneous ADR reporting.
- 2020 – Strengthening of vaccine pharmacovigilance during the COVID-19 pandemic.

- 2021– Introduction of AEFI surveillance for COVID-19 vaccines– Digital ADR reporting via mobile apps and helplines.
- 2021– Introduction of AEFI surveillance for COVID-19 vaccines– Digital ADR reporting via mobile apps and helplines.
- 2023 – Focus on signal detection, risk communication, and regulatory decision-making.
- 2024 – Strengthening of quality reporting, data analytics, and international collaboration with WHO-UMC.
- 2025– PvPI functioning as a mature national pharmacovigilance system – Coverage includes drugs, vaccines, medical devices, biologicals, and patient safety initiatives – Continued expansion of AMCs and digital reporting platforms.[3]

ADR Type	Name	Characteristics	Example
Type A	**Augmented**	Dose-dependent, predictable, related to pharmacological action; most common	Hypoglycaemia (insulin), bleeding (warfarin), nephrotoxicity (aminoglycosides)
Type B	**Bizarre**	Dose-independent, unpredictable, often immunologic or idiosyncratic	Anaphylaxis (penicillin), Stevens–Johnson syndrome (sulphonamides), aplastic anaemia (chloramphenicol)
Type C	**Chronic**	Dose- and time-related; occurs with long-term use	Adrenal suppression (corticosteroids), analgesic nephropathy (NSAIDs)
Type D	**Delayed**	Appears after a prolonged time, even after stopping the drug	Teratogenicity (thalidomide), carcinogenesis (alkylating agents)
Type E	**End of use**	Occurs after sudden drug withdrawal	Rebound hypertension (clonidine), seizures (benzodiazepines)
Type F	**Failure of therapy**	Unexpected lack of therapeutic effect	Oral contraceptive failure (rifampicin), antibiotic resistance

AIMS OF PHARMACOVIGILANCE

a. Improve patient safety and treatment quality in the case of drug administration and other medical and paramedical procedures.
b. Assess the efficiency of drugs and follow their adverse effects from the laboratory to the pharmacy for many years.
c. Track any life-threatening effects of drugs. Improve public health and safety in the context of drug administration.
d. Be involved in the assessment of the risk, profit, and effectiveness of drugs, and advocate their safe, intelligent, and more productive and economical use.
e. Facilitate the understanding, education, and practical training in pharmacovigilance and communicate it effectively to the people**.**

SCOPE OF PV

PV is a booming concept dealing with chemical, botanical, and biological medicines, including medical devices. Information about suspect products is collected from healthcare providers and patients to detect and prevent abnormalities associated with them. Therefore, PV deals with the adverse effects of drugs and polypharmacy, paradoxical reactions, and severe adverse events. It also encompasses vaccination failure, irrational use, and lack of efficacy, drug interactions. poisoning, overdose, abuse, medication errors, and misuse of drugs.

IMPORTANCE OF PV

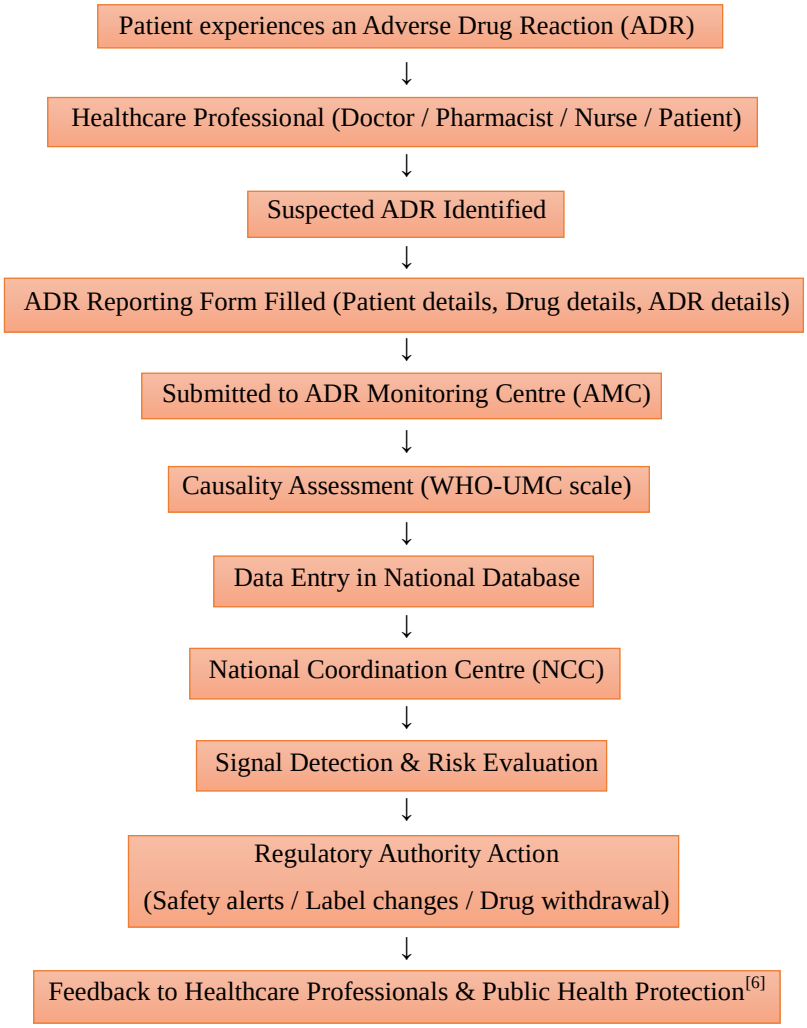
A new medicine launched without studies on its safety in the long run may not claim to be therapeutically safe and effective, and may show harmful or life-threatening effects. A few decades ago in India, the safety evaluation of a drug was based on the chronic use of the drug. But this practice was not accurate and failed to claim complete safety. Considering this fact, many Indian organizations or research funding bodies started investing in individual drug research and launching new products. Once the product is developed, new information tends to be generated, which may be positive or negative and impact the risk-benefit profile of that product. A complete study or assessment of newly generated information with the help of a PV system is essential to protect public health. The adverse effects of drugs may lead to morbidity or mortality, and the study of which is essential for minimizing risks and maximizing benefits. In the face of recent high-profile drug withdrawal, the pharmaceutical company and regulatory authorities are strictly focusing on the safety of a drug in the market, i.e., PV.[4]

LIST OF CENTRAL DRUG STANDARD CONTROL ORGANISATION (CDSCO) Zonal and Sub-Zonal Offices

- Zonal Centre-Ahmadabad
- Zonal Centre-Hyderabad
- North Zonal Centre-Ghaziabad a) Sub-Zone Office-Ghaziabad b) Chandigarh, c) Sub-Zonal Office, Jammu
- East Zonal Centre-Kolkata-Air Port and Sea Office, Kolkata
- West Zonal Centre-Mumbai-Air Port and Sea Office, Mumbai, Jawaharlal Nehru Port Office, Navi Mumbai

- South Zonal Centre-Chennai a) Airport and Sea Office, b) Sub-Zonal and Port Office, Chennai, c) Port Office, Kochi, Bangalore.[5]

TYPES OF ADRS
ADR REPORTING



ROLE OF THE PHARMACIST IN ADR REPORTING

The role of pharmacists in reporting adverse drug reactions (ADRs) has undergone significant changes over the last decade, although it still varies from one region to another. In Scandinavian nations, for instance, pharmacists were previously prohibited from independently reporting ADRs over a decade ago. In the United Kingdom, it took a lengthy ten-year debate before pharmacists were permitted to report ADRs on their own. On the other hand, in 2010, pharmacists in Malaysia were responsible for more than half of all ADR reports sent to the Malaysian National Pharmacovigilance Center. A global survey in 2004 involving member states within the WHO Drug Monitoring program also revealed notable differences in the responsibilities of pharmacists concerning ADR reporting. The discrepancies in pharmacists' participation in pharmacovigilance activities can be understood through the varied roles they play within health care systems worldwide, ranging from simple "dispensers" to key players in ensuring drug safety and patient welfare. As pharmacists' responsibilities continue to evolve in healthcare environments, their involvement in ADR reporting is becoming increasingly acknowledged. Research indicates that hiring pharmacists in public hospitals can effectively identify and report ADRs as well as prevent them, thus minimizing human and financial costs related to these reactions. Additionally, hospital pharmacists tend to report ADRs more than community pharmacists do. This may be because pharmacists with clinical training are usually more informed about the ADR reporting system and often collaborate with prescribers. Moreover, regular interactions with patients and access to their medical histories enable clinical pharmacists in hospitals to gain a deeper insight into potential ADRs. Nevertheless, community pharmacists play a vital role in ensuring drug safety by identifying and reporting ADRs, particularly in regions where access to general practitioners or primary healthcare providers is limited.

STRATEGIES TO IMPROVE ADR REPORTING

As a general guideline, approaches to enhancing ADR reporting should focus on both the system of healthcare and the individual pharmacist. Beyond motivating pharmacists to report ADRs, addressing their knowledge and skills deficits related to recognizing and reporting ADRs should be achieved through ongoing professional development programs. Research indicates that providing continuous education to healthcare workers plays a key role in altering their actions and views regarding ADR reporting. The purpose of this education should not just be to enhance pharmacists' understanding of ADRs, but also to influence their perspectives and attitudes toward reporting. Additionally, studies have found that greater training correlates with a higher probability of ADR reporting. Offering non-monetary rewards, such as recognition certificates, to pharmacists who report ADRs is another strategy for boosting spontaneous ADR reporting.

At the healthcare system level, to involve community pharmacists more actively in ADR reporting, granting them access to patients' medical and medication histories will assist pharmacists in determining the cause of ADRs and reporting them, as the inability to establish causation discourages pharmacists from making reports. Evidence from research also indicates that electronic ADR tools can enhance the spontaneous reporting of ADRs. The introduction of an electronic ADR reporting system alongside the hospital information system at a 400-bed hospital in Spain resulted in a rise in the number of ADR reports sent to the pharmacovigilance centre. This integrated ADR tool facilitated easier analysis of the submitted ADR reports and provided automatic alerts of possible allergies to the allergy department. The effectiveness of electronic reporting in boosting spontaneous ADR reports has also been observed in a children's hospital in the UK. This study aimed to evaluate the effects of electronic reporting and monitoring of ADRs in children and to see if it could complement the traditional Medicines and Healthcare Products Regulatory Agency Yellow Card reporting system used in the UK. Throughout the study, ADR reports were submitted through the electronic method, as opposed to a mere 8 reports submitted through the Yellow Card system, highlighting the advantages of the electronic system over the conventional paper-based method.[7]

ADR ASSESSMENT SCALES

Assessment of causality

World Health Organization (WHO)–Uppsala Monitoring Centre (UMC) Causality Assessment Criteria

The WHO causality assessment scale is a primary tool utilized for analyzing the causal connections present in case reports. This scale was established through the International Drug Monitoring Programme with input from national centres.

It is divided into six distinct categories, each defined by four fundamental criteria. These criteria are:

a) the timing of events,
b) the likelihood of the relationship and the absence of alternative explanations,
c) laboratory results, and
d) the results of de-challenge and re-challenge tests. The classification of "Unclassified" is applied when further information is required to properly assess the relationship.

Naranjo Scale

The Naranjo scale evaluates the relationship between a drug and its effects by utilizing conventional classifications: definite, probable, possible, and doubtful. It consists of a ten-item questionnaire that allows for yes, no, and unknown responses. The scores derived from these responses are categorized accordingly.

Limitation: The Naranjo Scale fails to consider aspects necessary for evaluating the causality of potential drug interactions.[8]

Assessment of preventability

The adjusted Schumock and Thornton preventability scale classifies adverse drug reactions (ADRs) into three categories: definitely preventable, probably preventable, and non-preventable. This scale comprises three segments: preventable, probably preventable, and non-preventable. Section A includes five questions, while Section B contains four questions. ADRs are labelled as "definitely preventable" if at least one answer in Section A is "Yes," categorized as "probably preventable" if at least one response in Section B is "Yes," and deemed non-preventable if all answers in both Sections A and B are "No."

A. Definitely Preventable

1. Was there a history of allergy or previous reaction to the drug?
2. Was the drug involved inappropriate for the patient's clinical condition?
3. Was the dose, route, or frequency of administration inappropriate for the patient's age, weight, or disease state?
4. Was the toxic serum drug concentration or lab monitoring test documented?
5. Were preventative measures not prescribed or administered to the patient?

B. Probable Preventable

6. Was required therapeutic drug monitoring or other necessary lab test not performed?
7. Was the drug interaction involved in ADRs?
8. Was poor compliance involved in ADR?

C. Not Preventable

9. If all the above criteria are not fulfilled.

Assessment of severity

The intensity of adverse drug reactions (ADRs) was evaluated by employing the Hartwig and Siegel severity classification, which is divided into three categories: mild (levels 1 and 2), moderate (levels 3, 4a, and 4b), and severe (levels 5 to 7). A level 1 reaction signifies that there is no need to alter the treatment, whereas a level 2 reaction necessitates that the suspected medication be paused, terminated, or switched without extending the duration of the hospital stay. For a level 3 reaction, the medication must be withheld, and an antidote or alternative treatment utilized without affecting the length of the hospital admission. Levels 4a and 4b indicate that the hospital stay was either prolonged or that the ADR was the cause for the patient's admission. Severe ADRs classified as level 5 require intensive care, level 6 results in lasting harm, and level 7 leads to the patient's death.[9]

LEVEL	ASSESSMENT CRITERIA
Level 1	An ADR occurred but required no change in treatment with the suspected drug
Level 2	The ADR required that treatment with the suspected drug be held, discontinued, or otherwise changed. No antidote or other treatment requirement was required. No increase in (LOS)
Level 3	The ADR required that treatment with the suspected drug be held, discontinued, or otherwise changed. AND/OR an antidote or other treatment was required. No increase in LOS.
Level 4	Any Level 3 ADR that increases the length of stay by at least 1 day. OR The ADR was the reason for the admission.
Level 5	Any Level 4 ADR that requires intensive medical care.
Level 6	The adverse reaction caused permanent harm to the patient.
Level 7	The adverse reaction either directly or indirectly led to the death of the patient

CONCLUSION

Pharmacovigilance is essential for protecting public health by ensuring that medications are used safely and effectively during their entire lifespan. Although thorough pre-clinical and clinical trials are conducted, the comprehensive safety profile of a drug can only be determined through ongoing monitoring after it hits the market. The tasks of identifying, assessing, and preventing adverse drug reactions (ADRs) are fundamental to pharmacovigilance efforts. In India, the development and continuous enhancement of the Pharmacovigilance Programme of India (PvPI) have notably advanced the practices of monitoring and reporting ADRs. Nevertheless, the issue of under-reporting ADRs persists, highlighting the need for increased awareness, education, and engagement from healthcare providers, especially pharmacists. The adoption of electronic reporting systems, organized assessment metrics, and regulatory supervision has improved the detection of safety signals and risk management strategies. It is vital to strengthen pharmacovigilance systems through training, technological advancements, and collaboration among various professional groups in order to enhance patient safety, maximize therapeutic results, and preserve public trust in healthcare frameworks.

REFERENCES

1. Girase AM, Mahale BM, Patil NM. Pharmacovigilance. Research Journal of Science and Technology, 2025 Mar 21; 41–7.
2. Montastruc JL, Sommet A, Bagheri H, Lapeyre-Mestre M. Benefits and strengths of the disproportionality analysis for identification of adverse drug reactions in a pharmacovigilance database. British Journal of Clinical Pharmacology, 2011 Nov 9; 72(6): 905–8.
3. Kalaiselvan V, Thota P, Singh G. Pharmacovigilance Programme of India: Recent developments and future perspectives. Indian Journal of Pharmacology. 2016; 48(6): 624.
4. Amale PN, Deshpande SA, Nakhate YD, Arsod NA. Pharmacovigilance process in India: an overview. *J Pharmacovigil.*, 2018; 6(2): 259. doi:10.4172/2329-6887.1000259.
5. Edwards IR, Aronson JK. Adverse Drug reactions: definitions, diagnosis, and Management. Lancet (London, England), 2000; 356(9237): 1255–9.
6. Lihite RJ, Mangala Lahkar. An update on the Pharmacovigilance Programme of India. Frontiers in Pharmacology, 2015 Sep 22; 6.
7. Hadi MA, Neoh CF, Zin RM, Elrggal M, Cheema E. Pharmacovigilance: pharmacists' perspective on spontaneous adverse drug reaction reporting. Integrated Pharmacy Research and Practice, 2017 Mar; Volume 6: 91–8.
8. View of AN OVERVIEW OF VARIOUS SCALES USED IN CAUSALITY ASSESSMENT OF ADVERSE DRUG REACTIONS | International Journal of Pharmacy and Pharmaceutical Sciences [Internet]. Innovareacademics.in. 2026 [cited 2026 Jan 23].
9. Adusumilli P, Bhoopathi D, Sunkara H, Chalasani SR. An overview of various scales used in causality assessment of adverse drug reactions. *Int J Pharm Pharm Sci.*, 2020; 12(5): 1–5. doi:10.22159/ijpps.2020v12i5.37209.