

**Lachoo Memorial College of Science & Technology (Autonomous), Jodhpur**

**Pharmacy - Wing**

**Project Work**

**Synopsis**

**“PHARMACOVIGILANCE REPORT ON ANTI DIABETIC DRUGS”**

**Supervised by:** **Submitted by:**

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**Dr. Roshan Issarani** **Ms. Aashi Katariya**

Head,

Department of Pharmaceutics B. Pharm. VIII Sem. (2022-2023)

Approved by: Title verified by:

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### Prof. Dr. G. K. Singh Dr. P. K. Choudhary

### Director

Convener Project Work Committee

Date of submission:

**Abstract:**

Diabetes mellitus is a chronic metabolic disorder mainly characterized by hyperglycemia caused by defective insulin secretion, resistance to insulin action, or a combination of both. Alterations of lipid and protein metabolism also are the important characteristic of these defects in insulin secretion or insulin action. The disease may give rise to multiple complications such as cardiovascular disease, nerve damage, kidney damage, eye damage, foot ulcer, liver damage etc., and in severe cases, coma. Patients must receive long-term treatment to maintain the stability in blood sugar, thereby reducing the risk of complications.(1)

India had 69.2 million people living with diabetes (8.7%) as per the 2015 data by WHO. of these, it remained undiagnosed in more than 36 million people. Effective management of diabetes and an adverse effect of drugs is associated with lower morbidity, mortality, and health care. Over time, high blood sugar can seriously compromise every major organ system in the body, causing heart attacks, strokes, nerve damage, kidney failure, blindness, impotence and infections that can lead to amputations. (2)Treatment for diabetes includes insulin and oral antidiabetic agents. Along with these drugs, diabetic patients generally take medications to treat dyslipidemia, an antihypertensive drug, and antiplatelet therapy. Adverse drug reaction associated with antidiabetic treatment are hypoglycemia, hypoglycemic coma, hypersensitivity, hepatotoxicity, drug induced erythema multiforme, photodermatitis etc. So, it is need of the new era to aware people about the adverse effects of an antidiabetic drug.(3) It is necessary to educate the patient on their medications and potential adverse events associated with each medication to limit potential treatment complications. The main objective of the article is to increase awareness about the drugs used in diabetes treatment, its consequences, and adverse drug reaction reactions.(4)

Analysis of adverse drug reaction reports is the way to monitor the safety of medicines. There is the potential for an adverse drug reaction to occur with the use of any medicine or vaccine – whether it is supplied on prescription, over-the-counter or as complementary medicine. When a medicine or vaccine is first registered and made available for use, information about its safety and efficacy is usually available only from clinical trials. Post-marketing surveillance of the marketed medicines and vaccines contributes to a better understanding of their possible adverse drug reactions when medicines are used outside the controlled conditions of clinical trials.(5)

Chapter Plan:

1. Introduction to Diabetes
2. Anti Diabetic drugs
3. Marketed Anti diabetic drugs
4. Adverse drug reaction (Reporting and Monitoring)
5. Clinical trial
6. Anti Diabetic drug reported ADR
7. Banned Anti diabetic drugs
8. Summary and Conclusions
9. References

References:

1. https://ijamscr.com/ijamscr/article/view/400/1577l Accessed on 3/4/23 .
2. https://www.who.int/news-room/fact-sheets/detail/diabetes. Accessed on 3/4/23
3. https://www.nice.org.uk/guidance/ng28. Accessed on 2/4/23
4. https://www.mdpi.com/2673-4540. Accessed on 2/4/23
5. https://link.springer.com/article/10.1007 Accessed on 2/4/23

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| **WORK SCHEDULE TABLE** |

## Criteria for Award of Marks for Timely Submission -

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| --- | --- |
| **Time duration of Synopsis/ Project work proofs and final report submission** | **Marks to be Awarded (5)** |
| Timely Submission | 5 |
| One week after the last date of submission | 3 |
| Two weeks after the last date of submission | 1 |
| After two weeks of the last date of submission | 0 |

**Students are required to get this table filled by the respective supervisor at the time of submission of Synopsis/ Project work final report.**

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| **Criteria** | **Due date for submission** | **Due Date** | **Submission Date** | **Marks Awarded** | **Signature of supervisor** |
| Submission of Synopsis  **Max marks: 5** | As per the synopsis submission notice |  |  |  |  |
| Submission of project work final report in the prescribed format  **Max marks: 5** | As per the report submission notice |  |  |  |  |
| Internal assessment by the supervisor  *(Based upon regularity, sincerity and quality of work of the student)*  **Max marks: 10** | | | |  |  |
|  | | | **Total Marks (20)** |  |  |