**Evaluation of the quality and *in vivo* therapeutic efficacy of a generic**

**Glimepiride manufactured in Algeria, compared to the brand name drug Amarel on alloxan diabetic rats.**

**Abstract**

The present study aims to evaluate physicochemical characteristics and the effectiveness of pharmacological effects of a Glimepiride generic product, compared to its originator Amarel a sulfonylurea used to treat type 2 diabetes mellitus. Two doses 2 and 4 mg per day were tested on male ***albinos*** rats diabetics with alloxan. Body weights, glycemia, HbA1c, lipid profile, total protein, the activity of certain enzymes and some renal parameters were determined. The results showed that physicochemical characteristics are compliant with standards of the American Pharmacopeia compared with the used reference substance. However, the biological study revealed a dose dependent effect of Amarel on body weights, blood glucose and lipid profile of rats during and after the treatment,which was not obtained with the generic. Total protein and enzymes activities of serum transaminases, amylase and lipase were almost identical in groups treated with 4 mg of originator and generic. The 2 mg dose has not exerted the expected therapeutic effect. These results show that the studied generic exhibited less efficacy than the originator despite compliance of physicochemical characteristics. A supply of the generic with the aqueous extract of a local medicinal plant ***(Zygophyllum cornutum***) was performed where the results of measuring blood glucose before and after sacrifice of rats were similar to those of healthy controls. No significant difference was recorded for renal parameters in all treated groups.

**Keywords:** Generic; Branded drug; Glimepiride; Alloxan diabetes.

**I. Reading comprehension**

1. **The type of text is :**

a) narrative b) argumentative c) descriptive

1. **Answer the questions according to the text**
2. Howmany doses per day were tested on male albino rats diabetics with alloxan?
3. Does the 2mg exert a therapeutic effect?
4. Do we find a difference between all treated groups in renal parameters?
5. **Are these statements true or false? 3pts**
6. The study aims to verify the diabetic effect of a glimepiride generic product. **b)** Type 2 diabetes, a chronic widespread disease, is one of the major challenges of the 21st century in terms of health and development.

**c)** Total protein and enzymes activities of serum transaminases, amylase and lipase were almost identical in groups treated with 40 mg of originator and generic.

***II.* Mastery of Language**

1. Give the synonym of: label= outcome=
2. Give the antonym of: low≠ specific ≠
3. Fill in the table below

|  |  |  |
| --- | --- | --- |
| Noun | Verb | adjectif |
| Experiment |  |  |
|  | To study |  |
| deviation |  |  |
|  |  | Successful |

1. Make the verb between brackets into the right form

The assays (to perform) according to the supplier’s specifications from the standard Kits.

**III. Production**

In a composition form, write about the Algerian awareness about diabetes’ disease.

**GOOD LUCK !!!**