7. ABSTRACT OF THE INVENTION:

Metabonomic studies have led to the invention of a new form of ~~an~~ a sublingual antidiabetic dosage (g Lipizide combination) which has a faster action (onset comparable to short action insulins) and a more prolonged duration (compared to currently available hypoglycemics). It acts at a much lower dose and is several times more effective than the currently available forms. The product has a much lower hepatotoxicity and side effects are much less severe on account of a low dose. Its faster onset enables it to be used in cases of diabetic coma of type-II D.M. and acid lactosis conditions which today have a record of approximately 50% mortality in patients. It is also more economical in use

Note:-

* Repeat boxes in case of more than one entry.
* To be sign ed by the applicant(s) or by authorised registered patent agent.
* Name of the applicant should be given in full, family name in the beginning.
* Complete address of the applicant should be given stating the postal index No./code, State and country.
* Strike out the column which is/are not applicable.

5. CLAIMS:

I claim that the product so invented:

(1) Has a higher effectivity than conventional drugs and is used at a lower dose.

(ii) Has fewer adverse reactions on account of lower dose

(iii) Has lower toxicity specially hepatotoxicity by avoiding the first pass metabolism.

(iv) Has a faster onset of action.

(v) May be used in cases of lacticacidosis and diabetic coma in type-II DM D.M.

(vi) Has a more prolonged duration of action.

(vii) Is economical on account of lower dosages.

6. DATE AND SIGNATURE

Dated this . 26th . . . . day of Apr . . . 2010

Signature . . . . . .

(Prof.(Dr.) Debasish Banerjee)

efficacy is limited due to cellular in sensitivity and rapid metabolism. Orally acting hypoglycemics are also in effective in such situation on account of longer onset times(more than 2 hours) a period which proves fatal for the patient. Here we have invented a sublingual low dose form of a hypoglycemic drug combination which acts within 0.5 to 0.7 hrs. and reduces high blood sugar level within the crucial first hour which very often is the cause of fatality. We have also optimised the dosage form to a much lower level through metabonomic studies and arrived at a higher efficacy lower dosage form which would be non hepatotoxic on long term therapy but show a higher activity level and a longer duration of action.

4. DESCRIPTION

Studies in metabonomics have today been the principal tool in dosage form optimization.

Ever since it has been recognised and appreciated that dosage form affixation on the basis of metabolic patterns of individuals can and do account for genomic and environmental (age, disease etc.) changes in a person and that the dosages so derived have fewer adverse reactions are more effective and have lower toxicity metabonomics has been used for affixation of dosages of different dosage forms which are metabolised through different metabolic processes in the body. Here this concept has been utilized to design a sublingual dosage form of glipizide and activity enhancer which has higher efficacy at a lower dosage range, has a faster onset time prolonged duration and lower hepatotoxicity. These properties enable it to be used as a first line treatment for type-II DM and diabetic coma associated with it and lactic acidosis conditions which presently record 50% mortality rates.

A sublingual dosage form of the drug combination was designed and dosages affixed through metabonomic studies so that the combination shows a

much higher effect at a lower dose during the first hour or so of administration. This form was tested for activity in humans and found to be atleast 3 - 6 time more effective than its corresponding oral dose. Its onset varies from 30 minutes to 50 minutes depending on the diabetic predisposition of the patient. Its duration of action is more than 24 hours and has to be subsequently reduced through effect estimation over prolonged periods. Its hepatotoxicity was much low and effect prolonged since it avoided first pass metabolism in the liver(only a small fraction of the dose reaching the liver) after being directly absorbed into the blood through the reticulated Vein (Major portion of the drug is directly absorbed into the tissue sites after sublingual Administration) Also since the drug is metabolised into in active metabolites in the liver avoiding first pass metabolism enabled the active forms of the drug being maintaine-d in high concentration at the tissue sites immediately after administration thereby prolonging therapeutic effect and lowering onset times.