A clear definition of this eye drop status (pharmaceutical preparation or not) is also necessary.

Biochemical quality controls, abandoned, to be resubmitted (molecules supposed to support ASEDs efficacy). Supplementary round necessary to decide the fate of the last item (solution volume in each eye drop bottle).

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

3PC-035 GALENIC DEVELOPMENT OF A GENERIC SPECIALTY WITH CONVENTIONAL RELEASE BASED ON ACARBOSE

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Background and Importance In the case of the development of a generic drug, the approach is based almost exclusively on galenic and analytical developments. However, to facilitate formulation, it is still necessary to go through a pre-formulation stage. Therefore, a generic drug must meet the same quality, safety and efficacy requirements as the originator drug.

Aim and Objectives The objective of our work consists on a pre-formulation stage followed by a formulation stage in order to arrive at an optimal, stable and effective galenic formula and to develop a generic oral anti-diabetic drug based on acarbose 50 mg.

Material and Methods During the development of this generic specialty, a preliminary study of the raw materials was conducted (physico-chemical characteristics, rheological properties and compatibility study) in order to determine the quantitative formula and the manufacturing process. Then, 6 formulas were prepared in order to improve the flow time. The tablets obtained were tested for uniformity of mass, hardness, friability, disintegration time and dissolution in vitro. Subsequently, a comparative study of the dissolution profiles obtained with that of the reference drug was made by calculating the difference factor f2 and similarity f1 in order to determine the best formula.

Results The method for the determination of the active substance by HPLC has been validated. The raw material has been well studied and the choice of excipients and the method of manufacture have been justified. Formula F5 having a friability percentage equal to 0,16%, a disintegration time (5,9 min) and a dissolution profile similar to that of the reference specialty (f1 <15% and f2> 50%) was selected. It was considered the closest to the princeps.

Conclusion and Relevance The generic specialty formulated presented an equivalence in terms of in vitro dissolution with the reference specialty. Thus, comparative studies in 3 different pH environments need to be completed to judge this in vitro equivalence.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. No conflict of interest.

Conflict of Interest No conflict of interest

3PC-036 CENTRALISED AND PERSONALISED PREPARATION OF INTRAVENOUS KETAMINE FOR PATIENTS WITH RESISTANT DEPRESSION

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Background and Importance Depression is the third leading cause of disability in the world and about 1/3 of depressive disorders have resistance to successive treatments.

Intravenous infusion of off-label ketamine in subanaesthetic doses has favourable therapeutic responses in a relatively short evaluation time. Accumulated safety evidence is considered an added value in the therapeutic arsenal to treat this pathology.

Safety issues of the use of central anaesthetics without the support of anaesthesiology are a pivotal drive for implementing a clinical protocol that includes the pharmacy. The use of fixed dilutions and rhythms of administration as well as personalised centralised preparation in the pharmacy overcomes most concerns about the regular and safe use of this approach on resistant depression.

Aim and Objectives Evaluate the implemented circuit, characterisation of the population and analysis of the impact on the effectiveness and safety of ketamine in resistant depression.

Material and Methods A 19-month retrospective analysis was made on the use of ketamine in patients with resistant depression. The pharmaceutical services database and the Soarian Clinicals® programme were used to collect information and to consult the electronic clinical process of patients that used this therapeutic approach.

Results Indication for ketamine treatment, in addition to the absence of contraindications, means that the patient is not responsive to at least three antidepressants SNRIs and a tricyclic, a potentiation strategies and a score $\geq$ 9 in *the Patient Health Questionnaire-9 (PHQ-9)*.

The data collected correspond to the period between 01/2021 and 07/2022 and are summarised in table 1.

Abstract 3PC-036 Table 1

Total of patients		9
Sex F (%)		77.8
Average age		45
Total number of preparations		118
Number of sessions (median)		12
Average dose (mg/kg)	Total	0.51
	Initial	0.27
	Final	0.66
Average duration of treatment		58 days

All cases reported psychopathological improvement recognised by themselves as well as by assistant psychiatrists.

Conclusion and Relevance Ketamine has shown to be a safe alternative provided that local strategies are created to ensure the implementation of criteria in patient selection, preparation, administration, and follow-up protocols. The acceptance and short-term recognition of the benefit of the treatment by patients and professionals allow for achieving the goal of clinical discharge.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest