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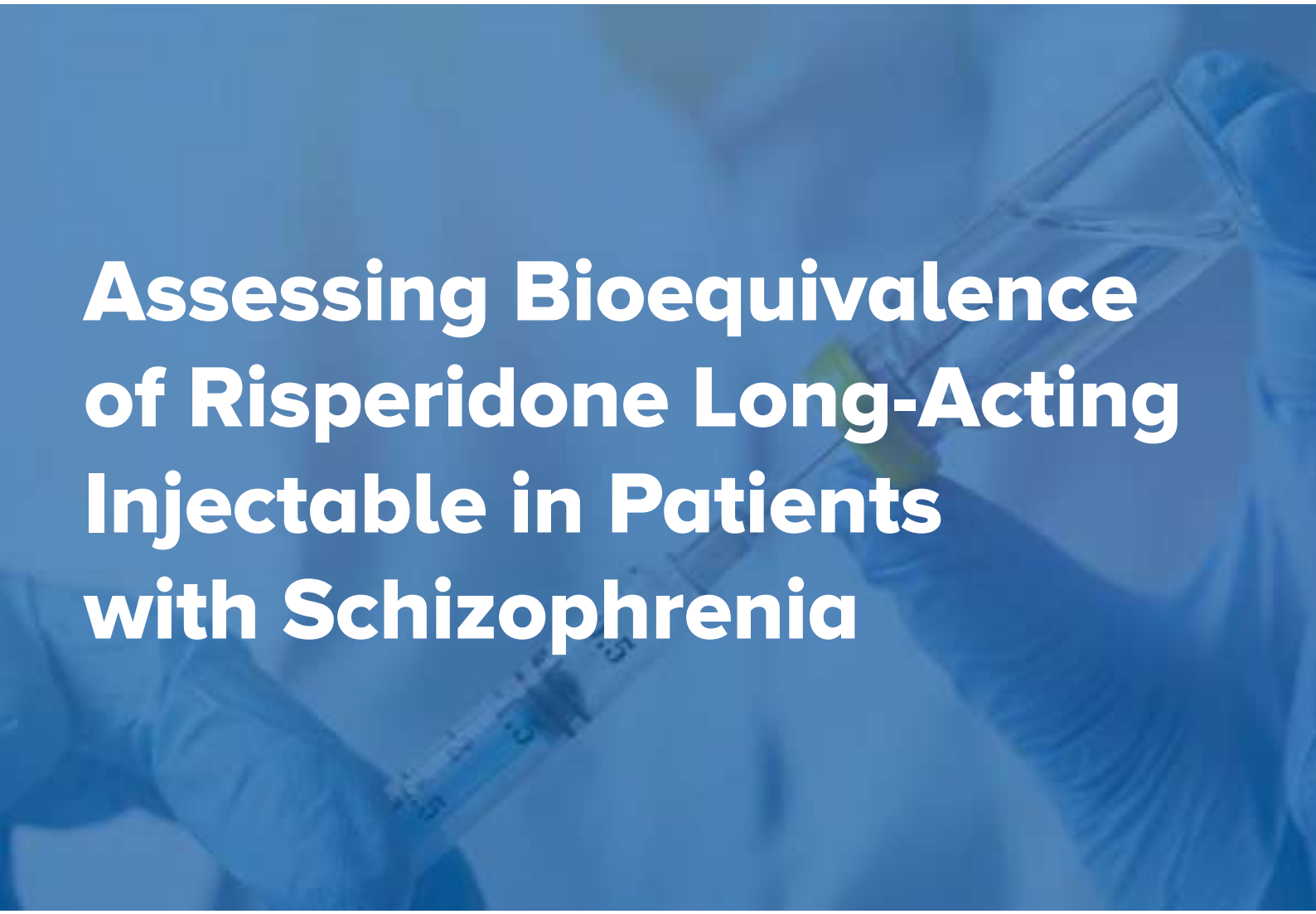

Assessing Bioequivalence of Risperidone Long-Acting Injectable in Patients with Schizophrenia

Type of Study

A randomized, multi center, open label, balanced, two-treatment, two-period, two-sequence, multiple dose, crossover, steady-state bioequivalence study of Risperidone prolonged-release suspension for intramuscular injection 25 mg/vial in Schizophrenic Patients.

Molecule Overview

Risperidone is a psychotropic agent belonging to the chemical class of benzisoxazole derivatives. Risperidone is a potent D2 antagonist, which is considered to improve the positive symptoms of schizophrenia, it causes less depression of motor activity and induction of catalepsy than classical antipsychotics. Balanced central serotonin and dopamine antagonism may reduce extrapyramidal side effect liability and extend the therapeutic activity to the negative and affective symptoms of schizophrenia.

Veeda supported the client in following services for the successful execution of the study

Study Design & Execution

Medical & Protocol Writing

Local Regulatory Applications

Ethics Committee Dossiers Submissions

Volunteer Recruitment & Retention

Investigational Product Management & Administration (IMP)

PK Blood Samples Management

Bioanalytical Method Validation & Analysis

Biostatistics & Data Management

Highlights of Results Delivered

- A Total of **108** patients enrolled, **73** completed both period
- Average Retention Rate: **68%**

Safety Assessment parameters assessed throughout the study as below

- Subjects throughout the study were monitored, and safety and preventive measures were ensured to minimise the risk of AEs.
- Safety parameter assessments such as Medical History, Vital Signs, Clinical Examinations, Clinical Laboratory Tests (Hematology, Biochemistry, Urinalysis, Hb1Ac, HIV & Hepatitis, and Fasting Blood Sugar-FBS), X-Ray & ECG were conducted.

Major Study Challenges & Actions

Major Challenges	Action Plan
Patient Compliance: Ensuring consistent patient compliance with the dosing regimen was challenging due to the nature of disease and potential cognitive impairments	Implementing rigorous quality assurance measures throughout the study, including monitoring dosing regimen and regular visits to study sites helped in achieving patient compliance
Concomitant Medications: Managing the potential influence of concomitant medications on the pharmacokinetics of Risperidone and its active metabolite was crucial	Careful evaluation of potential drug interactions due to concomitant medications with Risperidone was ensured by the clinical team
Adverse Events: Monitoring and managing adverse events related to Risperidone treatment throughout the study to ensure patient safety and retention	Implementation of rigorous adverse event monitoring and management protocols to promptly identify and address any safety concerns arising during the study

Results

- Within the designated timeline, the study was successfully completed.
- Bioequivalence was concluded based on the within-subject standard deviation of the reference formulation.

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