



TITLE PAGE

NON-INTERVENTIONAL RESEARCH CLINICAL STUDY

PROTOCOL PROC-521-0124

**A Prospective, Multicenter, Open-Label, Single-Arm, Post Marketing Observational Study
to Assess the Effectiveness and Safety of Prochlorperazine In Patients with Acute Vertigo**

Product Name: Stemetil MD[®] (prochlorperazine maleate 5 mg)

Type of Study: Post-marketing Observational Study (PMOS)

Protocol Version & Date: Version 1.0 dated 22-Nov-2021

CRO & Biometrics: iDD Research Solutions Pvt. Ltd.
Tek Meadows Campus, No 51, 3rd,
C block, Old Mahabalipuram Rd, Phone: +91 8520082152
Sholinganallur, Chennai, Tamil Nadu
600119

Sponsor: Abbott Healthcare Pvt. Limited
Floor 16, Godrej BKC
Plot No. C – 68, BKC Phone: +91-22-38160619
Near MCA Club, Bandra (E)
Mumbai 400 051

This study will be conducted in compliance with this protocol.

Confidential Information

**No use or disclosure outside Abbott is permitted without prior written authorization from
Abbott.**

This information is confidential to Abbott

Prochlorperazine – Stemetil MD[®]



SIGNATURE PAGE
INVESTIGATOR'S DECLARATION

I, the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and to comply with all requirements regarding the obligations of Investigators and all other Subject requirements of ICH-E6 R2 Guideline 2016 on 'Good Clinical Practice', New Drugs and Clinical Trials 2019, Declaration of Helsinki (Taipei 2016) and any other applicable regulations.

I further agree to ensure that all associates assisting in the conduct of study are informed regarding their obligations.

PRINCIPAL INVESTIGATOR

Signature Professor & Head,
Department of E.N.T.,
A.C.P.M. Medical College, Dhule [M.S.]

Date (08-12-2022)

Name : Dr. R.V.Patil

Address :

Telephone : +91

Email :

