

"I Ms. Shalmali Ambekar, Identity document number: H004513, with address at: Macleods Pharmaceuticals Ltd., G-2, Mahakali Caves Road, Shanti Nagar, Andheri - (East), Mumbai – 400 093, India; Phone number: 91-22-61132900, Fax number: 91-22-28304641, email: shalmalia@macleodspharma.com, on behalf of the Mr. Amol Choulwar as the main monitor of protocol No.: BEQ-379-IH (F)-2009, titled: Bioequivalence study of single dose of fixed dose combination of Irbesartan 300 mg and Hydrochlorothiazide 25 mg tablets (each tablet contains irbesartan 300 mg and hydrochlorothiazide 25 mg) manufactured by Macleods Pharmaceuticals Ltd., India comparing with Avalide® (irbesartan-hydrochlorothiazide) tablets 300/25 mg (each tablet contains irbesartan 300 mg and hydrochlorothiazide 25 mg) manufactured by Bristol-Myers Squibb Company USA in healthy, adult, human subjects under fasting condition, approved by the Independent Ethics Committee; approved on date: 06/07/10, performed by the principal investigator: Dr. Ashok Moses, with address at Macleods Pharmaceuticals Ltd., Bioequivalence Department, G-2, Mahakali Caves Road, Shanti Nagar, Andheri - (East), Mumbai – 400 093, India, Phone number: 91-22-61132900, Fax number: 91-22-28304641, email: drashish@macleodspharma.com, and sponsored by: Macleods Pharmaceuticals Ltd., Bioequivalence Department, G-2, Mahakali Caves Road, Shanti Nagar, Andheri - (East), Mumbai – 400 093, India, certify:

That the final report of the above mentioned protocol, report number BEQ-379-IH (F)-2009 (Version 01), issued with date 30/10/10 by the person Mr. Sunil Maurya, with address in Macleods Pharmaceuticals Ltd., Bioequivalence Department, G-2, Mahakali Caves Road, Shanti Nagar, Andheri - (East), Mumbai – 400 093, India, Phone number: 91-22-61132900, Fax number: 91-22-28304641, email: drashish@macleodspharma.com, is authentic.

Sign the present in Mumbai, India, on 14 of the month of December of the year 2018.

Signature,



Ms. Shalmali Ambekar

Asst. Manager – Medical Services

Date: 14<sup>th</sup> December 2018

**To whomsoever it may concern,**

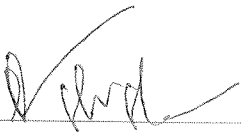
**Subject:** Declaration for the Monitor of Bioequivalence Study

**Reference:** Bioequivalence study of single dose of fixed dose combination of Irbesartan 300 mg and Hydrochlorothiazide 25 mg tablets (each tablet contains irbesartan 300 mg and hydrochlorothiazide 25 mg) manufactured by Macleods Pharmaceuticals Ltd., India comparing with Avalide<sup>®</sup> (irbesartan-hydrochlorothiazide) tablets 300/25 mg (each tablet contains irbesartan 300 mg and hydrochlorothiazide 25 mg) manufactured by Bristol-Myers Squibb Company USA in healthy, adult, human subjects under fasting condition.

**Study No.:** BEQ-379-IH (F)-2009

This is to inform that Mr. Amol Choulwar participated in the above mentioned Bioequivalence study as main Monitor in the Clinical process. Mr. Amol Choulwar worked as Deputy Manager- Medical Services had left Macleods Pharmaceuticals Limited before the document was signed; hence Ms. Shalmali Ambekar had signed that document. Please note that Dr. Sagar Pawar and Mr. Khurshid Shaikh were the staff in charge of Quality Assurance for the protocol BEQ-379-IH (F)-2009 during all the process of this Bioequivalence study.

Regards,



**Dr. Ashish Mungantiwar**

**Executive President - Medical Services**