



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 December 2016
EMA/CHMP/847556/2016

CHMP List of questions

To be addressed by the applicants/marketing authorisation holder(s) for medicinal products for which clinical and bioanalytical parts of the bioequivalence studies were performed at Micro Therapeutic Research Labs Pvt. Ltd Rajam Bhavanam, No. 6, Kamarajar Salai, Selaiyur, East Tambaram, Chennai - 600 059, India and Micro Therapeutic Research Labs Pvt. Ltd, No. 29 A, Krishna Madhuravanam, Vellokinar Pirivu, Thudiyalur, Coimbatore-641029, Tamil Nadu, India

Referral under Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A31/1450
Tadalafil Mylan EMEA/H/A31/1450/C/003787/0005



At Micro Therapeutic Research Labs Pvt. Ltd Rajam Bhavanam, No. 6 , Kamarajar Salai, Selaiyur, East Tambaram, Chennai - 600 059, India and Micro Therapeutic Research Labs Pvt. Ltd, No. 29 A, Krishna Madhuravanam, Vellokinar Pirivu, Thudiyalur, Coimbatore-641029, Tamil Nadu, India were subject to GCP inspection carried out February 2016 by the Dutch and Austrian competent authorities where critical findings were identified on the inspected studies, as well as serious deficiencies in the quality management system in place at the site (covering clinical and bioanalytical activities), which affect the trustworthiness of the data generated by the site between June 2012 and June 2016 and cast doubt on the reliability of the corresponding bioequivalence studies conducted during this period to support a marketing authorisation.

The marketing authorisation holders (MAHs) and applicants are invited to comment on the impact of the above on their marketing authorisation(s) or application(s). Demonstration of bioequivalence to the EU reference medicinal product (RMP) is a requirement of Article 10 of Directive 2001/83/EC, MAHs are therefore requested to provide evidence of bioequivalence (e.g. bioequivalence trials) with the EU reference medicinal product, in order to demonstrate a positive benefit-risk balance of the concerned medicinal products.