



1 April 2016
EMA/CHMP/228190/2016

Timetable for the procedure

Referral under article 31 of Directive 2001/83/EC

Medicinal products for which the clinical and/or bioanalytical parts of the bioequivalence studies were performed at Alkem Laboratories Limited, Department of Bioequivalence, C-17/7, MIDC Industrial estate, Taloja, Dist. Raigad – 410 208, India site between March 2013 and March 2015

Procedure no: EMEA/H/A-31/1436

Procedural step:	Date
Notification:	24 March 2016
Start of the procedure (CHMP):	March, 2016 CHMP
List of questions:	1 April 2016
Submission of responses:	12 May 2016
Re-start of the procedure:	26 May 2016
Rapporteur/co-rapporteur assessment report(s) circulated to CHMP:	8 June 2016
Comments:	13 June 2016
Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP:	16 June 2016
CHMP list of outstanding issues: CHMP opinion:	June 2016 CHMP

