

KELPharma Middle East manufactured Product List

Category	Product	Strengths	Date of Manufacturing of ICH batches	Innovator Details	Date of BE study Conducted
ACE inhibitor	Lisinopril Tablets	5mg, 10mg & 20mg	Batch No: LSD8004 Mfg. Date : September 2008	Zestril® 20 mg Tablets Astra Zeneca UK	study initiation date :23/01/2009 End date : 27/05/2009
Angiotensin II receptor antagonist	Irbesartan Tablets	150mg & 300mg	Batch No: J100104 (Mfg.Date: July 2010)	Apovel® 300 mg Tablets Sanofi Pharma Bristol- Myers Squibb Company, France	study initiation date :10/01/2011 end date : 21/01/2011
Angiotensin II receptor antagonist	Losartan Potassium Tablets	50mg & 100mg	Batch No: LPT1-09 (Mfg.Date: October 2010)	COZAAR TM 100 MG Tablets Merck Sharp and Dohme B.V., Netherlands	study initiation date :23/12/2010 end date : 28/02/2011
Antibacterial agent	Moxifloxacin Tablets	400 mg	Batch No: MOT4-06 (Mfg.Date: October 2010)	Avalox® 400 mg Tablets Bayer Health Care AG Germany	study initiation date : 23/12/2010 end date :17/02/2011
Antibiotic	Amoxicillin POS	125mg/5ml & 250mg/5ml	Batch No: AME8020 (Mfg Date: December 2008)	Amoxil Forte Dry syrup 250 mg/ 5 ml GlaxoSmithKline Manufactured by: SmithKline Beecham plc* Worthing, UK.* Member of the GlaxoSmithKline group of companies	study initiation date :7/4/2009 Study completion date: 27/04/2009
Antibiotic	Amoxicillin Capsules	250mg & 500mg	Batch No: AMCS-41B (Mfg.Date: Aug 2008)	Amoxil Capsules 500 mg SmithKline Beecham Pharmaceuticals, UK	study initiation date :02/12/2008 end date: 04/02/2009
Antibiotic	Amoxicillin & Clavulanic Acid POS	156.25mg/5ml & 312.5mg/5ml 228.5mg/5ml & 457mg/5ml	Batch No: XCG8001 (Mfg.Date: February 2008)	Augmentin 457 mg/5 ml syrup SmithKline Beecham PLC, UK	study initiation date : 01/3/2009 end date: 12/03/2009
Antibiotic	Amoxicillin & Clavulanic Acid Tablets	375mg & 625 mg	Batch No: XCT6-16B (Mfg.Date: July 2008)	AUGMENTIN Tablet 625 mg SmithKline Beecham PLC, UK	study initiation date : 24/08/2008 end date: 23/12/2008
Antibiotic	Amoxicillin & Clavulanic Acid Tablets	1g	Batch No: XCT8-12 (Mfg.Date: January 2008)	AUGMENTIN Tablet 1000 mg SmithKline Beecham PLC, UK	study initiation date : 16/02/2009 end date :31/05/2009
Antibiotic	Azithromycin Capsules	250 mg	Batch No: AZA8002 (Mfg.Date: September 2008)	ZITHROMAX TM 250 mg Capsules PFIZER INC., USA	study initiation date : 05/04/2009 end date :17/08/2009
Antibiotic	Azithromycin Powder	200 mg/ 5 ml	Batch No: AZB5001 (Mfg.Date: February 2015)	ZITHROMAX 200 mg/ 5 ml TM PFIZER INC., USA	study initiation date : 14/04/2015 end date :02/11/2015
Antibiotic	Ciprofloxacin Tablets	250mg & 500mg	Batch No: CFB9003 (Mfg.Date: January 2009)	CIPROBAY 500 mg tablet Bayer Healthcare AG, Germany	study initiation date :24/05/2009 end date : 17/09/2009
Antibiotic	Clarithromycin Tablets	250mg & 500mg	Batch No: CLB8002 (Mfg.Date: December 2008)	Klacid 500 mg Tablet Abbott Laboratories Ltd, England	study initiation date :05/04/2009 end date : 22/06/2009
Antibiotic	Clarithromycin POS	125mg/5ml & 250mg/5ml	Batch No: CLD2-25A (Mfg.Date: January 2010)	Klacid POS 250 mg/5 ml Manufactured by Aescia Queenborough Ltd., Queenborough, Kent, UK for Abbott Laboratories Ltd., Queenborough Kent, UK	study initiation date :15/04/2010 end date : 05/05/2010
Antibiotic	Levofloxacin Hemihydrate Tablets	500 mg	Batch No: LFT5-20 (Mfg. Date : May 2010)	TAVANIC tablet 500 mg Aventis Pharma	study initiation date :07/07/2010 end date: 30/12/2010
Anti-diabetic	Gliclazide XR Tablets	30 mg	Batch No: GLT3-21 Mfg Date : October 2008	DIAMICRON® MR 30 mg Tablets Les Laboratoires Servier-France	Fasting Study study initiation date :21/05/2009 end date :04/07/2009 Fed Study study initiation date :16/09/2009 end date : 07/10/2009
Anti-diabetic	Gliclazide XR Tablets	60mg	Batch No: GLT6-22 (Mfg.Date: November 2013)	DIAMICRON MR 60 mg Tablets Les Laboratoires Servier-France	study initiation date :02/07/2014 end date : 14/10/2014
Anti-diabetic	Metformin Hydrochloride Tablets	500mg, 850mg, 1g	Batch No: MHD9001 (Mfg.Date: January 2009)	GLUCOPHAGE® 1000 mg Tablets Merck Sante S.A.S., FRANCE	study initiation date :08/02/2010 end date : 25/04/2010
Anti-diabetic	Metformin Hydrochloride XR Tablets	500 mg	Batch No: MHB9014 (Mfg.Date: October 2009)	GLUCOPHAGE® XR 500 mg Tablets Merck Sante S.A.S., FRANCE	study initiation date :14/06/2010 end date : 09/08/2010
Anti-diarrhea	Loperamide Capsules	2 mg	Batch No: LHC2-09 Mfg Date : Oct 2008	Imodium® 2 mg Capsules Janssen Pharmaceutica N.V. Belgium	study initiation date :06/04/2009 end date :18/11/2009
Anti-emetic	Domperidone Tablets	10 mg	Batch No: DOT1-07 (Mfg.Date : May 2010)	Motilium 10 mg Tablets Lusomedicamenta Sociedade Tecnica Farmaceutica Estrada Consiglieri Portugal For Janssen Pharmaceutica Belgium	study initiation date : 29/11/2010 end date : 03/07/2011

Antifungal	Fluconazole Capsules	150 mg	Batch No:FCCI-10 (Mfg.Date:January 2009)	DIFLUCAN 150 mg capsules Pfizer PGM, France under authority of Pfizer, Inc.USA	study initiation date :14/04/2009 end date: 10/05/2009
Antihistamine	Cetirizine Tablets	10 mg	Batch No:CHB0001 (Mfg.Date:February 2010)	Zyrtec®10 mg Tablets UCB SA Belgium	study initiation date :19/07/2010 end date : 16/08/2010
Antihistamine	Desloratadine Tablets	5mg	Batch No: DET5-53A (Mfg.Date: November 2013)	AERIUS TM 5 mg Tablet Merck Sharp & Dohme Limited, UK	study initiation date :07/04/2015 end date : 30/07/2015
Antihistamine	Fexofenadine Hcl Tablets	180mg	Batch No:J110048 (Mfg.Date:March 2011)	Allegra ®180 mg Tablets Sanofi Aventis, USA	study initiation date :28/11/2011 end date : 08/12/2011
Antihistamine	Levocetirizine Dihydrochloride Tablets	5 mg	Batch No:E8024 (Mfg.Date:March 2008)	XAZAL ® 5 mg Tablets UCB Pharma, Barcelona	study initiation date :23/06/2008 end date :02/07/2008
Antiplatelet agent	Clopidogrel Tablets	75mg	Batch No:J110036 (Mfg.Date:Feb 2011)	PLAVIX ® 300 mg Tablets Bristol Myers Squibb, Canada	study initiation date :24/09/2011 end date :16/10/2011
Nonsteroidal anti-inflammatory drug	Diclofenac Potassium Tablets	50 mg	Batch No:DPT5-32 Mfg.Date : Nov 2009	CATAFLAM®50mg Tablets Novartis Farma S.p.A Torre Annunziata, Italy for Novartis Pharma AG,	study initiation date :13/12/2009 end date :24/12/2009
Nonsteroidal anti-inflammatory drug	Diclofenac Sodium Tablets	50 mg	Batch No:DSB8008 Mfg.Date: November 2008	Voltaren®50 mg Tablets Novartis Farma S.P.A.,Italy for Novartis Pharma AG, Switzerland	study initiation date :05/04/2009 end date : 30/07/2009
Nonsteroidal anti-inflammatory drug	Ibuprofen Tablets	200mg, 400mg & 600mg	Batch No:IBC7006 Mfg. Date : December 2007	BRUFEN ® 600 mg Tablets Abott GmbH & Co. KG Germany for Abott Laboratories Ltd., England.	study initiation date :18/03/2009 end date : 16/07/2009
Nonsteroidal anti-inflammatory drug	Ibuprofen Suspension	100 mg/ 5 ml	Batch No:IBU 1-11 Mfg.Date : April 2007	BRUFEN ®100 mg/5 ml Suspension Abott Laboratories Ltd., England.	study initiation date :06/03/2009 end date : 22/04/2009
Nonsteroidal anti-inflammatory drug	Mefenamic Acid Tablets	500 mg	Batch No:MAC8013 Mfg.Date: September 2008	Ponstan Forte 500 mg Tablets Godecke AG/Germany under license of Park- Davis	study initiation date :11/02/2010 end date : 22/02/2010
Nonsteroidal anti-inflammatory drug	Meloxicam Tablets	7.5mg & 15mg	Batch No:MXB8006 Mfg.Date:September 2008	MOBIC 15 mg Tablets Boehringer Ingelheim International GmbH Ingelheim am Rhein Germany	study initiation date :14/04/2009 end date : 17/05/2009