

Drug Alert for the Month of June 2014

S.No.	Name of the Drug/Medical Device/Cosmetic	B.No., D/M, D/E, Name of the Mfg. & Address	Reason for Failure with report in Form 13/34 No. & Date	Drawn By	From
1	Tapentadol & Paracetamol Tablets (PROXYVON® Forte)	Batch No – WAL2004 D/Mfg. – 12/2012 D/Exp. – 11/2014 Mfd. By- M/s. Acme Formulation Pvt. Ltd. Ropar Road, Nalagarh, Dist. Solan Himachal Pradesh – 174101	Assay of Tapentadol Hydrochloride RDTL/327/13-14 Date:- 26-06-14	CDSCO,N.Z. Ghaziabad	RDTL, Chandigarh
2	Ofloxacin Tablets IP (Zevid ® 200)	Batch No – ZT-8946 D/Mfg. – 03/2013 D/Exp. – 08/2015 Mfd. By- M/s. ZEE Laboratories, 47, Industrial Area, Paonta Sahib – 173205	Dissolution RDTL/484/13-14 Date:- 12-06-14	CDSCO,N.Z. Ghaziabad	RDTL, Chandigarh
3	Amoxicillin & Dicloxacillin Capcules (STANLAC-D)	Batch No – MCB09-01 D/Mfg. – 09/2012 D/Exp. – 08/2014 Mfd. By- M/s. Medox Lifesciences, Plot No 222-223, Phase – III, Ind.Area, Sansarpur-Terrace (H.P.)	Assay of Dicloxacillin Sodium RDTL/549/13-14 Date:- 24-06-14	CDSCO,N.Z. Ghaziabad	RDTL, Chandigarh
4	Misoprostol Tablets (MESOPOL - 100)	Batch No – TMSL-003 D/Mfg. – 02/2013 D/Exp. – 07/2014 Mfd. By- M/s. Medipol Pharmaceuticals India Pvt. Ltd., 1199/3 Bhud , Baddi Distt. Solan (HP) India	Assay RDTL/539/13-14 Date:- 24-06-14	CDSCO,N.Z. Ghaziabad	RDTL, Chandigarh
5	Amoxicillin & Potassium Clavulanate Tablet IP625 mg	Batch No – T-2625 D/Mfg. – 05/2012 D/Exp. – 04/2015 Mfd. By- M/s. Kwalitiy Pharmaceuticals (P) LTD Nag Kalan, Majitha Road, Amritsar India	Assay of Potassium Clavulanate RDTL/615/13-14 Date:- 10-06-14	CDSCO,N.Z. Ghaziabad	RDTL, Chandigarh

Drug Alert for the Month of June 2014

6	Amoxicillin & Potassium Clavulanate Tablet IP (MONAMOX – CL625)	Batch No – ZT-11564 D/Mfg. – 02/2013 D/Exp. – 07/2014 Mfd. By- M/s. ZEE Laboratories, 47, Industrial Area, Paonta Sahib – 173205	Assay of Potassium Clavulanate RDTL/671/13-14 Date:- 10-06-14	CDSCO,N.Z. Ghaziabad	RDTL, Chandigarh
7	Salbutamol Sulphate Tablets IP 2 mg (Asthalin 2)	Batch No – ADF3025 D/Mfg. – 05/2013 D/Exp. – 04/2016 Mfd. By- M/s. CIPLA LTD., 47, Industrial Area, T-82 , MIDC, Bhosari, Pune 411026 INDIA	Assay, RDTL/707/13-14 Date:- 13-06-14	CDSCO,N.Z. Ghaziabad	RDTL, Chandigarh
8	Salbutamol Tablets IP (SALBETOL 2)	Batch No – STT3014 D/Mfg. – 01/2013 D/Exp. – 12/2015 Mfd. By- M/s. FDC Limited , AT : Plot No. L121B Verna Industrial Estate , Verna Salcete Goa 403722	Assay, RDTL/769/13-14 Date:- 13-06-14	CDSCO,N.Z. Ghaziabad	RDTL, Chandigarh
9	Salbutamol Sulphate tablets IP 2mg	Batch No – SST-1002 D/Mfg. – 12/2012 D/Exp. – 11/2014 Mfd. By- M/s. Wings Pharmaceuticals Pvt. Ltd., 35, HPSIDC Industrial Area, Baddi – 173205 (H.P.)	Assay, RDTL/774/13-14 Date:- 13-06-14	CDSCO,N.Z. Ghaziabad	RDTL, Chandigarh
10	Cefuroxime Axetil Tablets IP (MAC-CEF™ -250)	Batch No – 12T518 D/Mfg. – 12/2013 D/Exp. – 11/2015 Mfd. By- M/s. Orison Pharma International Khari Mauza - Ogli, Kala Amb-173030 H.P.	Dissolution, RDTL/794/13-14 Date:- 13-06-14	CDSCO,N.Z. Ghaziabad	RDTL, Chandigarh
11	Escitalopram Oxalate Tablets IP (STALOPAM 5)	Batch No – J400453 D/Mfg. – 02/2014 D/Exp. – 01/2016 Mfd. By- M/s. Lupin Ltd., EPIP, SIDCO, Kartholi, Bari Brahmana, Jammu, J & K-181133	Dissolution, RDTL/873/13-14 Date:- 27-06-14	CDSCO,N.Z. Ghaziabad	RDTL, Chandigarh

Drug Alert for the Month of June 2014

12	Norfloxacin Tablets	B. No. 560613, D/Mfg. 06- 2013 , D/Exp. 05- 2015, Mfg. By. M/s Veejay Laboratories Pvt. Ltd., Unit of Grace Laboratories Pvt. Ltd., EPIP Zone, Amingaon, Guwahati, Assam- 781031.	Dissolution 09252/2014-15 Dated 04-06-2014	CDSCO,E.Z. Kolkata	RDTL, Guwahati
13	Norfloxacin Tablets	B. No. 040113, D/Mfg. 01- 2013, D/Exp. 12- 2015, Mfg. By. M/s Veejay Laboratories Pvt. Ltd., Unit of Grace Laboratories Pvt. Ltd., EPIP Zone, Amingaon, Guwahati, Assam- 781031.	Dissolution 09253/2014-15 Dated 04-06-2014	CDSCO,E.Z. Kolkata	RDTL, Guwahati
14	Megarab - 20 Tablets	B. No. S753775, D/Mfg. 06- 2013, D/Exp. 05- 2015, Mfg. By. M/s Scott-Edil Pharmacia Ltd., 56, EPIP, Phase-I, Jhamajri-173205.	Dissolution and Assay 09258/2014-15 Dated 06-06-2014	CDSCO,E.Z. Kolkata	RDTL, Guwahati
15	Albendazole Tablets	B. No. ZW-2012, D/Mfg. 08- 2012, D/Exp. 07- 2014, Mfg. By. M/s Vardhman Pharma, 32 Industrial Area, Trilokpur Road, Kala- Amb, Dist-Sirmour, Himachal Pradesh.	Uniformity of Weight and Assay 09271/2014-15 Dated 10-06-2014	CDSCO,E.Z. Kolkata	RDTL, Guwahati
16	Omeprazole Capsules	B. No. OZC29-03, D/Mfg. 08- 2012, D/Exp. 07- 2014, Mfg. By. M/s Unicure (India) Pvt. Ltd., C-22, Sector 3, Noida, Delhi-201301.	Dissolution 09316/2014-15 Dated 20-06-2014	CDSCO,E.Z. Kolkata	RDTL, Guwahati

Drug Alert for the Month of June 2014

17	Omeprazole Capsules	B. No. OZC29-04, D/Mfg. 08- 2012, D/Exp. 07- 2014, Mfg. By. M/s Unicare (India) Pvt. Ltd., C-22, Sector 3, Noida, Delhi-201301.	Dissolution 09318/2014-15 Dated 20-06-2014	CDSCO,E.Z. Kolkata	RDTL, Guwahati
18	Omeprazole Capsules	B. No. OZC01-22, D/Mfg. 07- 2013, D/Exp. 06- 2015, Mfg. By. M/s Unicare (India) Pvt. Ltd., C-22, Sector 3, Noida, Delhi-201301.	Dissolution 09332/2014-15 Dated 23-06-2014	CDSCO,E.Z. Kolkata	RDTL, Guwahati
19	Omeprazole Capsules	B. No. OZC29-03, D/Mfg. 08- 2012, D/Exp. 07- 2014, Mfg. By. M/s Unicare (India) Pvt. Ltd., C-22, Sector 3, Noida, Delhi-201301.	Dissolution 09327/2014-15 Dated 20-06-2014	CDSCO,E.Z. Kolkata	RDTL, Guwahati
20	Omeprazole Capsules	B. No. OZC01-22, D/Mfg. 07- 2013, D/Exp. 06- 2015, Mfg. By. M/s Unicare (India) Pvt. Ltd., C-22, Sector 3, Noida, Delhi-201301.	Dissolution 09329/2014-15 Dated 23-06-2014	CDSCO,E.Z. Kolkata	RDTL, Guwahati
21	Pantest Tablets	B. No. ERT-310, D/Mfg. 01- 2014, D/Exp. 12- 2015, Mfg. By. M/s Ester Formulations, 1611, Gotri, Vadodara, Gujarat.	Dissolution 09328/2014-15 Dated 23-06-2014	CDSCO,E.Z. Kolkata	RDTL, Guwahati
22	Absorbent Gauze Cloth	B. No. Nil, D/Mfg. Nil, D/Exp. Nil, Mfg. By. Nil	Misbranded RDTL/05/2014- 15 Dated 06-06-2014	CDSCO,E.Z. Kolkata	RDTL, Guwahati
23	Bleaching Powder	B. No. (K) 382, D/Mfg. 09- 2013, D/Exp. 02- 2015, Mfg. By. NIL.	Misbranded RDTL/01/2014- 15 Dated 06-06-2014	CDSCO,E.Z. Kolkata	RDTL, Guwahati

Drug Alert for the Month of June 2014

24	Handloom Cotton Cloth (Non-Sterilised)	B. No. 11, D/Mfg. 03-2013, D/Exp. NIL, Mfg. By. NIL.	Misbranded RDTL/07/2014-15 Dated 06-06-2014	CDSCO,E.Z. Kolkata	RDTL, Guwahati
25	Handloom Cotton Cloth	B. No. 13, D/Mfg. 12- 2013, D/Exp. NIL, Mfg. By. NIL.	Misbranded RDTL/02/2014-15 Dated 06-06-2014	CDSCO,E.Z. Kolkata	RDTL, Guwahati
26	Absorbent Gauze Cloth Super Special 90 cm.	B. No. NIL, D/Mfg. NIL, D/Exp. NIL, Mfg. By. NIL.	Misbranded RDTL/06/2014-15 Dated 06-06-2014	CDSCO,E.Z. Kolkata	RDTL, Guwahati
27	Handloom Cotton Cloth (Non-Sterilised)	B. No. 85, D/Mfg. NIL, D/Exp. NIL, Mfg. By. NIL.	Misbranded RDTL/04/2014-15 Dated 06-06-2014	CDSCO,E.Z. Kolkata	RDTL, Guwahati
28	Rolled Bandage (Non-Sterilised)	B. No. 10, D/Mfg. NIL, D/Exp. NIL, Mfg. By. M/S Sen Enterprises, Bongaon, Gaipukur, North 24 Parganas, West Bengal.	Misbranded RDTL/03/2014-15 Dated 06-06-2014	CDSCO,E.Z. Kolkata	RDTL, Guwahati
29	Sodium Chloride and Dextrose Injections	B. No. F13F048, D/Mfg. 06- 2013, D/Exp. 05- 2015, Mfg. By. M/s D. J. Laboratories Pvt. Ltd., 255, Sector-I, Industrial Area, Pithampur-454775.	BET Test 09349/2014-15 Dated 26-06-2014	CDSCO,E.Z. Kolkata	RDTL, Guwahati
30	Cefixi-DT (Cefixime Dispersible Tablets),	B. No.: DTBA-428 Mfg dt: 09/2012 Exp dt: 08/2014 Mfd by: M/s. Digital Vision, 176, Mauza Ogli, Nahan Road, Kala Amb, Sirmour (HP) 173030	Uniformity of Dispersion 32-8/2014-SS/ DCA(E)- 237/730 Dt. 30.06.2014	CDSCO,E.Z. Kolkata	CDL, Kolkata

Drug Alert for the Month of June 2014

31	Monotax 1 gm,	B. No.: EA9132023 Mfg dt: 03/2013 Exp dt: 02/2015 Mfd by: M/s. Biochem Pharmaceuticals Industries Ltd., Survey No. 49/3,51/1,51/2, Ringanwada, Daman 396210.	Particulate Matter & Clarity of Solution 32-8/2014-SS/ DCA(E)- 220/400 Dt. 09.06.2014	CDSCO,E.Z. Kolkata	CDL, Kolkata
32	Absorbent Cotton Wool IP,	B. No.: 29 Mfg dt: 11/2013 Exp dt: 3 years from the date of mfg. Mfd by: M/s. SN Surgicare & Healthcare Science Pvt. Ltd., Jalsukha, Nilqunjbazar, Kolkata	Acidity Alkalinity, Surface Active Substances, Water Soluble Substances, Sulphated ash 32-8/2014-SS/ DCA(E)- 365/403 Dt. 09.06.2014	CDSCO,E.Z. Kolkata	CDL, Kolkata
33	Wohinral (Trypsin Chymotrypsin Tablets),	B. No.: WA2K05F Mfg dt: 11/2012 Exp dt: 10/2014 Mfd by: M/s. Acme Formulations Pvt. Ltd., Ropar Road, Nalagarh, Solan, HP	Assay 32-12/2014-SS/ DCA(H)-02/535 Dt. 13.06.2014	CDSCO,E.Z. Kolkata	CDL, Kolkata
34	Glimepiride Tablets IP 2mg,	B. No.: T6-12306 Mfg dt: 06/2012 Exp dt: 05/2014 Mfd by: M/s. Rhydburg Pharmaceuticals Ltd., C-2 & 3, SIEL, Selaqui Dehradun 248197	Dissolution 32-13/2014-SS/ DCA(B)- 129/341 Dt. 03.06.2014	CDSCO,E.Z. Kolkata	CDL, Kolkata
35	Ceftrikor 1g,	B. No.: C0043008 Mfg dt: 10/2013 Exp dt: 09/2015 Mfd by: M/s. Dhruv Life Sciences Pvt. Ltd., Hill Top Industrial Area, Phase-I, Baddi 173205.	Particulate Matter & Clarity of Solution 32-18/2014-SS/ DCA(C)-34/307 Dt. 03.06.2014	CDSCO,E.Z. Kolkata	CDL, Kolkata
36	Weltrox - SB 1500 (Ceftriaxone & Sulbactam for Injection),	B. No.: UDD-3543F Mfg dt: 10/2013 Exp dt: 09/2015 Mfd by: M/s. Ultra Drugs Pvt. Ltd., Manpura, Nalagarh, Solan (HP)	Particulate Matter & Clarity of Solution 32-18/2014-SS/ DCA(C)-38/311 Dt. 03.06.2014	CDSCO,E.Z. Kolkata	CDL, Kolkata

Drug Alert for the Month of June 2014

37	Amoxicillin & Potassium Clavulanate Oral Suspension.	B. No.: OBAK59 Mfg dt: 04/2012 Exp dt: 03/2014 Mfd by: M/s. Akums Drugs & Pharmaceuticals Ltd., 19, 20, 21, Sector 6A, IIE, SIDCUL, Ranipur, Haridwar 249403.	Assay, Identification & pH 32-9/2013-SS/ DCA(W)-4/367 Dt. 05.06.2014	CDSCO,E.Z. Kolkata	CDL, Kolkata
38	Gencin 80mg/2ml Injection,	B. No.: MV3D03 Mfg dt: 04/2013, Exp dt: 03/2015 Mfd by: M/s. Martin & Brown Biosciences, K. No.918/419, Malkumajra, Nalagarh Road, Baddi, Solan (HP)	Particulate Matter 32-1/2014-SS/ DCA(N)-69/395 Dt. 09.06.2014	CDSCO,E.Z. Kolkata	CDL, Kolkata
39	Nirgent 10 ml (Gentamycin Injection IP)	B. No.: 5L20980 Mfg dt: 12/2012 Exp dt: 11/2014 Mfd by: M/s. Nirma Limited (Healthcare Division), Sachana, Gujarat.	Particulate Matter 32-11/2014-SS/ DCA(A)- 101/398 Dt. 09.06.2014	CDSCO,E.Z. Kolkata	CDL, Kolkata
40	Brakke (Ofloxacin & Ornidazole Tablets),	B. No.: V12021 Mfg dt: 12/2012 Exp dt: 11/2014 Mfd by: M/s. Vapi Care Pharma Pvt. Ltd., Plot No. 225/3, GIDC, Vapi 396195.	Disintegration 32-11/2013-SS/ DCA(A)-99/377 Dt. 06.06.2014	CDSCO,E.Z. Kolkata	CDL, Kolkata
41	Atorvastatin Tablets 10mg,	B. No.: T3415 Mfg dt: 08/2013 Exp dt: 07/2015 Mfd by: M/s. Stallion Laboratories Pvt. Ltd., C-1B, 305/2 &3, GIDC Kerala, Ahmedabad 382220	Dissolution 32-11/2014-SS/ DCA(A)- 109/347 Dt. 03.06.2014	CDSCO,E.Z. Kolkata	CDL, Kolkata