

LIST OF SUB-STANDARD DRUGS IN JAMMU & KASHMIR STATE DURING THE PERIOD OF 2016-17

S. No.	Name of the Drug	Manufacturer	Sample Lifted By	Batch No.	Test Report No. & Date	Reasons	Action Taken
1. D-T/1471	RABEX-D Tablets	M/s Glyco Labs H.B -86, Village Bhatian , Nalagarh , Distt. Solan (H.P)	DI- Ganderbal HQ	G-9826 M/D: Apr/2015 E/D: Mar/2017	L/DA/2015-16/1342 Dated: 22.03.2016	The Drug Sample fails in the "Disintegration test" of tests.	Stop Use Notice /DA issued. Matter referred to LA HP. Prosecution permission granted. Letter to SDC hp & Chandigarh sent for providing of Constitution. Communication to DDC J/K w.r.t all NSQ Drugs for 2016-17 till December 2016 sent for updation. Complaint filed & copy of same received.
2. D-T/1472	Lignocaine and Adrenaline Injection IP (30ml)	M/s Ramson Remedies 186,187 Industrial Focal Point Amritsar AO 2, G Floor Baktawar Malabar Hill Mumbai - 400006	DI- Zone II Jammu	7990 M/D: Apr/2015 E/D: Sep/2016	CFDL/J/2016-17/05 Dated: 23.04.2016	The Sample fails in particulate matter	DA issued. Matter referred to LA Punjab. Public Notice also sent to Information Deptt. Prosecution Permission granted. Suspension order of concerned LA forwarded to DDCJ for n/a. Also requested to provide copy of complaint.
3. D-T/1474	PAINHAS-SD	M/s Cyper Pharma.K.No. 825-827, Gullarwala , Sai Road , Baddi, Distt. Solan (H.P) - 173205	DI- Zone IV Srinagar	PHSD-1501 M/D: 11/2015 E/D: 10/2017	L/DA/2016-17/113 Dated: 28.04.2016	The contents of Diclofenac Sodium are found less than the claim made.	DA issued. Matter referred to LA HP. Public Notice also sent to Information Deptt. SCN of LA forwarded to DDCK. Suspersion order for one month by LA forwarded to DDCK & laso requested to forward the SCR at an earliest. Prosecution Permission grnated. Letter to SDC HP also sent for providing of constitution of the firm. Copy of complaint received.
4. D-T/1475	THIONAC	M/s Life Vision Healthcare, Plot No. 140,EPIP, Phase-I, Jharmajri , Baddi , Solan (H.P)	1. DI- Zone VI Srinagar 2. Drug Inspector Shopian 3. DI Pulwama HQ	LVT-13485 M/D: 10/2015 E/D: 09/2017	L/DA/2016-17/109 Dated: 27.04.2016 L/DA/2016-17/110 Dated: 27.04.2016 L/DA/2016-17/112 Dated: 27.04.2016	The sample is not labeled properly. Also titanium Dioxide is not shown official on the label of the strip.	Matter referred back to DA for specific reasoning of NSQ. Specific reason sought & accordingly matter referred to concerned LA for n/a. SCN of LA received. SCN forwarded to DDCK for n/a. Suspension order of LA forwarded to DDCK with the request to forward SCR for all the three cases under investigation by concerned Inspectors. Product Permission suspended for seven days w.e.f 12-09-2016 to 18-09-2016. Pursuant upon receipt of SCR , communication to DDCK sent w.r.t suspension order. SCR for sample of Pulwama & Shopian received. Suspension order again forwarded to DDCK for ready reference.
5. D-T/1479	PARACAD-650	M/s Omega Biotech Ltd. 7 th Milestone Dehradun Road Roorkee -247667 (Uttarakhand)	DI- Tral/Awantipora	OT-5002 M/D: 04/2015 E/D: 09/2017	L/DA/2016-17/245 Dated: 28.05.2016	The drug sample doesnot comply to IP requirement w.r.t "Uniformity of Weights".	DA Issued & letter sent to concerned LA . SCR received. Reminder to LA sent.
6. D-T/1485	Jumbo Brand	M/s J.K Bandage Industries , Gangyal , Jammu J&K	DI- Zone-I Jammu	30 M/D: Sep/2014 E/D: After 5 years	CFDL/J/2016-17/365 Dated: 22.07.2016	The sample fails in threads per dm and Fluorescence	DA Issued & SCN to Mfg. Sent. Product permission suspended till further orders. SCR received for Administrative action. Suspension already effected. & same forwarded to DDCK.
7. D-T/1486	Absorbent Guaze Cloth	M/s EVEREST Laboratories 3A Jain Nagar , Meerut Customer Lane No. 0121-2510570	DI- Zone-I Jammu	W-32 M/D: Oct/2015 E/D: Sep/2018	CFDL/J/2016-17/366 Dated: 22.07.2016	The sample fails in threads per dm , Absorbency and Fluorescence	DA Issued & letter sent to concerned LA. Reminder 1 to LA UP sent w.r.t Administrative Action taken pursuant upon receipt of SCR.

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8. D-T/1488	Hydrocort 100	M/s Scott-Edil Pharmacia Ltd. 56, EPIP Phase-I Jharmajri 173205	DI- Zone-IV Jammu	DG5133 M/D: 06-2015 E/D: 05-2017	CFDL/J/2016-17/653 Dated: 15.09.2016	The sample fails in 'Clarity of solution and Particulate matter.	DA Issued & letter sent to concerned LA . Letter to DDCJ Sent pursuant upon receipt of comm.. from Manufacturer. DDCJ asked to forward SCR at an earliest.. SCN by concerned LA forwarded to DDCJ with the request to forward SCR. Suspension Order of LA HP forwarded to DDCJ with the request to provide SCR at an earliest. SCR received. Prosecution Permission granted.
9. D-T/1491	ALBOMIN 2.5 %	M/s Minil Laboratories Pvt. Ltd 26, Industrial Estate Digiana Jammu – 180010.	DI- Zone-IV Jammu	L-2238 M/D: March /2016 E/D: Feb/2018	CFDL/J/2016-17/703 Dated: 27.09.2016	The sample fails in pH. The sample is also declared Misbranded as Albendazole suspension is not shown official in the label.	DA Issued & SCN sent to concerned Manufacturer. Communication from Sheep Husbandry forwarded to DDCJ for n/a. Reply of Mfg. received. Action to be initiated after receipt of SCR. SCR received & DDCJ requested to revisit recommendations in light of DCGI Guidelines Pra No. 4 & 5.
10. D-T/1492	Glimepride and Metformin Hydrochloride (SR) tablets	M/s Theon Pharmaceuticals Ltd. Village Saini Majra Tehsil Nalagarh Distt. Solan H.P-174101	DI- Jammu	GT160167 M/D: 02 /2016 E/D: 01/2018	CFDL/J/2016-17/815 Dated: 25.10.2016	The sample fails Description. The sample is also Misbranded as the colour mentioned in the label not as per Drugs & Cosmetics Act, 1945	DA Issued & letter sent to concerned LA . Communication of Manufacturer received & sent to DDCJ for n/a. Reminder 1 to LA HP sent w.r.t providing of Administrative action details pursuant upon receipt of SCR.
11. D-T/1497	AMSIL-SP	M/s Medox Lifesciences , Plot No. 222-223 , Phase-III, Ind. Area , Sansarpur-Terrace (H.P) Mrk. By: M/s Vass Pharmaceuticals Ahmedabad.	DI- Samba	MT160640 M/D: 06 /2016 E/D: 05/2018	CFDL/J/2016-17/928 Dated: 26.11.2016	The sample is declared Grossly Sub-Standard as it fails in the tests :- 1. Disintegration test 2. Assay content of Paracetamol (66.39% of the claim made) 3. Assay Content of Aceclofenac (02.46% of the claim made).	DA & PN Issued & letter sent to concerned LA Prosecution Permission granted after receipt of SCR. . Communication from CDL w.r.t M.O.A forwarded to LA concerned for n/a.
12. D-T/1498	ANSAID-P	M/s Accura Care Pharmaceuticals Pvt. Ltd , Vill. Moginand , Nahan Road , Kala Amb, Distt. Sirmour H.P-173030 Mrk.By: M/s Heal All Pharmaceuticals Private Ltd. Gujrat India.	DI- Zone II Jammu	AT-1601137 M/D: Jan /2016 E/D: Dec /2017	CFDL/J/2016-17/978 Dated: 30.11.2016	The sample is fails in the Assay Content of Aceclofenac i.e 52.15% of the claim made.	DA & PN Issued & letter sent to concerned LA . Copy of Communication received from Manufacturer & letter to sent to DDCJ for providing latest status in the matter. SCR received. Prosecution permission granted.
13. D-T/1499	EUROPOD-100	M/s Systole Remedies Pvt. Ltd. Vill. Ogli , Kala Amb, Tehsil Nahan , Distt. Sirmour (HP)	DI- Leh	BGY-791 M/D: Dec /2015 E/D: Nov/2017	LSD/RDTL/0354/16-17 Dated: 03.11.2016	The sample doesnot conforms to claim as per IP 2014 in respect to the Dissolution (Cefpodoxime Proxetil calculated as Cefpodoxime) and the Assay of Cefpodoxime Proxetil calculated as Cefpodoxime..	DA & PN Issued & letter sent to concerned LA . On the request of DDCK , Constitution sought from LA concerned. Suspension order of LA forwarded to DDCK with the request to provide SCR.
14. D-T/1503	Biopron	M/s Allkind Healthcare Plot No. 88-B, Export Promotion Industryal Park Phase –II Village Thana Baddi Distt. Solan 173205 (H.P)	DI- Doda	AKT 8549 M/D: 03/2016 E/D: 02/2018	CFDL/L/2016-17/1007 Dated: 13.12.2016	The sample fails in the Description.	DA & letter sent to concerned LA . SCN forwarded to DDCJ for n/a. Suspension order of LA HP forwarded to DDCJ with the request to provided SCR.

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15 D-T/1504	ACLONOVA-P Tablets	M/s Medoz Pharmaceuticals Pvt. Ltd. , Vill, Chanal Majra The. Nalagarh Distt. Solani HP . Mrk. By: Cheminova Lifesciences Chandigarh.	DI- Rajouri	MGT-14675 M/D: 12/2014 E/D: 05/2017	CFDL/L/2016-17/1063 Dated: 24.12.2016	The sample fails in assay content of Aceclofenac viz 16.25 % of the claim made for the tests applied as above.	DA , PN & letter sent to concerned LA sent. . SCN forwarded to DDCJ for n/a. Suspension order of LA HP forwarded to DDCJ with the request to provided SCR
16 D-T/1506	Meriflox	M/s Veteran Pharma , 202 , Abhishek Plaza , Ashram Road , Ahmedabad – 380009 At 70/1 , G.I.D.C Kansari - 388630 (Guj). Mrk. By: Vetoquinol India Animal Health Pvt. Ltd , Unit No. 801 , Sigma , Hiranandani Business Park , Powai , Mumbai- 400 076- India.	DI- Zone VI Jammu	VMR16004 M/D: 05/2016 E/D: 04/2018	CFDL/J/2016-17/1085 Dated: 30.12.2016	The sample fails in the pH & is also found Misbranded as the Levofloxacin Injection is not shown official as Levofloxacin Injection I.P in the label.	DA letter sent to concerned LA's sent.. SCN forwarded to DDCJ for n/a.
17 D-T/1507	ACECLOTIDE- SP Tablets	M/s PDC Healthcare , Village Kunja , Paonta Sahib , Distt. Sirmour – 173205 H.P	DI- Udhampur	T-1650 M/D: 01/2016 E/D: 12/2017	CFDL/J/2016-17/1086 Dated: 30.12.2016	The sample fails in Assay of Paracetamol & Aceclofenac.	DA , PN & letter sent to concerned LA sent.. Letter to SDC is sent for providing of Constitution & technical staff details.
18 D-T/1508	Tumicain	M/s Ravenbhel Healthcare Pvt. Ltd 16-17, EPIP,SIDCO , Kartholi , Bari Brahma , Jammu- 181133 Mrk. By: Neomac Pharmaceuticals Pvt. Ltd , 12 Preet Vihar , Circular Road , Amritsar ,102 Triveni complex , Jawahar Park , Laxmi Nagar , Delhi-110092	DI- Kulgam	75115004 M/D: Sep /2015 E/D: Feb /2017	L/DA/2016-17/892 Dated: 10.01.2017	The contents of Dried Aluminium Hydroxide Gel calculated as Aluminium Oxide in the sample are found less than the claim made.	DA , PN issued. SCN to Manufacturer also sent. Meantime communication of Manufacturer received & same forwarded to DDCK for n/a. Also requested to Direct DI Concerned to proceed for retesting as per section 24(4) to make a conclusive evidence as sample is going to exoire in Feb. 2017. Licence in part suspended till further orders. M.O.A & working standard requested by CDL Kolkatta. Letter sent to Manufacturer through DI Mfg. for immediate action.
19 D-T/1509	Lin-P	M/s Upkar Pharmaceuticals , 101 , Industrial Area , Gondpur , Paonta Sahib , Distt. Sirmour (HP)- 173205 Mrk. By: Linex Pharmaceuticals , 7 Baliram Industrial Estate , S.V Road , Dahisar , Mum. 68.	DI- Zone II Srinagar	UTC-068 M/D: Jun /2015 E/D: May /2017	L/DA/2016-17/929 Dated: 16.01.2017	The Drug sample fails in “Disintegration Test”.	DA , PN issued. Letter to concerned LA also sent. SCR received. Prosecution Permission granted.

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20 D-T/1510	Amoxicillin Capsules LP 500 mg JKMSCL Supply – Not for sale	M/s Theon Pharmaceuticals Ltd. Village Saini Majra Tehsil Nalagarh Solan (H.P) 174101	DI- Jammu Nisar Ahmad	BC160005 M/D: 01 /2016 E/D: 12 /2017	CFDL/J/2016-17/1179 Dated: 23.01.2017	The sample fails in Assay of Amoxicillin	DA , PN issued. Letter to concerned LA also sent. SCR Received. Prosecution Permission Granted. Suspension order of LA HP forwarded to DDCJ with the request to provide copy of complaint.
21 D-T/1511	Ceftriazone Injection LP 1g JKMSCL Supply – Not for sale	M/s Theon Pharmaceuticals Ltd. Village Saini Majra Tehsil Nalagarh Solan (H.P) 174101	DI- Jammu Amit Bali	CFXM16031 M/D: 04 /2016 E/D: 03 /2018	CFDL/J/2016-17/1180 Dated: 23.01.2017	The sample fails in Particulate Matter & clarity of solution.	DA , PN issued. Letter to concerned LA also sent. SCR Received. Prosecution Permission Granted.
22 D-T/1512	Ceftriaxone Injection LP JKMSCL Supply – Not for sale	M/s Theon Pharmaceuticals Ltd. Village Saini Majra Tehsil Nalagarh Solan (H.P) 174101	DI- Jammu Sanjay Bhat	CFXI 16002 M/D: 01 /2016 E/D: 12 /2017	CFDL/J/2016-17/1184 Dated: 23.01.2017	The sample fails in Particulate Matter & clarity of solution.	DA , PN issued. Letter to concerned LA also sent. SCR Received. Prosecution Permission Granted. . Suspension order of LA HP forwarded to DDCJ with the request to provide copy of complaint.
23 D-T/1513	Aceclofenac 100 mg Tablets JKMSCL Supply Govt Supply – Not for sale	M/s Salus Pharmaceuticals , 480/211, Vill. Harralpur , Nalagarh Road , Baddi , Solan (HP) -173205 Mrk. By: Concept Pharmaceuticals Ltd. 501, Jai Singh Business Centre , 119 Sahar Road , Andheri (East) , Mumbai - 400099	*DI- Zone IV Srinagar **Drug Inspector Rajouri HQ	FSP16090 M/D: 04 /2016 E/D: 03 /2018	*L/DA/2016-17/977 Dated: 24.01.2017 **CFDL/J/2016- 17/1260 dt: 16-02-2017	*1.The contents of Aceclofenac in the sample are found less than the claim made. 2. Aceclofenac Tablets not shown official on label 3. Titanium Dioxide also not shown official on label of the strip. **The sample is Misbranded as Aceclofenac tablets are not shown official as I.P on the label with respect to the sample portion received.	DA , PN issued. Letter to concerned LA also sent. Letter to DDC J-K sent for directing Drug Inspectors to prefer an appeal before the appellate authority. Suspension order of LA HP forwarded to DDC J/K with the request to provide latest status w.r.t re-testing of samples.
24 D-T/1516	Glimipride & Metformin Hydrochloride (SR Tablets)	M/s Theon Pharmaceuticals Ltd. Village Saini Majra Tehsil Nalagarh , Distt. Solan (H.P) 174101	DI- Doda / Kishtwar	GT160179 M/D: Feb /2016 E/D: Jan /2018	LSD/RDTL/0418/16-17 Dated: 20.12.2016	The sample doesnot conforms to claim as per patent & proprietary in respect to the Assay of Glimipride.	DA , Letter to concerned LA also sent. SCN forwarded to DDC J for n/a. Suspension order of LA HP forwarded to DDCJ with the request to provide SCR. Coomunication of Theon Pharmaceuticals forwarded to DDC J for n/a.
25 D-T/1517	Prado	M/s Dr. Edwin Lab. Plot No. 517, Industrial Artea , Phase-IX , sas Nagar – 160059. Mrk. By: H& Care Incorp. SCF 250 , gf.m.mkt, Manla Majra Chandigarh - 160101	DI Pulwama (HQ)	DET-1587 M/D: 07 /2015 E/D: 06 /2017	L/DA/2016-17/981 Dated: 28.01.2017	The sample fails in the “ Disintegration test “	DA , Letter to concerned LA also sent.

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26 D-T/1518	Cetfast	M/s Syncom Healthcare Ltd; D-42 , UPSIDC Industrial Area , Selaqui (Dehradun) – 248197 , Uttarakhand.. Mrk. By: Elder Pharmaceuticals Ltd. , Elder House , Plot No. C-9 , Dala Industrial Estate , Off. Veera Desai Road , Andheri (W) , Mumbai – 400053.	DI Bandipora	150451 M/D: 12-2015 E/D: 11-2018	L/DA/2016-17/1042 Dated: 03.02.2017	The sample fails in the “ Description of tablets”	DA , Letter to concerned LA ‘s sent.
27 D-T/1519	OSTAFRESH-P	M/s PDC Healthcare Village Kunja Paonta Sahib Distt. Sirmour (HP) - 173205.. Mrk. By: Pharma Drugs & Chemicals 28-A , Industrial complex G.I.D.C Ramoli Baroda - 391350	DI Rajouri (HQ)	T-8454 M/D: 09/2016 E/D: 08/2018	CFDL/J/2016-17/1261 Dated: 16.02.2017	The sample doesnot conform with respect to the assay of Aceclofenac (i.e 50.54% of the claim made) and also found misbranded for false claim of colour specified on the label.	DA , Letter to concerned LA ‘s sent.
28 D-T/1521	FB-OZ Tablets	M/s Parkin Laboratories , Adjoining to Plot D-1 , Industrial Estate , Roorkee (U.K) Mrk. By: M/s Frank Biotech Remedies (India) Limited , 351/1 , 28 Civil Lines , Roorkee , Distt. Haridwar (U.K) .	DI Kokernag /Shangus	PLT-385 M/D: 02/2016 E/D: 01/2018	L/DA/2016-17/1153 Dated: 28.02.2017	The drug sample fails in Uniformity of Weight , Disintegration Test & Assay.	DA , PN & Letter to concerned LA sent.
29 D-T/1522	Handloom Rolled Cotton Bandage	M/s Yahoo Manufacturers , Industrial Estate , Khonmoh , Phase-III, Plot-2, Srinagar J&K	DI Mfg. Kashmir	01 M/D: Dec.2016 E/D: After 3 Years	L/DA/2016-17/1154 Dated: 28.02.2017	The sample fails in : - 1. Threads / dm 2. Weight in g/meter square. 3. Measurement of length. .	DA & SCN to Manufacturer issued.
30 D-T/1523	Fenamol-MR Tablets	M/s Dr. Edwin Lab , Plot No. 517 , Industrial Area , Phase IX SAS Nagar 160059 (Pb).	DI Rajouri	DET-1163 M/D: April / 2015 E/D: March / 2017	LSD/RDTL/0863/16-17 Dated: 17.02.2017	The sample doesnot conforms to claim as per patent & proprietary in respect to the Disintegration Test. .	DA & letter to concerned Licensing Authority sent. Letter to DDDC J also sent w.r.t re-testing of sample.

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31 D-T/1524	Rare-D Tablets	M/s Alive Healthcare 123 , HPSIDC , Baddi , Distt. Solan - 173205	DI Pulwama (HQ)	160192 M/D: Jan / 2016 E/D: Jun / 2017	LSD/RDTL/0811/16-17 Dated: 23.02.2017	The sample doesnot conforms to claim as per patent & proprietary in respect to the assay of Rabeprazole sodium calculated as Rabeprazole (35.45 %) .	DA /PN issued. Letter to concerned Licensing Authority sent.
32 D-T/1525	Linof-OZ	M/s Accurate Pharmaceuticals , C-3 (a&b), Industrial Area , Gondpur , Paonta Sahib – 173025 (H.P) Mrk. By: M/s Linex Pharmaceuticals 7 , Beliram Indl. Estate , S.V Road , Dahisar , Mumbai-68	DI Zone II Srinagar	APTN-1036 M/D: 03 / 2016 E/D: 02 / 2018	L/DA/2016-17/1274 Dated: 16.03.2017	The sample doesnot conforms to the IP requirements w.r.t the Disintegration Test of Tablets.	DA / PN issued. Letter to concerned Licensing Authorities sent.
33 D-T/1527	Utirab-20 Tablets	M/s Unital Formulations , Plot No. 114-B, epip , p[HASE-I, Jharmajri , Baddi , Distt. Solan (HP) Mrk. By: M/s Utility Pharmaceuticals , Plot No. 42 A , Ground Floor , Sector-I, Parwanoo , Distt. Solan (HP)	DI Zone VI Srinagar	UFT-682 M/D: 10 / 2015 E/D: 09 / 2017	L/DA/2016-17/1277 Dated: 16.03.2017	<ol style="list-style-type: none"> 1. The contents of Rabeprazole Sodium in the sample are found less than the claim made. 2. The sample also fails in Disintegration Test of tablets. 	DA / PN issued. Letter to concerned Licensing Authorities sent.