

**LIST OF DRUGS DECLARED AS MISBRANDED OR HAVING LABELING ERRORS IN JAMMU & KASHMIR STATE 2016-17**

S.No.	Name of the Drug	Manufacturer	Sample Lifted By	Batch No. MD/ED	Test Report No. & Date	Reasons	Action Taken
1. D-T/1473	TUPENT-40	M/s Tuttsan Pharma Pvt. Ltd , Plot No. 10 , Block No. 58, AT & Post Khat.Ta. Kalol , Distt. Gandhi Nagar	DI Zone VI / RS Pura Jammu	T1731 M/D: 09/2014, E/D: 08/2016	CFDL/J/2016-17/06 Dated: 23.04.2016	The sample is declared Misbranded as the label does not depict Pantoprazole Tablets official where as it is official in IP 2014	DA & letter to LA sent. Reminder 1 dt: 07-10-2016 sent to LA for Administrative Action pursuant upon SCR.
2. D-T/1476	PARLIN-650	M/s Go-Ish Remedies Ltd., Baddi Nalagarh Road , 174101 Distt. Solan (HP)	DI Pampore	T-310E M/D: 09/2014, E/D: 08/2017	L/DA/2016-17/114 Dated: 28.04.2016	The contents are found within specified limits. However the sample is not labeled properly. Hence "Misbranded".	Letter to DA DTL sent for specific reason of Misbranded. Specific reason sought & accordingly matter referred to concerned LA for n/a. SCN of LA forwarded to DDCK for n/a. Suspension order of LA forwarded to DDK with the request to forward SCR at an earliest. Product Permission suspended for seven days w.e.f 12-09-2016 to 18-09-2016. Pursuant upon receipt of SCR , letter to DDCK sent w.r.t Suspension Order.
3. D-T/1477	COPAR 650	M//s Comed Chemicals Ltd. , Unit III , Village Dassomajra , P.O Bhud, Baddi, Tehsil Nalagarh, Distt. Solan H.P	DI- Kathua HQ	B137411 M/D: 10/2013 E/D: 09/2016	CFDL/J/2016-17/01 Dated: 21.04.2016	The sample is declared Misbranded for the reason that Paracetamol Tablets is not shown official whereas it is official in I.P 2014	DA & letter to concerned LA Sent. Reminder 1 pursuant to SCR sent to LA for Administrative Action. SCN of LA received. Reminder 2 to LA HP sent for Administrative Action. Suspension order of LA forwarded to DDCJ & others. Product Permission suspended by concerned LA for one day on 05-09-2016.
4. D-T/1478	Jointone	M//s Legen Healthcare , Plot No. 20 , Sector-5, Parwanoo , Distt. Solan HP -173220	DI- Kathua HQ	TX-6908 M/D: 02/2015 E/D: 07/2016	CFDL/J/2016-17/02 Dated: 22.04.2016	The sample is declared Misbranded as the color mentioned on the label is erythrosine whereas the color of the tablets appears to be tartrazine.	DA & letter to concerned LA Sent. After receipt of SCR , Letter to LA sent for Administrative Action. SCN of LA Received & Remoinder-2 sent to LA for Adminstrative Action. Suspension order of LA forwarded to DDCJ & others. Product Permission suspended by concerned LA for three days w.e.f 01-09-2016 to 03-09-2016.
5. D-T/1480	Carpen-40	M//Ocean Organics Pvt. Ltd. P.O Khana Nagar , Amritsar - 143004	DI- Hiranagar/ Billawar	CPN-112 M/D: 08/2015 E/D: 07/2017	CFDL/L/2016-17/132 Dated: 25.05.2016	The sample is declared Misbranded as pantoprazole tablets is not shown official on the label where as it is official in IP 2014	DA & letter to concerned LA Sent. Reminder 1 pursuant to SCR sent to LA for Administrative Action.
6 D-T/1481	Telring-40	Manufactured At: Life Vision Healthcare , Plot No. 140 , E.P.I.P , Phase-I , Jharmajri , Baddi Solan (H.P)	DI- Zone V Srinagar	LVT-11007 M/D: 04/2015 E/D: 03/2017	L/DA/2016-17/294 Dated: 10.06.2016	The tested parameters are found within limits . However , the name of Manufacturer is not mentioned on the label of strip. Hence – "Misbranded".	DA & letter to concerned LA Sent. SCN of LA forwarded to DDCK for n/a. Suspension order of LA forwarded to DDK with the request to forward SCR at an earliest. Product Permission suspended for fifteen days w.e.f 12-09-2016 to 26-09-2016. SCR received for Administrative Action. Suspension already done by LA & same conveyed to DDCK.
7 D-T/1482	MENADIONE SODIUM BISULPHITE INJ. I.P (1 ml)	Manufactured By: Ramson Remedies , 186-187, Industrial Focal Point , Amritsar	DI- Doda	7975 M/D: 03/2015 E/D: 08/2016	CFDL/J/2016-17/228 Dated: 13.06.2016	The sample is declared Misbranded for the reasons that Menadione Sodium Bisulphite Injection & Menadione Sodium Bisulphite active ingredient has been shown as I.P whereas it is not official in I.P 2014 and Addendum 2015.	DA & letter to concerned LA Sent. Pursuant upon SCR , Reminder 1 to LA dated: 07-09-2016 sent.
8 D-T/1483	Nutracid-40	Manufactured By: Modgal Pharmaceuticals (P) Ltd. 134-136 M.I.E Bahadurgarh -124507	Drug Inspector Jammu Zone VI / R S Pura	T-811 M/D: 11/2014 E/D: 10/2017	CFDL/J/2016-17/229 Dated: 14.06.2016	The sample is Misbranded as the label doesnot show Pantoprazole as official in I.P	DA & letter to concerned LA Sent. Reminder1 to LA Haryana is sent for Sharing of Administrative Action pursuant upon Receipt of SCR dated : 22-11-2016. Licence of the Manufacturer suspended for one month by LA Concerned & same forwarded to DDCJ for information & n/a.
9 D-T/1484	Pantro IV 40 mg	Manufactured By: Supermax Drug & Pharmaceuticals (P) Ltd, H-1231 , DSIDC Indl.	Drug Inspector Doda	PAN-02 M/D: 11/2015 E/D: 04/2017	CFDL/L/2016-17/364 Dated: 22.07.2016	The sample is declared Misbranded as Pantoprazole Sodium in composition is not shown official whereas it is official in IP 2014	DA & letter to concerned LA Sent. SCR received. Reminder-1 to LA Delhi sent for sharing Administrative Action details.

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		Complex Narela Delhi 110040					
10 D-T/1487	Thiogestic-AP	Manufactured By: Lifecare Formulations Pvt. Ltd , Plot No. 2 & 3 , 91/5 ,Link Road, Sonia Gandhi Nagar Extn. Near Mettupalayam UIndustrial Estate , Puducherry – 605 009. Mrkd. By: INTRA- LABS Bangalore-560053	Drug Inspector Akhnoor	459602T  M/D: Feb- 2016 E/D: Jan-2018	CFDL/J/2016-17/652 Dated: 15.09.2016	The sample is declared Misbranded as colour mentioned on the label is “ Iron oxide of yellow” whereas it should be mentioned as “ Yellow oxide of Iron” as specified under Rule 127 of the Drugs & Cosmetics Rule , 1945.	DA & letter to concerned LA Sent. Memorandum issued in favor of Manufacturer by LA forwarded to DDCJ for n/a with the request to forward SCR. SCR received for Administrative Action. Reminder to LA Puducherry sent for providing of same. Suspension Order for one month by LA forwarded to DDC J for n/a.
11 D-T/1489	AVZOLE (VETERINARY)	Manufactured By: South East Pharmaceutical 25A ,SIDCO Industrial Estate Chennai- 60009-India.	Drug Inspector Zone IV Jammu	AZ-103  M/D: Dec/2015 E/D: Dec/2017	CFDL/J/2016-17/654 Dated: 15.09.2016	The sample is declared Misbranded as Albendazole suspension is not shown official in the label.	DA & letter to concerned LA Sent.
12 D-T/1490	KANDEM	Manufactured By: Life Virion Healthcare , Plot No. 140 , E.P.I.P , Phase- 1 , Jharmajri , Baddi , Solani (H.P)	Drug Inspector Akhnoor	LVT-13819  M/D: Oct- /2015 E/D: Sep-2018	CFDL/J/2016-17/655 Dated: 15.09.2016	The sample is declared Misbranded as it is not labeled as per Indian Pharmacopoeia , 2014 as Ondansetron orally disintegrating tablets I.P	DA & letter to concerned LA Sent. SCN by concerned LA forwarded to DDCJ with the request to forward SCR. SCR received for Administrative Action. Suspension order of LA concerned forwarded to DDCJ.
13 D-T/1493	Socid - O	Manufactured By: Sarthaak Biotech Pvt. Ltd. 198-A , Sec-3 , HSIIDG Karnal 132001 (Haryana)	Drug Inspector Kathua	SBC-170  M/D: 03//2016 E/D: 02/2018	CFDL/J/2016-17/790 Dated: 17.10.2016	The sample is declared Misbranded as drug manufacturing licence number is not shown on the label.	DA & letter to concerned LA Sent. Suspension order of LA forwarded to DDCJ with the request to provide SCR.
14 D-T/1494	EDLOX-200	Manufactured By: Edifice Laboratories , Industrial Complex , Bhatha Dhua – 141 110	Drug Inspector Kathua (HQ)	6928  M/D: Mar. 2016 E/D: AUG. 2017	CFDL/J/2016-17/791 Dated: 17.10.2016	The sample is declared Misbranded as the formulation Ofloxacin tablets has not been mentioned as I.P , whereas it is official in I.P 2014	DA & letter to concerned LA Sent. SCR received for Administrative action. Letter to LA sent for providing of Administrative action details.
15 D-T/1495	LOXOF-500 mg	Manufactured By: Solrex Pharmaceuticals Co. , Kh. No. 1335-1340 , Bhatoli Kalan , Baddi , H.P- 173205	Drug Inspector Zone-I Jammu	2753256  M/D: 01/ 2016 E/D: 12 / 2017	CFDL/J/2016-17/792 Dated: 17.10.2016	The sample is declared Misbranded for the reasons that the colours mentioned on the label i.e Ferric Oxide (Red) USNF & Ferric Oxide (Yellow) USNF are not as per Rule 127 of the Drugs & Cosmetics Rukes , 1945.	DA & letter to concerned LA Sent. As per SCR , personal hearing opportunity granted to Manufacturer for presence before this office on 03-02-2017
16 D-T/1496	ALBOMIN 2.5 % ( 500 ml )	Manufactured By: M/s Minil Laboratories Pvt. Ltd , 26 , Industrial Estate , Digiana , Jammu - 180010	Drug Inspector Samba	L-2127  M/D: DEC 2015 E/D: NOV 2017	CFDL/J/2016-17/927 Dated: 21.11.2016	The sample is declared Misbranded as the formulation Albendazole Oral Suspension has not been mentioned as I.P whereas it is official in I.P 2014	DA & SCN to Manufacturer sent. Pursuant upon receipt of SCR , Licence of Manufacturer suspended for seven days by SLA J&K alongwith necessary directions to Manufacturer.
17 D-T/1500	PANCAR-40	Manufactured By: M/s Horizon Bioceticals Pvt. Ltd, Nahan Road , Kala-Amb, Distt. Sirmour (HP). Mrkd. By: M/s Nimoli Pharmaceuticals (p) Ltd. Delhi.	Drug Inspector Sopore/ Rafiabab	TE-15104  M/D: May- 2015 E/D: Apr.2017	L/DA/2016-17/790 Dated: 09.12.2016	“Pantoprazole Gastro release tablets IP” as mentioned on the label of the drug , is not official in Indian Pharmacopoeia. Hence Misbranded.	DA & letter to concerned LA Sent for n/a. Suspension order of LA forwarded to DDCK with the request to forward SCR.
18 D-T/1501	DROTBIG INJ	Manufactured By: M/s Scott-Edill Pharmacia Limited , 56- EPIP , Phase-I , Jharmajri –	Drug Inspector Zone II Srinagar	A15146  M/D: 03/2015 E/D: 02/2017	L/DA/2016-17/J-62 Dated: 10.12.2016	The tested parameters are found within limits. But , the drug Drotaverine Hydrochloride is not shown official on the label of strip.	DA & letter to concerned LA Sent for n/a. Suspension Order of LA forwarded to DDCK. With the request to forward SCR. SCR received for Administrative action. Suspension order forwarded

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		173205 (HP)				Hence " Misbranded".	again for ready reference.
19 D-T/1502	Analgin Tablets IP 0.5g	Manufactured By: M/s Pharma Drugs Mfg Co. 7/8 , Industrial Estate Jammu-180003	Drug Inspector Kishtwar	289  M/D: 07/2015 E/D: 06/2018	CFDL/J/2016-17/1006 Dated: 13.12.2016	The sample is misbranded as Analgin Tablets I.P is not official in I.P 2014 where as it has been shown official on the label.	DA & SCN to manufacturer sent. Reply of Manufacturer forwarded to DDCJ for providing SCR. SCR received & letter sent to DDCJ for providing of latest status w.r.t operation of the firm.
20 D-T/1505	ONDISITICA-4	Manufactured By: M/s Sheram Lab , Village Nangal , Uparla Nalagarh Distt. Solan (HP) Mrk. By: Zestica Pharma Baddi T.Series Road Tehsil Baddi Distt. Solan (HP).	Drug Inspector Jammu Zone III	SLT-194  M/D: 06/2016 E/D: 05/2018	CFDL/J/2016-17/1064 Dated: 26.12.2016	The sample is misbranded for the reason that "Ondansetron Tablets" have not been shown official as "Ondansetron Tablets I.P " in the label.	DA & letter 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
21 D-T/1514	PANTONID- DSR	Manufactured By: M/s Bonsai Pharma , Kishanpura , Baddi , Nalagarh Road , PO Guru Majra , Distt. Solan (HP).	Drug Inspector Khag-Magam- Beerwah.	JUN16168  M/D: Jun/2016 E/D: May /2018	L/DA/2016-17/934 Dated: 16.01.2017	The Drug Pantoprazole sodium not shown official on strip. Hence Misbranded.	DA & letter to concerned LA sent. SCN forwarded to DDC K for n/a. Suspension order of LA HP forwarded to DDCK with the request to provide SCR. Suspension order forwarded to DDCK. Clarification w.r.t suspension of Pantonid-40 sought from LA HP via email.
22 D-T/1515	PANTONID-40	Manufactured By: M/s Bonsai Pharma , Kishanpura , Baddi , Nalagarh Road , PO Guru Majra , Distt. Solan (HP).	Drug Inspector Khag-Magam- Beerwah.	AUG16311  M/D: Aug/2016 E/D: May /2018	L/DA/2016-17/935 Dated: 16.01.2017	The Drug Pantoprazole sodium not shown official on strip. Hence Misbranded.	DA & letter to concerned LA sent. SCN forwarded to DDC K for n/a.
23 D-T/1520	INORAB-DSR	M/s H.L Healthcare Pvt. Ltd. Plot No. 25 , Industrial area Phase – II , Gagret- 177201 (HP) Mrk. By: H.L Healthcare Pvt. Ltd spo: D-4/65 , Vashist Park Extension Pankha Road New Delhi - 110046	Drug Inspector Poonch	NC-16136  M/D: Aug /2016 E/D: July /2018	CFDL/J/2016-17/1259 Dated: 16.02.2017	The sample is Misbranded as Rabeprazole Sodium is not shown official as IP on the label.	DA & letter to concerned LA's sent.
24 D-T/1526	Reckresp Plus	M/s MSG Pharmaceuticals , Lane No. 4 , Phase-1 SIDCO Complex , Baribrahmna , Jammu - 181133 Mrk. By: Pulse on Pharma	Drug Inspector Kokernag	MS-T-119  M/D: 02/2016 E/D: 01/2018	L/DA/2016-17/1275 Dated: 16-03-2017	The ingredients Phenylephrine Hydrochloride , Caffeine Anhydrous , Chlorpheniramine Maleate in the sample are not shown official on the label , hence Misbranded.	DA & letter to concerned LA's sent.

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