

List of Drugs reported to be Not of Standard Quality by  
Drugs Control Laboratory Maharashtra For the period  
From : 01 September 2011 TO :30 September 2011

Sr. No	Name of the Drug and B No,M/d,E/d	Manufacturer	Govt Analyst's Opinion
<b>GUJARAT</b>			
1	NORMAFIX INFUSION SET BNo. 019 M/D. 01/12/2010 E/D 30/11/2013 AR No : M/1474/2011 Dt. 02/09/2011 Prod ID : AR-6512	ASCENT MEDICAL THCHNOLOGIES Manjusar,Savli,Baroda	The sample does not comply with IS:12655(Part-4):2003,ISO 8536-4:1998 specification for "infusion equipment for medical Use"with respect to test for Sterility as given in the protocol.
2	NID-XT SUSPENSION BNo. 17008 M/D. 01/04/2011 E/D 30/09/2012 AR No : M/1802/2011 Dt. 22/09/2011 Prod ID : AR-6519	HEALTH CARE FORMULATION PVT.LTD Sardar Estate,Baroda-390019	Content of Ferrous Fumarate in the sample is less (50.81 % of the labelled amount) than the labelled amount.
3	ROMBIPRA TABLETS BNo. R101050 M/D. 09/2010 E/D 08/2012 AR No : M/15731/2011 Dt. 04/07/2011 Prod ID : AR-6522	RHOMBUS PHARMA PVT.LTD 816/1,Raknapur,Kalol	The content of Rabeprazole sodium in the sample is less than IP limits (i.e. 22.75 % of labelled amount) The sample does not comply with IP requirements for Related Substances. NB-The above formulation is official in IP.Hence the drugs is misbranded under rule 96 and section 17(b).
<b>HIMACHAL PRADES</b>			
1	ONLIFE GOLD BNo. GTB-8521 M/D. 01/10/2010 E/D 31/03/2012 AR No : M/1461/2011 Dt. 27/09/2011 Prod ID : AR-6525	ELFIN DRUGS PVT.LTD Berson,Nalagarh,Solan,H.P.	Content of Cyanobalamin in the sample is less (34 % of the labelled amount) than the labelled amount.
2	CEFUROXIME AXETIL TABLETS I.P. BNo. GPB-11168 M/D. 01/09/2010 E/D 31/08/2012 AR No : M/882/2011 Dt. 02/09/2011 Prod ID : AR-6514	GNOSIS PHARMACEUTICALS PVT.LTD Moginand Kala-Amb,Sirmour,	the sample does not complies with I.P.requirements for the test of Dissolution.
3	MULTI BERRY SYRUP BNo. BMBL-003	LABORATE PHARMACEUTICALS INDIA LTD	Content of Thiamine Hydrochloride in the sample is less (43.67 % of the labelled

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<b>HIMACHAL PRADES</b>			
	M/D. 01/03/2011 E/D 31/08/2012 AR No : M/2036/2011 Dt. 27/09/2011 Prod ID : AR-6527	Nariwala,Paonta Sahib,	amount) than the labelled amount.
4	ARGELLA TABLETS BNo. MCRT-247 M/D. 01/02/2011 E/D 31/01/2014 AR No : M/916/2011 Dt. 25/08/2011 Prod ID : AR-6510	MED CARE REMEDIES PVT.LTD Kaloh,Tehsil,Una,	The sample does not comply with I.P. requirements for the tests related substances and Dissolution. (N.B.Levocetirizine tablets are officical monograph (drug) in I.P. 2007 and 2010.But the manufacturer does not stated as I.P. on container (strips) label as well as on Carton label, hence the drug is misbranded vide rule 96,Section 17(b) of the drugs and Cosmetics Act,1940 and Rules there under.)
<b>JAMMU &amp; KASHMIR</b>			
1	VALUE THRAL READYMIX 200 SUSPENSION BNo. 41310003 M/D. 01/11/2010 E/D 31/10/2012 AR No : M/1512/2011 Dt. 09/09/2011 Prod ID : AR-6515	RAVENBHEL HEALTHCARE (P) LTD SIDCO,Kartholi,Jammu	The sample does not comply with IP requirements of 'Azithromycin Oral Suspension' as given in the protocol. The content of Azithromicinn in the sample is less (i.e. 32.47 % of the labelled amount) permissible limits. (Note-The above formulation is Official in IP as 'Azithromycin Oral Suspension'.The sample is misbranded vide rule 96 and section 17 (b) o D & C Act and Rules there under.)
<b>MADHYA PRADESH</b>			
1	FRUSEMIDE TABLETS I.P. BNo. 0310 M/D. 01/09/2010 E/D 31/08/2012 AR No : M/2057/2011 Dt. 12/09/2011 Prod ID : AR-6516	ENDOLABS LIMITED A.B.Road,Pigdamber-453446	The sample received for analysis show variation of result as given below. Out of 100 tablets received in coding Division. A) 40 coated Tablets received for analysis

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MADHYA PRADESH

gives the following result-

1) Average Weight :0.1776gm

2) The sample does not give IR identification test for the presence of Frusemide.

The final solution obtained in Assay does not show absorption maxima at about 271 nm and 333nm.

The sample does not give IP identification test for the presence of Frusemide.

B)Out of remaining 602 tablets,30 coated tablets received for analysis gives the following result-

1) Average Weight-0.1836gm

2)Content of Frusemide in the sample is 27.38 gm which is 69.5 % of the labeled amount.

C) 3 x10 remaining intact tablets received for analysis

Analysis of above intact tablets gives following results.

Strip I -1x10 tablets:Average weight:0.1936gm

Frusemide 39.93 mg/tablet which is 99.82 % of the labelled amount.

Strip II-1)Weight of tablets-0.1776g/Tablet

2) the final solution Obtained in Assay does not show absorption maxima at about 271 nm and 333nm

the sample does not give IP identification test for the presence of the Frusemide.



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Sr. No	Name of the Drug and B No,M/d,E/d	Manufacturer	Govt Analyst's Opinion
<b>UTTARANCHAL</b>			
1	PANTOPRAZOLE TABLETS I.P. BNo. 1101 M/D. 01/02/2011 E/D 31/01/2013 AR No : M/1073/2011 Dt. 22/08/2011 Prod ID : AR-6513	ACACIA BIOTECH LTD Pant nagar,SIDCUL,	The sample does not comply with I.P.requirements for Dissolution test at (B) Buffer stage.
2	CLEAR BREATH CAPSULES BNo. SCBH-006 M/D. 01/02/2010 E/D 31/01/2012 AR No : M/229/2011 Dt. 25/08/2011 Prod ID : AR-6509	D.R.JOHN'S LAB PVT.LTD Sec.6A,I.I.E.,SIDCUL,Haridwar	The content of Camphor and Eucalyptol in the swampl are less (56.4 % and 32.04 % of stated amount respectively) than the permissible limits and 2)The content of Chlorothymol and Terpeneol in the sample are more (121.14 % and 138.58 of the stated amount respectively) than the permissible limits.
3	ONSET-4 TABLETS BNo. LTI-129/10 M/D. 01/08/2010 E/D 31/07/2012 AR No : M/1121/2011 Dt. 25/08/2011 Prod ID : AR-6508	LUCENT BIOTECH LTD. Roorkee,Haridwar,	The sample does not comply with I.P. requirements for dissolution test. (N.B.: Ondansetron tablets are official monograph (drug) in I.P. 2007 and 2010.But the manufacturer does not state as I.P. on container (strip) label as well as on Carton label, hence the drug is misbranded vide Rule 96,Section17(b) of the Drugs and Cosmetic Act,1940 and Rules there under.)