

List of Drugs reported to be Not of Standard Quality by  
Drugs Control Laboratory Maharashtra For the period  
From : 01 October 2011 TO :31 October 2011

Sr. No	Name of the Drug and B No,M/d,E/d	Manufacturer	Govt Analyst's Opinion
<b>DADRA, NAGAR HA</b>			
1	SALBUTAMOL SULPHATE TABLETS I.P. BNo. PP/5241 M/D. 01/02/2010 E/D 31/01/2013 AR No : M/1686/2011 Dt. 17/10/2011 Prod ID : AR-6574	PENTA PHARMACEUTICALS Rakhali,Silvasa 396230	the content of Salbutamol in the sample is less than IP limits (i.e. 63.95 % of the labelled amount.)
<b>DAMAN (U. T.)</b>			
1	ANGEMOX 250/AMOXYCILLIN TRIHYDRATE CAPSULES I.P. BNo. AH10005 M/D. 01/07/2010 E/D 30/06/2012 AR No : M/2123/2011 Dt. 10/10/2011 Prod ID : AR-6551	ANKUR DRUGS AND PHARMA LIMITED Dabhel,Nani Daman	The sample does not give IP 2007 Identification tests A and B for the presence of Amoxicillin Trihydrate. 2)the sample does not give IP 85 identification tests A,B, and C for the presence of Amoxicillin Trihydrate. 3)The sample does not give IP 96 identification tests A and C for the presence of Amoxicillin Trihydrate. Hence the drug sample is Spurious under section 17 (B) (d) of drugs and cosmetics Act 1940 and rules thereunder.
2	NUROSOFT CAPSULES BNo. SPU0610 M/D. 01/12/2010 E/D 31/05/2012 AR No : M/1622/2011 Dt. 24/10/2011 Prod ID : AR-6581	SOFTECH PHARMA PVT.LTD 708/6,Somnath Road,Dabhel	Content of Alpha Lipoic Acid in the sample is less (43.84 % of the labelled amount) than the permissible limits.
<b>GUJARAT</b>			
1	MISOPROSTOL TABLETS 200 MCG BNo. TO299 M/D. 01/11/2010 E/D 31/10/2012 AR No : M/1219/2011 Dt. 19/10/2011 Prod ID : AR-6578	BHARAT PARENTERALS LTD Haripura,Vadodara 391520	The content of Misoprostol in the sample is less than permissible limits(i.e. 70.50 % of the labelled amount.)
2	LOPRA/LOPERAMIDE HYDROCHLORIDE TABLETS IP	MODI ANTIBIOTICS GIDC,Odhava,Ahamedabad	The sample does not comply with IP requirements for Dissolution.

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**GUJARAT**

BNo. 101226  
M/D. 01/12/2010 E/D 30/11/2013  
AR No : M/744/2011 Dt. 07/10/2011  
Prod ID : AR-6550

3	AZITHROMYCIN ORAL SUSPENSION I.P. "AZIROS-200" BNo. 143/T M/D. 01/10/2010 E/D 31/09/2012 AR No : M/1102/2011 Dt. 23/09/2011 Prod ID : AR-6528	PRIYAL PHARMA Moraiya,TA.Sanand,Ahmedabad	The sample does not gives IP Identification test for Azithromycin. The sample is considered spurious under section 17(B)(d) of Drugs and Cosmetics Act 1940 and rules thereunder.
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4	AZIROS /AZITHROMYCIN ORAL SUSPENSION IP BNo. 144/T M/D. 10/2010 E/D 09/2012 AR No : M/17835/2011 Dt. 13/10/2011 Prod ID : AR-6566	PRIYAL PHARMA Moraiya,MahagujaratEst Ahemada	The sample does not gives I.P. Identification test for presence of Azithromycin. 2) The sample is considered spurious under Section 17 (B)(d) of Drugs and Cosmetics Act 1940 and rules thereunder.
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**HIMACHAL PRADES**

1	RABIFIN-D TABLETS BNo. AT-1504 M/D. 01/06/2010 E/D 31/05/2012 AR No : M/1161/2011 Dt. 28/09/2011 Prod ID : AR-6546	ALLIAANCE BIOTECH Baddi,Solan	Content of Rabeprazole in the sample is less than permissible limits.(74.61 % of labelled amount) 2)The sample does not comply wiht IP requirements for Disintegration test for Enteric coated Tablets.Out of 5x10 blister strips received for analysis,1x10 blister strip was found empty.
2	RABIFIN-D TABLETS BNo. AT-1504 M/D. 01/06/2010 E/D 31/05/2012 AR No : M/963/2011 Dt. 28/09/2011 Prod ID : AR-6547	ALLIAANCE BIOTECH Baddi,Solan	Content of Rabeprazole in the sample is less than permissible limits (70.86 % of labelled amount). 2)The sample does not comply wiht IP requirements for Disintegration test for Enteric coated Tablets.

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HIMACHAL PRADES			
3	NEBASPOR BNo. 17110-22 M/D. 01/11/2010 E/D 31/10/2012 AR No : M/1292/2011 Dt. 14/10/2011 Prod ID : AR-6570	BIOGENETIC DRUGS PVT.LTD Jharmajri,Baddi,Solan	Content of Bacitracin in the sample is less (49.96 % of the labelled amount) than the permissible limits.
4	RABEPRAZ 20 MG/RABEPRAZOLE TABLETS IP BNo. RPT-004 M/D. 05/2011 E/D 04/2013 AR No : M/17047/2011 Dt. 01/10/2011 Prod ID : AR-6560	IOSIS REMEDIES Tehsil,Nalagarh,Solan	The sample does not comply with I.P.requirements for the test's Dissolution,related substances and Assay. 2) Teh content of Rabeprazole in the sample is less (79.9 % of the stated amount) than the I.P.limits (I.P.limits -Not less than 90 % and not more than 110 % of the stated amount).
5	PANTOLET-D TABLETS BNo. PLD-004 M/D. 06/2011 E/D 05/2013 AR No : M/17045/2011 Dt. 30/09/2011 Prod ID : AR-6561	IOSIS REMEDIES Tehsil,Nalagarh,Solan	The sample does not comply with I.P.requirements for Disintegration test.
6	MUCORID COUGH FORMULA BNo. 4033 M/D. 01/2011 E/D 12/2012 AR No : M/16004/2011 Dt. 13/10/2011 Prod ID : AR-6572	MERIDIAN MEDICARE LIMITED Shanti,Solan,173212.	The content of Terbutaline in the sample is less (12.80 % of labelled amount) than the permissible limits (permissible limits 90 % to 110 % of lab amount.)
7	CPDOX DRY SYRUP BNo. INO-050 M/D. 06/2010 E/D 05/2012 AR No : M/16339/2011 Dt. 27/09/2011 Prod ID : AR-6542	PARK PHARMACEUTICALS Barotiwala,Kasauli,Solan	The sample does not comply with USP-32 requirements of Cefpodoxime Proxetil for Oral Suspension for Assay as given in the protocol.The content of Cefprodoxime is less (i.e. 64.42 % of labelled amount) thanthe USP limit.
8	CLAMOX 625 TABLETS/AMOXYCILLIN AND CLAVULANATE POT BNo. SBTK178D	SANCHEZ LABORATORIES Kunjai,Baddi,Solan,	Content of Clavulanic acid in the sample is less (51.71 % of the labelled amount) than USP limits.

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<b>HIMACHAL PRADES</b>			
	M/D. 04/2011 E/D 03/2013 AR No : M/16989/2011 Dt. 10/10/2011 Prod ID : AR-6552		2)The sample does not comply with USP requirements for requirements for Dissolution of Clavulanic Acid test.
9	PEPMARK TABLETS BNo. UBT-0999 M/D. 01/2011 E/D 12/2012 AR No : M/16116/2011 Dt. 28/09/2011 Prod ID : AR-6548	UNIBIOTECH FORMULATIONS Katha,Baddi,Solan	The sample does not comply with I.P. requirements for the Dissolution-B test.
10	VARYCER SUSPENSION BNo. MN10302 M/D. 03/10 E/D 02/12 AR No : M/16942/2011 Dt. 13/10/2011 Prod ID : AR-6567	VALANCE HEALTHCARE Kandrori,Kangra,	Content of Cefixime in the sample is less (61.71 % of the labelled amount) than USP limits. 2) The sample does not comply with USP requirements for "Water" test.
11	SEPTOCLAV DRY SYRUP BNo. SV110601 M/D. 06/2011 E/D 11/2012 AR No : M/16895/2011 Dt. 11/10/2011 Prod ID : AR-6564	VALENCE HEALTHCARE Tehsil,Kangra,H.P.	Content of Clavulanic acid in the sample (when freshly prepared) is less (71.97 % of the labelled amount) than IP 2010 limits as given in the protocol. 2)Content of Clavulanic acid in the sample (when stored) is less (30.04 % of the labelled amount) than IP 2010 limits as given in the protocol.
12	ROXINOVA SUSPENSION BNo. RXS-1002 M/D. 01/02/2011 E/D 31/01/2013 AR No : M/1750/2011 Dt. 28/09/2011 Prod ID : AR-6544	WINGS PHARMACEUTICALS PVT.LTD HPSIDC IND.Area,Baddi,	Content of Roxithromycin in the sample is less (70.4 % of the labelled amount) than the permissible limits.

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<b>JAMMU &amp; KASHMIR</b>			
1	RABIFIN-20 TABLETS BNo. RBSIL002 M/D. 12/2010 E/D 11/2012 AR No : M/17134/2011 Dt. 13/10/2011 Prod ID : AR-6571	IND-SWIFT LIMITED Ind Growth Center,Samba,Jammu	The sample does not comply with I.P. requirements for Dissolution test.
<b>MADHYA PRADESH</b>			
1	PARACETAMOL TABLETS IP.P.FIVE TABLETS BNo. 3410 M/D. 11/2010 E/D 10/2012 AR No : M/17419/2011 Dt. 01/10/2011 Prod ID : AR-6554	ENDOLABS LIMITED A.B.Road,Pigdamber	The smple does not comply with requirements for the Dissolution test.
2	GENTIAN VIOLET(CRYSTAL VIOLET) U.S.P./GEVTIAN VIOL BNo. WG-06 M/D. 01/02/2010 E/D 31/01/2012 AR No : M/4279/2010 Dt. 29/09/2011 Prod ID : AR-6539	WALLIS PHARMACEUTICALS Lasudia Mori,Indore	The sample does not comply with USP -32 requirements for 'Gentian Violet Topical Solution' for Assay as given in the protocol. The content of Gentian violet (Crystal Violet) in the sample is less than (i.e. 0.5816 % W/W) the permissible limits.(USP Limit 0.95 to 1.05 % W/W) (Note-1)Sample is labelled as Gentian Violet (Crystal Violet) USP which not correct,it should labelled as crystal Violet Topical Solution USP. 2)Gentian Violet USP is an Official monograph of raw material Crystal Violet. 3)Composition of Gential Violet in Gentian Violet Topical solution is not stated on the carton and container label. Hence drug is misbranded vide rule 96 and section 17 (b) of D & C act and the rules there under.)

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Sr. No	Name of the Drug and B No,M/d,E/d	Manufacturer	Govt Analyst's Opinion
<b>THANE</b>			
1	KRANTI CONCENTRATED FLOOR CLEANER,RWC.5,GRADE III BNo. B.175 M/D. 06/2011 E/D 05/2011 AR No : M17879/2011 Dt. 24/10/2011 Prod ID : AR-6588	GAYATRI GRAMIN VIKAS SEVA SANGH (GRAM UDYOG) Virar,Vasai,Thane	The sample does not comply with "Schedule "O" requirements of Drugs and Cosmetics Act 1940 and rules thereunder for "Black disinfectant fluids "As Rideal Walker Coefficient (RWC) of the sample is less than 1. which is less than Grade II" Limit.
2	KRANTI PHENYL (CONCENTRATED FLOOR CLEANER) BNo. B-175 M/D. 06/2011 E/D 06/2012 AR No : M/17571/2011 Dt. 24/10/2011 Prod ID : AR-6589	GAYATRI GRAMIN VIKAS SEVA SANGH (GRAM UDYOG) Virar,Vasai,Thane	The sample does not comply with "Schedule "O" requirements of Drugs and Cosmetic Act 1940 and rules thereunder for "Black Disinfectant fluids "As Rideal Walker Coefficient (RWC)of the sample is less than 1. which is less than Grade III" limit.
3	KRANTI PHENYL (CONCENTRATED FLOOR CLEANER)(RWC-5,G BNo. B-223 M/D. 09/2011 E/D 07/2012 AR No : M/17360/2011 Dt. 24/10/2011 Prod ID : AR-6587	GSYATRI GRAMIN VIKAS SEVA SANGH Virar,Vasai,Thane	The sample does not comply with Schedule "O" requirements of Drugs and cosmetics Act 1940 and rules thereunder for "Black Disinfectant Fluids" as Rideal Walker Coefficient (RWC) of the sample is less than 1. which is less than "Grade III" limit.
<b>UTTARANCHAL</b>			
1	FLAMCLOV DRY SYRUP BNo. FPAW04 M/D. 06/2010 E/D 11/2011 AR No : M/17522/2011 Dt. 19/10/2011 Prod ID : AR-6577	AKUMS DRUGS & PHARMACEUTICALS LTD SIDCUL,Ranipur,Haridwar	Content of Clavulanic acid in the sample (when freshly prepared) is less (57.58 % of the labelled amount) than IP 2007 limits as given in the protocol. 2)Content of Clavulanic acid in the sample (when stored) is less (37.07 % of the labelled amount) than IP 2007 limits as given in the protocol.
2	PREDNI-5 MG TABLET BNo. 11/05 M/D. 05/2011 E/D 04/2013	FIZARK HEALTHCARE Salempur,Roorkee	The content of Perdnisolone in the sample is less than IP limits (i.e. 17.56 % of the labelled amount)

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UTTARANCHAL

AR No : M/16937/2011 Dt. 19/10/2011  
Prod ID : AR-6579

2)The sample does not complies with IP  
requiremennts for related substances.  
3)The sample does not comly with I.p.  
requirements for related Dissolution.

3 JB AMPICLOX CAPSULE

J.B.REMEDIES PVT.LTD

Content of Dicloxacillin in the sample is  
less (58.36 % of labelled amount) than the  
permissible limits.

BNo. JBC-222

Roorkee,Haridwar

M/D. 01/12/2010 E/D 30/11/2012

AR No : M/1738/2011 Dt. 28/09/2011

Prod ID : AR-6543

4 WECLAV/AMOXYCILLIN & POTASSIUM

ZENEKA HEALTHCARE PVT.LTD

Content of Clavulanic acid in the sample  
(when stored)is less (52.79 % of the  
labelled amount) than IP limits as given in  
the protocol.

CLAVULANATE ORAL SU

Ranipur,Haridwar,249403

BNo. ZB110303

M/D. 03/2011 E/D 08/2012

AR No : M/17123/2011 Dt. 11/10/2011

Prod ID : AR-6565