

From

Drugs Inspector
Chandigarh Administration
Chandigarh

To

President
Chandigarh Chemist Association
SCF No. 16, Sector-19-C,
Chandigarh

Memo No. DIS-2017/1093

Dated, Chandigarh the:- 18.

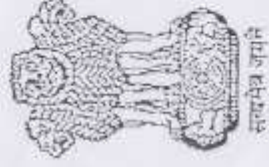
Subject:- Drugs Reported to be "Not of Standard Quality"-
regarding.

In reference to the letter received from Dy. Drugs Controller, Govt of India, CDSCO, Chennai, Ref No. 10-2/SZ/2017-18/709, Dated 23.May.2017 regarding List of "Not of Standard Quality" Drugs-Reported communicated. (Copy enclosed herewith).

You are hereby directed to further inform the retail & whole sale chemists to not purchase/ sale of these particular batches of these drugs & if any drugs stock is available them, then immediately inform to this office.

Drugs Inspector
Chandigarh Administration
Chandigarh

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
स्वास्थ्य सेवा महानिदेशालय
केन्द्रीय औषध मानक नियंत्रण संगठन
दक्षिण क्षेत्र
उप औषध नियंत्रक (भारत) का कार्यालय
दूसरी मंजिल, शास्त्री भवन एनेक्सी,
26, हार्डवेय रोड, चेन्नई - 600 006.
टेलीफोन: 044-28278186, टेलीफैक्स: 044-28213079
ई-मेल : ddcsz@nic.in



सत्यमेव जयते

CDSO

GOVERNMENT OF INDIA
Ministry of Health and Family Welfare
Directorate General of Health Services
Central Drugs Standard Control Organization
South Zone

Office of The Deputy Drugs Controller (I)

Second Floor, Shastri Bhavan Annexe,
26, Haddows Road, Chennai - 600 006.

Telephone: 044-28278186, Tele Fax: 044-28278186

E-mail: ddcsz@nic.in

(An ISO 9001:2008 certified office)

No. 10-2/SZ/2017-18/709

E-mail only

Dated 23rd May 2017

To

1. The Director of Drugs Control, Tamil Nadu.
2. The Licensing Authority, Department of Drugs Control, Puducherry.
3. The Director, Medical and Health Services, Lakshadweep.

Sub: Drugs reported to be "Not of Standard Quality" - reg.

Sir,

The Drugs Controller, Kerala, informed this office that following drug samples were drawn and sent for test by their department have been declared to be "Not of Standard Quality".

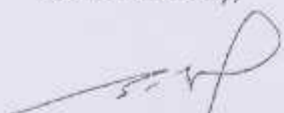
Sl.No.	Name of the Product, Batch No., D/M & D/E	Manufacturer's name	Reason for declaring "Not of Standard Quality"
1.	AB-PAR-650 (Paracetamol Tablets IP 650mg) Batch No. SPT-16276, D/M: 07/2015 D/E: 06/2018	M/s. Shervotec Pharmaceuticals, 82/4&82/5, HPSIDC Indl. Area, Baddi, Solan	The sample does not conform to IP Standards. This particular batch of sample fails the test Dissolution.
2.	ACBRO-M(Terbinafine HCL with Mometasone Furoate Cream.-15 gm) Batch No. 5526 D/M: 08/2016 D/E: 07/2018	M/s. Lyra Laboratories Pvt. Ltd., Baddi, Barotiwala Road, Buranwala, Dist.Solan, Himachal Pradesh - 174 103	This particular batch of sample fails the test Assay of Mometasone Furoate.

3.	Arofen S Tablets Batch No. AEV6004CL, D/M: 05/2016 D/E: 04/2018	M/s. Pinnacle Life Sciences Pvt Ltd., Khasra No. 1328-1330, Vill. Manpura, Tehsil-Baddi, Dist.Solan (HP)-174 101	The sample does not conform to IP Standards. This particular batch of sample fails the test Disintegration.
4.	TELOBY-40 (Telmisartan Tablets 40mg) Batch No. T 604, D/M: 10/2015 D/E: 09/2018	M/s. Biocin Healthcare, Sector - 6, Plot No.26, SIDCUL, IIE, Panthenagar, Rudrapur, U.S.Nagar, Uttarakhand	The sample does not conform to IP Standards. This particular batch of sample fails the test Dissolution.
5.	Organic Hair Colour Herbal Hair Colour Cream Batch No. WCBL 16060005, D/M: 06/2016 D/E: 06/2019	M/s. Guangzhou Wenda Refinement Chemical Co Ltd., PRC Imported by Siso Importers & Trader, Trivandrum, Kerala	The sample contains 2.5089% of Paraphenyl Diamine PPD. But on picking the label claims NOPPD. The sample is not labeled in the prescribed manner and statement on packing is false and misleading. So as per section 17C (b)&(c) of D&C Act & Rules the sample is MISBRANDED.
6.	LANUM - C - 500 (Calcium Carbonate Tab I.P.) Batch No. T0431602, D/M: 02/2016 D/E: 01/2018	M/s. Stanford Laboratories Pvt Ltd, 8, Indl.Area, Mehatpur (H.P.) - 174 315	The sample does not conform to IP Standards. This particular batch of sample fails the test Disintegration.
7.	Organic Hair Colour Herbal Hair Colour Cream (Brown) Batch No. WCBR 16060005, D/M: 06/2016 D/E: 06/2019	M/s. Guangzhou Wenda Refinement Chemical Co Ltd., PRC Imported by Siso Importers & Trader, Trivandrum, Kerala	The sample contains 1.105% of Paraphenyl Diamine PPD. But on picking the label claims NOPPD. The sample is not labeled in the prescribed manner and statement on packing is false and misleading. So as per section 17C (b)&(c) of D&C Act & Rules the sample is MISBRANDED.

8.	SYNAMOL-650 (Paracetamol Tablets IP 650mg) Batch No. ZT-1481503, D/M: 01/2016 D/E: 12/2017	M/s. Progressive Life Sciences Pvt Ltd., Latherdevahoon, P.O.Jhabrera, Roorkee, Distt. Haridwar (U.K) - 247 665	The sample does not conform to IP Standards. This particular batch of sample fails the test Dissolution.
9.	Rosuvastatin Tablets I.P.10mg Batch No. FW37J601, D/M: 09/2016 D/E: 08/2019	M/s. ZIM Laboraories Ltd.,B- 21,22, MIDC Area, Kalmeshwar, Dist-Nagpur - 441 501	The sample does not conform to IP Standards. This particular batch of sample fails the tests Dissolution and assay.
10.	Cephalexin Oral Suspension IP Dry Syrup Batch No. CFS 15008, D/M: 06/2015 D/E: 05/2017	M/s. Vivek Pharma Chem (India) Ltd., NH-8, Chimanpura, Amer - 303 102	The sample does not conform to IP Standards. This particular batch of sample fails the tests assay.
11.	VISNAC-P (Aceclofenac & Paracetamol Tablets) Batch No. CBT-377/16, D/M: 09/2016 D/E: 08/2018	M/s. C.B.Healthcare Village Messa, Tibba Nalagarh, Distt. Solan - 174 101	This particular batch of sample fails the test Assay of Aceclofenac.

Therefore, you are hereby requested to alert the Drugs Inspectors under your control on the movement of the subject batch of drugs and take necessary action.

Yours faithfully,



No. S.5012/2017/DC



Office of the Drugs Controller,
Red Cross Road
Thiruvananthapuram-695035
Tel: 0471-2471896
Email: dckerala@gmail.com
Dated: 02/05/2017.

From

The Drugs Controller,
Kerala State.

To

The State Drugs Controller
Controlling Cum Licensing Authority,
Baddi, Dist. Solan, H.P - 173205.

Sir,

Sub:- Testing of - Paracetamol Tablets IP 650, AB-PAR 650, Batch No. SPT-16276, Mfd. by: M/s. Shervotec Pharmaceuticals, 82/4 & 82/5, HPSIDC Indl. Area, Baddi, Solan - **Not of Standard Quality** - reg.

I am enclosing a copy of certificate of test/or analysis in Form 13 along with Laboratory Protocol issued by the Government Analyst, Regional Drugs Testing Laboratory, Ernakulam on a sample of the subject drug which is self explanatory. The sample has been declared as **Not of Standard Quality**.

The matter is referred to you for taking necessary action against the manufacturer.

Action taken by your office in this regard may please be communicated to this office at the earliest.

FORM 13

(See Rule 46)

Certificate of Test or analysis by Government Analyst Under
Section 25(1) of the Drugs and cosmetics Act, 1940

1. Name of inspector from whom received. : Santhi Krishna.U, Drugs Inspector,
O/o the Drugs Inspector, Malappuram.
2. Serial No. and date of inspector's memorandum : MLP/ None /FRM/ 56470/KL-EKM
dated 11/01/17
3. Number of sample. : 38/17
4. Date of Receipt. : 19/01/17
5. Name of drug purporting to be contained
in the sample : Paracetamol Tablets IP 650 mg,
AB-PAR 650
Batch No: SPT -16276
Mfd by : Shervotec pharmaceuticals,
82/4& 82/5, HPSIDC Indl. Area,
Baddi, Solan.
6. Condition of seals on the package. : Intact; compared with the specimen impression of
the seal sent separately and found to be
identical.
7. Result of Test or analysis with protocols of test
or analysis applied. : IP

In the opinion of the undersigned the sample referred to above is of Not of standard quality as defined in the
Drugs and Cosmetics Act, 1940, and Rules there under for the reason given below:-

NOT OF STANDARD QUALITY

The sample does not conform to IP standards. This particular batch of sample
is of Standard quality Medicine.

LABORATORY PROTOCOL

Protocol No : 38/17
Received from : Santhi Krishna.U
Drugs Inspector
Malappuram.

Date of Receipt : 19/01/2017

Date of test : 23/02/2017

Completed on : 13/03/2017

Date of Report : 13/03/2017

Details of Sample : Paracetamol Tablets IP 650 mg, AB-PAR 650
Each uncoated tablet contains: Paracetamol IP 650 mg

Batch No : SPT- 16276
Date of Manufacture : 07/ 2015
Date of Expiry : 06/ 2018
Mfg.Lic.No. : MNB/05/166 &
MB/05/167

Manufactured /Repacked by
Shervotec pharmaceuticals,
82/4& 82/5, HPSIDC Indl. Area,
Baddi, Solan.

Results / Calculations

Description : White oval shaped biconvex tablet having a dosagline engraved on one side.
Identification : Gives positive result for the presence of Paracetamol.
Dissolution : Does not comply with IP
Uniformity of weight : Complies with IP

No. S.5015/2017/DC

Office of the Drugs Controller,
Red Cross Road
Thiruvananthapuram-695035
Tel: 0471-2471896
Email: dcKERALA@gmail.com
Dated: 02/05/2017.

From

The Drugs Controller,
Kerala State.

To

The State Drugs Controller
Controlling Cum Licensing Authority,
Baddi, Dist. Solan, H.P - 173205.

Sir,

Sub:- Testing of - ACBRO-M (Terbinafine Hcl with Mometasone Furoate Cream - 15gm), Batch No:5526, Mfd. by: M/s.Lyra Laboratories Pvt. Ltd., Baddi, Barotiwala Road, Buranwala, Dist. Solan, Himachal Pradesh - 174 103 - **Not of Standard Quality** - reg.

I am enclosing a copy of certificate of test/or analysis in Form 13 along with Laboratory Protocol issued by the Government Analyst, Drugs Testing Laboratory, Thiruvananthapuram on a sample of the subject drug which is self explanatory. The sample has been declared as **Not of Standard Quality**.

The matter is referred to you for taking necessary action against the manufacturer.

Action taken by your office in this regard may please be communicated to this office at the earliest.

FORM 13
(See Rule 46)

SW/6404/16/DTL

Certificate of Test or Analysis by Government Analyst under Section 25 (1)
of the Drugs and Cosmetics Act, 1940

1. Name of the Inspector from whom received : Mahesh.C.D., Drugs Inspector.
O/o. the Drugs Inspector, Kottayam.
2. Serial No. and date of the Inspector's Memorandum : KTM/None/FRM/56228/KL-TVM
dtd. 30/12/2016.
3. Number of sample : 2710/16
4. Date of receipt : 31/12/2016
5. Name of the Drugs purporting to be contained in the sample : ACBRO-M(Terbinafine Hcl with Mometasone
Furoate Cream.-15gm)
Batch No. 5526
Mfd. by : Lyra Laboratories Pvt. Ltd,
Baddi, Barotiwala Road, Buranwala, Dist. Solan,
Himachal Pradesh - 174 103.
6. Condition of seal on the packet or on portion of sample or container : Intact: Compared with the specimen impre-
: ssion of the seal sent separately by the
Drugs Inspector and found to be identical.
7. Results of test or analysis with protocols of test or analysis applied : Mfgs method

In the opinion of the undersigned the sample referred to above is not of standard quality as defined in the Drugs and Cosmetics Act, 1940 and Rules thereunder for the reasons given below :-

Not of Standard Quality

LABORATORY PROTOCOL

Protocol No. 2710/16 Date of Receipt : 31/12/2016

Received from : Date of Test : 14/03/2017

Mahesh.C.D.,

Drugs Inspector,

O/o. the Drugs Inspector,

Kottayam.

Completed on : 27/03/2017

Date of Report : 28/03/2017

Details of sample. Terbinafine Hcl with Mometasone Furoate Cream 15gm
ACBRO-M Cream. Composition : Terbinafine Hydrochloride
BP 1.0%w/w Mometasone Furoate USP 0.1% w/w in a cream base.

Batch No : 5526

Manufactured by:

Date of manufacture : 08/2016

Lyra Laboratories Pvt. Ltd,

Baddi, Barotiwalla Road, Buranwala,

Dist. Solan, Himachal Pradesh - 174 103.

Date of expiry : 07/2018

Mfg./Rpg. Lic. No. : MB/06/337 &
MNB/05/258

RESULTS/CALCULATIONS

Description : A white cream.

Identification : Gives positive results for the presence of Terbinafine Hydrochloride
and Mometasone Furoate.

No. S.5019/2017/DC

Office of the Drugs Controller,
Red Cross Road
Thiruvananthapuram-695035
Tel: 0471-2471896
Email: dckerala@gmail.com
Dated: 02/05/2017.

From

The Drugs Controller,
Kerala State.

To

The State Drugs Controller
Controlling Cum Licensing Authority,
Baddi, Dist. Solan, H.P. - 173205.

Sir,

Sub:- Testing of - Arofen-S Tablets, Batch No.AEV6004CL, Mfd. by: M/s.
Pinacle Life Science Pvt. Ltd., Khasra No.1328-1330, Vill. Manpura
Tehsil-Baddi, Dist. Solan (HP) - 174 101- **Not of Standard Quality**
- reg.

I am enclosing a copy of certificate of test/or analysis in Form 13 along with Laboratory Protocol issued by the Government Analyst, Regional Drugs Testing Laboratory, Ernakulam on a sample of the subject drug which is self explanatory. The sample has been declared as **Not of Standard Quality**.

The matter is referred to you for taking necessary action against the manufacturer.

Action taken by your office in this regard may please be communicated to this office at the earliest.

FORM 13*(See Rule 46)***Certificate of Test or analysis by Government Analyst Under
Section 25(1) of the Drugs and cosmetics Act, 1940**

1. Name of inspector from whom received. : Vinayan.M.P., Drugs Inspector,
Office of the Asst.Drugs Controller,
Thrissur
2. Serial No. and date of inspector's memorandum : TSR/None /FRM/ 55808/KL-EKM
dated : 13/12/2016
3. Number of sample. : 4/17
4. Date of Receipt. : 10/01/2017
5. Name of drug purporting to be contained
in the sample : Arofen-S Tablets
Batch No: AEV6004CL
Mfd.by: Pinnacle Life Science Pvt.Ltd.,
Khasra No-1328-1330, Vill.Manpura,
Tehsil-Baddi, Dist-Solan (HP)-174 101.
6. Condition of seals on the package. : Intact; compared with the specimen impression of
the seal sent separately and found to be
identical.
7. Result of Test or analysis with protocols of test
or analysis applied. : IP

In the opinion of the undersigned the sample referred to above is of **Not of standard quality** as defined in the
Drugs and Cosmetics Act, 1940, and Rules there under for the reason given below:-

NOT OF STANDARD QUALITY

LABORATORY PROTOCOL

Protocol No : 4/17
Received from : Vinayan.M.P., Drugs Inspector,
Office of the Asst.Drugs Controller,
Thrissur

Date of Receipt : 10/01/2017
Date of test : 14/03/2017
Completed on : 29/03/2017
Date of Report : 29/03/2017

Details of Sample : Serratiopeptidase & Diclofenac Potassium Tablets. AROFEN-S
Composition : Each enteric coated tablet contains:
Diclofenac Potassium B.P. -50mg,
Serratiopeptidase I.P. -10mg. (20,000 Units)
Excipients.q.s., Colour: Sunset Yellow FcF & Titanium Dioxide I.P.

Batch No : AEV6004CL
Date of Manufacture: 05/2016
Date of Expiry : 04/2018
Mfg.Lic.No. : MB/08/730

Manufactured /Repacked-by
Pinnacle Life Science Pvt.Ltd.,
Khasra No-1328-1330, Vill.Manpura,
Tehsil-Baddi, Dist-Solan (HP)-174 101.

Results / Calculations

Description : Orange coloured, circular, biconvex tablets.

Identification : Gives positive result for the presence of Serratiopeptidase & Diclofenac Potassium

No. S.5014/2017/DC

Office of the Drugs Controller,
Red Cross Road
Thiruvananthapuram-695035
Tel: 0471-2471896
Email: dckerala@gmail.com
Dated:02/05/2017.

From

The Drugs Controller,
Kerala State.

To

The Drugs Controller,
Dept. of Medical Health and Family Welfare,
Village Danda Lakhond,
Near Rajiv Gandhi Play Ground,
Sahasradhara Road, Dehradun, U.K.

Sir,

Sub:- Testing of -- TELOBY-40 Telmisartan Tablets 40mg, Batch No. T 604,
Mfd. by:M/s. Biocin Healthcare, Sector - 6, Plot No.26, SIDCUL, IIE,
Pantnagar, Rudrapur, U.S.Nagar, Uttarakhand - **Not of Standard
Quality** - reg.

I am enclosing a copy of certificate of test/or analysis in Form 13 along with Laboratory Protocol issued by the Government Analyst, Regional Drugs Testing Laboratory, Ernakulam on a sample of the subject drug which is self explanatory. The sample has been declared as **Not of Standard Quality**.

The matter is referred to you for taking necessary action against the manufacturer.

Action taken by your office in this regard may please be communicated to

FORM 13

(See Rule 46)

Certificate of Test or analysis by Government Analyst Under
Section 25(1) of the Drugs and cosmetics Act, 1940

1. Name of inspector from whom received. : Manju Prathap, Drugs Inspector,
O/o the Asst. Drugs Controller,
Ernakulam. 682030
2. Serial No. and date of inspector's memorandum : EKM/ None /FRM/ 55451/KL-EKM
dated 23/11/16
3. Number of sample. : 1611/16
4. Date of Receipt. : 13/12/16
5. Name of drug purporting to be contained
in the sample : TELOBY- 40
Telmisartan Tablets 40 mg
Batch No : T 604
Mfd. by : Biocin Healthcare, Sector-6,
Plot No. 26, SIDCUL, IIE, Pantnagar,
Rudrapur, U.S. Nagar, Uttarakhand..
6. Condition of seals on the package. : Intact; compared with the specimen impression of
the seal sent separately and found to be identical
7. Result of Test or analysis with protocols of test
or analysis applied. : IP

In the opinion of the undersigned the sample referred to above is of Not of standard quality as defined in the
Drugs and Cosmetics Act, 1940, and Rules there under for the reason given below:-

NOT OF STANDARD QUALITY

LABORATORY PROTOCOL

Protocol No : 1611/16
Received from : Manju Prathap
Drugs Inspector
Ernakulam.

Date of Receipt : 13/12/2016

Date of test : 04/03/2017

Completed on : 23/03/2017

Date of Report : 23/03/2017

Details of Sample : Telmisartan Tablets 40 mg, TELOBY - 40
Each uncoated tablet contains: Telmisartan 40 mg

Batch No : T 604
Date of Manufacture : 10 / 2015
Date of Expiry : 09 / 2018
Mfg.Lic.No. : 31/UA/2005

Manufactured /Repacked by

Biocin Healthcare, Sector-6,
Plot No. 26, SIDCUL, IIE, Pantnagar,
Rudrapur, U.S. Nagar, Uttarakhand..

Results / Calculations

Description : White circular biconvex tablet with a dosage line engraved on one surface.
Identification : Gives positive result for the presence of Telmisartan.

Received sample with ID

No.S.2999/2017/DC

Office of the Drugs Controller,
(Drugs Control Department),
Red Cross Road,
Thiruvananthapuram,
Tel: 0471-2471896, 2774601
Email: dckerala@gmail.com
Web: www.dc.kerala.gov.in
Dated : 06/05/2017

From

Drugs Controller

To

The Central Drugs Standard Control Organisation
Chennai.

Sub:- **Not of Standard Quality Drug:** – Organic Hair Color Herbal Hair Color
Cream (Natural Black) WCBL 16060005 Mfd by: Guangzhou Wenda
Refinement Chemical Co. Ltd, Imported by: Siso Importers & Trader,
Pattom, Thiruvananthapuram details seeking of – reg.

Ref:- SW 5571/16/DTL dated 01/03/2017.

I am enclosing a copy of certificate of test/analysis in Form 13, along with
Laboratory Protocol issued by the Government Analyst, Drugs Testing Laboratory,
Thiruvananthapuram on a sample of the subject product which is self explanatory.

SW- 5571/16/DTL

FORM 34

(See Rules 131 & 150)

**CERTIFICATE OF TESTS OR ANALYSIS OF COSMETICS BY THE
GOVERNMENT ANALYST**

1. Name of the Officer or Inspector from whom received. : Moniveena M.G., Drugs Inspector, (SIB),
Thiruvananthapuram.
2. Serial No. and date of the Officers/ Inspectors Memorandum : TVM/Top Priority/FRM/55288/KL-TVM
Dated, 16/11/2016
3. Number of sample : 2409/16
4. Date of receipt : 16/11/2016
5. Name of the Cosmetic purporting to be contained in the sample : Organic Hair Colour Herbal Hair Colour Cream
(Natural Black)
Batch No: WCBL 16060005
Mfg. By: Guangzhou Wenda Refinement Chemical Co. Ltd.,
PRC, Imported By : Siso Importers & Trader,
Pattom Post, Trivandrum, Kerala - 695 004
6. Condition of seal on the packet or on portion of sample or container : Intact: Compared with the specimen
: impression of the seal sent separately by
the Drugs Inspector and found to be
identical.
7. Results of test or analysis : IS 8481:2005
The sample of Cosmetics
 - a. Contain a prescribed colour only :
Does not contain a prescribed colour
 - b. Does not contain harmful ingredients :
Contain harmful ingredients
 - c. Conform to claims made on the label
as to the nature & quality of
the cosmetic
Does not conform to claims made on

LABORATORY PROTOCOL

Protocol No. 2409/17 Date of Receipt : 16/11/2016
Received from : M.G Moniveena, Date of Test : 04/02/2017
Drugs Inspector, (SIB),
Thiruvananthapuram. Completed on : 25/02/2017
Date of Report : 27/02/2017

Details of sample **ORGANIC HAIR COLOUR**
.....
..... **HERBAL HAIR COLOUR CREAM (NATURAL BLACK)**

Batch No : WCBL16060005 Manufactured/repacked by
Date of manufacture : 06/2016 Guangzhou Wenda Refinement Chemical Co. Ltd.,
PRC
Date of expiry : 06/2019 Imported By: Siso Importers & Trader,
Pattom Post, Trivandrum, Kerala - 695 004.
Import. Lic. No. : COS-064/16

RESULTS/CALCULATIONS

Description : The given sample consist of two parts.
Black coloured dye and white developer with an applicator.

Requirements For Dye

- i) pH : Complies with IS 8481:2005.
ii) Active matter as PPD content, Percent by mass : Complies with IS 8481:2005
PPD content - 2.5089 %.
- [IS limit :- 2.5-4.0 for Type -1 (Black)]

No. S.5018/2017/DC

Office of the Drugs Controller,
Red Cross Road
Thiruvananthapuram-695035
Tel: 0471-2471896
Email: dcKERALA@gmail.com
Dated: 02/05/2017.

From

The Drugs Controller,
Kerala State.

To

The State Drugs Controller
Controlling Cum Licensing Authority,
Sai Road, Baddi, Dist. Solan, H.P.

Sir,

Sub:- Testing of - Larium C - 500, Calicum Carbonate Tab I.P., Batch No. T0431602, Mfd. by: M/s. Stanford Laboratories Pvt. Ltd., 8, Indl. Area, Mehatpur (H.P.) - 174315 - **Not of Standard Quality** - reg.

I am enclosing a copy of certificate of test/or analysis in Form 13 along with Laboratory Protocol issued by the Government Analyst, Regional Drugs Testing Laboratory, Ernakulam on a sample of the subject drug which is self explanatory. The sample has been declared as **Not of Standard Quality**.

The matter is referred to you for taking necessary action against the manufacturer.

Action taken by your office in this regard may please be communicated to this office at the earliest.

FORM 13

[See Rule 46]

Certificate of Test or analysis by Government Analyst Under
Section 25(1) of the Drugs and cosmetics Act, 1940

1. Name of inspector from whom received. : Shinu, V.K, Drugs Inspector,
O/o the Drugs Inspector, Malappuram.
2. Serial No. and date of inspector's memorandum : MLP/ None /FRM/ 55873/KL-EKM
dated 19/12/16
3. Number of sample. : 1710/16
4. Date of Receipt. : 30/12/16
5. Name of drug purporting to be contained
in the sample : Lanum C - 500,
Calcium Carbonate Tablets IP,
Batch No : T 0431602
Mfd.by : Stanford Laboratories Pvt. Ltd,
8, Indl. Area, Mehatpur (H.P) -174315.
6. Condition of seals on the package. : Intact compared with the specimen impression of
the seal sent separately and found to be
identical.
7. Result of Test or analysis with protocols of test
or analysis applied. : IP

In the opinion of the undersigned the sample referred to above is of Not of standard quality as defined in the
Drugs and Cosmetics Act, 1940, and Rules there under for the reason given below:-

NOT OF STANDARD QUALITY

LABORATORY PROTOCOL

Protocol No : 1710/16
Received from : Shinu V.K
Drugs Inspector
Malappuram.

Date of Receipt : 30/12/2016

Date of test : 27/02/2017

Completed on : 13/03/2017

Date of Report : 13/03/2017

Details of Sample : Calcium Carbonate Tablets IP, Lanum C - 500
Each uncoated tablet contains: Calcium carbonate I.P -1250 mg eq. to elemental
calcium 500 mg, Excipients q.s

Batch No : T 0431602
Date of Manufacture : 02 / 2016
Date of Expiry : 01 / 2018
Mfg.Lic.No. : MNB/08/695 &
MB/08/696

Manufactured /Repacked by

Stanford Laboratories Pvt. Ltd,
8, Indl. Area, Mehatpur (H.P) -174315.

Results / Calculations

Description : White elongated, biconvex tablets
Identification : Gives positive result for the presence of Calcium Carbonate
Disintegration : Does not comply with IP
Uniformity of weight : Complies with IP

No. S.2998/2017/DC

Office of the Drugs Controller,
Red Cross Road
Thiruvananthapuram-695035
Tel: 0471-2471896
Email: dckerala@gmail.com
Dated: 08/05/2017.

From

The Drugs Controller,
Kerala State.

To

Central Drugs Standard Control Organisation
Chennai.

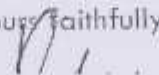
Sir,

Sub:- **Not of Standard Quality** Drug: - Organic Hair Colour- Herbal Hair Colour
Cream (Brown) Batch No: WCBR 16060005 Mfd by: Guangzhou Wenda
Refinement Chemical Co. Ltd, Imported by: Siso Importers & Traders, Pattom,
Thiruvananthapuram, Kerala.

Ref:- SW 5570/16/DTL dated 01/03/2017.

I am enclosing a copy of certificate of test/or analysis in Form 13 along
with Laboratory Protocol issued by the Government Analyst, Drugs Testing
Laboratory, Thiruvananthapuram on a sample of the subject product which is self
explanatory. The sample has been declared as **Not of Standard Quality**.

Yours faithfully,



FORM 34
(See Rules 131 & 150)

SW-5570/16/DTL

CERTIFICATE OF TESTS OR ANALYSIS OF COSMETICS BY THE
GOVERNMENT ANALYST

1. Name of the Officer or Inspector from whom received. : Moniveena M.G., Drugs Inspector, (SIB),
Thiruvananthapuram.
2. Serial No. and date of the Officers/ Inspectors Memorandum : TVM/Top Priority/FRM/55287/KL-TVM
Dated, 16/11/2016
3. Number of sample : 2408/16
4. Date of receipt : 16/11/2016
5. Name of the Cosmetic purporting to be contained in the sample : Organic Hair Colour
Herbal Hair Colour Cream (Brown)
Batch No: WCBR 16060005
Mfg. By: Guangzhou wenda Refinement Chemical Co. Ltd.,
PRC, Imported By : Siso Importers & Trader,
Pattom Post, Trivandrum, Kerala-695 004.
6. Condition of seal on the packet or on portion of sample or container : Intact: Compared with the specimen
impression of the seal sent separately by
the Drugs Inspector and found to be
identical.
7. Results of test or analysis :
The sample of Cosmetics IS 8481:2005
 - a. Contain a prescribed colour only :
Does not contain a prescribed colour
 - b. Does not contain harmful ingredients :
Contain harmful ingredients
 - c. Conform to claims made on the label as to the nature & quality of
the cosmetic
Does not conform to claims made on

LABORATORY PROTOCOL

Protocol No. 2408/17 Date of Receipt : 17/11/2016
Received from: Moniveena M.G., Date of Test : 03/02/2017
Drugs Inspector, (SIB),
Thiruvananthapuram. Completed on : 25/02/2017
Date of Report : 27/02/2017

Details of sample **ORGANIC HAIR COLOUR**
..... **HERBAL HAIR COLOUR CREAM (BROWN)**
.....

Batch No : WCBR 16060005 Manufactured/repacked by
Guangzhou wenda Refinement Chemical Co. Ltd.,
Date of manufacture : 06/2016 PRC
Imported By : Siso Importers & Trader,
Date of expiry : 06/2019 Pattom Post, Trivandrum,
Kerala-695 004.
Import. Lic. No. : COS-064/16

RESULTS/CALCULATIONS

Description : The given sample consist of two parts.
Brown coloured dye and white developer
with an applicator.

Requirements For Dye

- i) p^H : Complies with IS 8481:2005.
ii) Active matter as PPD content, Percent by mass : Complies with IS 8481 :2005
PPD content - 1.105%.

No. 5.5395/2017/DC

Office of the Drugs Controller,
Red Cross Road
Thiruvananthapuram-695035
Tel: 0471-2471896
Email: dckerala@gmail.com
Dated: 06/05/2017.

From

The Drugs Controller,
Kerala State.

To

The Drugs Controller
Dept. of Medical Health & Family Welfare,
Village Dandu Lakhond,
Near Rajiv Gandhi Play Ground, Sahsradhara Road,
Dehradun, Uttarakhand.

Sir,

Sub:- Testing of Paracetamol Tab IP 650mg, SYNAMOL- 650,
Batch No : ZT 1481503 Manufactured by Progressive Life
Science (P) Ltd, Roorkee, Haridwar, Uttarakhand -
Not of Standard Quality - reg.

Ref:- No. SW 72/17/RDTL dated, 03/04/2017.
02/17

I am enclosing a copy of certificate of test/or analysis in Form 13 along with Laboratory Protocol issued by the Government Analyst, Regional Drugs Testing Laboratory, Ernakulam on a sample of the subject drug which is self explanatory. The sample has been declared as **Not of Standard Quality**.

Requesting you to take necessary action against the

FORM 13

(See Rule 46)

**Certificate of Test or analysis by Government Analyst Under
Section 25(1) of the Drugs and cosmetics Act, 1940**

1. Name of inspector from whom received. : Vinayan.M.P., Drugs Inspector,
Office of the Asst.Drugs Controller,
Thrissur
2. Serial No. and date of inspector's memorandum : TSR/None /FRM/ 55812/KL-EKM
dated : 13/12/2016
3. Number of sample. : 2/17
4. Date of Receipt : 23/12/2016
5. Name of drug purporting to be contained
in the sample : Paracetamol Tablets I.P. 650mg., SYNAMOL-650
Batch No: ZT 1481503
Mfd.by: Progressive Life Sciences Pvt.Ltd.,
Latherdevahoon,P.O.Jhabrera, Roorkee,
Distt.Hardwar (U.K.)-247 665.
6. Condition of seals on the package. : Intact compared with the specimen impression of
the seal sent separately and found to be
identical.
7. Result of Test or analysis with protocols of test
or analysis applied. : IP

In the opinion of the undersigned the sample referred to above is of **Not of standard quality** as defined in the
Drugs and Cosmetics Act, 1940, and Rules there under for the reason given below:-