

Dce No 328/20

BEFORE THE DRUG COURT KHYBERPAKHTUNKHWA PESHAWAR

COMPLAINT NO : 025/DC-AD
DATED : March 10, 2020

STATED THROUGH : Imran Ul Haq
Provincial Drug Inspector, Abbottabad

VERSUS *Acquitted* 1. Muhammad Zarif Ahmed (Proprietor)
21/2/23 2. Zarin Gul (Branch Manager / Person Present at the time of
Inspection) M/S Pharmanet Distributor, 295 near modern age
school, Supply Abbottabad.
3. Junaid Rashid (warrantary)
4. Muhammad Usman (Regulatory Manager)
M/S Pacific Pharmaceuticals Limited, 30th km Multan Road
Lahore.
5. Managing Director
6. Humaira Saaddique (Quality Compliance manager)
M/S Reckitt Benckier Pakistan Limited (R-B), S.T.E Karachi.


INDEX

S.No	Documents	Dated	Page No.
1	Challan	12.03.2019	02
2	Case Summary	12-03-2019	03-04
3	Transfer Notification Predecessor Provincial Drug inspector	28-07-2015	05
4	Notification of Government Analyst DTL Peshawar	05-01-2011	06
5	Gazettee Notification of Provincial Drug inspector	26-12-2008	07
6	Transfer Notification Provincial Drug inspector	01-01-2015	08
7	Gazettee Notification of Provincial Drug Inspector/Complainant	06-11-2017	10
8	Form-5 1 copy	13-03-2018	11
09	Third/Fourth portion of drug samples	15-03-2018	12-13
10	Form-7 (copies)	13-03-2018	14-15
11	PQCB portions	15-03-2018	17-18
12	Form-3 (3 Copies)	18-05-2018	19-21
13	Notice to M/S Pharmanet	06-06-2018	22
14	Reply and invoices	13-06-2018	23-26
15	M/S Pacific Pharma	25-06-2018	27
16	Reply	06-21-2018	28-40
17	Notice to M/S Reckitt Benckiser	25-06-2018	41
18	Reply	07-02-2018	42-45
19	Letter to PQCB Peshawar	30-08-2018	46
20	PQCB Meeting Minutes NIH Report	16-12-2019	47-52

Imran Ul Haq
Provincial Drugs Inspector
District Abbottabad

CHALLAN FORM

- 1). Name and Designation of complainant
Imran Ul Haq
(The Provincial Drug Inspector Abbottabad)
- 2). Name and Address of the person /Store form whom the medicines was taken
1. Muhammad Zarif Ahmed (Proprietor)
2. Zaria Gul (Branch Manager / Person Present at the time of inspection) M/S Pharmamet Distributor, 2nd floor near modern age school, Supply Abbottabad
3. Junaid Rashid (warrantor)
4. Muhammad Usman (Regulatory Manager, M/S Pacific Pharmaceuticals Limited, 30th km Multan Road Lahore.
5. Managing Director
6. Nimaira Saddique (Quality Compliance manager) M/S Reckitt Benckler Pakistan Limited, F-18, M.T.A. Karachi.
- 3). Date of search and seizure of premises
13-03-2018 (Form-5)
- 4). Name of Medicine and Manufacturer Company. Warrantor if any
Suspension Crafilm 120ml Batch # 011604M M/S Pacific Pharmaceuticals
Gaviscon Advance Liquid Batch # 7115 & 7116 M/S Reckitt Benckler Pakistan. M/S Pharmamet Distributor Abbottabad.
- 5). Name of Manufacturer. Production. QC Manager
M/S Pacific Pharmaceuticals
M/S Reckitt Benckler Pakistan
- 6). Section of Law Contravention
23(1)(a)(v) of The Drugs Act, 1976.
- 7). Section of Law under which offences punishable
27(b) of the said Act.
- 8). Summary of the case (To be Produced an evidence to the court)
As above
- 9). Name of the Prosecution witness
1. Syed Aqib Ali Shah (Predecessor Provincial Drug Inspector Abbottabad)
2. Imran Ul Haq (Provincial Drug Inspector Abbottabad)
3. Muhammad Muhammad Shakeel Nawaz (Provincial Drug Inspector Abbottabad)
- 10). Brief summary of the offences and remarks.
Sale of substandard drugs i.e Suspension Crafilm 120ml Batch # 011604M and Gaviscon Advance Liquid Batch # 7115 & 7116 is violation of section 23(1)(a)(vii) of The Drugs Act 1976.


Imran Ul Haq
Provincial Drug Inspector
District Abbottabad

IN THE COURT OF CHAIRMAN DRUG COURT (KPK) PESHAWAR

State Through : Imran Ul Haq
Provincial Drug Inspector Abbottabad

Verses : 1. Muhammad Zari Ahmed (Proprietor)
2. Zarin Gul (Branch Manager / Person Present at the time of Inspection) M/S Pharmanet Distributor, 29E near modern age school, Supply Abbottabad.
3. Junaid Rashid (warrantor)
4. Muhammad Usman (Regulatory Manager) M/S Pacific Pharmaceuticals Limited, 30th km Multan Road Lahore.
5. Managing Director
6. Humaira Saddique (Quality Compliance manager) M/S Reckitt Benckier Pakistan Limited, F-18, S.I.T.E Karachi.

Offence : Section 23 (1)(a)(v) of The Drugs Act, 1976.

Punishable : 27(1) of the said Act.

Respectfully :

I have honor to state that, on march 13, 2018, my predecessor Provincial Drug Inspector, Abbottabad, inspected M/S Pharmanet Distributor Abbottabad. He sampled **Suspension Crafilm 120ml Batch # 011604M** manufactured by M/S Pacific Pharmaceuticals Limited, 30th km Multan Road Lahore & **Gaviscon Advance Liquid Batch # 7115 & 7113** for Test & Analysis.

The Government Analyst Provincial Drugs Testing Laboratory, Khyber Pakhtunkhwa Peshawar declared the sample as **SUBSTANDARD** vide Test Report No:

1. TRA NO. 55760 / DTL Dated Peshawar the 18-05-2018
2. TRA NO. 55761 / DTL Dated Peshawar the 18-05-2018
3. TRA NO. 55762 / DTL Dated Peshawar the 18-05-2018

Suspension Crafilm 120ml Batch # 011604M: M/S Pharmanet Distributor Abbottabad submitted warranted invoice of manufacturer M/S Pacific Pharmaceuticals Limited Lahore, on further investigation from manufacturer, in reply they **Challenge Provincial DTL Reports & Appeal for Sample Retesting** under the provision of Section 22 (2) of The Drugs Act, 1976

Gaviscon Advance Liquid Batch # 7115 & 7113: M/S Pharmanet Distributor submitted warranted invoice of manufacturer M/S Reckitt Benckier Pakistan Limited, F-18, S.I.T.E Karachi, on further investigation the reply received from manufacturer is not satisfactory.

On 30.08.2018, my predecessor Provincial Drug Inspector Abbottabad, sent case to the chairman Provincial Quality Control Board under section 19(b) of The Drugs Act, 1976 vide letter no.427-PDI/AD.


Imran Ul Haq
Provincial Drug Inspector

310th meeting of the Provincial Quality Control Board Khyber Pakhtunkhwa was held on 04.07.2019 at 10:00am in Health Department. Accused at serial no. 1 & 2 were appeared and heard with their alleged involvement in the sale of substandard drugs and has requested for Suspension Crafilm 120mi Batch # 01150543 retesting, while the others accused were absent. However, the board took the decision to send the sample for retesting to NIH Islamabad.

While, in 312th meeting of the Provincial Quality Control Board Khyber Pakhtunkhwa was held on 28.11.2019 at 10:00am in Health Department. The NIH Islamabad test reports were placed before the board. The NIH Islamabad declared substandard the said sample. However, the board took the decision to refer the case to drug court for judicial writs.

Secretary Provincial Quality Control Board Peshawar sent meeting minutes of PQCB vide letter No. SO(Drugs)/HD/2-15/2019 (312th PQCB) dated 16th December, 2019.

Sale/Stock of substandard drugs is violation of section 23(1)(a)(v) of the Drug Act, 1976.

1. Imran Ul Haq notified Provincial Drug Inspector was transferred to Abbottabad vide notification no.SOH-III/7-262/2019,dated January 01, 2019.

Therefore, undersigned after receiving Provincial Quality Control Board meeting minutes lodged compliant against the followings.

1. **Muhammad Zarif Ahmed (Proprietor)**
 2. **Zarin Gul (Branch Manager / Person present at the time of Inspection) M/S Pharmanet Distributor, 295 near motor college school, Supply Abbottabad.**
 3. **Junaid Rashid (warrantor)**
 4. **Muhammad Usman (Regulatory Manager)
M/S Pacific Pharmaceuticals Limited, 30th km Multan Road Lahore.**
 5. **Managing Director**
 6. **Humaira Saddique (Quality Compliance manager)
M/S Reckitt Benckier Pakistan Limited, F-13, S.I.T.E Karachi.**
- Witness

1. **Syed Aqib Ali Shah (Predecessor Provincial
Drug Inspector Abbottabad)**

2. **Imran Ul Haq (Provincial Drug
Inspector Abbottabad)**

3. **Muhammad Shakeel Nawaz (Provincial Drug
Inspector Abbottabad)**

Complaint
Imran Ul Haq
**Provincial Drug Inspector
District Abbottabad**

Imran Ul Haq
Provincial Drug Inspector
District Abbottabad



GOVT OF KHYBER PAKHTUNKHWA
HEALTH DEPARTMENT

Dated Peshawar the 28th July, 2015

NOTIFICATION

No. SOH-III/7-262/2015. The Competent Authority has been pleased to make the following posting/transfer of the Drug Inspectors with immediate effect in the public interest:-

S.NO	NAME OF DRUG INSPECTOR	FROM	TO
1.	Syed Aqib Ali Shah Drug Inspector (BS-17)	Haripur	Abbottabad
2.	Mr. Mehtab Afsar, Drug Inspector (BS-17)	Abbottabad	Haripur

SECRETARY HEALTH

Endst even No & date.

Copy forwarded to:-

1. The Director General Health Services, Khyber Pakhtunkhwa Peshawar.
2. The District Health Officers, Abbottabad & Haripur.
3. The District Accounts Officer, Abbottabad & Haripur.
4. PS to Senior Minister Health, Khyber Pakhtunkhwa.
5. PS to Secretary Health, Khyber Pakhtunkhwa.
6. PA to Special Secretary Health, Khyber Pakhtunkhwa.
7. The Deputy Director (I.T) Health, Khyber Pakhtunkhwa.
8. Officers concerned.

(Muhammad Tariq)
SECTION OFFICER-III



001

[Handwritten mark]

01/18/19/201

GOVERNMENT OF KHYBER PAKHTUNKHWA
HEALTH DEPARTMENT

Islamabad, the 05th January, 2019

NOTIFICATION

Notifying the public that the Government of Khyber Pakhtunkhwa Health Department has decided to...
The Government of Khyber Pakhtunkhwa Health Department has decided to...
The Government of Khyber Pakhtunkhwa Health Department has decided to...

S.N.	Name of the Officer	Designation	Office
1.	Mr. Habibullah Khan	Deputy Commissioner	Rawalakot
2.	Mr. Habibullah Khan	Deputy Commissioner	Nowshera
3.	Mr. Habibullah Khan	Deputy Commissioner	Chitral
4.	Mr. Habibullah Khan	Deputy Commissioner	Upper Dir
5.	Mr. Habibullah Khan	Deputy Commissioner	Lower Dir
6.	Mr. Habibullah Khan	Deputy Commissioner	Swat
7.	Mr. Habibullah Khan	Deputy Commissioner	Mardan
8.	Mr. Habibullah Khan	Deputy Commissioner	Mansehra
9.	Mr. Habibullah Khan	Deputy Commissioner	Islamabad Capital Territory
10.	Mr. Habibullah Khan	Deputy Commissioner	Other Districts



KHYBER PAKHTUNKHWA

Published by Authority

PESHAWAR, THURSDAY, 22ND MARCH, 2012.

GOVERNMENT OF KHYBER PAKHTUNKHWA HEALTH DEPARTMENT

NOTIFICATION

Dated Peshawar, the 16th December, 2011.

No. SOH-III/2-58/2009.— The Competent Authority on the recommendation of Khyber Pakhtunkhwa Public Service Commission has been pleased to appoint the following candidates as Drug Inspectors (BPS-17) on regular basis with immediate effect:-

S.No.	Name with father's name.
1.	Mr. Muhammad Zeeshan s/o Muhammad Aslam
2.	Mr. Amcer Zeb s/o Jahan Zeb Khan
3.	Mr. Ibrar Khan s/o Dil Nawaz Khan
4.	Mr. Zia Ullah s/o Zameen Gul
5.	Mr. Rehmat Gul Khan s/o Sher Ahmad Khan
6.	Syed Aqib Ali Shah s/o Syed Shujaat Hussain Shah

2. Their services will be governed under the NWFP (Now Khyber Pakhtunkhwa) Civil Servants Act, 1973 as amended vide Civil Servants (Amendment) Act, 2005 and rules made there under and other relevant laws and rules. They will be on probation for a period of one year extendable by another one year.

3. Consequent upon their appointment as Drug Inspectors (BPS-17), they are hereby posted in the districts as noted against their names:-

S.No.	Name with father's name	Present status	Place of posting	Remarks
1.	Mr. Muhammad Zeeshan s/o Muhammad Aslam	1st appointment	Drug Inspector(BPS-17) District Hangu	Against the vacant post
2.	Mr. Amcer Zeb s/o Jahan Zeb Khan	-do-	Drug Inspector(BPS-17) District Buner	-do-
3.	Mr. Ibrar Khan s/o Dil Nawaz Khan	-do-	Drug Inspector(BPS-17) District Sannu	-do-
4.	Mr. Zia Ullah s/o Zameen Gul	-do-	Drug Inspector(BPS-17) District Upper Dir	-do-
5.	Mr. Rehmat Gul Khan s/o Sher Ahmad Khan	-do-	Drug Inspector(BPS-17) District Tank	-do-
6.	Syed Aqib Ali Shah s/o Syed Shujaat Hussain Shah	-do-	Drug Inspector(BPS-17) District Haripur	-do-

4. They are directed to assume charge within 30 days in their respective place of posting after the issuance of this Notification, failing which, their appointment shall be treated as cancelled.

SECRETARY GOVERNMENT OF KHYBER PAKHTUNKHWA
HEALTH DEPARTMENT

3

GOVT. OF KHYBER PAKHTUNKHWA
HEALTH DEPARTMENT

Dated the Peshawar, 1st January, 2019

NOTIFICATION

No. SOH-III/7-262/2019. In partial modification of this department notification of even No. dated 07-12-2018, the Competent Authority is pleased to cancel the transfer order of Mr. Waheed Murad, Drug Inspector (BPS-17) under transfer to Swat at Serial No. 06.

2. Consequent upon above, Mr. Inayatullah, Drug Inspector (BPS-17) District Dir Lower is hereby transferred to District Abbottabad against the vacant post of Drug Inspector (BPS-17) with immediate effect in the public interest.

Secretary to Govt. of Khyber Pakhtunkhwa
Health Department

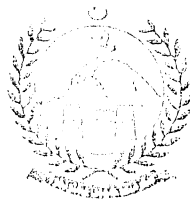
End of even No and Date.

Copy forwarded to:

1. The Director, General Health Services, Peshawar, Khyber Pakhtunkhwa.
2. The District Health Officers, Swat/Abbottabad Dir Lower.
3. The District Accounts Officers, Swat/Abbottabad Dir Lower.
4. PS to Secretary Health, Khyber Pakhtunkhwa.
5. PA to Deputy Secretary (Drugs) Health Department.
6. Deputy Director (D) Health Department.
7. Officers concerned.

Section Officer-III

Proved by Drug Inspector
2019-01-01



KHYBER PAKHTUNKHWA

Published by Authority

PESHAWAR, FRIDAY, 24TH NOVEMBER, 2017.

GOVERNMENT OF KHYBER PAKHTUNKHWA HEALTH DEPARTMENT

NOTIFICATION

Dated, Peshawar the 6th November, 2017

No. SO (D)H/2-43/2017/Dls.—In exercise of powers conferred under section 17 of the Drugs Act, 1976, the Government of Khyber Pakhtunkhwa is pleased to appoint the following Drug Inspectors for the area mentioned in column 4 against each with immediate effect:

1	2	3	4
S.No.	Name of Drug Inspector	Place of posting	Area of Jurisdiction
01.	Muhammad Shakeel Nawaz, Drug Inspector	District Abbottabad	District Abbottabad
02.	Sajid Noor, Drug Inspector	District Bannu	District Bannu
03.	Muhammad Waqas Salim, Drug Inspector	District Mardan	District Mardan
04.	Rooh Ullah, Drug Inspector	District Charsadda	District Charsadda
05.	Naamut Saed, Drug Inspector	District Shangla	District Shangla
06.	Muhammad Sajid, Drug Inspector	District Nowshera	District Nowshera
07.	Inran Ul Haq, Drug Inspector	District Swat	District Swat
08.	Muhammad Salim, Drug Inspector	District Karak	District Karak
09.	Mr. Yahya Khan, Drug Inspector	District Peshawar	District Peshawar
10.	Khushal Khan, Drug Inspector	District Nowshera	District Nowshera
11.	Muhammad Shoaib Khan, Drug Inspector	District Mardan	District Mardan
12.	Zia ur Rehman, Drug Inspector	District Bannu	District Bannu
13.	Muhammad Hamid Ullah, Drug Inspector	District Dir Upper	District Dir Upper
14.	Mr. Manzoor Ahmad, Drug Inspector	District Peshawar	District Peshawar

2. They shall also exercise powers under clauses (f) to (j) of section 18 of the said Act.

SECRETARY HEALTH

372

FORM 5

[See Rule-9(1)]

Intimation of purpose to person from whom sample is taken Mohammad Zang Ahmed

I have this day taken sample from the premises of M/S Pharmineel Distributors

Situated at House 11 245 near Modern Age School
Manselva Road Supply Bazar Abbottabad

Sample of the drug specified below for the purpose of test/analysis:

Date 13/02/2018

Inspector [Signature]

DETAIL OF SAMPLE OF DRUG

S.No.	Name of Drug	Name of Manufacturer	Reg No.	Batch No.	Qty.	Value
01)	Gaviscon Advance	Reckitt Benckiser	067066	801	1x10	123x10
02)	Gaviscon Advance	Reckitt Benckiser	067066	7118	1x10	123x10
03)	Croftin Suspension	Pacific Pharmaceuticals	018602	0160017	1x10	18x10
04)	Gaviscon Advance	Reckitt Benckiser	067066	7118	1x10	123x10

Dated 13/02/2018

[Signature]
 PROVISIONAL DRUG INSPECTOR
 Abbottabad

CERTIFICATE

1. Certified that the sample(s) of the drug, the particular of which is given above was/were taken from my premises in my presence and sealed in my presence.
2. Certified that the samples(s) was/were taken from the original sealed container of the company.
3. Certified that the sample(s) sealed of the above drug was handed over to me and I have signed and got one copy of this Form-5.

CERTIFIED THAT:

The sample(s) were taken and sealed in my presences and have signed the Form-5 as witnesses.

Signature of the owner of Chemist/Drugs Store [Signature]

1. [Signature] 2. [Signature]

NO. V.P.A.M-Ab Dated Abbottabad 12/06/2018

To,

MFG BY:
Pacific Pharmaceuticals Ltd,
30th KM, Multan Road, Lahore

Through:

PHARMANET DISTRIBUTOR, H# 295, NEAR MODREN AGE SCHOOL MANSEHRA ROAD,
ABBOTTABAD

Subject: THIRD / FOURTH PORTION OF DRUG SAMPLE.

Memo:


Received herewith third/fourth portion of the sample of drug as required under the provision of clause (iii) / (iv) of sub section (3) of Section 19 of the Drugs Act 1976 taken from PHARMANET DISTRIBUTOR, H# 295, NEAR MODREN AGE SCHOOL MANSEHRA ROAD, ABBOTTABAD, for the purpose of test / Analysis and to Drug Testing Laboratory K.P.K Peshawar.

The detail of which is as under:

S. No.	Name of Drugs	Drug Reg. No	Batch No.	Manufacturer
1	Crafilm 120ml Suspension	018602	011604M	Pacific Pharmaceuticals Ltd, 30 th KM, Multan Road, Lahore.

You are hereby directed to confirm that the above mentioned drug is manufactured/supplied by you or otherwise, in written form to the undersigned within seven days, after receipt of this letter, failing which it will be presumed that above mention Drug manufactured by you.




Syed Aqib Ali Shah
Provincial Drugs Inspector
Abbottabad.

NOTIFICATION Dated Abbottabad the 13th 03-2018

To,

MFG BY:
Reckitt Benckiser Pakistan Ltd
F-18, S.I.T.E, Karachi

Through:

PHARMANET DISTRIBUTOR, H# 295, NEAR MODREN AGE SCHOOL MANSEHRA ROAD,
ABBOTTABAD

Subject: **THIRD / FOURTH PORTION OF DRUG SAMPLE.**


Memo:

Received herewith third/fourth portion of the sample of drug as required under the provision of clause (iii) / (iv) of sub section (3) of Section 19 of the Drugs Act 1976 taken from PHARMANET DISTRIBUTOR, H# 295, NEAR MODREN AGE SCHOOL MANSEHRA ROAD, ABBOTTABAD, for the purpose of test / Analysis and to Drug Testing Laboratory K.P.K Peshawar.

The detail of which is as under:

S. No	Name of Drugs	Drug Reg. No	Batch No	Manufacturer
1	Gaviscon Advance Liquid	067066	7115	Reckitt Benckiser Pakistan Ltd F-18, S.I.T.E, Karachi
2	Gaviscon Advance Liquid	067066	7113	Reckitt Benckiser Pakistan Ltd F-18, S.I.T.E, Karachi
3	Gaviscon Advance Liquid	067065	8021	Reckitt Benckiser Pakistan Ltd F-18, S.I.T.E, Karachi

You are hereby directed to confirm that the above mentioned drug is manufactured/supplied by you or otherwise, in written form to the undersigned within seven days, after receipt of this letter, failing which it will be presumed that above mention Drug manufactured by you.


Syed Aqib Ali Shah
Provincial Drugs Inspector
Abbottabad

FROM-7
Memorandum to Analyst
[See Rule 9 (2)]

Serial No. of Memorandum 1058 PDI/AD

Dated 13-03-2018

From:

The Provincial Drugs Inspector
Office of the District Health Office
Abbottabad.

To,

The Analyst,
Government Drugs Testing Laboratory
Khyber Pakhtunkhwa Peshawar.

The portion of sample/container described below is sent herewith for test analysis under the provision of clause (i) of Sub-section 3 of section 19 of the Drugs Act, 1976

The sample is of the drug Confilm 120ml Suspension B. No: 011604M

D-Registration No: 018602

Exp Date: 03-2020

Mfg.: Pacific Pharmaceuticals LTD, 30th KM Multan Road, Lahore

and purport to contain ' Very Viscous and could not be shaken '

The portion of sample has been marked by me with the following marks

Dated 13-03-2018


(SYED AQIB ALI SHAH),
Provincial Drugs Inspector,
Office of the D.H.O, ABBOTTABAD

FROM-7
Memorandum to Analyst
[See Rule 9 (2)]

Serial No. of Memorandum 1057 PDI/AD

Dated 13-03-2018

From:

The Provincial Drugs Inspector
Office of the District Health Office
Abbottabad.

To,

The Analyst,
Government Drugs Testing Laboratory
Khyber Pakhtunkhwa Peshawar.

The portion of sample/container described below is sent herewith for test analysis under the provision of clause (i) of Sub-section 3 of section 19 of the Drugs Act, 1976.

The sample is of the drug Gaviscon Advance Liquid B. No: 7113

D-Registration No: 067066

Exp Date: 09-2019

Mfg., Reckitt Benckiser Pakistan Ltd, F-18, S.I.T.E, Karachi.

and purport to contain ' Very Viscous and could not be shaken '

The portion of sample has been marked by me with the following marks

Dated. 13-03-2018


(SYED AOIB ALI SHAHI),
Provincial Drugs Inspector,
Office of the D.H.O. ABBOTTABAD.

FROM-7
Memorandum to Analyst
[See Rule 9 (2)]

Serial No. of Memorandum 1056 PDI/AD

Dated 13-03-2018

From:

The Provincial Drugs Inspector
Office of the District Health Office
Abbottabad.

To,

The Analyst,
Government Drugs Testing Laboratory
Khyber Pakhtunkhwa Peshawar.

The portion of sample/container described below is sent herewith for test analysis under the provision of clause (i) of Sub-section 3 of section 19 of the Drugs Act, 1976.

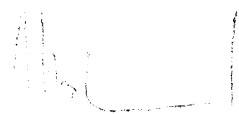
The sample is of the drug Gaviscon Advance Liquid B. No: 7115
D-Registration No: 067066 Exp. Date: 10-2019
Mfg.: Reckitt Benckiser Pakistan Ltd, F-18, S.I.T.E, Karachi.

and purport to contain ' Very Viscous and could not be shaken '

The portion of sample has been marked by me with the following marks

Dated: 13-03-2018




(SYED AQIB ALI SHAH),
Provincial Drugs Inspector,
Office of the D.H.O, ABBOTTABAD

By: 
Date: 13-03-2018

OFFICE OF THE
Provincial Drugs Inspector
District Abbottabad
NO 134 PDE-AD
DATED 13-03-2018

To

**The Chairman
Provincial Quality Control Board
Government of Khyber Pakhtunkhwa
Peshawar.**

SUBJECT:- PORTION OF DRUG SAMPLES

The portion of Sample/Container describe below is sent herewith as required under the provision of Clause (ii) of Sub-section (3) of Section 19 of the Drugs Act 1976. Detail of portion of Samples of Samples Containers with name of Drugs which is purport to contains:- counterfeit

S.NO	NAME OF DRUGS	REGISTRTION NO.	BATCH NO.	MFD:BY
1.	Gaviscon Advance Liquid	067066	7115	Reckitt Benckier Pakistan Limited, F-18, S.I.T.E Karachi
2.	Gaviscon Advance Liquid	067066	7115	Reckitt Benckier Pakistan Limited, F-18, S.I.T.E Karachi
2.	Gaviscon Advance Liquid	067066	3001	Reckitt Benckier Pakistan Limited, F-18, S.I.T.E Karachi

Provincial Drugs Inspector
District Abbottabad

OFFICE OF THE
Provincial Drugs Inspector
District Abbottabad
NO.133PDI-012
DATED 13-03-2018

To

The Chairman
Provincial Quality Control Board
Government of Khyber Pakhtunkhwa
Peshawar.

SUBJECT:- PORTION OF DRUG SAMPLES

The portion of Sample/Container describe below is sent herewith as required under the provision of Clause (ii) of Sub-section (3) of Section 19 of the Drugs Act 1976. Detail of portion of Samples of Samples/Containers with name of Drugs which is purport to contains counterfeit

S.NO	NAME OF DRUGS	REGISTRATION NO.	BATCH NO.	MED:BY
1.	Suspension Crafilm 120ml	018602	0116001M	Pacific Pharmaceuticals Limited, 30m km Multan Road Lahore

Provincial Drugs Inspector
District Abbottabad

FORM-3
[See Rule 6]

CERTIFICATE OF TEST OR ANALYSIS BY THE DRUGS TESTING
LABORATORY/GOVERNMENT ANALYST.

Certified that the samples bearing number 1058/PDI-AD

Purporting to be a sample of Suspension Crafilm 120ml, B.No 011604M

Mfd: by Pacific pharma ltd: 30th km multan road Lahore.

Received on 19-03-2018 with Memorandum No. 1058/PDI-AD

dated 13-03-2018 from

Provincial Drugs Inspector Distt: Abbottabad.

has been tested / analysed and that the result of such test/analysis as stated below: -

2. The condition of the seals on the packet on receipt was as follows: - Satisfactory.

3. In the opinion of the undersigned the sample is not/is adulterated/Sub-standard/ is branded/spurious as defined in the drug Act, 1976 for the reasons given below: -

(Details of results of test or analysis with protocols of test applied)

GOVERNMENT ANALYST

Description: - White color suspension filled in an amber glass bottle with white color cap.

Identification: - Sucralfate identified.

Assay:- Sucralfate = 80.94% Limit = 90-110%

Note:- The suspension in the provided bottle is broken and hard cake which do not dissolve even after vigorous shaking.

Conclusion:- The above sample of Suspension Crafilm 120ml, B.No 011604M is Sub-standard.

TRA No 55762 DTL

Forwarded to: -

Dated Peshawar, the 18-05-2018

1. The Inspector of Drugs Abbottabad DHO (II) Office Distt: Abbottabad.
2. The Chairman, Provincial Quality Control Board, Government of Khyber Pakhtunkhwa, Health Department, Peshawar.

GOVERNMENT ANALYST
Provincial Drugs Testing Laboratory
Chamber Peshawar House Peshawar

CERTIFICATE OF TEST OR ANALYSIS BY THE DRUGS TESTING
LABORATORY/GOVERNMENT ANALYST.

Certified that the samples bearing number 1056/PDI-AD

Purporting to be a sample of Gaviscon Advance liquid, B.No 7115

Mfd: by Reckitt Benkiser Pakistan Ltd; S.I.T.E Karachi.

Received on 19-03-2018 with Memorandum No. 1056/PDI-AD

dated 13-03-2018 from

Provincial Drugs Inspector Distt: Abbottabad.

has been tested / analysed and that the result of such test/analysis as stated below: -

1. The condition of the seals on the packet on receipt was as follows: - Satisfactory.
2. In the opinion of the under signed the sample is not is adulterated/Sub-standard/mis branded/spurious as defined in the drug Act, 1976 for the reasons given below: -

(Details of results of test or analysis with protocols of Government Analyst
Government Analyst
Shahid Hussain, Manager, District, Peshawar)

Description:- Off-white color thick and viscous suspension preparation filled in an amber glass bottle with white color cap.

Identification:- Sodium alginate & Potassium bicarbonate identified

Assay:- Sodium alginate = 92.70% Limit = 90-110%
Potassium bicarbonate = 95.30%

Note:- The suspension in the provided bottle is very viscous and have undissolved lumps. The color scheme and pattern of text on the label is quite different from the sample that is of standard quality.

Conclusion:- The above sample of Gaviscon Advance liquid, B.No 7115 is Sub-standard.

TRA No 55760 DTL.

Dated Peshawar, the 18-05-2018.

Forwarded to: -

1. The Inspector of Drugs Abbottabad DHO (H) Office Distt: Abbottabad.
2. The Chairman, Provincial Quality Control Board, Government of Khyber Pukhtunkhwa, Health Department, Peshawar.

CERTIFICATE OF TEST OR ANALYSIS BY THE DRUGS TESTING
LABORATORY/GOVERNMENT ANALYST.

Certified that the samples bearing number 1057/PDI-AD

Purporting to be a sample of Gaviscon Advance liquid, B.No 7113

Mfd: by Reckitt Benkiser Pakistan Ltd: S.I.T.E Karachi.

Received on 19-03-2018 with Memorandum No. 1057/PDI-AD

dated 13-03-2018 from

Provincial Drugs Inspector Distt: Abbottabad.

has been tested / analysed and that the result of such test/analysis as stated below: -

2. The condition of the seals on the packet on receipt was as follows: - Satisfactory.

3. In the opinion of the undersigned the sample is not/is adulterated/Sub-standard/mis branded/spurious as defined in the drug Act, 1976 for the reasons given below: -

GOVERNMENT ANALYST

(Details of results of test or analysis with protocols of GOVERNMENT ANALYST,
Provincial Drugs Testing Laboratory,
Chakras Peshawar, Khyber Pakhtunkhwa)

Description:- Off-white color thick and viscous suspension preparation filled in an amber glass bottle with white color cap.

Identification:- Sodium alginate & Potassium bicarbonate identified.

Assay:- Sodium alginate = 92.14% Limit = 90-110%
Potassium bicarbonate = 94.87%

Note:- The suspension in the provided bottle is very viscous and broken. The color scheme and pattern of text on the label is quite different from the sample that is of standard quality.

Conclusion:- The above sample of Gaviscon Advance liquid, B.No 7113 is Sub-standard.

TRA No 55761 DTL.

Dated Peshawar, the 18-05-2018.

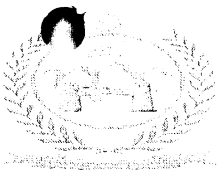
Forwarded to: -

1. The Inspector of Drugs Abbottabad DHO (H) Office Distt: Abbottabad.
2. The Chairman, Provincial Quality Control Board, Government of Khyber Pukhtunkhwa, Health Department Peshawar.

GOVERNMENT ANALYST

GOVERNMENT ANALYST
Provincial Drugs Testing Laboratory,
Chakras Peshawar, Khyber Pakhtunkhwa

Provincial Drug Inspector
Abbottabad



OFFICE OF THE PROVINCIAL DRUG INSPECTOR
DISTRICT HEALTH OFFICE, ABBOTTABAD, KPK

No. 1303 PDI-AD

Dated Abbottabad the 06-06-2018

To

Zarin Gul (Branch Manager / Person Present at the time of inspection)
M/S PharmaNet Distributor
295 near modern age Shool Supply, District Abbottabad.

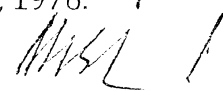
Subject: - **SHOW CAUSE FOR CONTRAVENTION OF THE PROVISION OF SECTION 23 1 (a) (v) OF THE DRUGS ACT, 1976.**

The undersigned During inspection of your business premises M/S Pharamanet Distributor Abbottabad on 13/03/2018, took sample of **Suspension Crafilm 120ml** Batch **01164M**, **Gaviscon Advance Liquid** Batch # **7115 & 7113**, for the purposes of test & analysis. The Provincial Government Analyst Khyber Pakhtunkhwa, Peshawar has declared Samples as **SUB-STANDARD** thus contravene Section 23 (1) (a)(v) of The Drugs Act, 1976.

Copies Enclosed:

1. TRA NO. 55760/DTL DATED PESHAWAR THE 18-05-2018.
2. TRA NO. 55761/DTL DATED PESHAWAR THE 18-05-2018.
3. TRA NO. 55762/DTL DATED PESHAWAR THE 18-05-2018.

You are therefore directed to submit original warranty/invoice from whom you purchased the under reference drug or otherwise, in written form to the undersigned within **SEVEN DAYS**, after receipt of this letter, failing which it will be presumed that you have no valid reasons / informations to offer, ex-parte proceedings shall be initiated against you under the Drugs Act, 1976.


Provincial Drug Inspector
Abbottabad.

Copy forwarded to: -

1. Chairman Provincial Quality Control Board Khyber Pakhtunkhwa Peshawar for information.

Provincial Drug Inspector
Abbottabad.



PharmaNet

Pharma & FMCG Distributors

Ref: PN /DI /ATD /2018

Dated 13.06.2018

To
The Provincial Drug Inspector
DHO Office, Abbottabad
KPK
Phone No. 0300-5863033

Subject: **Reply of Show Cause Notice**

Dear Sir, Assalam-O-Alaikum

Reference your letter No.1303 PDI-AD dated 06.06.2018 received here on 09.06.2018 following are the submissions.

- 1- **Crafilm Suspension 120ml Batch No. 011604M** Notarized copy of Invoice No. 127166 dated 18.12.2017 of M/S Pacific Pharmaceuticals Limited 30.th KM, Multan Road, Lahore.
Tel#042-35975291-93
- 2- **Gaviscon Advance 120ml Batch No. 7115** Notarized copy of Invoice No. 17042644 S1 dated 29.12.2017 of M/s Reckitt Benckiser Pakistan Limited. (Regd.office: 3rd Floor, Tenancy-04 & 05, Corporate Office Clifton, Karachi) ,(Factory: F-18, S.I.T.E, Karachi Tel#32573405-9), (Warehouse, 46-KM, Multan Road, Natha Khalsa, Lahore Tei#111-232-323)
- 3- **Gaviscon Advance 120ml Batch No. 7113** Notarized copy of Invoice No. 17041864 S1 dated 23.12.2017 of M/s Reckitt Benckiser Pakistan Limited. (Regd.office: 3rd Floor, Tenancy-04 & 05, Corporate Office Clifton, Karachi) ,(Factory: F-18, S.I.T.E, Karachi Tel#32573405-9), (Warehouse, 46-KM, Multan Road, Natha Khalsa, Lahore Tel#111-232-323)

We have purchased these items against above said / enclosed invoices and a copy of your show cause notice along with Test and Analysis Reports have also been forwarded to them for their information and further necessary action.

Original invoices are lying with us for the purpose as if they are required at any other occasion. However, original invoices can be presented for your perusal at anytime if required by your good self.

For any further detail or information, which you may require in future in this regard is always welcome.

Thanks with Regards

Sincerely Yours

Zarin Gul
PharmaNet Abbottabad

PharmaNet Islamabad
13/06/2018

CC: PharmaNet Islamabad

ISLAMABAD

Plot # 321, St. # 4, Sector I-9/3,
Industrial Area, Islamabad.
Ph: 051-4435913-4
Fax: 051-4101384
pharmanet.isb@gmail.com
munif_ahmed@yahoo.com

ABBOTTABAD

House # 295, Mansehra Road,
Supply Bazar, Abbottabad, Cantt.
Ph: 0992-343336
Fax: 0992-343339
pnetabr@gmail.com
munif_ahmed@yahoo.com

JHELUM

Mujahidabad
G.T. Road, Jhelum
Ph: 0544-526235
Fax: 0544-323357
pharmanet_jhel@yahoo.com
munif_ahmed@yahoo.com

MUZAFFARABAD (AJK)

Roshan Plaza, Near Neelum Park,
Ward No. 22, Western Bypass Road,
Bella Noor: Shah, Muzaffarabad.
Ph: 05822-440331-32
pnetmzd@gmail.com
munif_ahmed@yahoo.com

PESHAWAR

Jhagra, Main G.T Road,
Peshawar.
Cell: 0321-5376006
munif_ahmed@yahoo.com



Invoice

Pacific Pharmaceuticals Limited
30.th Km. Multan Road, Lahore.
Ph: 04225975001-03
Fax: 04225978356

Buyer Code : C0048
M/S : H/S Pharma Net
Address : JARROTABAD
PAKISTAN

Invoice No : 127166
Invoice Date : 18-Dec-17
Packing Slip : 262

Description	Packing	Batch #	Price	Qty.	Gross Amt.	Disc%	Discount	Net Amt.
LEVOPRAID TABLETS	2 X 10	027311M	186.00	600	112,860.00	7.00	7,900.20	104,959.80 PKR
LEVOPRAID 50MG TABLETS	2 X 10	015711M	361.79	100	36,179.00	7.00	2,532.53	33,646.47 PKR
CRAFILM SUSPENSION 120 M	120 ML	011604M	157.01	50	9,452.60	7.00	662.38	8,800.22 PKR
CRAFILM CHEWABLE TABLET	4 X 8	043711M	68.63	180	12,353.40	7.00	864.74	11,488.66 PKR
CLOMID TAB	1 X 10	009611M	346.59	359	127,891.71	7.00	8,952.42	118,939.29 PKR
CYSTALGON TAB	3 X 10	009511M	353.03	50	17,674.00	7.00	1,237.16	16,436.82 PKR
GENURIN FORTE 200MG	3 X 10	027111M	346.61	150	55,493.60	7.00	3,884.27	51,609.33 PKR
Gross Amount :					371,910.31		26,033.72	345,876.59 PKR

Sales Tax : 0.00 PKR
 Total Amount : 345,876.59 PKR
 Extra Discount : 0.00 PKR
 I-Tax Withheld Dist. : 0.00 PKR
 Net Amount Payable : 345,876.59 PKR

For Pacific Pharmaceuticals Ltd.

Warranty

(Under Section 23(1) (i) of the Drugs Act 1976)

I Junaid Rashid, being a person resident in Pakistan carrying on business at 30th Km. Multan Road, Lahore, under the name of Pacific Pharmaceuticals Limited, do hereby give this warranty that the drugs described above as sold by us specified and contained in the bill of sale invoice do not contravene in any way the provisions of Section 23 of the Drugs Act, 1976.

1. Name(s) of Drug(s)/Batch No.(s) as mentioned above.

Signature

F-523/F-524/F-525



RECKITT BENCKISER PAKISTAN LIMITE

Regd. Office: 3rd Floor, Tenancy-04 and 05, Corporate Off
Block Dolmen City, HC-3, Block-1, Scheme-
Clifton, Karachi-75600. UAN: 111-232-323
Factory: F-18, S.I.T.E. Karachi. TEL: 32573405-9
Warehouse: • 46-KM, Multan Road, Natha Khalsa, Lahor
• 3B-1, Industrial State, Phase-1 Multan
• Survey # 54, Deh Gondpass, Tapo Gabor,
Kearnari Town, RCD Highway,
Karachi, Pakistan.

SALES TAX & COMMERCIAL INVOICE

*****DUPLICATE*****

INVOICE #: 17041864 31 Date: 15/12/17 Exp Date: 23/12/17 Type of Supply: Pick Slip #: 35516485

Supplier's Name & Address RECKITT BENCKISER PAKISTAN LIMITED KOLACHI STORAGE PARK, PLOT NO.9-A/9, K-28 BLOCK A, PHASE II, TRANS LYARI QUARTERS, HAWKS BAY ROAD, KARACHI. NTN:0923778-6 KARACHI S T Registration No. (if any) NTN/CHIC No: 02-06-3405-001-55	Buyer's Name & Address PHARMA NET (PHARMA) PLOT NO. 321, STREET NO. 4 SECTOR I-9/3 ISLAMABAD ISLAMABAD S T Registration No. (if any) 17301-1539361-7 NTN/CHIC No: 1021735-5	Customer #: 34142141	Shipped to Region: 1N Area: 1A Zone: 60
---	---	----------------------	---

Order #: 17029880 Your order #: 1720771-00 PK. No.: Term of Sales: N00
Order Type: SO Shipment Date: 25/12/17 Shipper:

Item/Article Number & Description Unit of Measure & Quantity	Unit Price	Sales Value	Ret.Price Per Unit Excl. STAX	Ret.Price Excluding S.Tax	Sales Tax	Further Tax	Retail Price Inc. Sales Tax & Further Tax	Sale Value After S/Tax Further Tax
DSPOL, PK, DISPROL SUS, 60MLX40NP (NA)								
3029408 CA 34152								
3029408-7249 FG 50.000	1015.78	50689.00	.00	.00	.00			50689.00
GAVIS, PK, GAVSON ADV, 120MLX48NP (NA)								
3029409 CA 34152								
3029409-7117-7113 FG 25.000	4711.27	117781.75	.00	.00	.00	.00		117781.75
DSPOL, PK, DISPROL TAB, 200SX50NP (NA)								
3029411 CA 34152								
3029411-7244-7127 FG 9.000	9471.48	85243.32	.00	.00	.00	.00		85243.32
3029411-7205 FG-W 1.000	9471.48	9471.48	.00	.00	.00	.00		9471.48
GAVIS, PK, GAVSON LIQ, 120MLX48NP (NA)								
3029413 CA 34152								
3029413-7645 FG 149.000	2842.02	423460.98	.00	.00	.00	.00		423460.98
3029413-7646-7851 FG 1.000	2842.02	2842.02	.00	.00	.00	.00		2842.02
DSPRN, PK, DISPRIN, 100SX160 (NA)								
3029414 CA 34152								
3029414-7208 FG 10.000	16472.64	164726.40	.00	.00	.00	.00		164726.40
DSPRN, PK, DISPRIN, 609SX30NP (NA)								
3029415 CA 34152								
3029415-7129 FG 10.000	18531.00	185310.00	.00	.00	.00	.00		185310.00
DSPRN, PK, DISPRIN CV, 30SX100NP (NA)								
3029417 CA 34152								
3029417-7006 FG 5.000	2599.58	12997.90	.00	.00	.00	.00		12997.90
DETOL, PK, ASL, 50ML X 60 NP (NA)								
3029941 CA 34152								
3029941-7743 FG 50.000	2062.64	103132.00	.00	.00	17552.66			120665.66
STPSL, PK, H&L 14+, 150S X 20 (NA)								
3045753 CA 34152								
FG 10.000	12457.65	124576.50	.00	.00	21176.01			145754.51

Invoice Total: 1286032.35 .00 36710.67 .00 .00 1318943.02

PAK. RUPEES : ONE MILLION THREE HUNDRED EIGHTEEN THOUSAND NINE HUNDRED FORTY THREE AND TWO PAISA ONLY *****

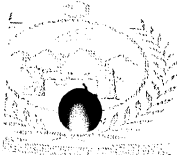


Handwritten text at the bottom of the page, possibly a date or reference number.

OFFICE OF THE PROVINCIAL DRUG INSPECTOR,
DISTRICT HEALTH OFFICE, ABBOTTABAD, KPK

No. 1308 IDI-AD

Dated Abbottabad the 25-03-2018



Junaid Rashid (Warrantor)
M/S Pacific Pharmaceuticals Limited
30th KM Multan Road, Lahore.
Phone 042-35975291-93

Subject: - SHOW CAUSE FOR CONTRAVENTION OF THE PROVISION OF SECTION 23 1 (a) (v) OF THE DRUGS ACT, 1976.

The undersigned During inspection of business premises M/S Pharmanet Distributor Abbottabad on 13/03/2018, took sample of Suspension Crafilm 120ml Batch 01164M manufactured by M/S Pacific Pharmaceuticals Limited Lahore, for the purposes of test & analysis. The Provincial Government Analyst Khyber Pakhtunkhwa, Peshawar has declared Samples as SUB-STANDARD thus contravene Section 23 (1) (a)(v) of The Drugs Act, 1976.

Copies Enclosed:

- 1. TRA NO. 55762/DTL DATED PESHAWAR THE 18-05-2018.

Show Cause Notice were Served to M/S Pharmanet Distributor Abbottabad, In reply they submitted your warranted invoice # 127166 dated 18-12-2017.

You are therefore directed to explain your position for the contravention and disclose the name of the Chief Executive, Partner, Production and Quality Control Incharge involved in the manufacturing of the drug, in written form to the undersigned within SEVEN DAYS, after receipt of this letter, failing which it will be presumed that you have no valid reasons / informations to offer. ex-parte proceedings shall be initiated against you under the Drugs Act, 1976

[Signature]
Provincial Drug Inspector
Abbottabad.

Copy forwarded to:-

- 1. Chairman Provincial Quality Control Board Khyber Pakhtunkhwa Peshawar for information.

Provincial Drug Inspector
Abbottabad.

No. 1258

For Insurance Notices see reverse.
Stamps affixed except in case of
uninsured letters of not more than
the initial weight prescribed in the
Post Office Guide or on which no
acknowledgement is due.

Rs. 40

Received a registered*
addressed to [Signature] Date-Stamp [Signature]

Initials of Receiving Officer with the word "postcard", "packet" or "parcel"
"to" before it when necessary.

Insured for Rs. (in figures) 40 (in words) 40



Ref: PDI/AD/001/18

Dated: June 21, 2018

**The Provincial Drug Inspector,
District Health Office (DHO),
Abbottabad – Pakistan.**

In re: Substandard Crafilm Suspension 120ml Batch No. 01164M Manufactured By
M/S Pacific Pharmaceuticals (Pvt.) Ltd 30th Km, Multan Road, Lahore – Pakistan

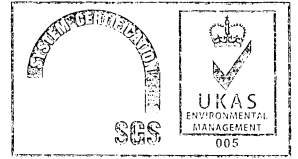
**Subject: REPLY TO THE LETTER NO. 1303/PDI/AD DATED 06.06.2018,
RECEIVED VIDE DATED [12-06-2018]**

Dear Sir,

1. Kindly refer to your letter no. 1303/PDI/AD, dated 06.06.2018 regarding the above captioned matter.
2. Through the letter under reply your good office informed the Company that its product Suspension Crafilm 120ml Batch no. 011604M (hereinafter referred as “**The Product**”) has allegedly been declared substandard by Government Analyst Drug Testing Laboratory (DTL) Peshawar vide a letter no. TRA 55762/DTL dated 18-05-2018.
3. The samples of the product were allegedly declared substandard on basis of non-compliance with the ASSAY, whereby the release limit is 90-110%. The results reported after the test is 80.94%
4. The note is mentioned in the DTL report stated as **“The suspension in the provided bottle is broken and hard cake which do not dissolve even after vigorous shaking”**
5. It is pertinent to mention here that while the broken bottle, the liquid part of the suspension leaked hence the hard cake is not dissolve in the remaining liquid part of suspension, so while performing the Assay Test at non dissolved hard cake even after vigorous shake and whilst declaring the Product to be in compliance with the Assay Results, wrongly declared our Product as **substandard**.

Plant:
30th Km, Multan Road, Lahore. P.O. Box 399, Lahore, Pakistan.
Tel : +92 42 35975291-93. Fax : +92 42 35975356
Email: info@pacificpharmaceuticals.com URL: www.pacificpharmaceuticals.com

Head Office:
13 Ghaziabad, Islamabad, Lahore - Pakistan.
Tel : +92 42 37214731. Fax: +92 42 37214631
Email: info@pacificpharmaceuticals.com URL: www.pacificpharmaceuticals.com



6. In order to prove our stance, we are enclosing herewith the following documents for your kind reference:

- Method of Analysis (SOP)
- Reference Standards
- COA of Batch No. 01164M

7. Further, we have checked retained samples of our Product and have found them within limits in all respect according to the prescribed pharmacopeia.

Copy of the test conducted by the company on its retained samples is enclosed herewith for your kind perusal.

8. We are hopeful that the foregoing will address your concerns regarding the quality of the drug produced by us. We remain available for any other clarification and provision of any further documents that may be required by your good-self.

9. Without prejudice to the foregoing, the Pacific Pharmaceuticals Ltd. reserves the right to produce evidence in contravention to the Report of the Government Analyst and request your good office to get the sample retested from the Appellate Lab / NIH Islamabad as we do not agree with the DTL Report TRA No. 55762/DTL dated 18-05-2018 issued by the Government Analyst, DTL, Peshawar. Accordingly, you are requested to have our sample re-analysed / re-tested from Appellate Testing Laboratory at NIH Islamabad.

With regards,

For Pacific Pharmaceuticals Ltd,

Muhammad Usman,
Manager Regulatory Affairs



Pacific Pharmaceuticals Ltd., Lahore - Pakistan

Reference
QCFG/03/0010

Finished Product Certificate of Analysis

Product: CRAFTILM SUSPENSION 120 ML Registration No: 018602 QC Number:- F10-441-17

Batch/Lot No.:- 011604M Batch size :- 2500 Litre Mfg. Date:- April 2017

Analysis Date:- 13-Oct-2017 Expiry Date:- March 2020

TESTS	SPECIFICATIONS	RESULTS
Description	An opaque, homogeneous white suspension	Complies
Density	1.13 – 1.25g/ml	1.17 g/ml
Viscosity (Spindle NO 2 at 5rpm)	1200 – 2000 cps	1450 cps
Filling Volume	60 ± 3ml	60 ml
Filling Volume	120 ± 4ml	120 ml
Identification by chemical test: Aluminium	White gelatinous precipitates are produced	Conforms
QUANTITATIVE ASSAY BY TITRATION Each 5ml suspension contains: Sucralfate..... 1.0g	90.0 – 110.0 %	99.62 %
Total viable count	NMT 1000 Col/ml	352 col/ml
E-coli	Absent	Absent
Salmonella species	Absent	Absent

Remarks: Results conform to Finished product specifications (APR) craftilm suspension

Analysis By: _____

13/10/17

Reviewed By: _____

13/10/2017

QC Manager: _____

13-10-17

Product Drug Inspector
KINDLY SIGN
13-10-17

Reference
QCFG/03/0010

Finished Product Certificate of Analysis

Product: CRAFTILM SUSPENSION 120 ML Registration No:- 018602 QC Number:- F10-441-17
Batch/Lot No.:- 011604M Batch size :- 2500 Litre Mfg. Date:- April 2017
Analysis Date:- 13-Jun-2018 Expiry Date:- March 2020

TESTS	SPECIFICATIONS	RESULTS
Description	An opaque, homogeneous white suspension	Complies
Density	1.13 – 1.25g/ml	1.17 g/ml
Viscosity (Spindle NO 2 at 5rpm)	1200 – 2000 cps	1420 cps
Filling Volume	60 ± 3ml	60 ml
Filling Volume	120 ± 4ml	120 ml
Identification by chemical test: Aluminium	White gelatinous precipitates are produced	Conforms
QUANTITATIVE ASSAY BY TITRATION Each 5ml suspension contains: Sucralfate..... 1.0g	90.0 – 110.0 %	98.40 %
Total viable count	NMT 1000 Col/ml	352 col/ml
E-coli	Absent	Absent
Salmonella species	Absent	Absent

Remarks: Results conform to Finished product specifications (APR) craftilm suspension

Retaining Sample Record of Testing

Analysis By:

[Signature]
13/06/18

Reviewed By:

[Signature]
13/06/18

QC Manager:

[Signature]
13/06/2018



Department: Quality Control

Effective Date:

Title: Finished Product Specification of Crafilm Suspension

TEST APPLIED	SPECIFICATIONS
Description	An opaque, homogeneous white suspension
Density	1.13 - 1.25g/ml
Viscosity (Spindle NO 2 at 5rpm)	1200 - 2000cps
Filled Volume	60 ± 3ml 120 ± 4ml
Identification by chemical test:	
Aluminium	White gelatinous precipitates are produced
Quantitative Assay by Titration	
Each 5ml suspension contains:	
Sucralfate.....1.0g	90.0 - 110.0 %
Microbial Quality	
Total viable count	NMT 10 col/ml
Escherichia coli	Absent
Salmonella species	Absent
Staphylococcus aureus	Absent
Pseudomonas aeruginosa	Absent


 Quality Control Manager,
 Pacific Pharmaceuticals Ltd.
 Lahore

	Written by:	Approved by:	Authorized by:	Page #
Name				1 of 1
Designation				
Sign. & date				



Department: Quality Control

Effective Date:

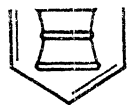
Title: SOP for Finished Product Testing of Crafilm Suspension

Table of content

1.0	Purpose	02
2.0	Scope	02
3.0	Responsibilities	02
4.0	Definitions	02
5.0	Materials & Equipments	02
6.0	Safety Considerations	03
7.0	Flow Diagram (If required)	03
8.0	Procedure	03
9.0	Required Documents	07
10.0	Attached Documents	08
11.0	Revision History	08
12.0	List of Recipients	08
13.0	Annexure A & B	NA

[Handwritten Signature]
Quality Control Manager,
Pacific Pharmaceuticals Ltd
Labore

	Written by:	Approved by:	Authorized by:	Page #
Name				
Designation				
Sign. & date				1 of 8



Department: Quality Control

Effective Date:

Title: SOP for Finished Product Testing of Crafilm Suspension

1.0 Purpose

1.1 To describe procedures for Finished Product Testing of Crafilm Suspension by QC lab

2.0 Scope

2.1 The scope of this SOP pertains to Finished Product Testing of Crafilm suspension

3.0 Responsibilities

3.1 It is the responsibility of QC analyst to follow this SOP as it is written

3.2 It is the responsibility of QC manager to review and update this SOP as necessary and to ensure that this SOP is followed in its entirety

4.0 Definitions

NA

5.0 Materials and Equipments

5.1 Density meter

5.2 Viscometer

5.3 Analytical balance

5.4 pH meter

5.5 Digital burette

5.6 Hot plate, Velp

5.7 Glacial Acetic Acid

5.8 Zinc sulphate

5.9 EDTA

5.10 Hydrochloric acid

[Signature]
Quality Control Manager,
Pacific Pharmaceuticals Ltd.
Labo

	Written by:	Approved by:	Authorized by:	Page #
Name				2 of 8
Designation				
Sign. & date				



Department: Quality Control	Effective Date:
Title: SOP for Finished Product Testing of Crafilm Suspension	

- 5.11 Ammonia
- 5.12 Ammonium acetate
- 5.13 Ethanol
- 5.14 Sodium hydroxide
- 5.15 Xylenol orange
- 5.16 Hexamethylenetetramine

6.0 Safety Considerations

6.1 Wear lab coat, gloves and safety glasses at all time during testing

7.0 Flow Diagram

NA

8.0 Procedures

8.1 Preparation of reagents

8.1.1 Preparation of 0.05 M EDTA

Weigh 18.6g of EDTA and transfer it to 1000ml volumetric flask. Add 500ml of RO water, and dissolve by sonication for 5minutes. Bring up volume to 1000ml with RO water and mix well.

8.1.2 Standardization of 0.05 M EDTA

Weigh 0.100g of zinc powder and transfer it in a 100ml volumetric flask. Add 4ml of 7M hydrochloric acid and dissolve by sonication. Add 0.1ml of bromine water, Boil to remove excess bromine, cool at room temperature and bring up volume to 100ml with water. Take 25ml of this solution with the help of a bulb pipette and transfer to a 500ml conical flask. Add 200ml of RO water. Add 50mg of xylenol orange triturate, the solution becomes yellow. Add hexamethylenetetramine until the color of solution turns violet-pink from yellow. Add 2g of hexamethylenetetramine in excess. Titrate with

	Written by:	Approved by:	Authorized by: Quality Pacific Pharmaceutical Laboratory	Page # 3 of 8
Name				
Designation				
Sign. & date				



Department: Quality Control

Effective Date:

Title: SOP for Finished Product Testing of Crafilm Suspension

EDTA solution until violet-pink color turns yellow. Each ml of 0.05 M EDTA VS is equivalent to 3.269mg of Zn.

8.1.3 Preparation of 0.05 M Zinc sulphate solution

Weigh 8.79g of Zinc sulphate monohydrate and transfer it in a 1000ml volumetric flask. Add 500ml RO water and dissolve by sonication for 5 minutes. Bring up volume to 1000ml with RO water and mix well.

8.1.4 Standardization of 0.05 M zinc sulphate solution

Transfer 10ml of 0.05 M EDTA solution in a 100ml conical flask with the help of 10ml bulb pipette. Add 10ml of acetic acid – ammonium acetate buffer pH 4.5, 50ml of ethanol and 2ml of dithizone. Titrate with zinc sulphate solution to a clear rose pink color end point. Record volume of zinc sulphate solution used and calculate exact molarity using following formula.

$$\text{Molarity of Zinc sulphate solution} = \frac{10 \times F \times 0.05}{V}$$

Where

10 = volume taken of 0.05 M EDTA solution

F = factor of 0.05 EDTA solution

0.05 = Molarity of EDTA solution

V = volume used of zinc sulphate solution

8.1.5 Dithizone indicator solution

Weigh 25.6 mg of dithizone and transfer it to 100 ml volumetric flask. Add approximately 60 ml of ethanol and sonicate for 5 minutes. Bring up volume to 100 ml with ethanol.

8.1.6 Acetic acid ammonium acetate buffer (pH 4.5)

Weigh 77.1 g of ammonium acetate and transfer in 500 ml of beaker. Add in it 300 ml of RO water and sonicate for 20 minutes. Add 70 ml of glacial acetic acid in it and transfer it to 1000 ml of volumetric flask. Bring up volume to 1000 ml with RO water and mix well by swirling.

	Written by:	Approved by:	Authorized by:	Page #
Name				
Designation				
Sign. & date				4 of 8



Department: Quality Control

Effective Date:

Title: SOP for Finished Product Testing of Crafilm Suspension

8.1.7 Ammonia solution (6M)

Accurately measure 33.5 ml of 35 % ammonia and transfer it to 100 ml volumetric flask. Bring up volume to 100 ml with RO water.

8.1.8 1N Sodium hydroxide

Accurately weigh 4.0 g sodium hydroxide to 100 ml volumetric flask. Add 50 ml RO water and sonicate for 15 minutes. Bring up volume to 100 ml with RO water.

8.1.9 Hydrochloric acid (3M)

Measure 26.10ml of concentrated hydrochloric acid and transfer it to 100 ml volumetric flask already containing 50 ml of RO water. Bring up volume to 100 ml with RO water and mix well by swirling.

8.1.10 Hydrochloric acid (1.0M)

Measure 8.3ml of concentrated hydrochloric acid and transfer it to 100 ml volumetric flask already containing 50 ml of RO water. Bring up volume to 100 ml with RO water and mix well by swirling.

8.2 Finished Product Testing

8.2.1 Physical tests

8.2.1.1 Description

Verify appearance, color and odour of Crafilm suspension

8.2.1.2 Filled Volume

Determine the filled volume of crafilm suspension using graduated cylinder

8.2.1.3 Density

Determine the density of sample using density meter QCOP/02/0014

8.2.1.4 Viscosity

Determine the viscosity of sample using viscometer QCOP/02/0015

	Written by:	Approved by:	Authorized by:	Page #
Name				5 of 8
Designation				
Sign. & date				

Quality Control
PACIFIC

QCOP/02/0015



Department: Quality Control

Effective Date:

Title: SOP for Finished Product Testing of Crafilm Suspension

8.3 Chemical Tests

8.3.1 Identification of Aluminium

Take 2.5ml of sample and transfer it to 100ml beaker and add 10ml of 1.0M hydrochloric acid. Add 6M ammonia, gelatinous white precipitates are produced which dissolve on further addition of 1N sodium hydroxide.

8.3.2 Quantitative determination of Sucralfate on aluminium basis

8.3.2.1 Preparation of sample solution

Shake sample well, Take 5g of sample and transfer it to 250 ml volumetric flask. Add 7ml of concentrated hydrochloric acid and 10ml of RO water. Heat on water bath at 60°C for 15minutes with occasional shaking. Add 30ml of RO water pre-heated at 60°C. Filter the solution and collect filtrate in 250ml volumetric flask. Wash filter paper with hot water and collect filtrate. Allow it to cool at room temperature. Bring up volume to 250ml with RO water.

8.3.2.2 Titration of sample

Transfer 25ml of sample stock solution in a 500ml conical flask. Add 50ml of RO water, 25ml of 0.05M EDTA solution and 10ml of acetic acid ammonium acetate buffer to adjust pH to 4.5. Heat for 5minutes, cool at room temperature. Add 50ml of ethanol and 5ml of dithizone. Titrate excess 0.05M EDTA solution with 0.05M Zinc sulphate solution. The end point appears when color of solution turns from green to rose pink. Record the volume of 0.05M Zinc sulphate solution used. Calculate the volume of 0.05M EDTA solution consumed. Each ml of 0.05M EDTA is equivalent to 1.3491mg of aluminium.

Determine mg of aluminium by using the following formulae

$$\text{mg of aluminium} / 5\text{ml} = M = \frac{(25 \times A - B \times C) \times 1.3491 \times 250 \times 5 \times D}{W \times \text{vol of stock sol. taken}}$$

	Written by:	Approved by:	Authorized by:	Page #
Name				6 of 8
Designation				
Sign. & date				



Department: Quality Control

Effective Date:

Title: SOP for Finished Product Testing of Crafilm Suspension

Where,

- 25 = volume of EDTA solution
- A = standardization factor of 0.05M EDTA
- B = volume of 0.05M Zinc sulphate solution
- C = standardization factor of 0.05M Zinc sulphate
- 1.3491 = titration factor
- 250 = total volume of stock solution
- Ws = weight of sample in gm
- D = Density
- M = mg of aluminium found per 5 ml of finished product

Calculate mg of Sucralfate in 5 ml by using the following formulae:

$$\text{mg of Sucralfate/ 5ml} = A = \frac{M}{17} \times 100$$

Convert mg of Sucralfate to gram of Sucralfate in 5 ml by using the following formulae

$$\text{gm of Sucralfate/ 5ml} = C = \frac{A}{1000}$$

Calculate percent amount of Sucralfate per 5 ml using the following formula:

$$\text{Percent of Sucralfate} = \frac{C}{1} \times 100$$

Where '1' is the label claim of sucralfate per 5ml in gram

9.0 Required Documents

- 9.1 Standard operating procedures for Analytical balance QCOP/02/0003
- 9.2 Standard operating procedures for pH meter QCOP/02/0007
- 9.3 Standard operating procedure for operation and calibration of Density meter QCOP/02/0014

	Written by:	Approved by:	Authorized by:	Page # 7 of 8
Name				
Designation				
Sign. & date				



Department: Quality Control

Effective Date:

Title: SOP for Finished Product Testing of Crafilm Suspension

9.4 Standard operating procedure for operation and calibration of Viscometer QCOP/02/0015

9.5 Finished Product specifications of Crafilm suspension QCFS/03/0010

10.0 Attached Documents

10.1 Certificate of Analysis of Crafilm Suspension FQC/04/0007

10.2 Record of Finished Product testing of Crafilm Suspension FQC/05/0008

11.0 Revision History

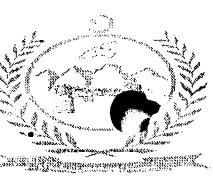
Revision No.	Date	Responsible Person / Designation	Description of Change
01			
02			

12.0 List of Recipients

Recipients	Issued on (Date / Signature)	Withdrawn on (Date / Signature)
Quality Assurance		
Quality Control		
QC Analyst		

	Written by:	Approved by:	Authorized by:	Page #
Name				3 of 8
Designation				
Sign. & date				

Product Prod Inspector
[Signature]



OFFICE OF THE PROVINCIAL DRUG INSPECTOR
DISTRICT HEALTH OFFICE, ABBOTTABAD, KPK

No. 1309 DD-AD
Dated Abbottabad the 25-06-2018



To
Managing Director
M/S Reckitt Benckiser Pakistan Limited
F-18, S.I.T.E Karachi.
Tel: 32573405-9

Subject: - **SHOW CAUSE FOR CONTRAVENTION OF THE PROVISION OF SECTION 23 1 (a) (v) OF THE DRUGS ACT, 1976.**

The undersigned During inspection of business premises M/S Pharmanet Distributor Abbottabad on 13/03/2018, took sample of **Gaviscon Advance Liquid** Batch # **7115 & 7113** manufactured by M/S Reckitt Bankiser Pakistan Ltd, Karachi, for the purposes of test & analysis. The Provincial Government Analyst Khyber Pakhtunkhwa, Peshawar has declared Samples as **SUB-STANDARD** thus contravene Section 23 (1) (a)(v) of The Drugs Act, 1976.

- Copies Enclosed:
1. TRA NO. 55760/DTL DATED PESHAWAR THE 18-05-2018.
2. TRA NO. 55761/DTL DATED PESHAWAR THE 18-05-2018.

Show Cause were served to M/S Pharmanet Distributor Abbottabad, in reply they submitted your invoice # 17042644 S1, 17041864 S1 dated 29-12-2017 & 23-12-2017 respectively.

You are therefore directed to explain your position for the contravention and disclose the name of the Chief Executive, Partner, Production and Quality Control Incharge involved in the manufacturing of the drug, in written form to the undersigned within **SEVEN DAYS**, after receipt of this letter, failing which it will be presumed that you have no valid reasons / informations to offer, ex-parte proceedings shall be initiated against you under the Drugs Act, 1976

PK

Provincial Drug Inspector
Abbottabad.

- Copy forwarded to: -
1. Chairman Provincial Quality Control Board Khyber Pakhtunkhwa Peshawar for information.

Provincial Drug Inspector
Abbottabad.

No. 1259

For Insurance Notices see reverse. Rs. Ps.
Stamps affixed except in case of uninsured letters of not more than the initial weight prescribed in the Post Office Guide or on which no acknowledgement is due.

Received a registered* addressed to _____ Date Stamp _____
Write here "letter", "postcard", "packet" or "parcel" with the word "insured" before it when necessary.
Insured for Rs. 1000 (in words)

Ref: QM-026/2018

Date: July 2, 2018

To,

The Provincial Drug Inspector,
District Health Office,
Abbottabad. KPK.

Subject: Show Cause for Contravention of The Provision Of Section 231 (a) (v) of The Drug Act, 1976.

Dear Sir,

We write with reference to your letter number: 1309 PDI-AD dated 25th June 2018, declaring our product Gaviscon Advance Liquid Batch no. 7115 & 7113 sub-standard subsequent to testing by The drug Testing Laboratory Khyber Pukhtun Khwa , Peshawar , on the subject cited above.

We have received the letter on 29th June 2018 and therefore, would like to request to you for giving the appropriate time for discussion.

Furthermore, we had not received warranty portion which is a legal obligation to furnish. Kindly provide the samples for the said product which has been declared substandard with us so that we may test authenticity and specification.

Further, we request no coercive action be taken against us in the meantime.

Assuring you our best cooperation all time.

Yours sincerely,

On the behalf of Reckitt Benckiser Pakistan



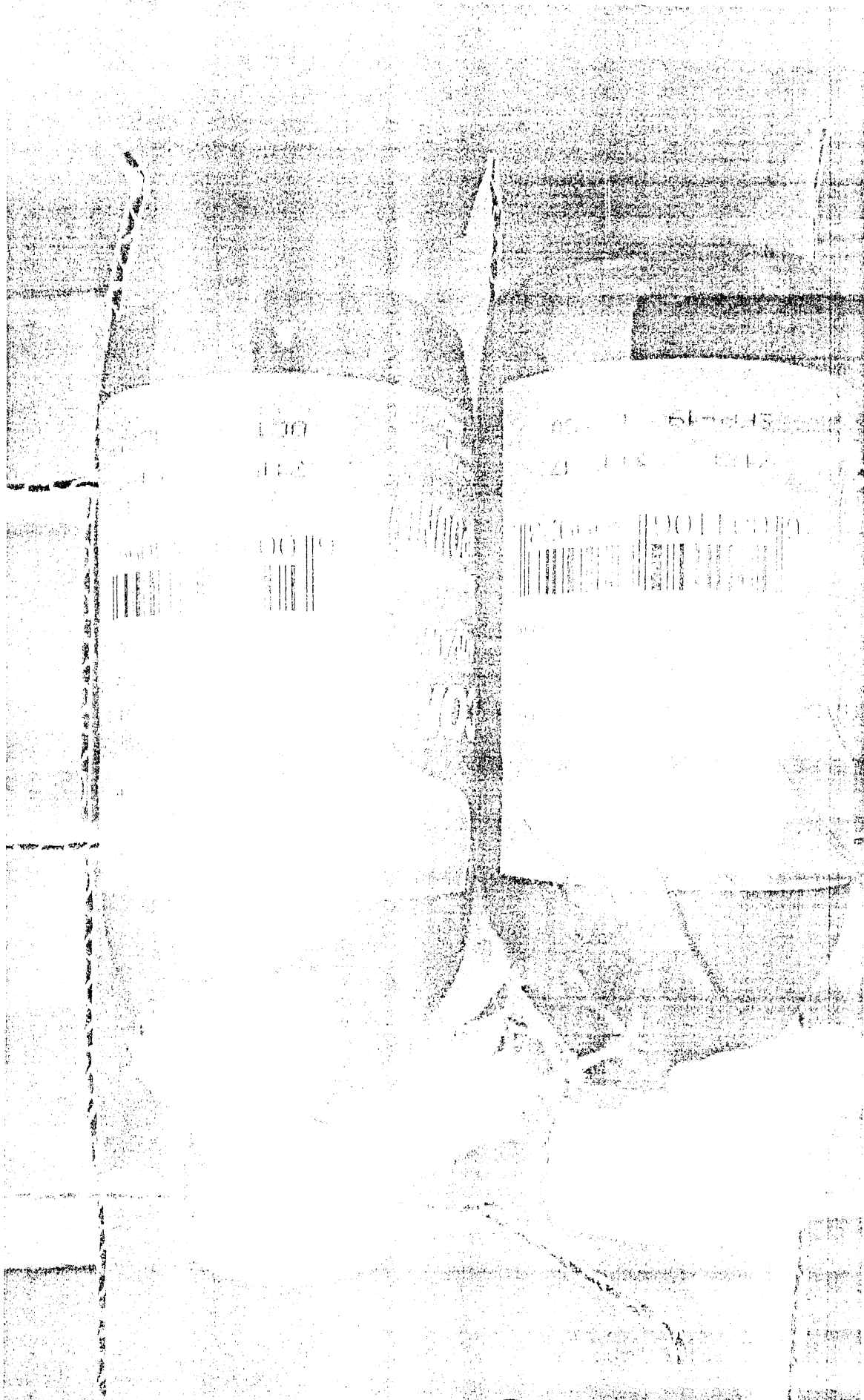
(Humaira Siddique)

Quality Compliance Manager

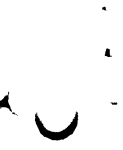
cc: Humaira Siddique

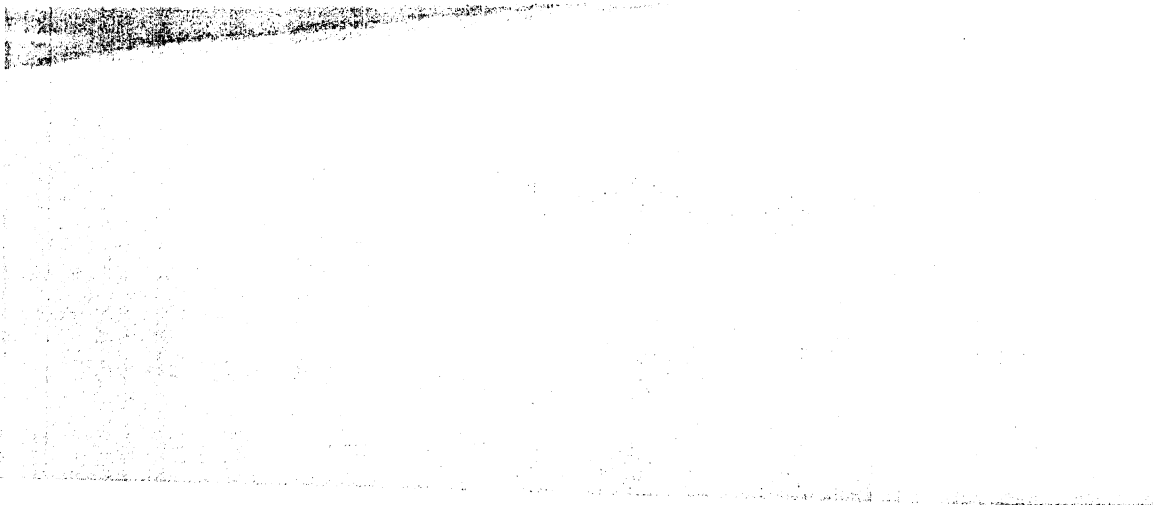
Provincial Drug Inspector
Abbottabad

Provincial Drug Inspector
Abbottabad



43





LEOPARDS COURIER SERVICES PVT. LTD. 320859302 IZ

From		To		Leopards	
To				Pieces	
From				Weight	
CREDIT		NO. OF RECEIPTS	DATE	TIME	SIG
		VALUE			

Leopards Accepts Above Mentioned Items on Shipper's Risk & Shipper Accepts All the Conditions Printed on Reverse

For Customer's Complaints to Customer Care @ 111-300-766 or New Branch Office To Your Nearest One - By Leopards Express

CONFIDENTIAL AND VERY IMPORTANT

TO
 Mr. Mushfiq Hussain
 Reckitt Benckiser Pakistan Limited,
 3rd Floor, Tenancy 04 & 05,
 Corporate City Hc-3, Block 4,
 Scheme 5, Clifton
 KARACHI-75600



From
 PharmaNet
 Abbottabad.

(Handwritten signature and scribbles)

The Chairman,
Provincial Quality Control Board
Khyber Pakhtunkhwa Peshawar.

Subject: - **SUBMISSION OF REPORT AGAIN'**

1. **Muhammad Zarif Ahmed (P**
2. **Zarin Gul (Branch Manager ,**
M/S Pharmanet Distributor, 29...
3. **Junaid Rashid (warrantor)**
4. **Muhammad Usman (Regulatory Manager)**
M/S Pacific Pharmaceuticals Limited, 30th km Multan Road Lahore.
5. **Managing Director**
6. **Humaira Saddique (Quality Compliance manager)**
M/S Reckitt Benckier Pakistan Limited, F-18, S.I.T.E Karachi.

Offence: **SECTION 23 (1)(a)(v) OF THE DRUGS ACT, 1976.**

R/Sir,

I have the honor to state that undersigned on 13-03-2018 during inspection of M/S Pharmanet Distributor Abbottabad, sampled the **Suspension Crafilm 120ml Batch # 01164M** manufactured by M/S **Pacific Pharmaceuticals Limited, 30th km Multan Road Lahore & Gaviscon Advance Liquid Batch 7115 & 7113** for Test & Anaylsis. The Government Analyst Provincial Drugs Testing Laboratory, Khyber Pakhtunkhwa Peshawar declared the sample as **SUBSTANDARD** vide Test Report No:

1. TRA NO. 55760 / DTL Dated Peshawar, the 18-05-2018.
2. TRA NO. 55761 / DTL Dated Peshawar, the 18-05-2018.
3. TRA NO. 55762 / DTL Dated Peshawar, the 18-05-2018.

Suspension Crafilm 120ml Batch # 01164M: M/S Pharmanet Distributor Abbottabad, Submitted warranted invoice of manufacturer M/S Pacific Pharmaceuticals Limited Lahore, on further investigation from manufacturer, in reply they **Challenge Provincial DTL Reports & Appeal for Sample Retesting** under the provision of Section 22 (2) of The Drugs Act, 1976

Gaviscon Advance Liquid Batch # 7115 & 7113: M/S Pharmanet Distributor submitted warranted invoice of manufacturer M/S **Reckitt Benckier Pakistan Limited, F-18, S.I.T.E Karachi,** On further investigation the reply received from manufacturer is not satisfactory.

They have contravened the provision of Section 23 1 (a)(v) of the Drugs Act, 1976.
The case is therefore submitted for scrutiny and further direction to the undersigned.

(SYED AQIB ALI SHAH)
Provincial Drugs Inspector
Abbottabad.

Received a registered addressed to _____ Date Stamp 18/5/18

Write here "letter", "postcard", "packet" or "parcel" with the word "insured" when necessary.

Initials of Receiving Officer _____

Insured for Rs. (in figures) _____ (in words) _____

Insurance fee Rs. _____ Pk. _____ (in words) _____

Name and address _____

Weight _____ Kilo _____ Grams _____

9191v



GOVERNMENT OF PUNJAB
DEPARTMENT OF HEALTH AND FAMILY WELFARE

PROVINCIAL QUALITY CONTROL BOARD
KHYBER PAKHTUNKHWA

To

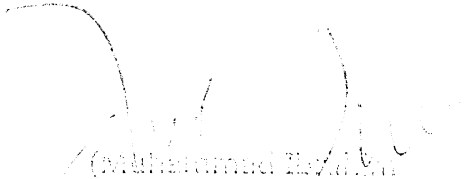
The Provincial Drug Inspector,
Office of the District Health Officer,
RAIKOT

Subject- MINUTES OF THE MEETING OF PROVINCIAL QUALITY CONTROL BOARD KHYBER PAKHTUNKHWA

I am directed to refer to your complaint vide memo no. 621-107/AD dated 24/10/11 and to enclose herewith minutes of the meeting of Provincial Quality Control Board, Khyber Pakhtunkhwa held on 07.11.2011 at Raikot. In favour of with or necessary addition to your and in view of the fact that you have one week for lodging the writ petition in the District Court, Raikot.

The Board shall also report to the Government of Punjab on the final outcome/decision of the Court and a copy of the decision of the Court of this letter and the copy of decision of the Court shall be provided to you. Comments/recommendations for further administrative measures (if any) may be submitted to the maximum.

Yours faithfully,


(M. H. Khan),
Secretary,
Provincial Quality Control Board,
Khyber Pakhtunkhwa

Enclosed for your file.

Copy along with minutes forwarded to the District Health Officer, Raikot, Khyber Pakhtunkhwa, Peshawar for information.


Secretary,
Provincial Quality Control Board,
Khyber Pakhtunkhwa

**MINUTES OF THE 310TH MEETING OF PROVINCIAL QUALITY CONTROL BOARD, KHYBER PAKHTUNKHWA, PESHAWAR
HELD ON 04-07-2019 AT 10:00 AM.**

Meeting was held on 04-07-2019 at 10:00 am in the committee room of Health Department, Peshawar and was chaired by Dr. Iqbal Jamil, Secretary Health Department as Chairman PQCB. The meeting was attended by the members of the Board, as under:-

Dr. Iqbal Shah, representing Head of Pharmacology Department, KMC, Peshawar as member PQCB.

Dr. Iqbal Jamil, Director Health merged Areas as member PQCB.

Dr. Iqbal Abdul Waheed, M/S Afghani Dawakhana, Peshawar as member PQCB.

Dr. Iqbal Javed Khan, Chief Drug Inspector, Khyber Pakhtunkhwa as member PQCB.

Dr. Iqbal Ahmad, Section Officer (Drugs), Health Department as member PQCB.

Dr. Iqbal Ahmad Ibrahim, Deputy Secretary (Drugs), Health Department as Secretary PQCB.

Dr. Iqbal Jamil, Chairman PCDA, Khyber Pakhtunkhwa participated in the meeting in capacity as observer member.

In providing opportunity of hearing to the accused parties, the following decision was made by the Board.

Abbottabad	1. Muhammad Zarif Ahmad (Proprietor) 2. Zarin Gul (Branch Manager/Person Present) M/s Pharmanet Distributor, 295 Near Modern Age School Supply Abbottabad. 3. Junaid Rashid (Warrantor) 4. Muhammad Usman (Regulatory Manager) M/s Pacific Pharmaceuticals Limited, 30th Km Multan Road Lahore 5. Managing Director 6. Humaira Saddique (Quality Compliance Manager) M/s Reckitt Benckier Pakistan Limited F-18 SITE Karachi.	Susp. Crafilm 120 ml Batch No. 0116M Gaviscon Advance Liquid Batch No. 7115 Batch No. 7113	Sale/Stock of Sub-Standard Drug Section 23(1)(a)(v) of the Drug Act 1976.	Accused at serial no. 1 & 2 appeared and were heard in connection with their alleged involvement in sale of substandard drugs Susp. Crafilm 120 ml Batch No. 0116M Gaviscon Advance Liquid Batch No. 7115 Batch No. 7113 while the other accused were absent. The firm challenged the report of DTL, Peshawar and requested for retesting at NIH. After threadbare discussion, the Board agreed on the following decision: Decision: To send the sample for retesting to the NIH, Islamabad at the cost of manufacture.
------------	--	---	--	--



Phone No: 51-9255210
Fax No: 9255099
Email: edofficenih@gmail.com

**National Institute of Health
Drugs Control & Traditional Medicines Division
ISLAMABAD – PAKISTAN**

No.F.1-20/03-KPK/2019-DC&TMD:

13th September, 2019.

The Secretary
Provincial Quality Control Board
Khyber Pakhtunkhwa Health Secretariat
Peshawar.

SUBJECT: - TEST REPORT OF THE SAMPLE:

Reference your letter SO(D)/2-15/2019/PQCB/310th (002) dated 15-07-2019.
Please find enclosed herewith the test report of the sample of "**Crafilm Suspension (Sucrafate)**;
Batch No. 011604M, manufactured by M/s Pacific Pharmaceuticals (Pvt) Ltd 30th Multan Road,
Lahore Pakistan. (Test Report No.03-KPK/2019).

(Dr. Shahzad Hussain)
Chief

No.F.1-20/03-KPK/2019-DC&TMD

Form (6) (See Rule-16)



TEST REPORT NO.03-KPK/2019

Dated 13th September, 2019.

CERTIFICATE OF TEST/ANALYSIS BY THE DRUGS CONTROL AND TRADITIONAL MEDICINES DIVISION, NATIONAL INSTITUTE OF HEALTH, ISLAMABAD.

Certified that the sample (s) bearing number 1058/PDI-AD purporting to be a sample of Crafilm Suspension (Sucralfate) received on 16-07-2019 from The Chairman, Drug Court, Khyber Pakhtunkhwa, Peshawar, vide memo SO(D)/2-15/2019/POCB/310th (002) dated 15-07-2019 has been tested /analyzed and that the result of such test/analysis is stated below: -

2. The condition of seal on the packet. **Sealed.**

<u>DESCRIPTION:</u>	Two layered heterogeneous suspension contained in amber colored labeled glass bottle further packed in an outer carton. The upper layer consists of free flowing liquid whereas the lower layer consists of hard cake which does not disperse even on shaking. (Does not comply with manufacturer specification which states that "An opaque, homogenous suspension"	
<u>E.COLI:</u>	Absent	Complies with manufacturer specification.
<u>SALMONELLA SPECIES:</u>	Absent	Complies with manufacturer specification.
<u>S.AUREUS:</u>	Absent	Complies with manufacturer specification.
<u>PSEUDOMONAS AERUGINOSA:</u>	Absent	Complies with manufacturer specification.
<u>TOTAL VIAL COUNT:</u>	Absent	Complies with manufacturer specification.

3. In the opinion of the undersigned the sample is **Sub-Standard** quality as defined in the Drug Act, 1976 for the reason (s) given below:-

DESCRIPTION: Two layered heterogeneous suspension contained in amber colored labeled glass bottle further packed in an outer carton. The upper layer consists of free flowing liquid whereas the lower layer consists of hard cake which does not disperse even on shaking. (Does not comply with manufacturer specification which states that "An opaque, homogenous suspension"

CHIEF

Drugs Control and Traditional Medicines Division, National Institute of Health, Islamabad/Authorized Officer /Government Analyst

DETAILS OF RESULT OF TEST AND ANALYSIS

(With protocols of test applied)

<u>NOMENCLATURE:</u>	Crafilm Suspension (Sucralfate).
<u>BATCH NO.</u>	011604M.
<u>DATE OF MANUF:</u>	04-2017.
<u>DATE OF EXPIRY:</u>	03-2020.
<u>MANUFACTURER:</u>	M/s. Pacific Pharmaceuticals Ltd 30 th Km Multan Road Lahore Pakistan.
<u>DESCRIPTION:</u>	Two layered heterogeneous suspension contained in amber colored labeled glass bottle further packed in an outer carton. The upper layer consists of free flowing liquid whereas the lower layer consists of hard cake which does not disperse even on shaking. (Does not comply with manufacturer specification which states that "An opaque, homogenous suspension"

Cont. at page-2

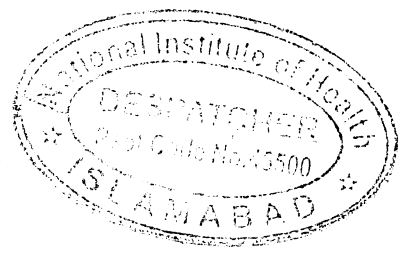


CONFIDENTIAL

No.F.1-20/03-KPK/2019-DC&TMD:

5951

The Secretary
Provincial Quality Control Board
Khyber Pakhtunkhwa Health Secretariat
Peshawar.



NO. SO(Drugs)/HD/2-15/2019 (312TH PQCB)
Dated Peshawar the, 16th December, 2019

To

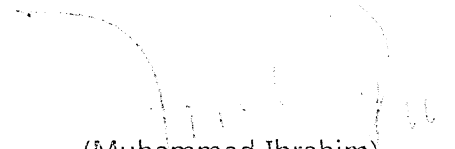
The Provincial Drug Inspector,
Office of the District Health Officer,

Subject:- MINUTES OF THE MEETING OF PROVINCIAL QUALITY CONTROL BOARD KHYBER PAKHTUNKHWA.

I am directed to refer to your complaint vide memo No. 15/17/2019 dated 10/11/2019 and to enclose herewith minutes of the meeting of Provincial Quality Control Board, Khyber Pakhtunkhwa held on 28/11/2019 at 10:00 AM for favour of further necessary action at your end under intimation to this Board within one week for lodging FIR and within fortnight in cases to be instituted in the Drug Court.

The Board shall be kept informed of the progress of the case and the final outcome/decision of the Court shall be intimated to this Board giving reference of this letter and the copy of decision of the Court shall be produced along with your comments/recommendations for further immediate necessary action (within fortnight at the maximum).

Encl: As above.


(Muhammad Ibrahim)
Secretary
Provincial Quality Control Board
Khyber Pakhtunkhwa, Peshawar

Endst: No. & Date Even.

Copy along with minutes forwarded to the Chairman Drug Court, Khyber Pakhtunkhwa, Peshawar for information.

Secretary
Provincial Quality Control Board
Khyber Pakhtunkhwa, Peshawar



**MINUTES OF THE MEETING OF 312TH PROVINCIAL QUALITY CONTROL BOARD, KHYBER PAKHT
PESHAWAR HELD ON 28-11-2019 AT 10:00 AM.**

The subject meeting was held on 28-11-2019 at 10:00 am in the committee room of Health Department, Peshawar and was chaired by Mr. K Baloch, Additional Secretary Health (Dev) as Vice Chairman PQCB. The meeting was attended by the members of the Board, as under:-

1. Prof. Dr. Syed Muhammad Ashhad Halimi, representing Chairman Pharmacy Department, University of Peshawar, Peshawar as member F
2. Dr. Muhammad Rauf Wazir, representing Director Health Services merged Areas as member PQCB.
3. Dr. Nizamuddin, Assistant Professor representing Head of Pharmacology Department, Khyber Medical College, Peshawar as member PQCE
4. Dr. Abbass Khan, Chief Drug Inspector, Khyber Pakhtunkhwa as member PQCB.
5. Muhammad Ibrahim, Deputy Secretary (Drugs), Health Department as Secretary/member PQCB.

Mr. Ismail, Chairman Chemist & Druggist Association Khyber Pakhtunkhwa Peshawar Zone as an observer member PQCB.

After affording opportunity of hearing to the accused parties, the following decision was made by the Board.

Agenda Item NO. 2

Abbottabad	1. Muhammad Zarif Ahmad (Proprietor) 2. Zarin Gul (Branch Manager/Person Present) M/s Pharmanet Distributor, 295 Near Modern Age School Supply Abbottabad. 3. Junaid Rashid (Warrantor) 4. Muhammad Usman (Regulatory Manager) M/s Pacific Pharmaceuticals Limited, 30th Km Multan Road Lahore 5. Managing Director 6. Humaira Saddique (Quality Compliance Manager) M/s Reckitt Benckier Pakistan Limited F-18 SITE Karachi.	Susp. Crafilm 120 ml Batch No. 011604M Gaviscon Advance Liquid Batch No. 7115 Batch No. 7113	Sale/Stock of Sub-Standard Drug Section 23(1)(a)(v) of the Drug Act 1976.	The NIH, Islamabad test report in the instance placed before the Board. NIH, Islamabad declared as substandard. After threadbare discussion, made the following Decision: The test reports of NIH, Islamabad to Drug Inspector concerned for prosecution in Drug
------------	--	---	---	---



Pharma Net

Pharma & FMCG Distributors



To
The Provincial Drug Inspector
DHO Office, Abbottabad
KPK
Phone No. 0300-5863033

Provincial Drug Inspector
ABBOTTABAD

From
↓

ISLAMABAD

Plot # 321, St. # 4, Sector I-9/3,
Industrial Area, Islamabad.

Ph: 051-4435913-4

Fax: 051-4101384

pharmenet.isb@gmail.com

ABBOTTABAD

House No. 295, Mansehra Road,
Supply Bazar, Abbottabad, Cantt.

Ph: 0992-343336

Fax: 0992-343339,

phnetah@gmail.com

JHELUM / GUJRAT

Majahidabad G.T Road,
Jhelum.

Ph: 0544-626239

Fax: 0544-628357

phnet.jhelum@gmail.com

MUZAFFARABAD (AJK)

Roshan Plaza, Near Neelum Park,
Ward No. 22, Western Bypass Road,
Bella Noor Shah, Muzaifarabad.

Ph: 05872-446021, 22

PESHAWAR

Main G.T Road, Jhagra
Peshawar

Mob: 0321-5376006



**RECKITT
BENCKISER**



The Provisional Inspector
District Health office
Abbottabad
KPK

> [Signature]

[Signature]

RECKITT BENCKISER PAKISTAN LIMITED

11th Floor, State Life Building No. 11,

Abdullah Haroon Road, G.P.O. Box 625, Karachi-74400.

Dalman City, C.B.

Clifton Karachi

TCS

MR. AQIB ALI SHAH

(PROVINCIAL DRUG INSPECTOR)

DRUG CONTROL OFFICE (DCO)

DISTRICT HEALTH OFFICE (DHQ) ABBOTTABAD

 TCS[®]



40067112838

