## Chapter 2: Performance Audits

## HEALTH & FAMILY WELFARE DEPARTMENT

### *2.1 Drug Control in West Bengal*


**Executive Summary**

The Government of India (GoI) had enacted the Drugs & Cosmetics Act, 1940 followed by the Drugs & Cosmetics (D & C) Rules, 1945 to regulate manufacture, distribution and sale of drugs and cosmetics in the country. These were applicable to Allopathic, Homeopathic, Unani and Siddha drugs as well as other health related items. The Government of West Bengal established (1965) the Directorate of Drug Control (DDC) under the Health & Family Welfare (H&FW) Department for enforcement of the aforesaid Act and Rules. The DDC was mandated with licensing and inspections of manufacturing units, blood banks and sales premises, approval of formulations of drug for manufacture, drawal and testing of drugs samples for monitoring quality standards and initiating prosecution against offenders. A Performance Audit covering the period from 2012-13 to 2016-17 showed the following shortcomings:

- The activities of drug control in the State were adversely affected by acute shortage in the cadre of Drug Inspectors as well as infrastructural and manpower shortcomings in the West Bengal State Drug Control and Research Laboratory (SDCRL). Inspections and sampling was meagre to effectively combat the sale of 'Not of Standard Quality (NSQ)'/ spurious drugs.
- Significant number of manufacturers/ sellers continued to be in the drug business without valid licences.
- The test results of the Laboratory were doubtful as it often did not run all the mandatory tests on the samples. There was also delay in generation of test results by the laboratory by which time the NSQ drugs had been consumed by the patients. The Department was unable to create adequate deterrence against NSQ/ spurious drugs owing to inaction on cases reported to be NSQ and the inability to further the prosecution orders.

Thus, consumers in the State remained exposed to serious health hazards from spurious and not of standard quality drugs.


#### *2.1.1 Introduction*

The Government of India had enacted the Drugs & Cosmetics Act, 1940 (Act) to regulate manufacture, distribution and sale of drugs and cosmetics in the country. This was followed by the Drugs & Cosmetics (D & C) Rules, 1945 (Rules). It was applicable to Allopathic, Homeopathic, Unani and Siddha drugs as well as other health related items. The Government of West Bengal established (1965) the Directorate of Drug Control (DDC) under the Health & Family Welfare Department for enforcement of the aforesaid Act and Rules. The DDC was mandated with:

(a) licensing and inspections of manufacturing units, blood banks and sales premises;

(b) approval of formulations of drugs for manufacture;

(c) drawal and testing of drugs samples and

(d) initiating prosecution against offenders.

A Report on the Implementation of Drugs & Cosmetic Act, 1940 was featured (*paragraph 3.2*) in the Report of the C&AG of India (Civil), Government of West Bengal for the year ended March 2003. The report had flagged issues like non-renewal of licences, inadequate inspection and sampling, delay in laboratory reports, etc. Instances of inaction against manufacturers of 'Not of Standard Quality' (NSQ) drugs were also reported. The present audit noted that these issues persisted and continued to be a matter of concern.

### *2.1.2 Organisational set-up*

Director of Drug Control (DDC) in the Health & Family Welfare (H&FW) Department was responsible for issuing licences to all drug manufacturing units and blood banks except Indian System of Medicines (ISM) in the State. Power of licensing of sale premises was delegated to Assistant Directors of Drug Control[1]. Drug Inspectors under the DDC were responsible for inspecting the premises of drug manufacturing/ selling units. They draw samples for testing at the statutory laboratory. The State Drug Control and Research Laboratory (SDCRL) was the only statutory laboratory [2] in the State under direct supervision of H & FW Department for testing of drugs and cosmetic samples. As per provisions of the Act and Rules, punitive action was to be taken against the manufacturer and trader of the drugs found 'Not of Standard Quality' (NSQ) in statutory analysis[3].

### *2.1.3 Audit Objectives*

The audit objectives were to examine whether

- Requisite infrastructure and resources were in place and licensing & renewal was done as per the provisions of the Act;
- Inspections, sample testing and prosecutions were conducted as per the Act;
- State Drug Control and Research Laboratory, Kolkata was adequately equipped to conduct statutory testing of the drug samples and
- Adequate mechanism was in place to effectively monitor drug related activities in the State.

[1] *Power of licensing of sales premises in the Kolkata (areas with PIN code 700001 to 700108) area is delegated to five Assistant Directors of Drug Control. In case of remaining districts, licences are issued by the Assistant Directors of Drug Control in charge of the respective districts.*

[2] *Where the drug testing was done by the Government analyst.*

[3] *The portion of statutory sample was to be sent by an Inspector to the Government analyst for test under Sub-section (4) of Section 23 of D&C Act, 1940. Statutory Analysis was done by the Govt. Analyst on the basis of the statutory sample. The sample was to be enclosed with a Memorandum in Form 18. Test report of such statutory analysis should be disclosed by the Govt. Analyst in Form 13 under Rule 46 of D&C Rules, 1945.*

### *2.1.4 Audit Criteria*

Audit comments were framed against criteria drawn from the following sources

- Drugs and Cosmetics Act, 1940;
- Drugs and Cosmetics Rules, 1945;
- Indian, British and United States Pharmacopoeias and
- Regulations, Guidelines and Manuals issued by the Department of Health and Family Welfare, West Bengal and the Central Drug Standard Control Organisation from time to time.

### *2.1.5 Audit coverage and methodology*

The scope of this performance audit covered the period from 2012-13 to 2016-17. Audit scrutinised the records of the i) Directorate of Drug Control, ii) State Drugs Control & Research Laboratory (SDCRL), iii) Central Medical Store, Kolkata and iv) Assistant Directors of Drugs Control in five[4] districts (out of 20 districts). These five districts were selected by applying Population Proportional to Size Without Replacement methodology with number of licences as the size. In each district, audit also covered, a minimum of 20 *per cent* of the health facilities (selected using Simple Random Sampling Without Replacement - SRSWOR). These were facilities to which 'Not of Standard Quality' drugs had been distributed from the District Reserve Stores. Apart from this, audit also covered nine major hospitals in the five test-checked districts.

The audit scope, objectives, methodology, etc. were discussed with the Principal Secretary of the Department in an entry conference held in March 2017. The observations arising out of the performance audit were discussed with the Department in an Exit Conference held in February 2018. The reply of the Department and views expressed in the Exit Conference had been suitably incorporated in the Report.

## Audit Findings

### *2.1.6 Licensing and renewal*

A licence granted to any manufacturing unit was a token of evidence of its working with due adherence to Good Manufacturing Practices and Laboratories Practices. It was also granted to any selling unit on the basis of possession of adequate space, storage facilities, cold chain, qualified personnel, etc. Periodic renewal of licences signified continued adherence to those standards by the units. Inspection of the units before issuing or renewing licences was, thus, of paramount importance for safety of the consumers. However, records of the test checked districts showed deficiencies, as discussed in the subsequent paragraphs.

#### *2.1.6.1 Shortage of manpower*

The status of sanctioned strength *vis-à-vis* men-in-position of various technical posts under the Directorate of Drug Control as of March 2017 is indicated in **Table 2.1.1**.

[4] *Kolkata, Burdwan, Murshidabad, Malda and Jalpaiguri.*

**Table 2.1.1: Availability of man power *vis-à-vis* sanctioned strength**

| Name of the post | Sanctioned strength | Men-in-position | Vacancy |
|---|---|---|---|
| Director | 1 | 1 | 0 |
| Addl. Director | 1 | 0 | 1 |
| Dy. Director (Non-technical) | 1 | 0 | 1 |
| Asstt. Director (Non-technical) | 1 | 0 | 1 |
| Law Officer | 1 | 1 | 0 |
| Dy. Director (Technical) | 6 | 5 | 1 |
| Asstt. Director (Technical) | 35 | 31 | 4 |
| Sr. Drug Inspector/ Drug Inspector | 140 | 32 | 108 |
| Admn. Officer | 1 | 0 | 1 |
| Public Relation Officer | 1 | 1 | 0 |
| Bengali Translator | 1 | 1 | 0 |

*Source: Directorate of Drug Control, West Bengal*

Since 2000, the number of drug business operators had increased significantly, but, the sanctioned strength of drug inspectors remained the same. Acute shortage (77 *per cent*) in the post of key functionaries like Drug Inspectors/ Sr. Drug Inspectors affected activities like issue and renewal of licences, inspections, statutory sampling and consequently drug control in general.

The Department stated (January 2018) that appropriate steps for appointment of 79 Drug Inspectors had already been taken to tide over the crisis. During Exit Conference (February 2018), the Principal Secretary attributed the shortfall in inspections and sample testing to shortage of manpower in key posts.

The acute shortage of human resources seems to be the root cause behind (i) non-observance of prescribed licence renewal procedures, (ii) non-undertaking of requisite quantum of inspections, (iii) non-drawal of requisite quantum of samples and (iv) non-conducting of requisite tests.

### *2.1.6.2 Non-renewal of licences*

In terms of Rules 63 of Drugs & Cosmetics Rules, 1945, original/ renewed licence to manufacture/ sale shall be valid for five years. The renewal status of manufacturing and selling units as per Licence Registers upto March 2017 is indicated in **Table 2.1.2** and **Table 2.1.3**.

**Table 2.1.2: Status of renewal of licences of manufacturing units in the State**

| Category of license | Number of | | | |
|---|---|---|---|---|
| | **Live licences as per register as of March 2012** | **Renewal application received during 2012-17** | **Application not received (*percentage to total live licences*)** | **Renewal certificates issued upto March 2017 (*percentage to total renewable ones*)** |
| Manufacturer of modern drugs - Non-Biological | 551 | 180 | 371 (67) | 47 (26%) |
| Manufacturer of modern Drugs - Biological | 446 | 107 | 339 (76) | 29 (27%) |
| Homoeopathy Medicine Manufacturer | 660 | 155 | 505 (77) | 50 (32%) |
| Cosmetic Manufacturer | 861 | 143 | 718 (83) | 16 (11%) |
| **Total** | **2518** | **585** | **1933 (77)** | **142 (24%)** |

*Source: Directorate of Drug Control, West Bengal*

The Directorate did not furnish state level information regarding renewal status of selling drug licenses. However, the renewal status as ascertained from the records of the Assistant Directors of Drug Control in test-checked districts is shown in **Table 2.1.3**.

**Table 2.1.3: Status of renewal of licences of units selling modern medicine in test-checked districts**

| Name of district | No. of live licences as of March 2012 *(only cases with available particulars)* | Number of renewal application received during 2012-17 | No. of licences not received *(percentage to total live licences)* | Number of renewal certificate issued during 2012-17 *(percentage to total renewable ones)* |
|---|---|---|---|---|
| Kolkata | 15071 | 6249 | 8822 (59) | 231(4) |
| Murshidabad | 5158 | 1978 | 3180 (62) | 11 (0.5) |
| Malda | 2471 | 924 | 1547 (63) | 49 (5) |
| Jalpaiguri | 3115 | 1153 | 1962 (63) | 56 (5) |
| Bardhaman | 8421 | 3743 | 4678 (56) | 46 (1) |
| **Total** | **34236** | **14047** | **20189 (59)** | **393 (3)** |

*Source: Directorate of Drug Control, West Bengal*

Thus, significant number of manufacturers and drug sellers did not apply for renewing their licences. There are 5,191 (1,358 retail and 3,833 wholesale) cases where particulars of licenses were not available in the register. The renewal process could only be initiated after submission of renewal application. But, the drug business was being continued even in case of those who did not apply for renewal. This indicated that DDC was not watching the expiry of licences. Further, licences were renewed only to 24 *per cent* of the manufacturing applicants and three *per cent* of the drug selling applicants.

Accordingly, renewal certificates were issued only against the cases which involved change in the nature of the ownership of the unit.

This also led to loss to government in the form of renewal fee in contravention to Rules 59. (2) and 69. 2(c) of the Drugs & Cosmetics Rules, 1945.

The Department stated (January 2018) that an online application e-Vesoj had recently been launched for all processes of licensing under the Directorate of Drug Control. Moreover, significant changes had been made (October 2017) in the Drugs and Cosmetic Rules, 1945 to ease the process of granting licenses. It was expected that the compliance rate would improve substantially as a result.

During the exit conference (February 2018), the Principal Secretary informed that as per latest amendment (October 2017) in the Rules, depositing the licence retention fee by the licencee would only lead to retention of licence.

### *2.1.6.3 Deficiencies in renewal procedure*

Scrutiny of records by Audit relating to the renewal procedure, disclosed the following deficiencies:

***(i) Improper maintenance of records:*** Under Rule 68 of the Rules, the licencing authority needs to satisfy itself about the veracity of the statements made by the applicants in its renewal application form. This calls for maintenance of proper records by licensing authority of the

particulars of the original licence issued. Audit observed deficiencies in maintenance of records relating to licensing and renewal both at the State level (*i.e.,* the Directorate of Drug Control) and in the test-checked districts (*i.e.*, at the offices of the Assistant Directors). Both the levels were dependent on manual records during the period covered under audit. However, the pages of the licence registers were found torn/ missing. The Directorate did not maintain records indicating the collective list of drugs endorsed for manufacture to a particular unit. It was being maintained in separate files in an isolated manner. Hence, it became difficult to ascertain the comprehensive list of drugs to be manufactured by a particular unit in case of renewal of licenses. The DDC stated (June 2017) that non-availability of records was one of the major impediments in issuing the renewal certificate to manufacturing firms in time. In view of such lack of availability of records, there was a serious need to migrate the manual process to a digitised platform.

***(ii) Improper implementation of online licensing system:*** In order to upgrade the existing system of licensing of selling of Modern Drugs and to make it more accountable, transparent and user-friendly, it was decided (January 2017) that the licensing procedure would be carried out by using a web-based software. Accordingly, the State Government issued (January 2017) notification to introduce the use of software based licensing system in a phased manner for all the districts. Online licensing for selling of modern drugs was introduced in Kolkata from January 2017. However, it did not commence in other districts till the date of audit (June 2017). Further, information about the existing licence holders of modern drug sellers remained outside the digitised platform, as the software captured only the new cases of licences and renewal.

Pendency in issue of licences persisted, though the Department commenced (January 2017) online application for grant and renewal in Kolkata. Out of 513 (new: 231 and renewal: 282) applications received online during January to May 2017, only 92 (new: 86 and renewal: six) licences could be issued.

In this connection, the Department stated (February 2017) that an initiative was taken to preserve the data digitally during 2009-10, but was not fruitful. Director of Drug Control stated that file tracking system would be introduced to avoid misplacement of important files shortly.

***(iii) Incomplete renewal process of drug licenses:*** In terms of Rule 64 of D & C Rules, 1945, a drug license would not be granted/ renewed unless the authority was satisfied that the premises in respect of which the license is to be granted (or renewed) are adequate and equipped. The Certificate for grant or renewal of licence was to be issued subject to satisfactory inspection report from the concerned Drug Inspector. Audit, however, observed during test-check that the drug controlling authorities did not conduct any inspection[5] in case of renewal. As a result, renewal process of drug licences could not be fulfilled.

[5] *Except for the cases involving change in constitution of the ownership of the units.*

***(iv) Operation of drug business on the strength of DCR:*** As per the Act, renewal certificates were to be issued in prescribed formats[6]. However, only a Duplicate Carbon Receipt (DCR) was issued by the Assistant Director's office against the remittance of requisite fee to the Government account. The said DCR was considered as a token of renewal. Thus, the drug manufacturing/ selling businesses were allowed to continue merely on the basis of remittance of fees[7]. Adherence to norms were not ensured in most of the cases.

***(v) Renewal allowed without ensuring engagement of pharmacist:*** In terms of Rule 65, licence for retail business of modern drugs should not be granted/ renewed without engagement of registered pharmacist. Latest renewal certificate of the engaged pharmacist issued by the Pharmacy Council was also required to be attached with the renewal application of drug licence. In 195[8] renewal cases (November 2016 to March 2017) in two test-checked districts, no document was attached in support of engagement of pharmacist. Thus, the district licensing authority did not ensure the engagement of pharmacist in retail drug business before allowing renewal.

***(vi) Failure in exercise of vigilance over remittance:*** In Murshidabad, the District Licensing Authority did not cross-verify the paid challans with the treasury records before issuing fresh licence/ DCR. Assistant Director detected (January 2016), 12 cases (related to 2014-15), where fake bank challans with acknowledgement of receipts (₹ 0.36 lakh) had been submitted and Drug Licences were renewed. An FIR was lodged in February 2016. A departmental enquiry was also underway in this regard.

Audit came across 36 more cases (involving total fees of ₹ 1.08 lakh) pertaining to 2013-16, where the bank challans were found fake. In those cases, also, the concerned units were allowed renewal of licences. On this being pointed out by Audit, the Assistant Director stated (March 2017) that efforts were on to make an exhaustive list of such fake challans.

Thus, the district licensing authority of Murshidabad failed to exercise vigilance over remittance of licence fees in the Government Account. This facilitated such fraudulent practice.

### *2.1.6.4 Lack of training facilities*

The State did not have infrastructure to train the technical cadre so as to update their knowledge of pharmacology. Even the selected technical personnel did not take part in training programmes arranged by Central Drug Standard Control Organisation (CDSCO). The Department stated (February 2017) that the selected personnel could not avail of training for administrative reasons.

### *2.1.6.5 Deficiencies in control over manufacturing units of modern drugs*

Audit observed the following deficiencies in control over manufacturing units of modern drugs:

[6] *Form 25 in respect of manufacturers and Form 21 in respect of drug sellers*
[7] *Collections through DCR was ₹4.11 crore, during the period under review.*
[8] *Bardhaman: 188 and Murshidabad: 7*

**(i) List of drugs in licence not available:** Manufacturing Drug licences were to be issued in Form 25 specifying each item of drugs. Audit, however, found that licenses were issued by the DDC without incorporating the list of drugs to be manufactured. This assumed significance as correctness of items of drugs for renewal could not be ensured.

**(ii) Licences renewed despite deficiencies:** Rule 79 required the Inspector to inspect the establishment to ensure that the manufacturing firm complies with the conditions of licence. Scrutiny of the renewal status of 13 out of 180 firms (***Appendix 2.1.1***) showed major deficiencies in manufacturing and quality control process as noticed during inspection. However, the Directorate issued certificate of renewal/ Good Manufacturing Practices (GMP)/ Good Laboratory Practices (GLP) in favour of them. Moreover, products of 12 out of such 13 manufacturing firms were found 'Not of Standard Quality (NSQ)' multiple times by different Drug Testing Laboratories.

On this being pointed out, the DDC did not explain why the deficiencies had not been rectified.

#### *2.1.6.6 Functioning of Blood Banks with expired license*

As per Rule 122 (H) of D & C Rules, 1945, the license for a blood bank is valid for five years.

Out of 125 blood banks in the State, 48 (38 *per cent*) were functioning without valid licences as of March 2017. Their licences were not renewed due to shortcomings in infrastructure as well as manpower. Of these, 36 blood banks were functioning without valid licences for the last 15 to 20 years. Audit test-checked records of four blood banks. The deficiencies noticed by the drug inspectors are detailed in ***Appendix 2.1.2***. In all those cases, show-cause notices were issued, however, no further action was taken.

A paragraph (Para no. 3.2) on 'Functioning of Government blood banks in West Bengal' was featured in the Audit Report (General & Social Sector) for the year ending March 2014. The paragraph had flagged the issue of functioning of blood banks without valid licences. In reply to this, the Department had stated (August 2014) that the matter had already been taken care of. It is, however, a matter of concern that the issue persisted even after three years.

### *2.1.7 Inspections, sample testing and prosecutions*

As a mechanism for quality assurance, the Drugs & Cosmetics Act, 1945, *inter alia*, empowers every Inspector of the State Licensing Authority to inspect drug manufacturing units. Such inspections were meant for assessing the means employed for standardising and testing the products, premises used for sale/ distribution/ stocking of drugs. To ensure adherence to the desired quality parameters of such products, the Inspectors were also empowered to take samples of any drug from the manufacturer/ distributor/ seller. Those samples were to be analysed in Government-approved laboratories. The inspector was then to initiate action against manufacturer/ trader, if the drug is Not of Standard Quality (NSQ).

The deficiencies found in inspections have been discussed in the subsequent paragraphs.

#### *2.1.7.1 Poor coverage in inspection*

As per Rule 51, each Inspector was to inspect establishments licensed for sale of drugs at least once in a year. The district drug controlling authorities did not prepare any schedule of inspection. Audit found that shortfall in inspections ranged between 89 and 100 *per cent* for drug selling units in the test-checked districts ***(Appendix 2.1.3)***.

Acute shortage of drug inspectors (overall shortage being 77 *per cent*), who were the key functionaries for the implementation of the Act, was the main reason attributable to meagre inspections. Assistant Directors of Drug Control of three[9] selected districts stated that non-availability of Government vehicles also affected the inspection and drawal of samples. But, there was nothing on record to indicate that the Directorate had ever initiated any proposal to the Department for providing a Government vehicle for the purpose.

#### *2.1.7.2 Statutory sampling*

D & C Rules 51 & 52 empower the inspectors to take samples of the drugs and send them for tests to SDCRL, Kolkata under intimation to the Directorate. As per DDC's order dated 29 May 2007, each Drug Inspector/ Senior Drug Inspector was to draw at least four samples per month from the licensed premises. Noting with concern that there was lack of sincerity in giving due cognizance to the above order, DDC in October 2007 re-emphasised on strict compliance to the same. However, in September 2011, on the plea of heavy work load of Inspectors and limitations in the testing capacity of the SDCRL, the target of four samples per month was reduced to three in every two months. Hence, quality control measures were significantly diluted. This assumed further significance especially as samples had failed the quality test.

Scrutiny of Sample Receiving Register of SDCRL indicated shortfall in sampling as shown in **Table 2.1.4**.

**Table 2.1.4: Details of Statutory samples during 2012-17**

| Name of the district | Average no. of inspectors | Number of statutory samples to be drawn | Number of statutory samples drawn | Percentage of shortfall |
|---|---|---|---|---|
| Kolkata | 20 | 1800 | 849* | 53 |
| Murshidabad | 3 | 270 | 165 | 39 |
| Malda | 2 | 180 | 128 | 29 |
| Jalpaiguri | 3 | 270 | 218 | 19 |
| Bardhaman | 4 | 360 | 253 | 30 |
| **Total** | **32** | **2880** | **1613** | **44** |

** Up to December 2016, Source: Statutory sample receiving register of SDCRL*

Audit also noticed that samples of sera[10], vaccine and cosmetics were not drawn for testing. This left ample scope for distribution of sub-standard/ spurious drugs.

The Department stated (January 2018) that shortage of technical manpower, inspecting staff in particular, was the root cause of the problem and the performance would increase significantly after filling-up the vacancies.

#### *2.1.7.3 Ineffective punitive mechanism on NSQ drugs*

As per Section 27 of the Drugs & Cosmetics Act, the Director was to take penal measures against manufacturers of NSQ drugs/ cosmetics. Such measures

[9] *Malda, Murshidabd and Jalpaiguri.*
[10] *Sera denote the plural form of blood serum.*

include suspension or cancellation of licences or compounding of offences, prosecution, etc.

A Quality Control Register was maintained by the Directorate to record the individual drug samples, test results and action taken report. The position of NSQ reports received and action taken there against during 2012-17 is depicted in **Table 2.1.5**.

**Table 2.1.5: Position of NSQ drugs and action taken thereon during 2012-17**

| Reports received from | Number of NSQ drugs | Product suspended | Under prosecution cell | No. of cases where show cause notices issued | No. of firms against which action awaited | No. of reports referred to other states | License cancelled/ surrendered | Contravening firms not identified |
|---|---|---|---|---|---|---|---|---|
| SDCRL | 93 | 12 | 12 | 2 | 2 | 63 | 2 | - |
| CDL | 25 | 9 | - | 2 | 13 | - | - | 1 |
| Other States | 81 | 29 | - | 19 | 28 | - | 1 | 4 |
| **Total** | **199** | **50** | **12** | **23** | **43** | **63** | **3** | **5** |

*Source: Directorate of Drug control, West Bengal*

As is clear from the **Table 2.1.5**, DDC did not take action in respect of 43 (22 *per cent*) cases out of 199 NSQ drugs as of December 2016. Show-cause notices were issued to 23 firms for manufacturing NSQ drugs. However, replies were not received from them. No further action was initiated against them.

In 50 cases, product suspension orders were issued. However, there was no system to ensure, whether the firms adhered to the suspension orders. In 12 cases during 2012-15, orders for prosecution were given. However, prosecution was not initiated despite lapse of three to four years.

**Case Study 1**

***Action not taken against a manufacturer whose drugs were found NSQ repeatedly***

Audit noticed that several medicines (Paracetamol Tab 50 mg. IP, Salbutamol Sulphate Tablets, Vitamin B Complex Tab, Halazone Tabs, etc.) manufactured by M/s Luxmi Pharmaceuticals Private Limited were found NSQ during April 2012 to May 2013. The Directorate did not take any action in these cases other than issuing show-cause notices. Central Drugs Laboratory declared (September 2015) one of their products *viz*. Salbutamol Sulphate Tablets (Batch No. 130310) as NSQ. A joint inspection of the premises of the firm was undertaken with the Drug Inspector, CDSCO, Eastern Zone and Sr. Inspector of Drugs, DDC, West Bengal. During the Inspection, it was seen that the 7.17 lakh out of 8 lakh impugned drug manufactured were distributed to Government hospitals. The remaining stock could not be reconciled. The firm did not test the impugned drug as per the Indian Pharmacopoeia specifications. The firm had also not performed the process validation, analytical method validation and stability data before sale of drugs.

In view of the above, the inspecting team concluded that the drug might be NSQ due to inadequate testing procedure and recommended appropriate action against the firm under the Act. It was, however, seen that no action was taken against this firm.

Thus, a firm whose products were declared NSQ repeatedly was allowed to continue the operations leaving the public vulnerable. In this regard, Audit noted that the latest renewal certificate issued (March 2015) to the firm with validity upto December 2017 was not as per the format prescribed in the Act. There was no mention of the list of drugs for which the licence had been issued as required by the Act.

The guidelines prescribe action on samples of drugs declared spurious or NSQ. Accordingly, action is initiated on the basis of test reports. Categorisation of reports was done for the purpose. However, the category of non-standardisation of NSQ[11] was not recorded in the Quality Control Register.

Audit analysed test results of 32 drugs reported as NSQ (***Appendix 2.1.4***) between June 2012 and September 2016. It was found that all of them had been adjudged as grossly substandard. In 31 cases, the active ingredient was not within the permissible limits. In one case, the dietary supplement contained steroid. In 11 out of 32 cases, prosecution was not initiated despite order of Director of Drug Control (DDC). In 21 cases, no action was taken at all. Out of these 21 cases, 18 pertained to manufacturers outside West Bengal. The Directorate stated (June 2017) that these were reported to the concerned Licensing authorities.

Thus, the punitive mechanism to create adequate deterrence and to discourage manufacture of NSQ drugs was not functional in the State.

#### *2.1.7.4 Action not taken against NSQ drugs reported by authorities in other States*

DDC is responsible for taking action against manufacturers in West Bengal, if Drug Controllers of other States request to take action against the manufactures in West Bengal whose drugs are reported NSQ in those States. During test-check of 17 such cases involving 11 manufacturers, Audit found that only show-cause notices were issued to three[12] firms, whose medicines were found NSQ repeatedly. Audit noted that despite DDC's order, inspections were not carried out at the premises of these firms. This indicated indifference towards adverse reports received from other States. This also pointed to the fact that such NSQ drugs could have been available and used in West Bengal too.

#### *2.1.7.5 Redressal of public grievances*

The Directorate received complaints from the general public regarding irregular practices in drug business. The Directorate maintained a Complaint Register from September 2014 for this purpose. Scrutiny of this Register indicated that out of 117 complaints received during September 2014 to March 2017, action was taken against 62 only. The remaining 55 (47 *per cent*) cases remained un-attended. Out of these 62 cases, the DDC forwarded 56 complaints to the concerned Assistant Directors. The cases were pending with the Assistant Directors without any follow up from the Directorate. Only six (five *per cent)* out of total 117 complaints received were settled as of June 2017.

[11] *Category A-Spurious and Adulterated drugs, Category B- Grossly sub-standard drugs, Category C: Minor defects.*

[12] *M/s Caplet India Pvt. Ltd., M/s Allen Laboratories Ltd. and M/s NI Pharmaceutical Works (P) Ltd.*

**Case Study 2**

***Action taken on information received on illegal drug manufacture***

On receiving a complaint, the Directorate raided (March 2017) the premises at 21 B, Canning Street with the help of Police. There they found a large stock of expired Qutes Forte Softget Capsules (Batch No. 0360215D, Manufacture February 2015, Expiry January 2017) and another stock of Qutes Forte Softgel Capsules in which the Batch No., Manufacturing Date and Expiry Date had been erased. Erasing liquid used for erasing the inscriptions in the strips was also found. It was found that the accused was engaged in re-labelling of drugs. Labelling of drug is a manufacturing activity which requires a valid drug manufacturing license. The accused, however, failed to produce a valid license. Accordingly, a prosecution case was lodged (March 2017) in the court.

The Department stated (February 2017) that the departmental grievance redressal system to monitor the disposal of complaint cases on counterfeit, spurious, adulterated drug manufacturing/ trading in the State was absent. The Department also added that necessary action was to be taken shortly in this regard. Considering the seriousness of the malpractices (*vide* case study) reported by the public complaints, Department needs to develop an effective Public Grievance system. Further, these incidents also pointed to the need for a strong surveillance mechanism.

### *2.1.8 Functioning of the State Drug Control and Research Laboratory*

In terms of Rules 51(6) and 52(4), drug inspectors were authorised to draw samples from the manufacturing and selling units and to send them for testing to a Drug Control Laboratory. In West Bengal, there is only one such laboratory *viz*. State Drug Control & Research Laboratory (SDCRL), Kolkata. Punitive action could be taken against the manufacturer/ supplier of NSQ drugs only on the basis of test reports of the SDCRL. Accordingly, quality of laboratory testing was of utmost importance. Audit noticed the following deficiencies in the functioning of the laboratory:

#### *2.1.8.1 Non-utilisation of equipment as well as manpower deficiencies at the SDCRL*

SDCRL was not accredited with NABL [13]. No steps were taken for its accreditation. Audit found that there were deficiencies in infrastructure and manpower at the SDCRL and consequently laboratory was not in a position to test the targeted number of samples.

***Non-utilisation of equipment:*** Audit noticed that equipment costing ₹ 2.01 crore (***Appendix 2.1.5***) procured between March 2014 and January 2017 was not put to use as of June 2017. The reasons were lack of technical manpower and operating software. These instruments were required for detection of metals, dissolution test, identification and quantification of each component in a mixture, chemical analysis of drug samples, etc. No action was taken to utilise the said equipment.

***Shortage of manpower:*** Against the sanctioned post of 96, there were a total of 56 personnel (permanent: 40 and contractual: 16) in place. However, as regards technical posts, the vacancy position was alarming (especially in the cadres of

[13] *National Accreditation Board for Testing and Calibration of Laboratories*

Assistant Directors, Senior Scientific Officers and Junior Scientific Assistants) even after taking into account the contractual staff as shown in the **Table 2.1.6**.

**Table 2.1.6: Availability of manpower *vis-à-vis* sanctioned strength (as on 31 December 2016) in Technical posts in SDCRL, West Bengal**

| Name of the post | Sanctioned strength | Men-in-position | Vacancy |
|---|---|---|---|
| Director | 1 | 1 (on Deputation) | 0 |
| Assistant Director | 4 | 1 | 3 |
| Senior Scientific Officer | 5 | 0 | 5 |
| Junior Scientific Officer | 5 | 5 | 0 |
| Senior Scientific Assistant | 10 | 10 | 0 |
| Junior Scientific Assistant | 14 | 2 + 6 (Contractual) = 8 | 6 |
| Senior Technical Assistant | 1 | 0 | 1 |
| Sample Warden | 1 | 0 | 1 |
| Junior Technical Assistant | 1 | 0 | 1 |
| Laboratory Assistant | 9 | 0 | 9 |
| Laboratory Attendant | 9 | 4 | 5 |
| **Total** | **60** | **29** | **31** |

*Source: State Drug Control & Research Laboratory, West Bengal*

The above deficiencies hampered the testing of drug samples and adversely affected the quality of analysis. The Laboratory could not conduct all the stipulated tests on the samples. Moreover, the laboratory also failed to conduct the tests within the stipulated time schedule as is evident from the following paragraphs.

During the Exit Conference (February 2018), Principal Secretary opined that though accreditation from NABL was not a mandatory provision, but it could be highlighted as a recommendation in the Audit Report.

### *2.1.8.2 Non- conducting of requisite tests*

Out of 9,617[14] samples to be tested during April 2012 and March 2017, SDCRL could test only 6,933 (72 *per cent*). Of these, 2,190 samples expired between April 2012 and March 2017 as the samples could not be tested within time. The attributable reason was mainly shortage in the technical cadre of the laboratory. The laboratory did not function properly due to lack of infrastructure and manpower.

Audit test-checked the testing procedure of samples, the details of which are shown in **Table 2.1.7**.

**Table 2.1.7: Tests done on drug samples selected by Audit**

| Year | No. of selected samples | All test done | Test partially done | Test not done | Test result | |
|---|---|---|---|---|---|---|
| | | | | | Standard | Non-standard |
| 2012-13 | 40 | 10 | 19 | 11 | 27 | 2 |
| 2013-14 | 40 | 4 | 25 | 11 | 29 | Nil |
| 2014-15 | 40 | 9 | 22 | 9 | 30 | 1 |
| 2015-16 | 40 | 8 | 26 | 6 | 33 | 1 |
| 2016-17 | 40 | 7 | 18 | 15 | 23 | 2 |
| **Total** | **200** | **38** | **110** | **52** | **142** | **6** |

*Source: Extracted from the records of SDCRL*

[14] *Un-tested samples as on 1 April 2012: 1568 and samples received: 8049*

As is evident from the Table, all the prescribed tests could be done only on 38 (19 *per cent*) samples, while 52 (26 *per cent*) were not tested at all. Out of 148 [15] samples tested, 104 (70 *per cent*) were declared 'standard' without conducting all the stipulated tests. Hence, the reliability of test results was suspect.

Further, as per the Drug Consultative Committee (DCC) recommendations, the time limit for testing of drug samples subject to availability of method of analysis is 45 or 90 days depending on the type of drugs[16]. Audit observed that out of 148 fully or partially analysed samples test-checked, SDCRL failed to adhere to the stipulated time schedule in respect of 128 (86 *per cent*). There were delays of more than three and six months in case of 51 and 77 cases respectively. Such delays gave opportunity to the sellers of spurious drug to sell their drugs un-detected exposing the society to health risk.

SDCRL stated (January 2017) that tests could not be conducted owing to non-availability of Reference Standards and methods of analysis for non-pharmacopeial samples[17]. This argument of the Laboratory was not tenable as the Drugs Consultative Committee[18] (DCC) had recommended (July 2012) that the Government Analyst was free to test the sample as per the method available in the standard books or journals, if the manufacturer did not send the method of analysis for patent and proprietary medicines. Further, Audit observed that all requisite tests were not done even in case of pharmacopeial samples as was seen in case of 100 such samples out of the 200 test-checked.

This assumed further significance as the operation of the punitive mechanism of the Act was based on the laboratory results. Such inadequacies in the Drug Control mechanism in West Bengal had left the public exposed to substandard drugs.

During the exit conference (February 2018) the Principal Secretary, while expressing concern about such non-testing and delay in testing of drug samples, instructed the concerned officials to be more vigilant in this regard.

### *2.1.9 Monitoring*

#### *2.1.9.1 Consumption of NSQ drugs by the patients of Government hospitals*

As per order (July 2012) of the Department, medicines to the Government health facilities were supplied by the drug firms selected by the Central Medical Store (CMS) under the Health & Family Welfare Department. Sample from each batch of drugs procured was to be sent, through CMS, to the selected NABL approved laboratories or SDCRL for analysis. Similarly, samples were sent to these laboratories from the medicines procured by the Fair Price Medicine Shops (FPMS) established within Government Hospitals of the State also. These laboratories were to dispatch the test reports within 10 days in case of ordinary drugs and 20 days in case of injectable drugs[19]. If found NSQ on analysis, distribution of medicines was to be stopped immediately by blocking

[15] *38 plus 110*
[16] *90 days in respect of drugs which require High Performance Liquid Chromatography.*
[17] *There were two types of drugs - pharmacopeial and non-pharmacopeial. Reference standard of non-pharmacopeial drugs were to be obtained from the concerned manufacturer.*
[18] *The Drugs Consultative Committee is an Advisory Committee constituted by the Central Government under the Act.*
[19] *16 days for tablet/ capsule and 26 days for injection in case of FPMS.*

the distribution of medicine in the Store Management Information System (SMIS) software.

Audit analysed the time taken for receiving test reports of 13 NSQ drugs. It was found that in all these 13 cases, there were delays of 10 to 52 days in receiving the test reports. Due to these delays, NSQ drugs were distributed to the patients in Government health facilities.

Similar problem was noted in Fair Price Medicine Shops also. During 2014-17, out of 3122 samples drawn, 49 were found NSQ. Reports in respect of 340 were not received, while in respect of 49 drugs found NSQ, it took 32 to 187 days (SDCRL: 44 to 187 days, other laboratories: 32 to 118 days) to receive reports after the sample collection.

Further, Audit observed that distribution of NSQ medicines was not blocked in SMIS. This, coupled with the delay in receiving test reports, resulted in consumption of NSQ drugs by the patients.

In the exit conference (February 2018), the Principal Secretary while expressing concern at the state of affairs assured Audit that punitive measures would be taken against the laboratories for violation of the norms and committing inordinate delays in submission of test reports. He also added that to address the issue appropriately, testing of drugs would be done before its supply and also after drugs are supplied to the Government health care units.

#### *2.1.9.2 Failure to take action against manufacturers*

The sampling at the time of procurement was non-statutory. In order to initiate punitive action under Sub-section (4) & (5) of Section 23 of D &C Act, statutory sampling[20] was required to be done by the Drug Inspectors. Accordingly, information about drugs found NSQ in non-statutory analysis was communicated to the Directorate of Drug Control for statutory sampling.

Audit, however, noticed that during 2014-17, against 168 cases reported to DDC as NSQ in non-statutory sampling, DDC did statutory sampling only in eight (five *per cent*) cases. As a result, the manufacturers of NSQ drugs could not be brought into the punitive mechanism as samples were not drawn for statutory analysis.

DDC attributed that the stock of NSQ drugs was duly consumed at the health facility by the time information for statutory sampling reached the Drug Inspectors. Audit, however, found that DDC made an attempt to draw statutory sample in respect of 14 cases only. Sampling of the remaining 146 (87 *per cent*) cases was not done by DDC. This was despite the fact that the CMS authority had issued several reminders for early sampling of these medicines.

Similar issue was noticed in Fair Price Medicine Shops established within Government Hospitals of the State. It was observed that 49 out of 3,122 samples (drawn from FPMS) analysed were found NSQ. However, samples of these medicines were not drawn for statutory analysis which would have set in the legal process.

[20] *Statutory sampling is done by the Drug Inspector in terms of Section 23 of Drugs & Cosmetics (D&C) Act, 1940. The portion of statutory sample is to be sent to the Govt. Analyst for test in accordance with sub-section (4) of Section 23 of D&C Act, 1940. As per Rule 57 of the D&C Rules, 1945, the sample is to be sent to the Govt. Analyst with a Memorandum in Form 18.*

This not only exposed the public to health hazards by way of consumption of NSQ drugs, but also prevented the authorities from initiating punitive action against the manufacturer. Thus the objective of ensuring quality of drugs was not achieved.

### *2.1.9.3 Consumption of untested drug in the Government patient care system*

As per departmental instructions (July 2012), every batch of procured drug had to be tested at the H&FW approved Testing Labs. The position of sampling of medicines in four test-checked districts during 2014-16 was as indicated in **Table 2.1.8**.

**Table 2.1.8: Position of sampling of medicines purchased in the Government health facilities of test-checked districts**

| District | Year | Type of drugs | Total number of batches procured by the respective CMOH | Number of batches not tested as per records of CMS | Percentage of batches not tested |
|---|---|---|---|---|---|
| Bardhaman | 2014-15 | 134 | 976 | 496 | 51 |
| | 2015-16 | 156 | 1255 | 652 | 52 |
| Jalpaiguri | 2014-15 | 166 | 728 | 396 | 54 |
| | 2015-16 | 165 | 756 | 469 | 62 |
| Malda | 2014-15 | 113 | 622 | 440 | 71 |
| | 2015-16 | 126 | 579 | 378 | 65 |
| Murshidabad | 2012-13 | 78 | 715 | 636 | 89 |
| | 2015-16 | 117 | 607 | 411 | 68 |
| **Total** | | **1055** | **6238** | **3878** | **62** |

*Source: Information provided by CMOH of the respective districts*.

In four test-checked districts, 62 *per cent* of the medicines purchased were distributed to patients without ensuring quality. This was due to the reason that CMOHs did not send samples from every batch of medicines procured. This was a deviation from the extant Government order. Thus, the system meant for eliminating the risk of public consumption of substandard, counterfeit or contaminated pharmaceutical product was not functioning effectively. This left the patients vulnerable.

### *2.1.9.4 Mechanism to ensure supply of quality medicines not working effectively*

As per conditions[21] of tender for supply of medicines to government health facilities, if any batch of medicine failed in the quality testing, the cost of procurement of such non-standard drugs was not to be paid.

Audit observed that in the four[22] test-checked districts, 26 medicines costing ₹ 16.95 lakh were found NSQ. However, the cost of these medicines was paid to the vendors in contravention to the tender conditions.

### *2.1.9.5 Improper implementation of Pharmacovigilance Programme of India (PvPI)*

With the vision of monitoring drug safety and thereby reducing the risk associated with use of medicines, the PvPI was launched (April 2011) by the Indian Pharmacopoeia Commission (IPC) under the aegis of Ministry of Health & Family Welfare, Government of India. An 'Adverse Drug Reactions (ADRs)

[21] *Clause 21 (d) of the Notice Inviting Tender (NIT) for drug items floated vide No. HST/1P-01-2015/GD/2015-17/024 dated 20.08.2015).*

[22] *Murshidabad, Malda, Jalpaiguri and Bardhaman.*

reporting culture' was promoted with contribution from all the Healthcare Professionals to reinforce the PvPI. Accordingly, several ADR Monitoring Centres (AMCs) were established throughout the country to upload the monthly ADR reports. There were 11 such AMCs[23] in West Bengal.

Audit found that only four[24] out of these 11 AMCs were uploading the ADR reports as of March 2017. The Ministry of Health & Family Welfare, GoI, requested (October 2016) the State Government to take necessary steps for sensitizing and advising all health care professionals to mandatorily adopt reporting of ADRs to PvPI. The State Government took little effort to strengthen the Adverse Drug Reporting system in the State.

In this regard, Audit had interacted with physicians and nurses of the selected hospitals regarding efficacy as well as adverse effect of drugs. It transpired that the excess usage of antibiotics was leading to resistance in germs. Besides, the side effects of various medicines were a matter of grave concern. They also were very concerned about the low efficacy of medicines supplied in the government facilities. The specific issues raised by the test-checked hospitals are indicated in the **Table 2.1.9**.

**Table 2.1.9: Issues of drug resistance, low efficacy and side effects raised by test-checked hospitals**

| Name of the Hospital | Name of the medicine | Issues |
|---|---|---|
| Bardhaman Medical College & Hospital | Ringer Lactate, 5% Dextrose Solution, Paediatric Electolyte Maintenance Solution, etc. | Patient suffered from rigor and chill on its application that created a multi-dimensional problem. |
| | | Development of antibiotic resistance among paediatric patients in near future. |
| | Hydrocortisone Inj, Glimipride Tab and Metformin Tab | Feeble action of drugs leading to delayed recovery of patients. |
| Malda Medical College & Hospital | Anawin Heavy (Bupivacaine) Inj. | Causes convulsion. |
| | Mephentermine Inj. | Patients was in a semi-conscious state for three to four days after administering the medicine. One patient died on its application. |
| | Inj. Oxytocin, Feracrylum Gel, Eptoin Tab, Inj. Diazepam, Inj. Lorazepam | Feeble action of drugs leading to delayed recovery of patients. |
| District Hospital, Jalpaiguri | Ringer Lactate, 5% Dextrose Solution | Patient suffered from rigor on its application that created a multi-dimensional problem. |
| | Pantoprazole, Omeprazole, Rabeprazole | Excessive and un-controlled use of such drug enhanced the probability of some deadly disease like stomach cancer. |
| | Lignocaine Adrenaline Inj., Bupivacaine Inj., Betadine Lotion | Feeble action of drugs leading to delayed recovery of patients. |
| North Bengal Medical College & Hospital | Prednisolone Tab, Diclofenac Sodium Inj., Ciprofloxacin Tab, Inj. Labetalol, Misoprostol Tab, Amoxycillin and Potassium Clavulanate Tab I.P. | Feeble action of drugs leading to delayed recovery of patients. |

*Source: Minutes of interactions with health care professionals of respective facilities.*

[23] *IPGMER – Kolkata, STM – Kolkata, NSMC – Kolkata, ICAREIMS/R – Haldia, BMC – Bardhaman, BSMC – Bankura, RGKMC – Kolkata, MMCH – Berhampore, MMCH – Kolkata, CNMC – Kolkata and CMJNM – Nadia.*

[24] *IPGMER – Kolkata, STM – Kolkata, NSMC – Kolkata and ICAREIMS/R – Haldia.*

The above emphasises the need for strengthening the reporting system of ADRs under PvPI.

The Department stated (January 2018) that implementation of the Parmacovigilance Programme had been initiated from 1 January 2018.

#### *2.1.9.6 Lack of control over sale of sedatives leading to crimes*

It is a common crime to steal valuables from the passengers of running trains after giving them food laced with sedatives. Divisional Security Commissioner, Railway Protection Force, Asansol, Eastern Railway reported (December 2015) 12 such cases in 2015 (up to November 2015). It was also reported that a large quantity of sleeping pills and sleep inducing drugs like Wyeth, Prazepam, Pasmovan, etc. were seized from criminals. During interrogation, these criminals stated that they committed the crime using low cost sedatives which were easily available without prescription of a registered Medical Practitioner. Therefore, Railway authorities requested (December 2015) the Regional Drug Control Authority, Bardhaman Division to initiate necessary action to stop the retail sale of such medicines. Accordingly, the Regional Director of Drug Control (RDDC), Bardhaman Division directed (May 2016) the Assistant Director of Drug Control, Bardhaman to investigate the matter and to submit a report.

Audit, however, noted that no investigation report was submitted. Further, no action was taken by the authority to restrict the sale of such sedatives without prescription.

In this regard Audit observed that the Bardhaman district drug control authority did not conduct the yearly routine inspection (at least once in a year) of the retailers/ wholesalers. Inspections were not also conducted during renewal of licences. Thus, there was no control on the sale of medicines which aided the criminals in committing crimes.

### *2.1.10 Conclusion*

The drug control in the State suffered seriously owing to acute shortage in the cadre of Drug Inspectors. This was compounded by infrastructural and manpower shortcomings in the West Bengal State Drug Control and Research Laboratory (SDCRL). Inspections and sampling were meagre to effectively combat the sale of 'Not of Standard Quality (NSQ)'/ spurious drugs. Significant number of manufacturers/ sellers continued to be in the drug business without valid licences as mandatory inspections could not be conducted owing to manpower shortages.

The test results of laboratory were doubtful, as it often did not run all the mandatory tests on the samples. There were delays in generation of test results by laboratory by which time the drugs had been consumed by the patients. The Department was unable to create adequate deterrence against NSQ/ spurious drugs owing to inaction on cases reported to be NSQ and the inability to further the prosecution orders.

Thus, consumers in the State remained exposed to serious health hazards from spurious and not of standard quality drugs.

### *2.1.11 Recommendations*

The following recommendations are made:

- ***Manpower shortages especially that of Drug Inspectors may be addressed for effective implementation of the Act and the Rules;***
- ***Prosecutions need to be initiated immediately so as to create adequate deterrence and***
- ***Infrastructural and manpower deficiencies in the Drug Testing Laboratory need to be taken care of as the edifice of punitive mechanism is the test results generated by the Laboratory.***

## Appendix 2.1.1

*(Refer paragraph 2.1.6.5 (ii), page 14)*

### List of firms which were issued renewal certificates despite finding major deficiencies during inspection

| Sl. No. | Name and Address of the firm | Licence Nos. | Major findings of inspection | Renewal status | Drugs declared as NSQ on testing | | |
|---|---|---|---|---|---|---|---|
| | | | | | Name of the NSQ drug | Total no. of batches of the NSQ drug | Date of report |
| 1 | Associated Chemical & Pharmaceutical Industries, Doharia, P.O. Ganganagar, 24 PGNS (N) | DL – 1553 (M) | Manufacturing process and cleaning validation was to be performed. Stability chamber was to be procured. Water connection was to be provided at the Hot Zone, etc. | Renewal certificate issued with GMP[5] and GLP[6]. | Bengal Konium Chloride Solutions IP | 1 | 21.11.2012 |
| | | | | | Benzyl Benzoate Application IP 25% | 10 | 07.09.2015<br>01.10.2015<br>02.12.2015<br>14.12.2015 |
| 2 | La Chemico (P) Ltd., Taki Road, Kadambgachi, 24 PGNS (N) | DL(CS) – 9M & 7MB | Water system was not validated as per standard guidelines. Separate hygrometers were to be placed in the capsule/tablet coating/ compression rooms. Five stage sub-culture process was to be developed. Paracetamol Oral Suspension was to be tested as per IP 2014, etc. | Renewal certificate not issued but, GMP and GLP had been issued upto 31.12.17 and 31.12.16 respectively. | Trifluioparazine Tab | 1 | 28.07.2015 |
| | | | | | Metronidazole Tab | 4 | 18.08.2016 |
| | | | | | Metformin Tab IP | 1 | July 2015 |
| | | | | | Metformin Tab IP 500 mg. | 4 | 15.06.2015 |
| | | | | | Metformin Hydrocloride Tab. IP 500 mg. | 3 | 15.05.2015<br>18.02.2015 |
| | | | | | Metronidazole IP 200 mg. | 1 | 18.02.2015 |
| | | | | | Trimethoprime & Salphamethaxozole oral suspension | 1 | 21.11.2012 |
| | | | | | Metronidazole IP 200 mg. | 1 | 23.08.2012 |
| | | | | | Vitamin B Complex Tab NFI III | 1 | 09.04.2012 |

[5] *Good Manufacturing Practice*
[6] *Good Laboratory Practice*

| Sl. No. | Name and Address of the firm | Licence Nos. | Major findings of inspection | Renewal status | Drugs declared as NSQ on testing | | |
|---|---|---|---|---|---|---|---|
| | | | | | Name of the NSQ drug | Total no. of batches of the NSQ drug | Date of report |
| 3 | A.N. Pharma Cia Pvt. Ltd., 14/1, Salua Dasadrone Main Road, Kolkata – 136 | DL – 1466M & 741MB | Manufacturing process and cleaning validation was to be performed. Stability chamber was to be procured. Ref standard of all the API used is to be procured, etc. | Renewal certificate not issued but, GLP issued upto 31.12.16 | Relivon – 1 (Risperidone Tab 1 mg.) | 1 | 20.09.2016 |
| 4 | M/s Indian Drug House, 66 Darir Road, Dhamaitala, 24 PGNS (S) | DL – 1381M | Manufacturing process and testing validation was to be performed. Procurement of HPLC machine was recommended to perform complete test of raw materials and finished product. Emulsifier was to be replaced in Benzyl Benzoate manufacturing section. Validation of AHU was also to be carried out. The firm was asked to engage more chemist for QC Section, etc. | Renewal certificate was issued earlier; GLP certificate was issued upto 31.12.15. The firm applied (July 2016) for renewal as well as CNC, but no inspection was done therefore. | Sodium Hypochloride | 1 | 04.09.2015 |
| 5 | M/s Greenco Biologicals Pvt. Ltd., GN-1, Saltlake City, Kolkata – 91 | DL – 1460M & 628MB | Analytical method validation was to be performed for different products. Growth promotion test of medias was to be performed as per IP 2014. Arrangement for detection of metallic particles was to be provided. | Renewal certificate not issued but, GLP issued upto 31.12.16 | Calcium Carbonate | 15 | 19.08.2016 and 28.09.2016 |

| Sl. No. | Name and Address of the firm | Licence Nos. | Major findings of inspection | Renewal status | Drugs declared as NSQ on testing | | |
|---|---|---|---|---|---|---|---|
| | | | | | Name of the NSQ drug | Total no. of batches of the NSQ drug | Date of report |
| 6 | M/s Pharma Impex Ltd., 620, D.H. Road, Kolkata – 34 | DL – 673 MB | Stability Study Chamber was to be procured. HEPA unit of RLAF of Dispensing booth of raw material store needed replacement. The Blending machine of β lactum Capsule section was to be provided with Dust extractor unit. All required column of HPLC was to be procured | Renewal certificate was issued earlier; GLP certificate was issued upto 31.07.17 on the basis of this IR. | Gentamycin Sulphate Inj. IP 80 mg. 2 ml. | 1 | 10.02.2016 |
| | | | | | Diclofenac Sodium Inj. IP 75 mg. 3ml. | 3 | 25.11.2014 |
| | | | | | Lignocaine 25 and Adrenaline | 1 | 24.02.2015 |
| 7 | M/s Life Pharmaceutical Pvt. Ltd., 53(P), 54(P), U.I.G.C., Howrah – 711316 | DL – 1460M & 628MB | Both the filling and ampoule washing rooms of the injectable section was found in dirty condition. Procedure as laid down in D&C Rule for sterilization in lots was not followed. Complete test as per pharmacopoeia was not performed for all RM & FG due to non-availability of facility/ reagents. Related substances were not tested for Ranitidine Hydrochloride IP and formulation (injection). | Show-cause notice was issued (November 2016) as to why their licence would not be suspended or cancelled for non-compliance with condition of licences. | Drotavarine Tab IP 40 mg. | 2 | 17.07.2015 |
| 8 | Pasture Laboratory Pvt. Ltd., 24, Bidhan Sarani, Kolkata -15 | 858M & 342MB | Effluent water treatment plant was not in use. SOP of Effluent water treatment was to be reviewed as various test of effluent water e.g. TSS, Ph, etc. not being done. | Renewal certificate not issued. GMP & GLP certificate Renewed. | — | — | — |

| Sl. No. | Name and Address of the firm | Licence Nos. | Major findings of inspection | Renewal status | Drugs declared as NSQ on testing | | |
|---|---|---|---|---|---|---|---|
| | | | | | Name of the NSQ drug | Total no. of batches of the NSQ drug | Date of report |
| 9 | Dusap Pharmaceuticals, 115, BC Roy Road, Rajpur, 24 PGNS (S) | 1324M & 584MB | Shortage in staff. Not performing micro-biological test of purified water. Raw material not kept in acceptable temperature. RLAF was not working properly in Beta-lactum capsul production as well as warehousing section. Proper change room not provided in Beta-lactum capsul section area. Equipment were not calibrated. Records of water tank cleaning was not available | Renewal certificate not issued. GMP & GLP certificate Renewed. | Iron & Folic Acid Syrups<br>Duclean Antisceptic Lotion | 2<br>4 | 11.04.2016<br>09.10.2013 |
| 10 | Square Pharmaceuticals, Mahispota, Kolkata-113 | 1520M & 781MB | Raw material and finished goods were not tested as per Pharmacopoeial specification. Microbiological test for non-sterilized pharmaceutical product was not conducted. Temperature and humidity monitoring devise were not working properly. The firm is using material with extended life without having documented permission for it. | Renewal certificate not issued. | Ranitidine Hydrochloride Tabs IP | 1 | 26.12.2011 |
| 11 | Kansas Laboratory Pvt. Ltd., Kolkata-61 | 1594M & 817 MB | Space constraints was noticed. SOP of Production process and machine operation was yet to be | Renewal certificate not issued. GMP & GLP certificate Renewed. | Vitamin B complex Tab | 1 | 09.04.2012 |

| Sl. No. | Name and Address of the firm | Licence Nos. | Major findings of inspection | Renewal status | Drugs declared as NSQ on testing | | |
|---|---|---|---|---|---|---|---|
| | | | | | Name of the NSQ drug | Total no. of batches of the NSQ drug | Date of report |
| | | | prepared. Calibration of PH meter and conductivity meter were not carried out in water plant. In tablet section de-dusting machine with compression was not provided. In quality control section various test e.g. validity test for culture, growth promotion test for media related substance and limit test were not being performed. There was shortage of staff in quality control section compared to work load. | | | | |
| 12 | Panacea Biotech, Sodepur, Kolkata-111 | 703M & 265 MB | Differential air pressure monitoring devises not yet provided. Records of testing of effluent water is not maintained. BAIT diagram not yet prepared. Stability chamber to carry out both real time and accelerated stability study not provided. Packing materials are stored on floor. The firm was using commercial sugar instead of Pharmaceutical grade sugar. Cleaning validation of manufacturing vats, storage tank, pipe line filling sealing machine | Renewal certificate not issued. GMP & GLP certificate Renewed. | Ibuprofen Tab IP 200 mg. | 1 | 12.03.2013 |

| Sl. No. | Name and Address of the firm | Licence Nos. | Major findings of inspection | Renewal status | Drugs declared as NSQ on testing | | |
|---|---|---|---|---|---|---|---|
| | | | | | Name of the NSQ drug | Total no. of batches of the NSQ drug | Date of report |
| | | | was not performed. Dust extractor was not provided in tablet section. In quality control section HPLC, Stability chamber and BOD incubator for microbiology section was not procured. | | | | |
| 13 | Superb Drugs, Dum Dum Road, Kolkata-2 | 836 MB | Medical examination of personnel was not conducted. Hygiene in solution preparation was not maintained. Air handling unit was not working properly. Temperature and humidity was not monitored. Capacity of autoclave is not sufficient as per the column of activity. Records of raw material was not maintained as per schedule U of the drugs and cosmetics rule 1945. It was noticed that various product was released without generation of microbial test report. Equipment in quality control section was not calibrated. Staffs were not properly trained. The firm was re inspected on 16.07.14 but non-compliance was noticed. | Renewal certificate not issued. GMP & GLP certificate Renewal withheld. | Aminophylline Injection IP (10 ml.)<br>Quinine Dihydrochloride Injection IP | 1<br>1 | 03.12.2014<br>04.12.2013 |

*Source: Directorate of Drug Control, West Bengal*

## Appendix 2.1.2

*(Refer paragraph 2.1.6.6, page 14)*

**Deficiencies found by Drug Inspectors in test-checked four Blood Banks**

| Sl. No. | Name of Blood Bank | Deficiencies found |
|---|---|---|
| 1. | MR Bangur Hospital Blood Bank | Non-engagement of registered nurses on full time basis; Absence of Autoclave machine, separate refreshment, registration and examination room with AC; Non-conducting of sterility test and requisite test for unexpected antibodies; physical verification of stored blood not done with proper SOP; Non-availability of reference books like Indian Pharmacopeia, Drugs and cosmetics Act, 1940 and Rule 1945; Non-calibration of equipment. |
| 2. | Basirhat SD Hospital Blood Bank | Non-conducting quality control test of kits and reagents; Lack of facility for critical TTI/ TTD[7] tests by ELISA method; Absence of easily washable floor and walls to maintain hygiene; Not giving information to the authorities regarding change in technical person; Non-issue of Blood cross match slip to patients along with blood bags. |
| 3. | Life care medical complex (P) Ltd. Blood Bank | Blood component section area was less than 50 square meter; Records not maintained to ascertain the time gap between collection of blood and its processing of component; Collection of blood in excess of component separation capacity and the consequent supply of extra units to Plasmagen, a blood product manufacturer; Non-mentioning of expiry date of the platelet on the label. Multiple units of blood supplied to single patient without issuing cross match cum slip for each unit. |
| 4. | North Bengal Voluntary Blood Bank and Research Centre | Non-uniformity in quantity of collected blood unit due to non-calibration of blood collection monitor rendering amount of blood collected disproportional to the anti-coagulant added which may result in transfusion related health hazard; Non-conducting of requisite test for unexpected antibodies, quality Control test; absence of mandatory equipment like automatic ELISA readers with printers & washer. |

*Source: Records of the Directorate*

[7] *Transfusion transmitted infection/ Transfusion transmitted diseases.*

## Appendix 2.1.3

*(Refer paragraph 2.1.7.1, page 15)*

**Shortfall in inspections of drug selling units**

| Name of the District | Year | No. of inspections to be done | No. of inspections actually conducted | Percentage of shortfall |
|---|---|---|---|---|
| Kolkata | 2012-13 | 11232[8] | 36 | 99 |
| | 2013-14 | 11232 | 860 | 92 |
| | 2014-15 | 11232 | 858 | 92 |
| | 2015-16 | 11232 | 996 | 91 |
| | 2016-17 | 11232 | 711 | 94 |
| **Total** | | **56160** | **3461** | **93.84** |
| Murshidabad | 2012-13 | 5314 | 0 | 100 |
| | 2013-14 | 5438 | 323 | 94 |
| | 2014-15 | 5683 | 463 | 92 |
| | 2015-16 | 5949 | 370 | 94 |
| | 2016-17 | 6113 | 444 | 93 |
| **Total** | | **28497** | **1600** | **94.39** |
| Malda | 2012-13 | 2576 | 281 | 89 |
| | 2013-14 | 2676 | 165 | 94 |
| | 2014-15 | 2784 | 128 | 95 |
| | 2015-16 | 2915 | 196 | 93 |
| | 2016-17 | 3028 | 198 | 93 |
| **Total** | | **13979** | **968** | **93.01** |
| Jalpaiguri | 2012-13 | 3348 | 146 | 96 |
| | 2013-14 | 3437 | 149 | 96 |
| | 2014-15 | 3582 | 184 | 95 |
| | 2015-16 | 3757 | 205 | 95 |
| | 2016-17 | 3873 | 196 | 95 |
| **Total** | | **17997** | **880** | **95.11** |
| Bardhaman | 2012-13 | 8564 | 95 | 99 |
| | 2013-14 | 8734 | 286 | 97 |
| | 2014-15 | 8895 | 401 | 95 |
| | 2015-16 | 9124 | 388 | 96 |
| | 2016-17 | 9397 | 449 | 95 |
| **Total** | | **44714** | **1619** | **96.38** |

*Source: Directorate of Drug Control, West Bengal and Assistant Directors of Drug Control of respective districts*

[8] *There were 11,232 licensed units as of December 2016 (Manufacturing units – 192, Modern Drug Wholesale – 4,315, Modern Drug Retail – 5,179, Homeo Retail – 1,546 units). Since year-wise figures of live licences were not provided by DDC, the minimum number of live units is assumed to be 11,232 every year.*

## Appendix 2.1.4

*(Refer paragraph 2.1.7.3, page 17)*

**List of 32 drugs declared as not of standard quality (NSQ) and particulars of the test reports**

| Sl. No. | Name of drug/ cosmetic | Batch No. | Name of manufacturer | Brief particulars of test reports and follow-up action, if any |
|---|---|---|---|---|
| 1 | Vitamin B Complex Tab | 110807 | M/s Luxmi Pharmaceutical Works, P-18, Kanungo Park, Kolkata - 84 | Assay of the active drug ingredient Pyridoxine Hydrochloride was 80 *per cent* as reported by the Government Analyst of SDCRL. An investigation was conducted on 18-12-2012 by the Inspector of drugs. Several irregularities were found during inspection. But, no such action was taken by the authority against the firm as of June 2017. |
| 2 | Salbut Tab | 100301 | M/s Luxmi Pharmaceutical Works, P-18, Kanungo Park, Kolkata - 84 | Assay of the sampled drug was 85 *per cent* as reported by the Government Analyst of SDCRL. Despite the order of the Director, no investigation was conducted at the manufacturing premises. As the firm adduced the report, the concerned Inspector of Drug was directed (11-02-2013) by the Director to take necessary action as per the provision of the Act. But, the inspector did not take any action against the firm. |
| 3 | Irotone Liquid I | GSR-1101 | M/s Calchem Laboratories, Ramkrishna Pally, PO Shyamnagar, 24 PGNS (N) | Assay of the active drug ingredients, Thiamine Hydrochloride was 47.76 *per cent* and Cyanocobalamine was 37.71 *per cent* as reported by the Government Analyst of SDCRL. According to DCC guidelines, prosecution was to be launched. Therefore, the matter was referred to Prosecution Cell on 31-07-2013. But, no prosecution was initiated by the authority against the firm as of June 2017. |
| 4 | Norfloxacin Tab IP 400 mg. | T-2811 | M/s Emma Drugs & Chemicals, National Place, Buxarah, Howrah | Assay of the sampled drug was 32.33 *per cent* as reported by the Government Analyst of SDCRL. According to DCC guidelines, prosecution was to be launched. Therefore, the matter was referred to Prosecution Cell on 12-08-2014. But, no prosecution was initiated by the authority against the firm as of June 2017. |
| 5 | Halazone Tab | 120657 | M/s Luxmi Pharmaceutical Works, P-18, Kanungo Park, Kolkata - 84 | Assay of the sampled drug was 46.84 *per cent* as reported by the Government Analyst of SDCRL. According to DCC guidelines, prosecution was to be launched. Therefore, the matter was referred to Prosecution Cell on 12-08-2014. But, no prosecution was initiated by the authority against the firm as of June 2017. |

| Sl. No. | Name of drug/ cosmetic | Batch No. | Name of manufacturer | Brief particulars of test reports and follow-up action, if any |
|---|---|---|---|---|
| 6 | Antaron | ANT-045 | M/s Ronald Pharmaceuticals Pvt. Ltd., Phooltala Canning Road, Kolkata - 144 | Assay of active drug ingredient Dried Aluminium Hydroxide was 39.16 *per cent* as reported by the Government Analyst of SDCRL. According to DCC guidelines, prosecution was to be launched. Therefore, the matter was referred to Prosecution Cell on 20-11-2014. But, no prosecution was initiated by the authority against the firm as of June 2017. |
| 7 | Nihar Naturals Coconut Hair Oil | PM-078 | M/s Marico Industries Ltd., Khasra No. 425/408/2, 54, 55 & 424/408/1, Vill. Toklon, Dhaula Kaun, Panota Sahib, Himachal Pradesh | The sampled drug failed in Description as reported by the Government Analyst of SDCRL. As per order of the Director, the matter was referred to Prosecution Cell on 18-06-2013. But, no prosecution was initiated by the authority against the firm as of June 2017. |
| 8 | Glanpan IV | A013005 | M/s ANG Life Sciences (I) Pvt. Ltd., PO Manpura Tehsil Nalagarh, Dist. Solan, Himachal Pradesh | Assay of active drug ingredient Pantoprazole was 32.57 *per cent* as reported by the Government Analyst of SDCRL. According to DCC guidelines, prosecution was to be launched. Therefore, the matter was referred to Prosecution Cell on 12-03-2014. But, no prosecution was initiated by the authority against the firm as of June 2017. |
| 9 | LYCAL-D | B010413 | M/s Duck Bill Drugs Pvt. Ltd., Behala Industrial Estate, 620, DH Road, Building No. 2, Kolkata-34 | Assay of active drug ingredient Vitamin $D_3$ was 37.82 *per cent* as reported by the Government Analyst of SDCRL. According to DCC guidelines, prosecution was to be launched. Therefore, the matter was referred to Prosecution Cell on 10-06-2014. But, no prosecution was initiated by the authority against the firm as of June 2017. |
| 10 | Supradyn | MH-1546 | M/s Piramal Enterprise Ltd., K-1, Addl. MIDC Area, Mahad, Maharashtra. | Assay of the active drug ingredient Cyanocobalamine was 21.39 *per cent* as reported by the Government Analyst of SDCRL. According to DCC guidelines, prosecution was to be launched. Therefore, the matter was referred to Intelligence Cell on 14-01-2015. But, no prosecution was initiated by the authority against the firm as of June 2017. |
| 11 | Clopinol-AP | MT-123146 | M/s Mascor Health Services Pvt. Ltd., Haridwar-249409 | Assay of the active drug ingredient Clopidogrel Bisulphate was 216.32 *per cent* as reported by the Government Analyst of SDCRL. Director of Drug Control ordered for launching of prosecution. Therefore, the matter was referred to Prosecution Cell on 12-3-2015. But, no prosecution was initiated by the authority against the firm as of June 2017. |

| Sl. No. | Name of drug/ cosmetic | Batch No. | Name of manufacturer | Brief particulars of test reports and follow-up action, if any |
|---|---|---|---|---|
| 12 | Phensedyl New | PHB 1009 | Abbott Healthcare Pvt. Ltd., Vill. Bhatauli Khurd, Baddi – 173205 Dist. Solan, HP | The Chlorpheniramine Maleate (0.857%) & Codeine Phasphate (0.679%) content of the sample were found much less than the claim. |
| 13 | Phensedyl New | PHB 9376 | Piramal Healthcare Ltd., Vill. Bhatauli Khurd, Baddi – 173205 Dist. Solan, HP | The Chlorpheniramine Maleate (0.744%) & Codeine Phasphate (0.780%) content of the sample were found much less than the claim. |
| 14 | Cetramidosol | C 268 | Chowdhury Chemical Works, Dharampore, Chinsurah, Hooghly | The Cetrimide (67.61%) and Chlorhexidine (0.781%) content of the sample were found much less than the claim. |
| 15 | Rabikon-D | RBD 101 | Kon Test Chemicals Ltd., Mambapur Village, Jinnaram Mandal, Medak, Dist - 502313, AP | The Rabeprazole Sodium (62.85%) content of the sample was found much less than the claim. |
| 16 | Calcium with Vitamin D3 Tab | CD-084 | Green Co Biologicals Pvt. Ltd., GN-1, Salt Lake City, Sector-V, Kolkata-91 | The Vitamin D3 (11.89%) content of the sample was found much less than the claim. |
| 17 | Amclox | MSCA-56 | Martin and Harris Laboratories Ltd., Plot No. 33-34, Sector-6 A, SIDCUL, Rangipur, Haridwar, Uttarkhand | The Dicloxacillin Sodium (46.71%) content of the sample was found much less than the claim. |
| 18 | Omitrab-D | L 1662 | DM Pharma, Dist. Solan, HP – 173 205 | The Rabeprazole Sodium (34.9%) content of the sample was found much less than the claim. |
| 19 | Withania Somnifera (Dietary Supplement) | WS/D/173 | Atrey Pharmaceuticals, Saraspur, Ahmedabad | The sample is identified for the presence of steroid. |
| 20 | Aciloc-RD | W10003 | Cadila Pharmaceuticals Ltd., 1389, Dholka – 387 810, Dist. Ahmedabad | The Omeprazole Magnesium (67.63%) content of the sample was found much less than the claim. |
| 21 | Benzalkonium Chloride Solution IP | 61204 | Associated Chemical & Pharmaceuticals Ltd., Kolkata - 132 | The Benzalkonium Chloride (201.78%) content of the sample was found much higher than the claim. |
| 22 | Saizole-D | 4116 | Santo Formulations, Deonghat, PO Saproon, Dist. Solan (HP)-173 211 | The Pantoprazole (68.05%) content of the sample was found much less than the claim. |
| 23 | Gaspaz | GS 111 | Supra Pharmaceutical Pvt. Ltd., Sl No. 296/7/6 IDA Bollaram, Hyderabad | The Domperidone (64.6%) content of the sample was found much less than the claim. |
| 24 | RZOLE-DSR | 5013588 | Scott-Edil Pharmacia Ltd., 56, EPIP, Phase-Jharmajri-173205 | The Rabeprazole Sodium (54.95%) content of the sample was found much less than the claim. |
| 25 | Blood Administration Set | PN-240 | Shree Umiya Surgical Pvt. Ltd., 4704, GIDC, Phase-IV, Vatva, Ahmedabad | The sample does not confirm with respect to Sterility. |
| 26 | Rabium-20 | KR 1507 | Intas Pharmaceuticals, Rangpo, East Sikkim – 737 132 | The Rabeprazole Sodium (62.57%) content of the sample was found much less than the claim. |

| Sl. No. | Name of drug/ cosmetic | Batch No. | Name of manufacturer | Brief particulars of test reports and follow-up action, if any |
|---|---|---|---|---|
| 27 | Genosedyl | P4 V020 | Pro Laboratories Pvt. Ltd. | The Codeine Phosphate (2.05%) content of the sample was found much less than the claim. |
| 28 | RC Kuff Cough Syrup | RCS 1096 | Wings Pharmaceuticals Pvt. Ltd. | The Codeine Phosphate (48.73%) content of the sample was found much less than the claim. |
| 29 | Ascoril Expectorant | 11141491 | Glenmark Pharmaceuticals Ltd., Solan (HP) – 174011 | The Guaiphenesin (19.19%) content of the sample was found much less than the claim. |
| 30 | Duvepam DSR | 515-4 | Lanark Laboratories, Paonta Sahib – 173 025 | The Domperidone (65.56%) content of the sample was found much less than the claim. |
| 31 | 'INSTARYL' Expectorant | S 13601 | Aglowmed Ltd., 50, Rajpur, Roorkee – 247 661 | The Terbutaline Sulphate (252.57%) content of the sample was found much higher than the claim. |
| 32 | Rabalkem DSR | RBC – 1005 - TR | Tirupati Medicare Ltd. Dist – Sirmour, H.P. | The Rabeprazole Sodium (41.55%) content of the sample was found much less than the claim. |

*Source: Directorate of Drug Control, West Bengal and SDCRL*

## Appendix 2.1.5

*(Refer paragraph 2.1.8.1, page 18)*

**List of unused equipment in SDCRL**

| Name of the equipment | Date of procurement | Cost (₹ in lakh) | Function | Present status |
|---|---|---|---|---|
| Liquid Chromatography Mass Spectrometry | March 2014 | 118.15 | To detect the non-volatile sample of unknown molecular weight | Yet to be installed |
| High Performance Liquid Chromatography | January 2017 | 20.00 | To separate, identify and quantify each component in a mixture | Kept idle without having operational password |
| Dissolution Apparatus | May 2014 | 3.65 | -- | Kept in idle condition |
| High Performance Thin Layer Chromatography | March 2014 | 59.18 | For both quantitative and qualitative chemical analysis of drug samples | Kept in idle condition |
| **Total** | | **200.98** | | |

*Source: SDCRL*