

**Chapter - 5**

**Production and Quality Testing of Medicine**



## Chapter 5: Production and Quality Testing of Medicine

The State has two AYUSH Pharmacies, i.e. State Pharmacy of Ayurvedic and Unani Medicine, Lucknow (PAUM) and State Pharmacy of Ayurvedic Medicine, Pilibhit; and one State Drugs Testing Laboratory, Lucknow (DTL). This chapter deals with production of medicine in PAUM, test checked in audit, testing of medicines in DTL and other related issues.

### 5.1 Production of Ayurvedic and Unani medicine in State Pharmacy

PAUM was established in the year 1949 with the objective to produce quality Ayurveda and Unani medicines. It receives funds for production of medicine from the State Budget.

PAUM incurred a total expenditure of ₹ 22.86 crore and ₹ 8.08 crore, against the provision for the same amounts in production of Ayurvedic and Unani medicines during the years 2018-19 to 2022-23, as detailed in **Table 7**.

**Table 7: Details showing demand raised, allotment made, and expenditure incurred by State Pharmacy of Ayurveda and Unani Medicine, Lucknow**

Year	Ayurveda			Unani		
	Demand	Allotment	Expenditure	Demand	Allotment	Expenditure
2018-19	5.00	2.98	2.98	0.50	0.50	0.50
2019-20	5.00	3.60	3.60	1.00	0.75	0.75
2020-21	5.00	5.00	5.00	1.00	1.21	1.21
2021-22	5.50	6.00	6.00	1.50	2.81	2.81
2022-23	6.60	5.28	5.28	2.00	2.81	2.81
<b>Total</b>	<b>27.10</b>	<b>22.86</b>	<b>22.86</b>	<b>6.00</b>	<b>8.08</b>	<b>8.08</b>

(Rupees in crore)

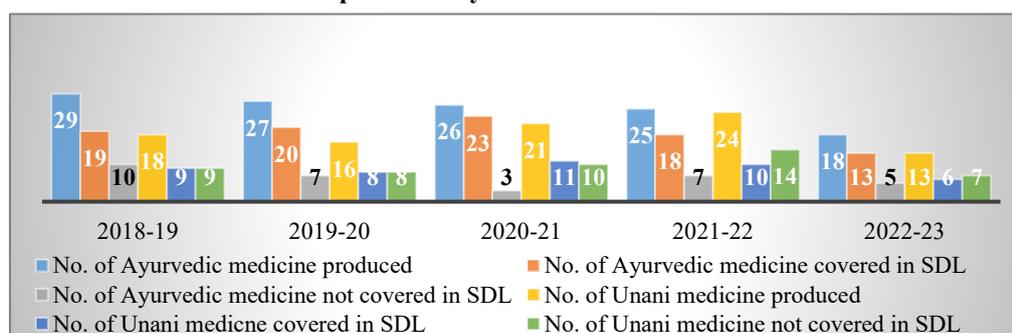
(Source: State Pharmacy of Ayurveda and Unani Medicine, Lucknow)

The findings on functioning of the pharmacy are discussed in succeeding paragraphs:

#### 5.1.1 Non-production of maximum number of approved medicines

PAUM is having licenses for production of 388 Ayurvedic and Unani medicines. GoUP approved (September 1999 and April 2018) lists of total 130 Ayurvedic<sup>1</sup> and 85 Unani medicines<sup>2</sup>, taken as State Drugs List (SDL), which were to be produced in the State Ayurvedic and Unani Pharmacies. The details given in **Chart 3** indicate year-wise position of medicines produced in PAUM, Lucknow and covered in EDL:

**Chart 3: Medicine produced by PAUM and medicine covered in SDL**



(Source: State Pharmacy of Ayurveda and Unani Medicine, Lucknow)

<sup>1</sup> 50 and 80 medicines (total 130) approved vide GO dated 28.09.1999 and 11.04.2018 respectively.

<sup>2</sup> 42 and 43 medicines (total 85) approved vide GO dated 28.09.1999 and 11.04.2018 respectively.

The above chart indicates that PAUM, during the years 2018-19 to 2022-23, produced an average of 25 Ayurvedic medicine (19.23 *per cent*) and 18.4 Unani medicine (21.65 *per cent*) per year against the list of 130 and 85 (total 215) approved Ayurvedic and Unani medicines, of which an average of 16 medicines were not covered in SDL.

The Government stated (January 2025) that after handing over of Unani Pharmacy building, production of medicines will increase and further stated that efforts are being made to provide budget for optimum utilisation of capacity of the Pharmacy. Reply is not acceptable as only Unani Pharmacy building was under construction as discussed in paragraph 5.2.1, whereas Ayurvedic medicines were also not produced. The Government should have utilised the production capacity of the pharmacy by providing funds available under NAM.

### 5.1.2 Non-achievement of target for production of medicine

The details given in **Table-8** indicates year-wise position of target fixed and achieved there against during the year 2018-19 to 2022-23:

**Table 8: Details showing year-wise position of targets and achievements thereagainst in respect of medicine produced in PAUM, Lucknow**

Year	Ayurvedic Medicine				Unani Medicine			
	Target		Achievement		Target		Achievement	
	No of Medicine	Production in Kg.	No of Medicine	Production in Kg.	No of Medicine	Production in Kg.	No of Medicine	Production in Kg.
2018-19	60	80,180.00	29	38,364.20	25	19,161.00	18	10,134.50
2019-20	29	55,546.00	27	52,588.00	22	12,513.00	16	15,846.50
2020-21	42	100,319.00	26	53,866.05	36	32,903.00	21	14,472.75
2021-22	42	93,470.00	25	84,875.00	32	35,792.00	24	34,685.50
2022-23	44	195,622.00	18	39,294.25	30	60,000.00	13	13,037.75
<b>Total</b>	<b>217</b>	<b>525,137.00</b>	<b>125</b>	<b>268,987.5</b>	<b>145</b>	<b>160,369.00</b>	<b>92</b>	<b>88,177.00</b>

(Source: State Pharmacy of Ayurveda and Unani Medicine, Lucknow)

The above table indicates that during the period 2018-19 to 2022-23, the achievement of targets in respect of number of Ayurvedic and Unani medicines produced was 59.94 *per cent*, whereas in terms of quantity, it was 51.35 *per cent*. The reasons for non-achievement of the targets were attributable to unavailability of funds and delayed supply (2022-23) of raw materials.

The Government stated (January 2025) that budget is provided according to requirement, which is being increased further. Reply confirms that limited funds were provided to the Pharmacy, and though NAM guidelines provided purchasing medicine from State Pharmacies, entire funds received under NAM for purchase of medicines were utilised in purchase of medicine from Indian Medicines and Pharmaceuticals Corporation Limited (IMPCL).

## 5.2 Creation of building infrastructure for the Pharmacy

### 5.2.1 Delay in establishment of Unani Pharmacy in PAUM, Lucknow

With the objective to provide timely supply of medicines to Unani hospitals and dispensaries, and to avoid adverse impact on production of Unani medicines due to unavailability of a separate Unani Pharmacy, GoUP accorded

(February 2019) A&FA of ₹ 4.81 crore<sup>3</sup> for the work. GoUP also accorded (January 2022) A&FA of ₹ 50 lakh for purchase of machinery and equipment for the upcoming Unani Pharmacy. Audit noticed that:

- MoU executed (February 2019) by Superintendent, PAUM with Uttar Pradesh Rajya Nirman Sahkari Sangh Limited (UPRNSS), nominated (March 2018) as EA for construction of a Unani Pharmacy, in the premises of PAUM, Lucknow and stipulated the period of completion as 12 months. Conditions 10 and 11 of GO issued (February 2020) for release of second instalment (₹ 232.05 lakh) stipulated that the completion of the project should be ensured within the approved cost, and no subsequent revision would be allowed. Funds of ₹ 1.49 crore, ₹ 2.32 crore and ₹ 0.76 crore (total: ₹ 4.81 crore) released<sup>4</sup> by GoUP, were released to EA in the months of March 2019, February 2020 and February 2021 respectively. Even after release of entire sanctioned cost of ₹ 4.81 crore (after deducting security deposit of 5 per cent) by February 2021, EA completed and handed over (February 2024) the building after a lapse of 3 years (against the completion period of 12 months) of release of the last instalment (February 2021).
- In all the standard contracts for civil work, time is considered as essence of the contract; and in case of failure in completion of work within the stipulated time, penalty at the rate of one per cent of the estimated cost per day, subject to a maximum of 10 per cent is recovered from the contractor. In deviation with the standard practice, MoU executed with EA stipulated a penalty of ₹ 500 per day for delayed completion of work. Further, even this penalty, which is worked out to ₹ 7.15 lakh (upto February 2024), has not been recovered from EA. This resulted in undue favour to EA and delay in achievement of the objective of providing a separate Unani Pharmacy.

The Government stated (January 2025) that EA was asked to pay the penalty for delay, but the latter refused to pay the same stating that the delay was due to Coronavirus Disease (Covid) pandemic. Reply is not acceptable as the second lockdown was ended in May 2021, whereas the building was handed over by EA in February 2024, i.e. after about three years of the end of 2<sup>nd</sup> lock down.

### 5.3 Drugs Testing and Quality Control

With a view to build faith of the people in AYUSH system of medicine, testing and quality control of AYUSH drugs is necessary. Audit noticed ineffective quality control mechanism in the state, as discussed in succeeding paragraphs:

#### 5.3.1 Under utilisation of State Drugs Testing Laboratory, Lucknow

State Drugs Testing Laboratory (DTL) - the only Government laboratory in the State, working under the Director of Ayurveda Services (no such laboratory for Homeopathic medicine was established by GoUP) was established in 1987 with the objective to provide testing facility of the samples of Ayurvedic and Unani

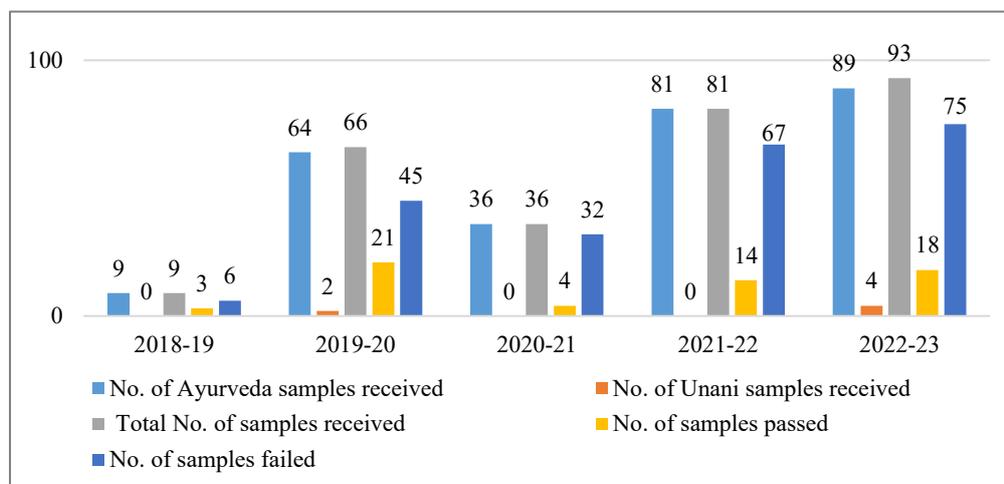
<sup>3</sup> UPRNSS submitted an estimate of ₹ 5.80 crore. The Project Formulation & Appraisal Division assessed the estimated the same for ₹ 4.81 crore. Executive Engineer, UPRNSS submitted a detailed estimate of ₹ 4.81 crore (excluding GST) for the work.

<sup>4</sup> Total ₹ 4.57 crore released in February 2019, February 2020 and September 2020. As per the condition 19 of GO (December 2020), the last instalment of 5 per cent was to be released after handing over of the building.

drugs provided by Drugs Inspectors/Divisional Ayurvedic and Unani Officers, Excise Department, Police Department etc. of the State.

The details given in **Chart 4** indicates year-wise position of samples of Ayurveda and Unani medicines received and tested in DTL:

**Chart 4: Samples of Ayurveda and Unani medicine received, passed and failed in testing done at DTL**



(Source: Information provided by Drugs Testing Laboratory, Lucknow)

Thus, DTL tested approximately one sample in a week during 2018-19 to 2022-23. Neither the Government fixed any norm for DTL nor DTL itself, for testing of samples. This resulted in underutilisation of DTL.

Audit also noticed that:

- The State Licensing Authorities are responsible for the implementation of provisions of Drugs & Cosmetic Act, 1940 for manufacture and sale of ASU&H drugs. Audit noticed that during the years 2018-19 to 2022-23, Drugs Inspectors (DIs) of only 21 districts<sup>5</sup> sent samples to DTL for testing. At the instance of audit, government issued (January 2025) instructions to all DAUOs/DIs for collection of drugs samples and inspection of Ayurvedic and Unani drugs manufacturing units.
- GoUP did not make it mandatory for DAUOs/RUOs to send the samples of medicine procured by them locally for testing in DTL. As a result, the procured medicines were provided to the patients without quality check. The high failure percentage (66.66 per cent to 88.88 per cent) of Ayurvedic and Unani medicines indicated risk of exposure of the consumers to substandard drugs.
- GoI provided funds of ₹ 25 lakh each for the year 2018-19 and 2019-20 for manpower in DTL under the component Quality Control of ASU&H drugs, which was not utilised. No funds were provided by GoI for human resources to DTL thereafter. The only employee of DTL holding the charge of Government Analyst<sup>6</sup> retired in August 2024

<sup>5</sup> 2018-19: 3 districts; 2019-20: 7 districts; 2020-21: 9 districts; 2021-22: 8 districts; 2022-23: 10 districts.

<sup>6</sup> Junior Analyst, DTL, Lucknow was given the additional charge of Government Analyst vide Gazette notification dated 21 August 2018.

The Government stated (January 2025) efforts are being made to strengthen DTL; instructions have been issued (January 2025) to check drugs manufacturing units and take action in case of sub-standard drugs; the test reports of the locally purchased drugs are provided by the suppliers; or these drugs are got tested at DTL; and proposal for creation of post relating to funds provided under NAM is in progress at Government level. Reply is not acceptable as out of 75 districts, DAUOs/DIs sent samples of only 3 to 10 districts *per year* (total 21 districts) to DTL during the period 2018-19 to 2022-23, indicating that DAUOs relied upon the test reports provided by suppliers themselves.

### 5.3.2 Delayed construction of laboratory building

The Government accorded (March 2018) A&FA of ₹ 1.18 crore<sup>7</sup> for construction of a laboratory building of Unani Pharmacy in PAUM. MoU executed (September 2018) with EA (UPRNSS), stipulated period of completion as 12 months.

Audit noticed that against A&FA, GoUP released funds of ₹ 1.00 lakh, ₹ 103.10 lakh and ₹ 13.91 lakh (Total: ₹ 1.18 crore) in the months of March 2018, July 2018 and January 2020 respectively which, in turn, was released<sup>8</sup> to the Superintendent, PAUM, Lucknow. The work, however, was completed in November 2023 with delay of more than 4 years.

The Government furnished no reply (January 2025).

### 5.3.3 Unfruitful expenditure on upgradation of DTL

DTL of ASU&H drugs are provided with non-recurring assistance for upgradation of building and equipment, and recurring grants for reagents, chemicals manpower etc. under NAM. Paragraph 12 of Chapter 1 of UPBM stipulates that every government servant should exercise the same vigilance and care in respect of expenditure from public money under his control as a person of ordinary prudence would exercise in respect of expenditure of his own money.

With a view to upgrade DTL, GoI sanctioned ₹ 1.00 crore under NAM, against SAAP for the year 2016-17. SAS transferred funds of ₹ 69.67 lakh (August 2020) and ₹ 33.33 lakh (January 2020) for upgradation of DTL building and purchase of equipment respectively. Audit noticed that:

- GoUP nominated (February 2019) UPPCL as EA for the strengthening work. UPPCL submitted (August 2020) an estimate of ₹ 69.94 lakh which was approved<sup>9</sup> for ₹ 61.92 lakh. At the instance (September 2021) of SAS, the Director surrendered (September 2021) the funds to SAS. A limit of ₹ 61.92 lakh was issued (October 2021) by SAS to UPPCL, after receiving

<sup>7</sup> Based on the proposal submitted by the Directorate of Unani Services and cost evaluated by a committee constituted (July 2017) by AYUSH Department, against the estimated cost for the work amounting to ₹ 118.28 lakh submitted by the nominated EA, i.e. UPRNSS.

<sup>8</sup> The superintendent released ₹ 1.00 lakh, ₹ 50.00 lakh, ₹ 53.10 lakh and ₹ 13.91 lakh in the months of March 2018, September 2018, March 2019 and February 2020.

<sup>9</sup> By the Competent authority, based on the technical examination done by Director General, Medical & Health Services, Lucknow for ₹ 61.92 lakh.

back the funds of ₹ 69.67 lakh, which was utilised (July 2022) in strengthening of DTL.

- Government Analyst at DTL provided a list of 16 required equipment valuing ₹ 30.33 lakh to the Director, Ayurveda Services, Lucknow. The proposal was forwarded (January 2020) to SAS, but no equipment was purchased for DTL. At the instance (September 2021) of SAS, the Director surrendered (September 2021) the entire funds to SAS. As a result, no equipment was purchased for DTL.

The above indicate that though the strengthening of the building was completed (July 2022) after more than 5 years of its sanction; the non-procurement of laboratory equipment resulted in unfruitful expenditure of ₹ 61.92 lakh, incurred on strengthening of DTL building. Audit also noticed that:

- Director, Ayurveda Services, Lucknow purchased (December 2010) a Spectrophotometer for testing of heavy/other metals in the drugs samples at a cost of ₹ 40.91 lakh; and supplied the same to DTL. The machine, however, was not utilised, leading to unfruitful expenditure of ₹ 40.91 lakh.
- Superintendent, PAUM purchased (September 2018) a blister machine (used to create blister packets/strips) under 'upgradation of PAUM' from M/s Ispa Trade Links Private Limited, Lucknow at a total cost of ₹ 21.20 lakh. The machine was never utilised due to unavailability of technical manpower.

The above indicates that due care was not taken while incurring expenditure from the public money.

The Director General, AYUSH accepted (November 2024) that procurement of equipment was not made due to delayed completion of DTL building and discontinuation of the component thereafter. The Government accepted (January 2025) the non-utilisation of the machinery purchased earlier and stated that efforts are being made to operationalise them. Reply indicates incomplete upgradation of DTL due to delayed completion of its building; and the machines were procured without ensuring its imminent requirement.

**To sum up**, State Pharmacy of Ayurvedic and Unani Medicine (PAUM) is having licenses for production of 388 Ayurvedic and Unani medicines. GoUP approved (September 1999 and April 2018) lists of total 130 Ayurvedic and 85 Unani medicines, which were to be produced in PAUM. During the years 2018-19 to 2022-23, PAUM produced an average of 25 Ayurvedic medicine (19.23 *per cent*) and 18.4 Unani medicine (21.65 *per cent*) per year against the list, of which an average of 16 medicines were not covered in the list approved by GoUP. The targets for production of Ayurvedic and Unani Medicines were not achieved by PAUM. During the period 2018-19 to 2022-23, the achievement of targets in respect of number of Ayurvedic and Unani medicines produced was 59.94 *per cent*, whereas in terms of quantity, it was 51.35 *per cent*. State Drugs Testing Laboratory (DTL), the only Government laboratory in the State, was established in 1987 with the objective to provide testing facility of the samples of Ayurvedic and Unani drugs. DTL tested approximately one sample in a week during 2018-19 to

2022-23. Neither the Government fixed any norm for DTL nor DTL itself, for testing of samples. This resulted in underutilisation of DTL. Most of the Drug Inspectors (DIs) were not sending drug samples for testing. Audit noticed that during the years 2018-19 to 2022-23, DIs of only 21 districts sent samples to DTL for testing. At the instance of audit, government issued (January 2025) instructions to all DAUOs/DIs for collection of drugs samples and inspection of Ayurvedic and Unani drugs manufacturing units.

**Recommendation 7:** To achieve the target for production of Ayurvedic and Unani medicine, sufficient budget and infrastructure should be provided to the State Pharmacy.

**Recommendation 8:** District-wise targets for sending of samples of the drugs to Drugs Testing Laboratory should be fixed for Drugs Inspectors.

