

FRAMEWORK FOR IMPLEMENTATION AND OPERATIONAL GUIDELINES

AYUSH OUSHADHI GUNVATTA EVAM UTTPADAN SAMVARDHAN YOJANA
(AOGUSY)

THE CENTRAL SECTOR SCHEME FOR
AUGMENTING QUALITY OF AYUSH DRUGS



सत्यमेव जयते

Government of India

Government of India
Ministry of AYUSH
(Drug Policy Section)

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FRAMEWORK FOR IMPLEMENTATION OF AYUSH OUSHADHI GUNVATTA EVAM UTTPADAN SAMVARDHAN YOJANA (AOGUSY) THE CENTRAL SECTOR SCHEME FOR AUGMENTING QUALITY OF AYUSH DRUGS

1. INTRODUCTION:

Regulation of Ayurveda, Siddha, Unani and Homoeopathic (ASU&H) medicines in India, are governed under the provisions of Drugs & Cosmetics Act, 1940 and the Rules made thereunder. The growth & development of traditional Indian and Homoeopathic medicines in the interest of public health is expected within the objective of making accessible, safe, effective and quality medicines to the people. Emerging global developments in the area of drug regulatory compliance are incorporated for ASU&H medicines in accordance with the national health circumstances and regulatory needs of standardization & quality control, research & development of ASU&H drugs.

Country has approximately more than 8000 licensed Ayurvedic, Siddha, Unani and Homoeopathy drugs manufacturers. Most of them are small and medium scale entrepreneurs with inadequate capacities and avenues for growth. Regulatory requirements and emerging demand for quality AYUSH products need adequate investment towards infrastructural facilities and quality control systems for production of AYUSH products in the domestic and international markets. Considering the range and scope of AYUSH products in national and international markets and the strategic steps needed for mainstreaming of AYUSH drug industry, it is envisaged to support the manufacturers in their efforts for adopting quality production technology, in-house quality control facilities, quality certification of products, strengthening and rationalizing the drug regulatory system, promotion of research and development in the pharmaceutical sector and building synergy and evolving a convergent approach with related sectors. In this backdrop the scheme of Ayush Oushadhi Gunvatta evam Utpadan Samvardhan Yojana (AOGUSY) intends to provide support for quality of AYUSH drugs and to achieve specific objectives and outcomes related to promotion of AYUSH drug industry and strengthen the regulatory framework.

The commercial production of ASU&H drugs without license is not permitted. Compliance to Good Manufacturing Practices (GMP) is mandatory for obtaining manufacturing license. Requirement of In house testing laboratories is prescribed under Drugs and Cosmetics Rules, 1945, Schedule T for the GMP of ASU Manufacturing units and Schedule M1 for Homoeopathy drugs manufacturing units. The units which doesn't have such facilities are allowed to get their drugs tested from approved laboratories for the purpose. Also, as per rule 161B of Drugs and Cosmetics Rules, 1945, stability study data has been made as mandatory requirement for license since 2019. Quality standards of identity, purity and strength of drugs and compliance for permissible limits of heavy metals, pesticide residue, and microbial load as prescribed in the respective Pharmacopoeias of ASU&H system are mandatory to follow. Drug inspectors, Technical Committees and Drug Testing Laboratories are provided for the Licensing Authorities to take considered and objective decisions in licensing and quality control matters.

With this background, Ministry of Ayush, Government of India has accordingly initiated the Central Sector Scheme for augmenting quality of Ayush drugs during the 15th Finance Cycle (2021-22 to 2025-26) by merging the existing Central Sector Schemes of Pharmacovigilance initiative, Central Drug Controller of Ayush and Quality Control of ASU&H drugs {Component of National Ayush Mission (NAM)} and inclusion of certain new elements to facilitate standardization, effective enforcement of rules/regulations, technology up-gradation for manufacturing and analytical testing, certification/accreditation, training and capacity building activities intended towards quality assurance of Ayush drugs.

This scheme is named as Ayush Oushadhi Gunvatta evam Utpadan Samvardhan Yojana (AOGUSY).

2. VISION:

The scheme intends to promote and project quality, acceptability and visibility of AYUSH products for enhancing people's confidence in their use for health care and for improving trade.

- i. To inculcate culture of quality production of AYUSH products assured with safety and efficacy.
- ii. To enable AYUSH drug industry in complying with national and global regulatory requirements and standards.
- iii. To build up visibility and demand- driven market presence of AYUSH products.
- iv. To strengthen AYUSH pharmaceutical industry for enhancing trade and exports.

3. OBJECTIVES:

- i. To enhance India's manufacturing capabilities and exports of traditional medicines and health promotion products under the initiative of Atmanirbhar Bharat.
- ii. To facilitate adequate infrastructural & technological upgradation and institutional activities in public and private sector for standardization, quality manufacturing and analytical testing of Ayush drugs & materials.
- iii. To strengthen regulatory frameworks at Central and State level for effective quality control, safety monitoring and surveillance of misleading advertisements of Ayush drugs.
- iv. To encourage building up synergies, collaborations and convergent approaches for promoting standards and quality of Ayush drugs & materials.

4. COMPONENTS:

A. Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards.

B. Pharmacovigilance of ASU&H drugs including surveillance of misleading advertisements.

C. Strengthening of Central and State regulatory frameworks including Technical Human Resource & Capacity Building programs for Ayush drugs.

D. Support for development of standards and accreditation/ certification of Ayush products & materials in collaboration with BIS, QCI and other relevant scientific institutions and industrial R&D centres.

The details of each component as mentioned above are provided as separate guidelines.

5. PROJECT APPROVAL

5.1 Time line for Receipt of Application

The applications would be received and processed in two quarters:

Quarter	Processing by the PAC	Processing by PSC
I	April first week	April last week
II	Dec. first week	Dec. last week

In case of Organisation/Institutions/GMP compliant Industries of ASU&H drugs/ Drug Testing laboratories of ASU&H drugs both in public & private sector the applications are to be submitted through their Controlling authorities/Head of the Institutions/Regulatory Authority/Authorized Signatory as applicable who will be designated authority responsible for quality work and utilization of the grant and are accountable in the event of any default.

5.2 Screening and Appraisal of the project

- Once the proposal is received the same shall be reviewed by concerned Adviser of the Ministry/Group of experienced persons for the respective components/Director General/ Director of the respective Research councils/Institution. They shall submit their opinion/ comments to Drug Policy Section of Ministry of AYUSH. The proposal may also be sent for the comments/ opinion of the eminent subject experts if required by the concerned Adviser of Ministry of AYUSH.

- The credential of the institutions/units will be verified by the respective State Govt./Council/Institution as indicated below:-

Component	Name of Research Council/Institution for credential verification
a. Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards	Ayush Vertical in CDSCO and or the State Govt. Authority
b. Pharmacovigilance	All India Institute of Ayurveda
c. Strengthening of Central and State regulatory frameworks including Technical Human Resource & Capacity Building programs for Ayush drugs.	Drug Policy Section, Ministry of Ayush and or the State Govt. Authority
d. Support for development of standards and accreditation/ certification of Ayush products & materials in collaboration with BIS, QCI and other relevant scientific institutions and industrial R&D centres.	PCIM&H, CCRH, CCRAS, CCRUM, CCRS

On the basis of the comments received from the concerned Adviser/Director General of the respective Research councils/Institution, the proposal if found suitable shall be placed before the PSC for further evaluation.

5.2.1 Project Appraisal Committee (PAC)

The proposals shall be screened by the PAC which shall be common for all components under this scheme and would comprise of the following:

1.	JS (AYUSH)/Advisor, Drug Policy Section, Ministry of AYUSH	Chairperson
2.	One expert from AIIA nominated by the Secretary (AYUSH)	Member
3.	One expert from PCIM&H/BIS/QCI(to be nominated by the Secretary (AYUSH)	Member
4.	Director Generals /Directors of the Concerned Council or his nominee (not below the rank of DD)	Member
5.	One representative of Department of Industrial Policy and Promotion	Member
6.	Adv./Jt. Adv./Dy. Adv. of all disciplines of AYUSH	Member
7.	Two co-opted member from Ayush vertical under CDSCO (to be co-opted by Chairperson)	Member
8.	Under Secretary of Drug Policy Section dealing with the Scheme	Member Secretary

5.2.2 The function of Project Appraisal Committee (PAC)

- Call for the applicants to explain their proposals in person/through video conferencing.
- Invite comments from the expert(s) in the concerned field.
- Ask the applicants to modify their proposals (as per observations of the Committee).

- Recommend the proposal to PSC for consideration and approval.
- Return back the proposal to the applicant highlighting their deficiencies, with instructions to re-submit the proposals after fulfilling the shortcoming.
- Reject the proposal.
- Give extension of ongoing project for one year without any financial assistance.
- Evaluate progress and achievement-cum-performance reports, Utilization Certificates for making recommendations for release of subsequent installments of the approved funds.
- The PAC shall meet at least once in six months provided fresh proposals and progress reports are fit for appraisal and evaluation.
- Recommend specific deliverables to be achieved by the applicant.

5.2.3 The PAC, after thorough evaluation of the technical as well as financial aspects of the proposals will forward the recommended proposals to the PSC for consideration, approval and sanction of funds.

5.2.4 The work done by the Institution/Unit funded will also be periodically reviewed by PAC. The PAC will also approve the subsequent installments.

5.3 Project Sanctioning Committee (PSC)

Project Sanctioning Committee chaired by the Secretary, Ministry of AYUSH, would consider the proposals recommended by the PAC for acceptance. The PSC would comprise as under:-

1.	Secretary (AYUSH)	Chairperson
2.	Chairperson of PAC	Member
3.	Financial Adviser or his/her representative (not below the rank of DS)	Member
4.	Adviser/Joint Adviser/Deputy Adviser of all disciplines of AYUSH	Member
5.	Director/Director General AIIA, PCIM&H, Research Council	Member
6.	Deputy Drug Controller Ayush	Member
7.	Under Secretary of Drug Policy Section dealing with the Scheme	Member Secretary

5.3.1 The Chairperson of the PSC may invite other specialist(s) to attend the meeting of the PSC to give their expert views on the project proposals. The decision of the PSC in respect of approval of the project (s) and sanction/release of funds shall be final.

The PSC will approve the specific deliverable before it is conveyed to the applicant agency. In case the applicant agency desires to change any of the deliverables then the power to approve the change will lie with the Project Sanctioning Committee.

6. DURATION OF THE SCHEME:

The Scheme is currently valid up to 31.03.2026 and would be extended further after approval of the competent authority.

7. MANAGEMENT OF THE SCHEME:

The Scheme would be implemented, managed, monitored and operationalized by the Program Management Unit (PMU), established in the Ministry of AYUSH, New Delhi, with adequate Manpower both Technical & Admn. etc. Details of PMU are enclosed at Annex. '1 (a)'.

The PMU staff will be engaged from the open market on contractual basis or outsourcing by the Administration of Ministry of Ayush and the expenditure on their salary will be met out of admissible administrative and managerial cost for the scheme.

Changes in the number of staffs will be made as per need basis.

8. MONITORING MECHANISM:

a) The status of project implementation will be verified by a Monitoring Committee constituted by the Ministry of AYUSH. The Monitoring Committee shall consist of representatives of Ministry of AYUSH, State Government and Central Ayush Research Council or National Institute and submit the report of project implementation on half yearly basis by physical verification of the site. In no case monitoring visit will be conducted by less than two members of the Monitoring Committee.

b) Concerned State / UT Government where the project is implemented under the scheme will be involved in the monitoring of the project by nominating a representative officer in the Monitoring Committee.

c) Up to 5% of the approved cost of the project may be utilized for monitoring of the project and concurrent evaluation.

Annexure I (a)

Program Management Unit (PMU)

S. No	Name of the post	No. of Posts	Monthly remuneration (in Rs.)	Age limit	Qualification
1.	Program Manager (Technical)	01	50,000/- provision of annual enhancement of 5% based on satisfactory performance to be decided by the Competent authority	Not exceeding 50 years on the date of advertisement in the newspapers	Essential Qualification: Graduation in any of Ayurveda, Siddha, Unani and Homoeopathy system from an institution/ university recognized under NCISM/NCH Act, 2020 or IMCC Act, 1970 / HCC Act, 1973 and have enrolled in the State Register for ISM / Homoeopathy.

					<p>Desirable:</p> <p>i. Having experience of working in any State Department/ Ministry/ Research Councils/ Public Sector Undertakings for 3 years.</p> <p>ii. Postgraduate degree in any of Ayurveda, Siddha, Unani and Homoeopathy system.</p>
2.	Program Manager (Administrative)	01	50000/- provision of annual enhancement of 5% based on satisfactory performance to be decided by the Competent authority	Not exceeding 50 years on the date of advertisement in the newspapers	<p>Essential Qualification: MBA (Hospital Administration)</p> <p>Desirable: Having experience of working in any State department/ Ministry/ Research Councils/ Public Sector Undertakings for 2 years preferably in the field of hospital administration.</p>
3.	Program Manager (Accounts)	01	50000/- provision of annual enhancement of 5% based on satisfactory performance to be decided by the Competent authority	Not exceeding 50 years on the date of advertisement in the newspapers	<p>Essential Qualifications: B.Com (Finance).</p> <p>Desirable: Having experience of working in any State department/ Ministry/ Research Councils/ Public Sector Undertakings for 3 years.</p>
4.	Data Assistant/ Data Entry Operator	02	20000/- provision of annual enhancement of 5% based on satisfactory performance to be decided by the Competent authority	Not exceeding 40 years on the date of advertisement in the newspapers	<p>Essential Qualification:</p> <p>i. Graduation from recognized institute or University with sound knowledge of Computer Application/ IT.</p> <p>ii. Knowledge of MS Office, MS Word, MS Power Point and MS Excel and other computer applications.</p> <p>iii. Having good typing speed i.e. 35 words per minute in English and 30 words per minute in Hindi</p>

N.B. TDS and other taxes will be levied as applicable.

General terms and conditions of man-power engagement:

- The appointment of all categories of staff would be made initially for one year and extended by specific orders for such period as may be necessary, but not exceeding one year at a time.
- Appointment will be of temporary and contractual nature for a maximum period of the duration of the scheme.
- The personnel will have no claim for regular/permanent appointment under the Research Councils / Ministry of AYUSH or the Grantee Institution on completion of the period of appointment.
- Dearness Allowance (DA) and City Compensatory Allowance (CCA) are not admissible to any category of staff employed under the Scheme.
- HRA to staffs are not admissible under the scheme.
- Staff will be eligible for the Casual Leave. However, Maternity Leave will be given to female staff as per rule of Govt. of India.
- Bonus, L.T.C and Retirement benefits are not admissible to staff employed for the scheme.

9. EXPENDITURE:

All recurring and non-recurring items under the scheme should be purchased in accordance with the procedures and guidelines of the State Government (for State Government, Private and Non-Governmental Institutions/Units) or those of the Central Government (in case of Central Government Institutions/Units). For permanent and semi-permanent assets acquired solely or mainly out of the grant, the grantee institute shall maintain a separate audited record in the form of register such as cash book, asset register, paid bills, bank statements and bank accounts, etc. The term "assets" means moveable property where the value exceeds Rs.1000/-. Separate assets registers may be maintained.

9.1 Non-Recurring Expenditure:

Essential scientific equipment including computer and software, if needed, may be permitted as non-recurring expenditure. However, the quantum of such expenditure will not be more than 10% of the total cost of salary. The equipment will become the property of the grantee institution(s) after successful completion of the project. Books purchased out of the contingencies may be retained by the grantee institution(s) after successful completion of the project.

It shall be ensured that the estimate of expenditure under equipment, books, software, etc of the required project is sought in the first year itself.

9.2 Recurring Expenditure:

The expenditure of recurring nature such as raw materials, reagents, chemicals, glassware, cost of investigations, testing, stationeries, postage, printing, photocopying, etc. may be allowed to be purchased as a part of the recurring contingencies. However, the quantum of such expenditure will not be more than 20% of the total cost of salary.

9.3 Guidelines for incurring expenditure (both recurring and non-recurring)

The grant can be utilized for purposes like, but not limited to:

1. Acquisition of books, in case these are not available in the library.
2. Chemicals/Consumable items required solely for testing purpose.
3. Charges for specialized investigations for which facilities do not exist in the grantee institutions.
4. Data entry charges.
5. Printing of reports, forms, etc.
6. Computer utilities, charges for analysis of data.
7. Typing and printing of reports.
8. Communication charges

The grant cannot be used for purchase of furniture items, office equipment's such as telephone, fax machine, photocopiers, etc.

9.4 Utilization of Travel grant:

The funds earmarked under TA/DA can be utilized, for travel within the country, by the staff working on the scheme for the following purposes:

- Taking up field work/travel connected with the research work.
- Visiting the Ministry of AYUSH for meetings related to the scheme.
- Attending a training course/seminar/conference/workshop related to the scheme.
- The travel grant cannot be used for foreign travel.

In utilization of Travel Grant, TA/DA should be as per the rules and guidelines for entitlement as prescribed by the State Government (for State Government, Private and Non-Governmental Organisations/Institutions) or those of the Central Government (in case of Central Government Organisations).

10. RELEASE OF FUNDS:

The approved grant will be released in the name of the Head of the Institution as yearly installments through PFMS only. All the units/institutes have to register/ open account in PFMS to avail funds. The first installment will be released along with the sanction letter, which would include the entire grant for purchase of equipment and books, and recurring grant for first year. The subsequent installment can be claimed on having utilization of 75% the previous installment subject to special permission of Ministry of Finance. The 2nd/3rd installment(s) would be released subject to the satisfactory progress of the project,

report of monitoring committee and timely receipt of the following documents in the prescribed format:-

- Annual Progress Report (**as per Annexure 1b**)
- No Financial Assistance Certificate (**as per Annexure-1c**)
- Statement of expenditure and Utilization Certificate (**Annexure 1d,1e**) in original, duly signed by the Head of the Institution and the Auditor;
- A certificate of actual utilization of the grants received for the purpose for which it was sanctioned in Form GFR 12A/12B/12C (whichever is applicable as per General Financial Rules issued by Ministry of Finance, Department of Expenditure from time to time) should be submitted in order to sanction of further grant-in-aid.
- Mid-term appraisal by monitoring committee or expert(s).
- 20% of the approved project cost of the project will be held back till the receipt and acceptance of final Report & the deliverables.
- This 20% will be released in 2 parts i.e. 10% after acceptance of final report & remaining 10% after receipt of the UC along with audited statement of accounts.

ANNEXURE- 1(b)

FORMAT FOR PROGRESS REPORT

1. Project title
2. Name and address of grantee institute
3. Date of start
4. Duration
5. Objectives of the proposal
6. Interim modification of proposal, if any (with justifications)
7. Summary on progress (during the period of report)
8. Milestones with deliverables achieved during the reporting period as proposed in the scheme
9. Applied value of the project
10. Work which remains to be done under the project
11. If additional budget or staff is required for the remaining part of the work, please give justifications and details.

Date: _____ Signature of Head/authorized signatory of the Grantee Unit/Institute

ANNEXURE-1(c)

**NO FINANCIAL ASSISTANCE CERTIFICATE
(To be submitted on Institution letter head)**

This is certify that no financial assistance has been received from any other Department of Central or State Government/Organisation/Institutions etc. for the project entitled(Name of the Project).... to (Name of the grantee unit/Institute).

Signature of Head of the Institution with date & Seal	
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ANNEXURE- 1(d)

Format for Annual Statement of Accounts to accompany request for release of next installment. (Year means Financial Year i.e. 1st April to 31st March of next year)

1. Sanction letter No. :
2. Total Project Cost : Rs.....
3. Sanction /Revised Project cost(if applicable) : Rs.....
4. Date of Commencement of Project :.....
5. Statement of Expenditure :.....

S. No.	Sanctioned /Heads	Funds Allocated	Expenditure Incurred			Balance as on (Date)	Requirement of Funds up to 31 st March	Remarks
			1 st year	2 nd Year	3 rd Year			
1	Salary							
2	Equipments							
3	Books							
4	Other Non-Recurring Expenditure							
5	Recurring Expenditure							
6	TA/DA							

7	Institutional Support							
9	Miscellaneous expenses							
10	Total							

Signature of Head of Institution with date& Seal	Signature of Authorized Auditor with date& Seal
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ANNEXURE-1(e)

Check list for covering note to accompany Utilization Certificate of grant for the project for the period ending 31st March, 20 __)

- 1) Title of the project
- 2) Name of the Institutions
- 3) Ministry of AYUSH letter No. and date sanctioning the project.
- 4) Head of account as given in the original sanction letter
- 5) Amount received during the financial year (Please give No. and date of Ministry's sanction letter for the amount)
- 6) Total amount that was available for expenditure (excluding commitments) during the financial year (including amount remaining from earlier installment)
- 7) Actual expenditure (excluding commitments) incurred during the financial year (upto 31st March).
- 8) Balance amount available at the end of the financial year.
- 9) Amount already committed, if any.

A. OPERATIONAL GUIDELINES OF STRENGTHENING AND UPGRADATION OF AYUSH PHARMACIES AND DRUG TESTING LABORATORIES TO ACHIEVE HIGHER STANDARDS.

The quality control of ASU&H drugs component of National Ayush Mission has now been merged into the present scheme of AOGUSY. In the earlier scheme each State Govt was provided financial assistance for testing of ASU&H drug samples. Requirement of In house testing laboratories is prescribed under Drugs and Cosmetics Rules, 1945, Schedule T for the GMP of ASU Manufacturing units and Schedule M1 for Homoeopathy drugs manufacturing units. The units which doesn't have such facilities are allowed to get their drugs tested from approved laboratories for the purpose. Also, as per rule 161B of Drugs and Cosmetics Rules, 1945, stability study data has been made as mandatory requirement for license since 2019. Whereas it is noted that more than 80% of the AYUSH industries falls under the category of micro and small enterprise and they fail to achieve these requirements.

Ministry of Ayush also advocates that AYUSH manufactures should have in-house drug testing laboratories duly approved by the National Accreditation Board for Testing and Calibration Laboratories and also to ensure stringent practicing of WHO prescribed Good Manufacturing Practices (GMP). Ministry is also making constant efforts for increasing the number of Drug Testing Laboratories and Drug Standardization Research Centers for assurance of quality drugs. While the present Central Sector Scheme of AOGUSY is intended to increase the standards of AYUSH Pharmacies and DTLs to WHO-GMP and NABL levels respectively; the quality of the products will only be assured with increased testing and stability study of the drugs in such sophisticated labs.

A1. Eligibility and Funding Pattern

Eligibility Criteria	Funding Pattern	Deliverables/ Expected Outcome
<p>State Govt./U.T.'s ASU&H Pharmacies/State ASU&H Cooperatives, State Govt. ASU&H PSUs</p> <p>i. The Pharmacy should be licensed under Drugs and Cosmetics Act, 1940 and Rules, 1945 and GMP certified.</p> <p>ii. The firms which do not have GMP certification can obtain certification through this scheme.</p> <p>iii. Priority will be given to those Government Pharmacies which were not granted funds in the</p>	<p>For Govt Pharmacies/PSUs: upto Rs. 6.00 crore for strengthening infrastructure & technology up-gradation and meeting associated recurring costs in the ratio of 70:30%.</p> <p>70% of the project cost (Rs. 4.20.cr) is for Non recurring expenditure and will be granted in 30:40:30 ratios in 2-3 instalments over five years on submission of utilization certificates.</p> <p>Non Recurring expenditure</p>	<p>Upgraded Pharmacy in terms of technology used and quantum of production.</p> <p>In turn such upgraded certified companies will encourage loan licensee applicants to avail the world class facilities at the rate BEC (Break Even Cost of Production) and 50% upon it for availing such facilities.</p>

<p>earlier schemes due to non availability of funds/could not consider submitted proposals due to technical reasons. Such firms will apply afresh and they will be kept in priority/ consideration zone.</p> <p>iv. Other Government Pharmacies which were supported funds but not to the full of the capping money in the earlier schemes will be considered to grant funds short to the capping level.</p> <p>v. ASU&H Pharmacies which have availed grant under old scheme will also be eligible for additional amount as per the revised new scheme provided they have fully utilized earlier grant sanctioned to them and provide work completion certificate from the concerned agency along with photographs of the work.</p> <p>vi. Existing Pharmacy should provide the Number of medicines manufactured during last three years with their batch capacity and number of batches produced per year for further grant under the scheme.</p> <p>vii. Applicant Pharmacies should demand rationale machinery technology and infrastructure which matches with their existing infrastructures for further strengthening of the pharmacy.</p> <p>viii. Application will be as per Format A1</p>	<p>covers:</p> <ol style="list-style-type: none"> 1. Building construction, renovation/modification of premises. 2. Machinery and Equipments for higher production and upgradation of technology. 3. For manufacturing new product line/new dosage forms. <p>Remaining 30% of the funds (i.e. Rs. 1.80 cr) meant for recurring expenditure will be released over five years. With an annual limit of Rs. 36.00 lakhs.</p> <p>Recurring funds to units also availing non recurring fund under the present scheme will be eligible only on completion of infrastructure or up gradation related works.</p> <p>Recurring expenditure covers:</p> <ol style="list-style-type: none"> 1. Contractual manpower as per quantum of work. 2. Raw materials, Chemicals, Reagents. 3. AMC of equipments which are funded under the scheme. 4. Packing materials and printing of labels. 5. Testing Charges. 6. Only 10% of the recurring expenditure can be used for any other consumables. 	<p>Facilities should be extended on end-to-end basis from processing to packaging of the products.</p>
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Eligibility Criteria	Funding Pattern	Deliverables/ Expected Outcome
<p>State./U.T. Govt ASU&H Drug Testing Laboratories Government and Research Councilslaboratories.</p> <p>i. The Drug Testing Laboratory should be licensed under Drugs and Cosmetics Act, 1940 and Rules, 1945.</p> <p>ii. Priority will be given to those Government DTLs which were not granted funds in the earlier schemes due to non availability of funds/could not consider submitted proposals due to technical reasons. Such laboratories will apply afresh and they will be kept in priority/consideration zone.</p> <p>iii. Other DTLs which were supported funds but not to the full of the capping money in the earlier schemes will be considered to grant funds short to the capping level.</p> <p>iv. ASU&H Drug Testing Laboratories which have availed grant under old scheme will also be eligible for additional amount as per the revised new scheme provided they have fully utilized earlier grant sanctioned to them and provide work completion certificate from the concerned agency along with photographs of the work and is functional.</p> <p>v. Existing ASU&H DTLs are required to provide number of ASU&H drug samples tested during last three years with number of samples passed/failed reports.</p> <p>vi. The Laboratory should have a Scientific Officer from AYUSH</p>	<p>Upto Rs. 3.00 crore for strengthening infrastructure & technology up-gradation to acquire NABL accreditation and meeting recurring costs of chemicals & reagents, consumables and technical manpower in the ratio of 70: 30%.</p> <p>70% of the project cost (Rs. 2.10 cr) is for Non recurring expenditure and will be granted in 30: 40:30 ratios in 2-3 instalments over five years on arrival of equipments in the lab, execution and installation of equipments and commissioning and functioning of the equipment.</p> <p>Non Recurring expenditure covers: 1. Addition of section in the existing building/renovation. 2. Equipments for achieving higher standards/upgradation of technology.</p> <p>Remaining 30% of the funds (i.e. Rs. 90.00 lakhs) meant for recurring expenditure will be released over five years. With an annual limit of Rs. 18.00 lakhs.</p> <p>Recurring funds to units also availing non recurring fund under the present scheme will be eligible only on completion of infrastructure or up gradation related works.</p> <p>Recurring expenditure</p>	<p>a) Labs should be fully equipped to carry out each and every test as per the list given in the API from time to time.</p> <p>b) Labs should follow NABL Guidelines & get accredited as 'NABL' in stipulated time-frame.</p> <p>c) Labs would provide their service at rates approved by AYUSH and expected to follow FIFO system (first in first out).</p> <p>d) Labs must also prepare to participate in calibration and harmonization programmes from time to time that would guarantee reliable results.</p> <p>e) Labs would be ready to participate in network research programmes initiated by Pharmacopoeia Committees, NMPB and Research Council from time to time.</p> <p>f) Labs would mask and share their test data for a National Survey and study as may be deemed fit by AYUSH.</p> <p>g) Labs would register and upload their tests report data and other details on the e-aushadhi portal.</p>

<p>stream and a notified Government Analyst.</p> <p>vii. DTLs of only that State/UT will be funded where there is functional ASU&H Pharmacy.</p> <p>viii. Applicant Laboratories should demand rationale equipments and infrastructure which matches with their existing infrastructures for further strengthening of the laboratory and to upgrade for NABL accreditation.</p> <p>ix. The equipments/instruments are allowed as per the list to purchase annexed as Annexure 2</p> <p>x. Application will be as per Format A2</p>	<p>covers 1. Upto 10 Contractual Technical manpower.</p> <p>2. Chemicals and Reagents.</p> <p>3. AMC of equipments which are funded under the scheme.</p> <p>4. Only 10% of the recurring expenditure can be used for any other consumables.</p>	
Eligibility Criteria	Funding Pattern	Deliverables/ Expected Outcome
<p>Private ASU&H Pharmacies</p> <p>i. The Pharmacy should be licensed under Drugs and Cosmetics Act, 1940 and Rules, 1945 and holding valid manufacturing license and GMP certificates for last ten years.</p> <p>ii. The firm should have total turnover of minimum ten crores from the date of their inception to the date of application.</p> <p>iii. The premises and the available machinery and equipments and utility bills should be in the name of the applicant/firm.</p> <p>iv. Pharmacies having other ASU&H Pharmacies within the vicinity or at arm's length will be given preference under this scheme.</p>	<p>Private manufacturing units will be supported with 50% of the project cost limited to Rs. 3.00 crore for equipment, machinery and scientific instruments to achieve higher standards of GMP (like WHO-GMP, cGMP, EU-GMP).</p> <p>List of Equipments and Infrastructure for upgradation of ASU manufacturing units for International competitiveness is placed at Annexure 1.</p> <p>a) Only machinery and electronic Management Information System (MIS) required for upgrading a schedule T or Schedule M1 plant into a WHO-GMP i.e., machinery to meet the gap only are to be</p>	<p>i. All beneficiary, to whom benefit of this scheme is extended, must obtain WHO-GMP certification within 2 and 1/2 years from the date of first disbursement of Grant in Aid.</p> <p>ii. In turn such upgraded certified companies will encourage loan licensee applicants to avail the world class facilities at the rate BEC (Break Even Cost of Production) and 50% upon it for availing such facilities.</p> <p>iii. Facilities should be extended on end-to-</p>

<p>v. Application will be as per Format A3</p>	<p>considered.</p> <p>b) An indicative list of such equipment categories is Annexed. This list would be updated from time to time, based on the recommendations of Ayush Vertical in CDSCO, depending on the requirement of the Ayush industry under the WHO-GMP norms.</p> <p>c) Under the Scheme, procurement of only new machinery will be permitted,</p>	<p>end basis i.e. from processing to packaging of the products.</p>
<p>Eligibility Criteria</p>	<p>Funding Pattern</p>	<p>Deliverables/ Expected Outcome</p>
<p>Private ASU&H Drug Testing Laboratories/in house Quality Control Lab of GMP certified ASU&H manufacturing units.</p> <p>i. The Laboratory having valid ASU&H drug testing license for last five years and not holding NABL.</p> <p>ii. The premises and the available machinery and equipments and utility bills should be in the name of the applicant/firm.</p> <p>iii. The laboratory should have an AYUSH stream scientific officer appointed on regular basis.</p> <p>iv. Existing ASU&H DTLs are required to provide number of ASU&H drug samples tested during last three years with number of samples passed/failed reports.</p> <p>v. DTLs of only that State/UT will be funded where there is functional ASU&H Pharmacy.</p> <p>vi. Applicant Laboratories should</p>	<p>Private ASU&H Laboratories will be supported with 50% of the project cost limited to Rs. 1.50 crore for acquiring scientific equipment and instruments for NABL accreditation.</p> <p>All above grants would be for Capital Expenditure for purchase of instruments and equipment only and not towards other laboratory infrastructure including furniture and fixtures.</p>	<p>a) Labs should be fully equipped to carry out each and every test as per the list given in the API from time to time.</p> <p>b) Labs should follow NABL Guidelines & get accredited as 'NABL' in stipulated time-frame.</p> <p>c) Labs would provide their service at rates approved by AYUSH and expected to follow FIFO system (first in first out).</p> <p>d) Labs must also prepare to participate in calibration and harmonization programmes from time to time that would guarantee reliable results.</p> <p>e) Labs would be ready to participate in network research programmes initiated by Pharmacopoeia Committees, NMPB</p>

<p>demand rationale equipments and infrastructure which matches with their existing infrastructures to upgrade for NABL accreditation.</p> <p>vii. The equipments/instruments are allowed as per the list to purchase annexed as Annexure 2</p> <p>viii. Application will be as per FormatA4</p>		<p>and Research Council from time to time.</p> <p>f) Labs would mask and share their test data for a National Survey and study as may be deemed fit by AYUSH.</p> <p>g) Labs would register and upload their tests report data and other details on the e-aushadhi portal.</p>
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A2. Mode of Application for Grant-In-Aid:

Ministry of AYUSH, shall invite proposals from the GMP compliant Industries and/or Licensed Drug Testing Laboratory of ASU&H drugs both in public & private sector for grants-in-aid, under the scheme and also through open advertisement placed in the National dailies, twice a year (First in the month of January and Second in the month of July). The advertisement would also be placed on the website of the Ministry of AYUSH/ e-aushadhi websites.

Application shall be submitted both in hard and soft version (in PDF / word files). The soft copy should be emailed at the designated Email ID of Drug Policy Section, Ministry of AYUSH on the following address:-dcc-ayush@nic.in.

A3. Administration & Monitoring Mechanism of the Scheme:

State/UT Government where Scheme is implemented will be involved in the monitoring of the Scheme. For this Purpose the committee should be constituted comprising the following members:-

- a. One Representative of State Government/Drug Controller AYUSH
- b. One representative from Ministry of AYUSH at the level of Deputy Advisor/Assistant Advisor (Ay./S/U/H) dealing with Drugs.

The monitoring committee will submit their report to the Ministry on half yearly basis. In no case monitoring visit will be conducted by less than two members of the monitoring committee.

A4. Structure of Proposals

Along with the application in prescribed format, a concept note of the proposal may be submitted clearly defining the objectives, action plan, milestones, and modalities of implementation, measurable outcomes and anticipated impact of intervention. The concept note should bring out the existing gaps, intended interventions with timelines, expenditure estimates and the applicant's contribution in rearing the project.

ANNEXURE 1

EQUIPMENT CATEGORIES REQUIRED FOR UPGRADATION OF AN AYUSH MANUFACTURING UNIT FROM SCHEDULE T/SCHEDULE M1 TO WHO-GMP NORMS*

1. Up gradation of HVAC (Heating, Ventilation, and Air Conditioning) system to WHO norms i.e. HEPA (High-Efficiency Particulate Air filters) etc
2. Stability testing chambers.
3. All equipment & instruments for operating a Microbiology laboratory including autoclaves, incubators, biosafety cabinets, colony counters, HVAC systems.
4. All lab scale and pilot scale manufacturing equipment required for R&D development - formulation/bulk.
5. State-of- art lab equipment for testing as per Pharmacopeia not limiting to NMR, HPLC, HPTLC, IR Spectrophotometer, Atomic Absorption Photometers, GC, Electrophoresis, and Dissolution apparatus.
6. Water management and purification systems including Steam systems.
7. Automatic particle counters for sterile areas
8. Laboratory information management system

* The list is subject to requirements/changes in WHO-GMP regulatory compliance to be informed/provided by DCGI and/or AYUSH vertical under CDSCO from time to time.

ANNEXURE-2

EQUIPMENT CATEGORIES SUPPORTED UNDER THE SCHEME FOR DRUG TESTING LABORATORY FOR ASU&H

1.	Lab Oven
2.	pH Meter
3.	Hot Water Bath
4.	TLC Cabinet with Photo recording
5.	Microscope
6.	Refractometer
7.	Heating Mental 20lit
8.	Heating Mental 5lit
9.	Analytical Balance
10.	Glassware and chemicals
11.	Soxlet Apparatus
12.	Oil Estimation Apparatus
13.	Water Still
14.	Microtome
15.	TLC Chambers glass
16.	Research Microscope (Image Analyser)
17.	Image Analysier software snazzi

18.	Parrafin Bath
19.	FrameGrabber Analysis software
20.	Tablet Disintegration App
21.	Lab Stirrer
22.	Alcohol Estimation Apparatus
23.	Vortex Mixer
24.	Polarimeter
25.	Digital Muffel Furnace
26.	Magnetic Stirrer
27.	Digital Tablet Fairability Apparatus
28.	I.R Moisture Balance
29.	Orbital Shaker
30.	U.V Spectrophotometer
31.	computer,Battery,UPS etc for UV Spectro
32.	Laminar Flow
33.	Digital Colony Counter
34.	230ltrs Doubledoor Fridge
35.	Air Conditioners 1.5Ton
36.	Analytical Balance
37.	Lab Furniture
38.	Vertical Autoclave
39.	Digital Incubator
40.	AAS
41.	HPLC
42.	HPTLC
43.	Stability Chambers
	* The list is subject to requirements/changes in regulatory compliance/NABL accreditation to be informed/provided by NABL, DCGI and/or AYUSH vertical under CDSCO from time to time.

FORMAT-A1

APPLICATION FORM FOR GRANT IN AID TO STATE GOVT. ASU&H PHARMACIES/ STATE GOVT. ASU&H COOPERATIVES, STATE GOVT. ASU&H PSU'S.

1. Name and address of the State Government/Directorate of AYUSH (along with email, tel. No., fax no's.):
2. Name of the in-charge of the Pharmacy (with qualification)
3. Place of Pharmacy with full address:
4. Year of establishment of Pharmacy
5. Annual Budget
6. Covered area available for laboratory and various sections for Ayurveda, Siddha, Unani & Homoeopathy Pharmacy.
7. Provide geographical coordinates of the Unit.

8. Present activity of Pharmacy
9. Turnover of Pharmacy in last three years (also give details for the number of medicines manufactured during last three years with their batch capacity and number of batches produced per year)
10. Existing manpower (with designations & qualifications)
11. Details of major existing equipment/machineries (this may be furnished in details in separate sheet)
12. Requirement of funds from Central Government (please use separate sheet)
 - (a) Building (specify with justification & map):
 - (b) Equipment with specification and justification and approximate cost:
 - (c) Manpower (with qualifications and nature of duties):
13. Total fund requirement from Central Government for (a), (b) and (c).
14. Willingness of the State Directorate to run the Pharmacy after availing the Central Government assistance.
15. Please specify how the infrastructure created shall be used for the scheme.
- 16- Whether any assistance has been received from any other Department of Central/ State/UT Government for similar scheme. If so" please specify and attach a certificate.
17. How State Government Organization propose to increase annual turnover of Ayurveda,Siddha, Unani& Homoeopathy drugs.
18. How are the accounts of Organization being audited (Govt. Auditors/Chartered Accountant)
19. Name of the Schedule Bank where accounts are maintained
20. Names of two offices bearers responsible for jointly operating the accounts
21. Any other relevant information justifying the request for financial assistance under the Scheme.
22. No. of ASU&H drugs manufacturing units in the State.
23. Recommendation of the Director, Department of ASU&H State Government UTs or the Controlling Officer of the Organization.
24. In case of other institution - recommendation of Head of the institution / registrar of University.
25. Attach attested copy of license.

Signature,
Name, Designation of the Head of the Institution/Registrar of university
Tel/Fax No. with Office Seal

FORMAT-A2

APPLICATION FORM FOR GRANT IN AID TO STATE DRUG TESTING LABORATORIES OF AYURVEDA, SIDDHA, UNANI AND HOMOEOPATHY (ASU&H) DRUGS

1. Name and address of the State Government/Directorate of ISM&H (alongwith email, tel no., fax nos.) or other institution:
2. Name of the Incharge of the Lab. (with qualification)
3. Place of Laboratory with full address

4. Year of establishment of Laboratory
5. Annual Budget
6. Covered area available for laboratory and various sections for Ayurveda, Siddha, Unani & Homoeopathy Drug Testing.
7. Provide geographical coordinates of the Unit.
8. Present activity of laboratory
9. Types of tests performed with the number of samples per annum (give details for the last 3 years)
10. Existing manpower (with assignments & qualifications)
11. Details of major existing equipment/machineries (this may be furnished in details in separate sheet)
 - i) Requirement of funds from Central Government (please use separate sheet)
 - (a) Building (specify with justification & map):
 - (b) Equipment with specification and justification and approximate cost:
 - (c) Manpower (with qualifications and nature of duties):
12. Total fund requirement from Central Government for (a), (b) and (c).
13. Willingness of the State Directorate to run the DTL after availing the Central Government assistance
14. Please specify how the infrastructure created shall be used for the scheme
15. Whether any assistance has been received from any other Department of Central/ State/UT Government for similar scheme. If so, please specify and attach a certificate.
16. How State Government Organization propose to increase the number of sample Testing of Ayurveda, Siddha, Unani & Homoeopathy drugs.
17. How are the accounts of Organization being audited (Govt. Auditors/ Chartered Accountant)
18. Name of the Schedule Bank where accounts are maintained
19. Names of two office bearers responsible for jointly operating the accounts
20. Any other relevant information justifying the request for financial assistance under the Scheme.
21. No. of ASU&H drugs manufacturing units in the State.
22. Recommendation of the Director, Department of ISM&H' State Government UTs or the Controlling Officer of the Organization.
23. In case of other institution - recommendation of Head of the institution/registrar of University.
24. Attach attested copy of license

Signature,
Name,
Designation of the Head of the Institution/Registrar of university
Tel/Fax No. with Office Seal.

FORMAT – A3

APPLICATION FORM FOR PRIVATE AYUSH DRUG MANUFACTURERS TO AVAIL FINANCIAL INCENTIVE UNDER THE CENTRAL SCHEME.

1. Name of the manufacturing company:
2. Year of establishment:
3. Registered Address: **Provide geographical coordinates of the Unit.**

4. License No. and period of validity:
5. Phone Number with STD Code-
Fax Number with STD Code –
E-mail:-
6. Authorized Owner/Signatory of the Company:
7. Address, phone number etc of the authorized Owner/Signatory:
8. Abstract of Audited Income & Expenditure details of last three years:
9. Bank Account Number and address (attach blank cancelled cheque):
10. Name of the component for which financial incentive is sought:
11. Concept paper of the proposal may be enclosed giving relevant details of the objectives, action plan, milestones, timelines, cost implications & break up, company's contribution for the project, expected difference between baseline status and after implementation of the project:
12. Justification of the proposal in accordance with scheme guidelines:
13. Cost of the project indicating total implication:
 - (i) Company's contribution:
 - (ii) Amount of loan from any recognized financial source:
 - (iii) Amount of financial assistance sought under the scheme:
14. How many products are manufactured:
 - Total:
 - (i) Classical/Generic:
 - (ii) Patent/Proprietary:
15. Total turnover of the firm from the year of inception to the year of application:
16. Number and list of products exported/registered in foreign markets:
17. Attach list of available equipment, machinery etc. of the in-house Quality Control Laboratory,
18. Major achievements of the company in last three years :
19. Amount of investment by the company for the proposed component :
20. Expected clear cut measurable deliverables and outcomes from the project:
21. Whether any financial support received earlier from Department/Ministry of AYUSH, if so, furnish the details thereof :
22. Whether any financial assistance received from any other Central/State Government source, if yes, furnish details thereof:
23. Number of ASU&H pharmacies within 200 km radius of the firm.

24. Essential documents to be enclosed:

- (1) Concept paper of the proposal
- (2) Audited statements of Income & Expenditure for the last three years
- (3) Non-conviction certificate in original from the State Licensing Authority/Drug Controller issued within 15 days of the application.
- (4) Undertaking for not having availed/being availed of financial assistance for the same purpose from any other Central or State Government source.
- (5) Attested copy of the Manufacturing License
- (6) Attested copy of the GMP Certificate.
- (7) Utility Bills in the name of the applicant/firm
- (8) Self-certified Undertaking for abiding to the Terms & Conditions as specified in the format at **Annexure 3**.

Signature

(Name and Seal of the Owner / authorized signatory of the Company)

FORMAT – A4

APPLICATION FORM FOR PRIVATE AYUSH DRUG TESTING LABORATORY TO AVAIL FINANCIAL INCENTIVE UNDER THE CENTRAL SCHEME.

1. Name of the Drug Testing Laboratory: **also Provide geographical coordinates of the Unit.**
2. Registered Address:
3. License No. and period of validity:
4. Phone Number with STD Code-
Fax Number with STD Code –
E-mail:-
5. Authorized Owner/Signatory of the Laboratory:
6. Address, phone number etc of the authorized Owner/Signatory:
7. Abstract of Audited Income & Expenditure details of last three years:
8. Bank Account Number and address (attach blank cancelled cheque):
9. Name of the component for which financial incentive is sought:
10. Concept paper of the proposal may be enclosed giving relevant details of the objectives, action plan, milestones, timelines, cost implications & break up, company's contribution for the project, expected difference between baseline status and after implementation of the project:
11. Justification of the proposal in accordance with scheme guidelines:

12. Cost of the project indicating total implication:
 - (iv) Laboratory's contribution:
 - (v) Amount of loan from any recognized financial source:
 - (vi) Amount of financial assistance sought under the scheme:
13. Types of tests performed with number of samples per annum(give details for last 3 years with no. of samples passed/failed):

14. Attach list of available equipment, machinery etc. of the Laboratory,
15. Major achievements of the laboratory in last three years :
16. Amount of investment by the laboratory for the proposed component :
17. Expected clear cut measurable deliverables and outcomes from the project:
18. Whether any financial support received earlier from Department/Ministry of AYUSH, if so, furnish the details thereof :
19. Whether any financial assistance received from any other Central/State Government source, if yes, furnish details thereof:
20. Essential documents to be enclosed:
 - (9) Concept paper of the proposal
 - (10) Audited statements of Income & Expenditure for the last three years
 - (11) Non-conviction certificate in original from the State Licensing Authority/Drug Controller issued within 15 days of the application.
 - (12) Undertaking for not having availed/being availed of financial assistance for the same purpose from any other Central or State Government source.
 - (13) Attested copy of the License
 - (14) Attested copy of any accreditation already available with the laboratory.
 - (15) Self-certified Undertaking for abiding to the Terms & Conditions as specified in the format at **Annexure 3**.

Signature

(Name and Seal of the Owner / authorized signatory of the Laboratory)

Recommendation of the State /UT Government Department

Reference/Diary No.

It is certified that the particulars given above and the credentials of the applicant company/laboratory are verified and the proposal is recommended for consideration of grant of financial assistance in accordance with the central scheme guidelines.

Signature, Name and Seal of the Recommending Officer

Format of Certificate required along with Application from the owner/authorized signatory of the Ayurvedic/Siddha/Unani/Homoeopathy Drugs Manufacturing Company/Drug Testing Laboratory.

Certified that:

(a) The manufacturing company/ Drug Testing Laboratory named as..... shall abide by all the 'Terms and Conditions' issued by the Department of AYUSH, Government of India from time to time.

(b) All records and reports related to the project will be maintained separately and furnished as and when required by the Ministry of AYUSH or its authorized representatives.

(c) Project shall be open for evaluation of its physical progress and utilization of funds at the discretion of Ministry of AYUSH.

(d) The undersigned shall be responsible for the authenticity of the information & documents furnished in the application and proposal.

(e) Ministry of AYUSH shall have the right to recover the given financial support with 12% interest from the date of release of funds for any default or deviation from the terms & conditions of sanction of funds and may also take any other action as deem fit on the basis of facts and circumstances of the case.

(f) Separate accounts for the project will be maintained.

(g) To enable release of funds, an irrevocable and unconditional Bank Guarantee equivalent to the amount of grant to be sanctioned with the right to Central Government/Ministry of AYUSH to forfeit the same in case of default or deviation from the terms & conditions and a Bond valid for three years to abide by all terms & conditions as mentioned in the sanction letter and GFR, component wise approved project cost and year wise deliverables/outcomes to be achieved under the project, shall be furnished.

Signature

Name and Stamp of the Applicant

Phone No.....

Fax No.....

Email :-----

B. OPERATIONAL GUIDELINES OF PHARMACOVIGILANCE OF AYURVEDA, SIDDHA, UNANI AND HOMOEOPATHY DRUGS INCLUDING SURVEILLANCE OF MISLEADING ADVERTISEMENTS

This component aims at developing safety monitoring mechanism for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs and surveillance system to check the veracity of misleading advertisements of AYUSH.

B1. Background:-

i). Pharmacovigilance refers to a continuous post-marketing monitoring system to systematically document the safety profile of a medicine. As defined by the World Health Organization, Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse events or any other possible drug-related problems.

ii). The Ayurveda, Siddha, Unani and Homoeopathic drugs are regulated in the country in accordance with the exclusive provisions of the Drugs & Cosmetics Act, 1940 and Rules thereunder. Similarly, Sowa Rigpa drugs are yet to be brought under the regulatory control. The quality issues of these drugs are raised from various sources and it is felt necessary in the interest of public health to oversee the impact of ASU&H drugs consumed by the people from the prospective of their safety profile. Dissemination and advertisement of improper drug information is also a matter of concern that needs to be addressed with a systematic surveillance and regulatory action.

iii) In view of the above, it is intended to develop a system of safety monitoring and surveillance of adverse reactions and advertisements of ASU&H drugs. Accordingly, proposed scheme of Pharmacovigilance has been envisaged towards detection, assessment, understanding, prevention and regulatory action of adverse events and misleading advertisement of ASU&H drugs.

B2. Aims and Objectives of the Scheme:

The purpose of the Pharmacovigilance initiative for ASU&H drugs is to collect, collate and analyze data to establish evidence for clinical safety of the ASU&H drugs in a scientific manner for documenting clinical evidences of safety of these drugs and undertake surveillance of advertisements of these drugs or on these system of medicines

The scheme aims at- (i) inculcating the reporting culture among the consumers as well as ASU&H practitioners to facilitate documentation of Adverse Drug Reactions (ADRs) and instances of misleading advertisements of Ayurveda, Siddha, Unani & Homoeopathy drugs; (ii) developing a system-wise database of Adverse Drug Reactions of ASU & H drugs; and (iii) evolving evidence based recommendations regarding the clinical safety and improper advertisements of ASU&H drugs for regulatory actions.

B3. Structural Framework:-

A three tier structure comprising of a National Pharmacovigilance Co-ordination Centre (NPvCC), Intermediary Pharmacovigilance Centres (IPvCs) and Peripheral Pharmacovigilance Centres (PPvCs) have already been put up in place.

The All India Institute of Ayurveda (AIIA), New Delhi, is the National Pharmacovigilance Co-ordination Centre (NPvCC) for the implementation of the National Pharmacovigilance program for ASU&H drugs. The NPvCC receives inputs in terms of suspected ADRs from the Intermediary Pharmacovigilance Centres (IPvCs), which at present includes:

- i. National Institute of Ayurveda, Jaipur.
- ii. Institute of Post-Graduate Training and Research in Ayurveda (IPGT&RA), Jamnagar.
- iii. National Institute of Unani Medicine, Bengaluru.
- iv. National Institute of Siddha, Chennai.
- v. National Institute of Homoeopathy, Kolkata

and later on more such capable institutions can be identified and included as Intermediary Pharmacovigilance Centres (IPvCs). Peripheral Pharmacovigilance Centres (PPvCs) are being identified on the basis of their infrastructural and functional capability to take up the responsibility of safety monitoring of ASU&H drugs and reporting of their ADRs. The Peripheral Pharmacovigilance Centres (PPvCs) operate under the purview of concerned Intermediary Centre.

B4. Operational Guidelines:

a) The National Pharmacovigilance Co-ordination Centre (NPvCC) in consultation with the concerned Intermediary Pharmacovigilance Centre (IPvC) identify the Peripheral Pharmacovigilance Centres (PPvCs) on the basis of following criteria:

- i. AYUSH teaching hospital recognized under NCISM/NCH Act, 2020/ IMCC Act / HCC Act / similar Regulatory body; or NABH accredited / Government ASU&H healthcare facility, healthcare facilities of the Research Councils under Ministry of AYUSH;
- ii. Technical competence and wherewithal to undertake surveillance and reporting requirements;
- iii. Institutions / Organizations having credible outcomes on similar projects are given preference.
- iv. Any AYUSH institution that has obtained funding from any Ministry/ Department of the Central Government and UCs are settled and no adverse remarks are reported.

AYUSH institutions/centres fulfilling the above criteria can also apply to the concerned Intermediary Pharmacovigilance Centre (IPvC) for inclusion as Peripheral Pharmacovigilance Centres (PPvCs).

b) The National Pharmacovigilance Co-ordination Centre (NPvCC) as well as the Intermediary Pharmacovigilance Centres (IPvCs) also undertake documentation and reporting of the ADRs.

c) An Intermediary Pharmacovigilance Centre (IPvC) have 10-20 Peripheral Pharmacovigilance Centres (PPvCs) under its purview. The Intermediary Pharmacovigilance Centre (IPvC) receive the information through the Peripheral Pharmacovigilance Centre (PPvC) as well as directly from the consumers, practitioners, industry and other stakeholders regarding any suspected Adverse Drug Reactions in the prescribed format and regarding misleading advertisements of Ayurveda, Siddha, Unani and Homoeopathic drugs on regular periodicity. Each Intermediary Pharmacovigilance Centre (IPvC) shall co-ordinate and receive inputs from Peripheral Pharmacovigilance Centres (PPvCs) selected from amongst recognized educational institutions; licensed ASU&H pharmacies; or accredited / Government approved ASU&H healthcare facilities, hospitals, practitioners, and other stakeholders.

d) The National Pharmacovigilance Co-ordination Centre (NPvCC) will undertake the pharmacovigilance activities under the guidance and technical support of W.H.O. collaborating centre for Pharmacovigilance- Indian Pharmacopoeia Commission and concerned programme officers of the W.H.O. Country Office. The National Pharmacovigilance Co-ordination Centre (NPvCC) in consultation with the Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM&H), if required, shall conduct the Causality Assessment of the signals received from the Intermediary Pharmacovigilance Centres (IPvCs) and intimate the Ministry of AYUSH regarding confirmed ADRs to enable suitable action.

B5. Funding Pattern of the Scheme:

Financial assistance will be provided to the National Pharmacovigilance Co-ordination Centre (NPvCC) for implementing pharmacovigilance of ASU&H drugs, which in turn will disburse the required funds to the Intermediary Pharmacovigilance Centres (IPvCs) as well as the selected Peripheral Pharmacovigilance Centres (PPvCs) on approval of the project proposals on periodic intervals. Progress report and audited statement of expenditure shall be submitted by all centres to the National Pharmacovigilance Co-ordination Centre (NPvCC).

Pattern of Financial Assistance

Institution	Funding Pattern
National Pharmacovigilance Co-ordination Centre (NPvCC)-01	Programme Management Unit (PMU)
	Establishment Cost
	One time grant for establishment of a Pharmacovigilance Centre towards purchase of office equipment (@ Rs. 10,00,000/-)
	Recurring Cost
	Technical Programme Officer-02 MD (Ayurveda/ Siddha / Unani / Homoeopathy) (@ Rs.50,000/- per month/ Technical Programme Officer) provision of annual enhancement of 5% based on satisfactory performance to be decided by the Competent authority
	Data Entry Operator -01 Degree Qualification (@ Rs.15,000/- per month) provision of annual enhancement of 5% based on satisfactory performance to be decided by the Competent authority
	CMEs and Awareness Programs
	Organization of 2 to 3 Orientation workshops / CMEs at least twice in a year (@ Rs. 10,00,000/-)
	IEC Materials
	One time grant for preparation, publication and distribution of IEC material (electronic & print media) for spreading awareness about pharmacovigilance in ASU&H drugs (@ Rs. 5,00,000/-)
Contingency	
One time grant towards contingency (@ Rs. 5,00,000/-)	
Intermediary Pharmacovigilance Centres (IPvCs)-05	Programme Management Unit (PMU)
	Establishment Cost
	One time grant for establishment of a Pharmacovigilance Centre towards purchase of office equipment (@ Rs. 10,00,000/-per centre)
	Recurring Cost
	Programme Associate-01 MD (Ayurveda/ Siddha / Unani / Homoeopathy) (@ Rs.40,000/- per month) provision of annual enhancement of 5% based on satisfactory performance to be decided by the Competent authority.
Data Entry Operator -01 Degree Qualification	

	(@ Rs.12,000/- per month) provision of annual enhancement of 5% based on satisfactory performance to be decided by the Competent authority.
	CMEs and Awareness Programs
	Organization of 2 to 3 Orientation workshops / CMEs at least twice in a year (@ 5,00,000/-per centre)
	IEC Materials
	One time grant for preparation, publication and distribution of IEC material (electronic & print media) for spreading awareness about pharmacovigilance in ASU&H drugs (@ 2,00,000/-per centre)
	Contingency
	One time grant towards contingency (@ Rs. 2,00,000/-per centre)
Peripheral Pharmacovigilance Centres (PPvCs)	Programme Management Unit (PMU)
	Recurring Cost
	Programme Assistant-01 Graduate in Ayurveda/Unani/Siddha/Homoeopathy (@ Rs.25,000/- per month) provision of annual enhancement of 5% based on satisfactory performance to be decided by the Competent authority.
	Data Entry Operator -01 Degree Qualification (@ Rs.10,000/- per month) provision of annual enhancement of 5% based on satisfactory performance to be decided by the Competent authority.

Note: The remuneration of all the contractual staff appointed under the scheme would be reviewed as and when needed in consultation with the IFD.

B6. Structure of Proposals and Submission of Applications:

Along with the application for participating as a Peripheral Pharmacovigilance Centre (PPvC), a concept note of the proposal may be submitted to the Intermediary Pharmacovigilance Centre (IPvC). Such applications may be addressed to the Director of the Intermediary Pharmacovigilance Centre (IPvC) along with an Undertaking to the effect that physical and financial performance under the Pharmacovigilance initiative would be done in accordance with the approved norms and guidelines and documents & records as & when required would be submitted to the Intermediary Centre. The proposal must reflect clearly the available infrastructure in terms of space, equipments and manpower as well as the objectives, action plan, duration, mode of implementation; logistic requirements, milestones, deliverables & outcomes and broad budget breakup of the project as per the given funding pattern. The application should be forwarded with recommendation from the head of the applicant institution.

National Pharmacovigilance Co-ordination Centre (NPvCC) on receipt of applications from the Intermediary Pharmacovigilance Centres (IPvCs) along with their comments,

will examine the proposal for the suitability and eligibility of the institution to become a Peripheral Pharmacovigilance Centre (PPvC) and with the approval of the Project Sanctioning Committee of the Ministry of AYUSH, shall declare it as a Peripheral Pharmacovigilance Centre (PPvC) under the Pharmacovigilance programme for ASU&H drugs for functioning as per the prescribed requirements.

B7. Approval Process and release of funds:

Applications received under the scheme shall be processed at three levels as under:

Step-1

The National Pharmacovigilance Co-ordination Centre (NPvCC) will examine the proposals under the National Pharmacovigilance Program for ASU&H drugs. The proposal and concept note not found suitable as per the scheme's guidelines i.e. proposals with major deficiencies in terms of objectives and eligibility criteria would be rejected and the applicant would be informed accordingly. The proposals found suitable will be placed for the consideration of the Project Appraisal Committee (PAC).

Step-2

Proposals found suitable in the initial examination, would be considered by the PAC and if needed, the applicant organization would be called for making a presentation before the committee to explain the required details. The proposals with clearly defined deliverables, budgetary details and other requisite information would be recommended for consideration of the Project Sanctioning Committee (PSC).

Step-3

The proposals recommended by the PAC would be considered by the PSC for final approval and sanction. Installments of the sanctioned grant would be released only after liquidation of the Utilization Certificate of previous installment and acceptance of Annual Performance Report and approval of the PSC and the Integrated Finance Division (IFD) of the Ministry.

B8. Monitoring Mechanism:

To monitor the implementation of the scheme, the component may be evaluated by the third party being appointed for the same by Planning and Evaluation Section of the Ministry of AYUSH. The National Pharmacovigilance Co-ordination Centre (NPvCC) will establish key indicators to measure the efficiency of (i) process (ii) outcome and (iii) impact of the programme.

i. Process Indicators:

- a. Number of ADR monitoring centers participating in the National Pharmacovigilance programme for ASU&H drugs and the surveillance of advertisements of ASU&H drugs and practices
- b. Number of personnel trained in ADR Monitoring and surveillance of advertisements of ASU&H drugs and practices
- c. Funds budgeted for Pharmacovigilance Programme of ASU&H Drugs and funds spent

ii. Outcome Indicators:

- a. Number of ADR reports received in a year
- b. Number of ADR reports processed in a year
- c. Number of misleading advertisements of ASU&H drugs and practices reported and processed in a year

iii. Impact Indicators:

- a. Number of signals generated and confirmed
- b. Number of safety related alerts issued by the Ministry of AYUSH
- c. Number of misleading advertisements of ASU&H drugs and practices rectified or withdrawn

B9. Management of the Scheme:

Ministry of AYUSH as PMU will engage a Programme Manager, a Programme Assistant and a Data Entry Operator on contractual basis for the administration of the scheme (as per the qualifications mentioned vide Annexure 1a of the scheme), for processing of proposals and related matters. The remuneration of all the staff appointed under the scheme would be reviewed as and when needed in consultation with the IFD.

B10. Responsibilities of the Pharmacovigilance Centres:

National Pharmacovigilance Co-ordination Centre (NPvCC):

The NPvCC shall-

- (i). Document and monitor the ADRs of ASU&H drugs
- (ii). Seek Periodic Safety Update Reports (PSURs) from the ASU&H drug manufacturing companies for all the Patent & Proprietary (P&P) drugs
- (iii). Shall organize awareness building and capacity building workshops for the stakeholders
- (iv). Scrutinize the project proposals of the Peripheral Pharmacovigilance Centres (PPvCs) in consultation with the concerned Intermediary Pharmacovigilance Centre (IPvC)
- (v). Conduct the causality assessment for all the signals regarding the ADRs of ASU&H drugs received from NPvCC, IPvCs as well as PPvCs for recommending necessary regulatory action by the Ministry of AYUSH
- (vi). Provide information to the end users through seminars, drug alerts and other means.
- (vii). Submit Annual proposals and the Supplementary proposals for seeking approval of the PAC and PSC.

Intermediary Pharmacovigilance Centres (IPvCs):

The IPvCs of the respective systems (Ayurveda/ Siddha/ Unani/ Homoeopathy) shall-

- (i). Document and monitor the ADRs of ASU&H drugs
- (ii). Collect the information regarding the ADRs of ASU&H drugs from the respective Peripheral Pharmacovigilance Centres (PPvCs)
- (iii). Report the ADRs of ASU&H drugs to the National Pharmacovigilance Centre (NPvCC) at regular intervals for causality assessment
- (iv). Organize awareness building and capacity building workshops for the stakeholders

(v). Scrutinize the project proposals received from the Peripheral Pharmacovigilance Centres (PPvCs) and forward the same to the National Pharmacovigilance Centre (NPvCC) along with comments.

Peripheral Pharmacovigilance Centres (PPvCs):

The IPvCs of the respective systems (Ayurveda/ Siddha/Unani/Homoeopathy) shall-

- (i). Document and monitor the ADRs of ASU&H drugs
- (ii). Report the ADRs of ASU&H drugs to the concerned Intermediary Pharmacovigilance Centre (IPvC) at regular intervals
- (iii). Report misleading advertisements to the higher centre and also to the concerned State licensing authority and submit the action taken report of the same monthly.

In reference to the orders of the Government of India, Ministry of Finance, Department of Economic Affairs vide OM No. F.1 (8)-B (AC)/ 2017 dated 21st March, 2017, out of the allocated budget under the present scheme, ten percent (10%) of the amount would be used for infrastructure, manpower, consumables, awareness campaigns and other activities to accomplish the objectives of the Swachhta Action Plan.

C. OPERATIONAL GUIDELINES STRENGTHENING OF CENTRAL AND STATE REGULATORY FRAMEWORKS INCLUDING TECHNICAL HUMAN RESOURCE & CAPACITY BUILDING PROGRAMS FOR AYUSH DRUGS.

Ayush Vertical has been established in CDSCO as a part of central regulatory framework for ASU&H drugs since February 2018 and Nine regulatory posts of 04 Drug Inspectors, 04 Assistant Drug Controllers and 01 Deputy Drug Controller has been created for regulation of Ayurvedic, Siddha, Unani and Homoeopathy drugs at central level and will manage the AYUSH Vertical in CDSCO in terms of implementation of the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 pertaining to ASU&H drugs and associated matters.

With a view to encourage further strengthening ASU&H Drug Control Framework in the Centre and States, it is proposed to provide an annual financial assistance for trainings, workshops, computerization, data management, infrastructure and strengthening of regulatory framework for ASU&H drugs.

Eligibility Criteria	Funding Pattern
<p>AYUSH vertical in CDSCO</p>	<p>Funding of Central Regulatory Framework of ASU&H drugs shall be for payment of professional charges, conduct of capacity building programs, training programs as per approved norms, documentation, publication and dissemination of quality control materials, upgradation of drug regulatory portal/website.</p> <p>Training programs for capacity building with fund of Rs. 5.00 lakhs cap each program not exceeding three such programs.</p>
<p>State AYUSH Directorate/State Drug Controller of AYUSH drugs.</p> <p>Only those State/UTs will be supported where there is a functional Drug Testing Laboratory and a separate functional Enforcement Mechanism for ASU&H drugs</p> <p>The States which are maintaining a data base of manufacturing units and their products and introduce dossier based licensing system for ASU&H medicines and undertake minimum number of inspection of manufacturing and drug testing units as per Drugs and Cosmetics Act 1940 and Rules, 1945 will be given preference.</p>	<p>Funding of State/UT regulatory & quality control activities including capacity building and testing of drug samples will be limited to Rs. 15.00 lakh per year per State/UT.</p> <p>Expenditure incurred on the following items would be reimbursed:</p> <ul style="list-style-type: none"> i. Expenditure on online portal maintenance and development of AYUSH Drug Controller/Licensing Authority. ii. Expenditure on collection and testing of statutory / survey samples. iii. Expenditure on training of technical staff at Pharmacopoeia Commission of Indian Medicine and Homoeopathy (PCIM&H)/ NABL as per approved cost norms. iv. Expenditure on awareness programmes, IEC activities, etc.

The grantee institute/Central/State Govt. may apply in the following performa–C1 for seeking grant-in-aid under the component.

FORMAT –C1

APPLICATION FORM FOR GRANT-IN-AID FOR STRENGTHENING OF ASU&H DRUG CONTROL FRAMEWORK

1. Name and address of the State Government/ Directorate of ISM&H/AYUSH vertical under CDSCO (alongwith Tel, fax No.)
2. Details of Organization set up of Functional State Licensing Authority of ISM&H.
3. Infrastructure:
 - (a) Existing manpower and their qualifications (attach in separate sheet).
 - (b) Existing building and equipments (Computer etc.)
 - (c) Number of Drug Inspectors and their qualifications.
4. Number of licensed Ayurvedic, Siddha, Unani and Homoeopathy Pharmacies in the State.
5. Number of Government Drug Testing Laboratories and other approved Private Drug Testing Laboratories.
6. Number of survey samples collected & tested and prosecuted under the Drugs and Cosmetics Rules during last three years.
7. Statutory samples collected, tested and prosecuted under the Drugs and Cosmetics Rules during the last three years.
8. The status of re-orientation training given to the Drug Inspectors.
9. Number of manufacturing units to whom GMP Certificate is issued.
10. Requirement from Central Government:
 - (a) Expenditure on online portal maintenance and development of AYUSH Drug Controller/Licensing Authority.
 - (b) Expenditure on collection and testing of statutory / survey samples.
 - (c) Expenditure on training of technical staff at Pharmacopoeia Commission of Indian Medicine and Homoeopathy (PCIM&H)/ NABL as per approved cost norms.
 - (d) Expenditure on awareness programmes, IEC activities, etc.
11. Total funds required from Central Government (From a to d).
12. How State Government/ Organization propose to increase the number of sample testing of ISM&H drugs.
13. How are the accounts of Organization being audited (Govt. Auditors/CA).
14. Name of the Scheduled Bank where accounts are maintained.
15. Name of the two office bearers responsible for jointly operating the accounts.
16. Any other relevant information justifying the request for financial assistance under the Scheme.
17. (i) No. of AYUSH drugs manufacturing units in the State.
(ii) Names of major units and their annual approximate sale.
(iii) No. of AYUSH drugs testing laboratories in the State

Recommendation of the Director, Department of AYUSH, State Govt./ UT's or the Controlling Officer of the Organization.

Place:
Signature,
Name,
Designation
Tel./Fax No. with Office Seal

Date:

D. OPERATIONAL GUIDELINES FOR SUPPORT FOR DEVELOPMENT OF STANDARDS AND ACCREDITATION/ CERTIFICATION OF AYUSH PRODUCTS & MATERIALS IN COLLABORATION WITH BIS, QCI AND OTHER RELEVANT SCIENTIFIC INSTITUTIONS AND INDUSTRIAL R&D CENTRES.

Eligibility	Funding Pattern	Deliverables
<p>Organization/Institutes engaged in development of Standards of Ayush materials.</p> <p>Medical, scientific and Standards Development institution, university/ institutional department in Govt. & Pvt. Sector with adequate infrastructure & technical expertise.</p>	<p>Funding upto Rs. 20.00 lakh per year per organization/institution for development of standards and associated activities.</p> <p>Expenditure incurred on the following items would be reimbursed:</p> <ul style="list-style-type: none"> i. Expenditure on salary of contractual manpower required for the project. ii. Expenditure on collection of samples and testing. iii. Expenditure on training of technical staff at Pharmacopoeia Commission of Indian Medicine and Homoeopathy (PCIM&H) / HPL / NABL etc. as per approved cost norms. iv. Office expenses incurred exclusively for this project. v. Any other expenditure incurred and justified for achieving the desired target. 	<p>Development of standards of 20 Ayush materials and associated activities per year.</p>