

DEPARTMENT OF AYUSH

Central Scheme for Evolving Pharmacopoeial Standards for Ayurveda, Siddha, Unani and Homoeopathy drugs and Standardized Operating Procedures (SOPs) of Manufacturing Processes of ASU&H drugs.

1. INTRODUCTION

a) The Government of India set up the Ayurvedic, Siddha, Unani and Homoeopathic Pharmacopoeia committees in the year 1962, 1975 & 1964 & 1962 respectively. These four committees are supported technically by the Pharmacopoeial Laboratory for Indian Medicine (PLIM) and Homoeopathic Pharmacopoeia Laboratory situated at Ghaziabad which are apex laboratories dedicated to developing Pharmacopoeial Standards of Indian and Homoeopathic Medicine. *The existing Pharmacopoeia work in Ayurveda Siddha, Unani and Homoeopathy is being done presently by these Committees which have published standards on single drugs and multi ingredient formulations of Ayurvedic , Siddha, Unani and Homoeopathy. There are about 2000 single drugs and an equal number of compound formulations where standards are yet to be developed.*

b) Ayurveda, Siddha, Unani and Homeopathy drugs consist of various kinds of formulations prepared from plants, minerals, metals, animal and marine products as raw material. These formulations are prepared after various kinds of processing with the specific methods prescribed in these systems. These formulations are grouped in various dosage form according to their method of preparation, palatability, bioavailability and theraeuptic values accordingly their nomenclature is given in texts mentioned in Drugs and cosmetic Act. 1940 viz Avleh, churna, Asava, Bhasma, Ghrita, Taila, Kupipakva, Gutika, Guggulu Modaka, Louh, Pisti etc. in Ayurveda. Churanam, Parpan, Chinduam, Kudnar, Mathrai in Siddha and Kushta, Majoon, Hubb, Safoof etc. in Unani, Nosodes, Sarcodes in Homoeopathic Systems of Medicines.

c) The National health Policy on AYUSH, 2002 reiterated the importance of Pharmacopoeial work related to Ayurveda, Siddha, Unani and Homoeopathy Drugs and had emphasised on its expeditious implementation. Although, significant achievements have been made by the existing pharmacopoeia set up, a need has been felt to have *a unified pharmacopoeial infrastructure for better coordination and results. Consequently, Pharmacopoeial standards are proposed to be developed through studies conducted both through in- house laboratories and through laboratories/institutions accredited by Government through two a stage bidding system. Therefore, the work of these individual pharmacopoeial committees will be subsumed in the instant scheme.*

2 OBJECTIVE OF THE SCHEME

- a) To develop pharmacopoeial standards of single and Multi ingredients drugs of plant mineral, metal and animal origin.
- b) To develop Standard Operating Procedures (SOP) of manufacturing processes ASU&H formulation.
- c) To develop Atlas of chromatography, and pharmacognosy atlas to facilitate the testing procedures of ASU&H drugs.
- d) To develop marker compounds/phytochemical standard material of ASU&H drugs
- e) To Develop DNA barcoding/finger printing of medicinal plant /material .
- f) Any other issue relating to the quality, safety and efficacy, documentation, compilation of reference standards for ASU&H Drugs.
- g) To develop Shelf life study ASU&H Drugs.

3 ELIGIBILITY UNDER THE SCHEME

- a) The applicant institutions should be NABL accredited, reputed AYUSH knowledge institutions in Government /Non-Governmental/ Private Sector engaged in one or more of the relevant fields, like of Botany, Phytochemistry, Organic Chemistry, Toxicology, Pharmaceutical Sciences, Pharmacy of Ayurveda, Unani, Siddha and Homoeopathy.
- b) The applicant institutions should have a track record of at least ten years of meritorious work in the AYUSH sector.
- c) The applicant institutions should have a competent core staff in the field in which the activity is proposed.
- d) The applicant institutions should have a credible governance structure and reputed persons on its management committee.
- e) Applicant institutions shall have to make information available regarding any assistance taken from any State/Central agency in the last 5 years.

4 OPERATION OF THE SCHEME

Conditions for grant

The institutions who have the infrastructure and expertise in Botany, Chemistry, Toxicology, Pharmaceutical Sciences, Pharmacy of Ayurveda, Unani, Siddha and Homoeopathy can be

assigned studies under scheme by applying in response to an Expression of Interest (EOI). The bidding will be invited on a two stage bidding Procedure as per prevailing Ministry of Finance Guidelines on the subject. The objective of the exercise is to ensure that all proposals conform to the same acceptable technical standards and meet the technical requirements of the schematic guidelines. Bids of Bidders who are unable or unwilling to bring their bids to conform to the acceptable technical standard may be rejected as deficient bids. The institutions will apply to the concerned Pharmacopoeial Committees.

a) The applications received for the grant and scrutinized to ensure their conformity to acceptable technical standards will be screened by the concerned pharmacopoeial committees. The Principal Investigator (PI) may be asked by the Pharmacopoeia Committee to make presentation of his/her field of expertise depicting his/her capabilities to handle this project with explicitly strong commitment of honoring the milestones and meeting the final targets to the entire satisfaction of the funding agency. If necessary, the Pharmacopoeia Committee will undertake site visit by deputing an expert team to ascertain/verify facilities offered by the laboratory/institution.

b) The applicant institution shall commit to be willing for regular supply of marker compounds to the Departmental Labs / institutions at a pre-agreed price.

c) The recommendations of the Pharmacopoeia Committee along with the price bids of successful bidders will be placed before the Project Evaluation committee (PEC). The Project Evaluation Committee (PEC) shall place the proposals alongwith the financial bids before the Project Approval Committee (PAC) for approval.

d) The approved intuitions shall enter into an agreement with the respective Pharmacopoeial Committees which will provide, among others, the following:

e) The grantee institutions will also adhere to the following points:-

- Advance agreement for timely execution of the project work and hand over of technologies- isolation processes to obtain the maker compounds.
- It should be ensured that the processes are reproducible.
- Certification regarding purity of markers.

f) Agreement will also include, among others, following points –

- i) The Grant-in-aid shall be utilized for the purpose of the scheme within the duration specified for the activity.
- ii) The grantee institute shall maintain an account of grant received and submit the statement of accounts duly audited by the Auditor/Chartered Accountant while submitting utilization certificate within 6 months of conclusion of the Project/Conference.

- iii) The grantee institute shall maintain an account with a scheduled bank in the name of the institute/department and not on any individual whether by name or by designation in current account.
- iv) The grantee institute will submit a report of the progress of work twice every year, in March and in September to the Pharmacopoeia Section of the Deptt. of AYUSH.
- v) The grantee institute shall not divert the grant for any other purpose other than the objects of the scheme.
- vi) The grantee institute shall maintain the record of the assets created out of the grant/material procured out of the grant.
- vii) The provision of Rajasthan Adhiniyam will be followed by the grantee institution.
- viii) All output/data generated out of work allocated under the scheme, would constitute a Joint IPR of the Deptt. of AYUSH & the Scientists/Institutions Labs. No publication in any journal, application for patents or further investigation may be carried out, without obtaining the expressed sanction of the Deptt. of AYUSH in writing.
- ix) Any suppression of the facts, false information submitted to the Govt. will be besides such other action as may be deemed fit, render institute ineligible for further grant and make it liable to refund the grant secured on such basis as per GFR.
- x) Designated authority of the laboratory who shall be held responsible in case the project is not completed at all or partially completed or not completed in time as agreed. Penal interest -@ 18% p.a will be levied in the case of defaulters not complying with the above terms and conditions. However, in exceptional cases, where extension of project time lines becomes necessary, completion time period of the projects may be extended without any additional financial implications. Extension upto maximum of one year period may be given by PEC after evaluating the progress report of the project. The extension may be given only with the condition that if the project is not complete within the extended period of one year, the PI and the institute may be blacklisted. The Government will transfer the project along with the assets created under the project to other suitable institutions. Head of Institution or Controlling Officer of PI will be requested to record adverse entry in ACR of P.I.
- xi) The laboratory shall provide full details of isolation/characterization for said marker along with entire data. The patent right for the process will remain with the Department/PLIM and the organization will have no claim to such patents.
- xii) The Laboratory shall provide all the stability data of the said marker and shall be held responsible if the marker is found to decompose within the known shelf life. Further, it will be incumbent on the institutions granted funds under the Scheme to

prove the efficacy of the result. The Department will be free to get the result verified by the National Laboratories.

- xiii) The Laboratory/Institution shall train one designated scientist of Ayush Laboratories in isolation/characterization of said marker.
- xvi) All the markers supplied shall have complete label giving details of analytical data seen as assay, shelf life etc.
- xv) While undertaking the project reference will be made to APC/HPC/UPC/SPC for this Scheme.
- xvi) PLIM will be responsible to cross check the validity of markers supplied by the grand institutions and to provide Phytochemical Marker (PCM) and Botanical Reference Markers (BRM) as wherein required by Industry at reasonable price.
- xvii) Minimum 3 labs should prepare monographs based on real work to avoid variation in standards due to chemo type/geno type and geographical location of plants. One lab can also take up three batches/ three samples of a formulation consisting of ingredients of different geographical location which will be cost effective.
- xviii) The PLIM will also be involved in the following sphere of work.
 - Checking and verification of the monographs before publication.
 - Collaboration for the production of technologies.
 - Monograph validation.
 - Establishment of a satellite centre for validation of the system.
- g) Self life study of Homoeopathic Drugs may also be undertaken under this Scheme.

5 PROJECT EVALUATION COMMITTEE(PEC) SHALL CONSIST OF THE FOLLOWING:

- | | | |
|----|--|----------|
| a) | JS (AYUSH) | Chairman |
| b) | Chief Executive Officer,(NMPB) or his representative | Member |
| c) | Nodal Officer dealing with the subject (AYUSH) | Member |
| d) | Experts of Ayurveda/Siddha/Unani & Homoeopathy | Members |
- To be nominated by Secretary (AYUSH)

e)	Advisers /Jt. Adv. Ayurveda & Dy. Adviser of ASU&H	Members
f)	Director PLIM & Director HPL	Members
g)	Director IFD or his representative	Member
h)	Sr. Chief Chemist	Member
i)	Member Secretary, APC,SPC,UPC & HPC	Members
j)	Director PCIM	Member Secretary

6 PROJECT APPROVAL COMMITTEE (PAC)

a)	Secretary (AYUSH)	-Chairman
b)	Financial Adviser or his representative Joint Secretary (AYUSH)	Member Member c)
d)	Chief Executive Officer, (NMPB) or his representative	Member
e)	Chairman of the APC, UPC, SPC & HPC	Member
f)	Advisers of Ayurveda/Unani/Siddha& Homoeopathy)	Member
g)	Member Secretary APC	Member
h)	Dy. Adviser Siddha	Member
i)	Member Secretary UPC	Member
j)	Member Secretary SPC	Member
k)	Member Secretary HPC	Member
l)	Director (HPL)	Member
m)	Director (PLIM)	Member
n)	Sr. Chief Chemist	Member
o)	Independent experts one each for Phytochemistry Pharmacognosy and concerned Ayurveda, Siddha, Unani and Homoeopathy experts- nominated by Secretary	Member
p)	Director (PCIM)	Member- Secretary

7 PHARMACOPOEIAL COMMITTEES UNDER THE SCHEME

The Ayurvedic Pharmacopoeial Committee (APC), Unani Pharmacopoeial Committee (UPC), Siddha Pharmacopoeial Committee (SPC) and Homoeopathy Pharmacopoeial Committee (HPC) are functioning for their systems and are constituted from time to time.

Sub-committee of these Pharmacopoeial Committees have been constituted from time to time for undertaking activities such as to lay down test for identity quality and purity and to ensure as far as possible uniformity in physical properties and active constituent as well as to provide all other information regarding the distinguishing characteristic, method of preparation, dosage, method of administration with various anupan and their toxicity for single and compound drugs by the Department of AYUSH. The sub-committee will continue to look into technical aspects assigned by the concerned Pharmacopoeial Committees to ensure that objectives of the scheme are met.

8 EVALUATION AND MONITORING

On an average one monograph has to be corrected 4 times to be placed before the PEC and APC. This requires intense efforts to analyse the data as well as editing by the respective experts of the required field in particular monograph. Therefore @ Rs. 100 per monograph will be paid in 2 installments which would include the evaluation of monographs at their different stages of approval and checking up to its printing level in the final publication as pharmacopoeia. All the components of pharmacopoeial monographs will follow the similar pattern independently and each expert for Botany portion, Chemistry portion, Ayurveda/Siddha/Unani and Homoeopathy portion will be paid Rs. 100/- per monograph separately.

Each project will be monitored and evaluated by the concerned pharmacopoeia committee on a quarterly basis and grant will be released on yearly basis after satisfactory progress reported by the Pharmacopoeia Committee. The pharmacopoeia committee may also depute an expert team for site visit to verify / evaluate the work done by the institution.

9 FINANCIAL ADMISSIBILITY:

Total assistance for a project for 3 year period will be Rs. 27.4 lakhs up to maximum of Rs. 30 Lakhs (actual). Proposals submitted in the bid may include the following components:-

a) Components of Financial Assistance admissible under APC scheme 1.4.2002 (for the new projects)

i). Two Research Associates or Ph. D. holders in relevant subject (consolidated) Ph.D./M.D. (Ay.S/U)/M.Pharm/M.Tech/Minerology/Metallurgy/Geology

1st year – Rs. 10,000

2nd year – Rs. 10,500

3rd year – Rs. 11,000

M.Sc. Rs. 7000/- fixed pharmacology/ biochemistry/histology/pathology 2.40 per year (based on average salary)

ii). Two SRF/JRF

1. SRF/M.Sc./BAMS/BUMS

BSMS/B.Pharma/B.Tech

iii). JRF-B.Sc. Botany/Chemistry 1.82 lakh per year (based on average salary) Rs. 7000 p.m. Rs. 6000 p.m.

HOWEVER, AFTER FINALIZING THE BID, IT IS UPTO THE GRANTEE TO FIX THE REMUNERATION AND MAKE PAYMENT TO RESEARCH ASSOCIATES, SRF & JRF etc.

iv). Equipments and working expenditure and related consumables/drugs/chemicals etc. Rs. 2.00 lakh per year

v). Charges for host institutions or extending infrastructure support to the project Rs. 1.50 lakh/year

vi). Cost of samples/chemicals documentation preparation of monographs Rs. 0.75 per year

vii). Contingencies to meet the TA/DA to attend the meetings relating to the scheme (actual would be permitted subject to the ceiling) Rs. 20,000 P.A

Out of the scientific manpower at least one should be of Ayurveda/Siddha/Unani and Homoeopathy systems and one each of Chemistry and Botany related specialities based on the nature of work.

b) COSTING OF DRUGS

The cost of the drug/formulations will depend upon the ingredients and the various process involved in its preparation will be reimbursed on actual basis.

Actual assistance will be calculated as per actual salary admissible as per qualifications.

Note :- Cost incurred to prepare SOPs of manufacturing process in association with the other manufacturing units/institutions could be met within the financial provisions of the scheme.

Scheme of support Workshops/Seminars/Conferences regarding Drugs/Medicinal Plants and related issues of Pharmacopoeial Standards/Quality control/Drugs Act.

The work of pharmacopoeial standard and quality control of Ayurveda, Siddha, Unani and Homoeopathy medicine is in the nature of research and development work. Presentation of results

of research and development among fellow researchers/professionals is a legitimate and well accepted mechanism for consolidating the results of research and development culture in the system and for upgrading the quality of research manpower in the system. However, there was no arrangement in the Deptt. to support this activity in the past and this is perhaps one of the reason for low motivation for research and development in ISM sector. Therefore the project implementation committee approved provision for assistance for organizing seminars and workshop. In case one or two per year this may be done by the Deptt. directly but normally this will be done by the NGO's, Universities and research and teaching institutions. The duration of the training workshop, expenditure on standard T.A/D.A/Expenditure on resource person, Honorarium etc. will be permissible.

In the 10th Plan, support for such workshop etc. would be provided strictly for seminars etc. needed in course of evolving pharmacopoeial standards.

10 TRAINING AND DEVELOPMENT OF HUMAN RESOURCES

Whereas it will be expected of the laboratory/institution undertaking pharmacopoeial work to hire trained and skilled scientists 1-4 week training for scientists of ISM/Botany/Chemistry/Pharmacy/Mineralogy/Metallurgy/Geology may be required to update their skill for the development. On an average expenditure of Rs. 10, 000 per scientist for 2 weeks would be needed but actuals would be decided on the basis of institutions providing training.

The Govt. of India will not be responsible about the service conditions etc. of the manpower engaged under the scheme.

11 TARGET

Where different parts of the plants make separate monographs, in such case, target of 10 drugs per year, but if all the drugs are separate and where assay of most common constituents is to be done, the target will be of 5 drugs/ per year.

For Multiple ingredients formulations the target will be 8 drugs for pharmacopoeial work. However if the ingredients are less than 5 the target will be 10 drugs per year.

For S.O.P development the target will depend on the number of ingredients and the various processes of manufacturing/preparation. Even the cost will be different for different constituents. Therefore based on the above the target will be 5 to 10 drugs in year irrespective of the availability of raw material and other facility that may be required.

To develop pharmacopoeial standards of SOP developed drugs the targets will be 5 to 8 drugs/year separately irrespective of the availability of raw material and other facility that may be required. These will be counted as separate monograph.

Depending on the capability of the Institution or lab, project could be given either to develop SOP or to develop Pharmacopoeial standards or for both the activities on the recommendations of PEC.

To develop SOP/Process Standards of a drug will be calculated as separate monograph of the drug similarly to develop Pharmacopoeial Standards of a drug will be calculated as a separate monograph of a drug.

12 DURATION OF THE SCHEME

The Scheme will be operational during XIth Plan. There will be a periodic review of the Scheme on yearly basis for mid-term corrections, if required.

The outcomes of the project will be included in the different volumes of ASU&H pharmacopoeias after getting them validated by PLIM/HPL and after approval of the concerned pharmacopeia committee.