Centrally Sponsored Scheme of Quality Control of Ayurveda, Siddha, Unani and Homeopathy drugs

Introduction

Enforcement of the provisions of Chapter IV A of the Drugs and Cosmetics Act, 1940 and Rules, 1945 relating to Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) medicines is the responsibility of the State Governments. Establishment of the State Drug Testing Laboratories and notification of State Analysts is also the statutory responsibility of the States under the Drugs & Cosmetics Act, 1940 and Rules, 1945. In order to provide financial assistance to the States for strengthening their ASU&H drug Enforcement Mechanism, the Centrally Sponsored Scheme for Quality Control of ASU&H Drugs was introduced towards the end of the 9th plan with an outlay of Rs. 40.00 Crores with the approval of Standing Finance Committee (SFC). So far 29 State Drug Testing Laboratories and 44 State Pharmacies of Ayurveda, Siddha, Unani and Homoeopathy have been financially assisted. In addition to assistance to States for the above purposes, a provision was also made for providing back ended subsidy to Ayurveda, Siddha and Unani manufacturing units to become Good Manufacturing Practices compliant. The off take under enforcement mechanism and Good Manufacturing Practices component has been rather negligible. Only 13 States took some assistance for strengthening of State Drug Enforcement Mechanism and 48Ayurveda, Siddha, Unani units have been assisted for becoming Good Manufacturing Practices compliant. An expenditure of Rs. 88.14 crore has been incurred during 9th & 10th plan period under this scheme.

Components of the revised scheme in 11th Plan

Reimbursement of expenditure incurred by States for Strengthening of Enforcement Mechanism of Ayurveda, Siddha and Unani drugs at the State level and expenditure incurred in testing of ASU&H medicines by NABL accredited laboratories subject to States having a functional Drug Testing Laboratory and a separate functional enforcement establishment for Ayurveda, Siddha, Unani and Homeopathy drugs.

Release of balance of financial assistance to strengthen State AYUSH Drug Testing Laboratories and Pharmacies subject to the States filling up vacant posts and ensuring availabilities of trained personnel for their proper functioning.

Assistance to ASU&H manufacturing units to establish in-house quality control laboratories for batch to batch testing of raw materials and finished products for ensuring quality control of ASU&H medicines.

Assistance to ASU&H units to upgrade their infrastructure to acquire WHO Good Manufacturing Practices /US FDA/ EU Good Manufacturing Practices certification for export purposes.

Project Appraisal Committee for appraisal of projects received under Central Sponsored Scheme of Quality Control of ASU&H drugs with the following composition :-

1.	Joint Secretary, Deptt. of AYUSH	-	Chairperson
2.	Concerned Advisor of Deptt. of AYUSH	-	Member
3.	Representative of Drug Controller General (India)	-	Member
4.	Representative of PHARMEXCIL	-	Member
5.	Representative of Export Inspection Council	-	Member
6.	Director, PLIM / HPL	-	Member
7.	One expert to be co-opted from a CSIR laboratory	-	Member
8.	Director, Deptt. of AYUSH dealing with drugs	-	Member-Secretary

Proposals approved by the Project Appraisal Committee will be screened by the Project Screening Committee which will be constituted as follows:-

1.	Secretary (AYUSH)	-	Chairperson
2.	Financial Adviser	-	Member
3.	Joint Secretary, Deptt. of AYUSH	-	Member
4.	Concerned Advisor of Department of AYUSH	-	Member
5.	Director, PLIM / HPL	-	Member
6.	Director, Deptt. of AYUSH dealing with drugs	-	Member-Secretary

SCHEME NO. 1

RELEASE OF BALANCE INSTALLMENT OF FINANCIAL ASSISTANCE SANCTIONED FOR ESTABLISHMENT / STRENGTHENING OF DRUG TESTING LABORATORIES AND PHARMACIES DURING THE 10TH PLAN.

Norms for release of the balance installment for the schemes sanctioned in 11th plan will be the same as those in the existing scheme in the 10th Plan. Balance assistance to State Drug Testing Laboratories (DTLs) approved in the 9th and 10th Plan would be released only if concerned states have sanctioned and filled up technical manpower to make DTLs / Pharmacies functional. No new scheme of strengthening of Drug Testing Laboratories / Pharmacies will be sanctioned in the 11th Plan to any state government.

SCHEME NO. 2

REIMBURSEMENT OF EXPENDITURE INCURRED BY STATE DIRECTORATE OF ISM&H/STATE LICENSING AUTHORITIES FOR TESTING OF AYURVEDA, SIDDHA, UNANI AND HOMOEOPATHY DRUGS SAMPLES THROUGH NABL ACCREDITED/ OTHER APPROVED LABORATORIES FOR TESTING OF HEAVY METALS/PESTICIDE RESIDUE/ MICROBIAL LOAD/ IDENTIFICATION OF INGREDIENTS ETC.

It is proposed to reimburse expenditure incurred by State Directorates of ISM&H/State Licensing Authorities for testing of Ayurveda, Siddha, Unani and Homoeopathy drugs samples through NABL accredited/other approved laboratories upto Rs.2000/- per sample depending upon the parameters like heavy metals/pesticide residue/ microbial load/identification of ingredients. This assistance will be confined to statutory as well as survey samples collected by enforcement agencies and or collected by authorized laboratories on their behalf. Assistance will be provided on a reimbursement basis subject to the condition that the State Drug Controllers/State Licensing Authorities have taken consequent legal action based on the drug testing.

State Authorities shall be required to get at least 20 samples per ASU&H manufacturing units collected and tested every year. To facilitate State Licensing Authorities to undertake this task, an advance of Rs.2.00 lakh per States will be given in the month of April of every year and subsequent releases would be by way of reimbursement on the basis of statement of expenditure incurred certified by Director/ Commissioner (ISM&H).

Reimbursement of expenditure incurred by State Labs for testing through NABL/ approved labs would be subject to clear-cut benchmarks to be incorporated in the scheme proposal for sanction. The grantee institute/State Govt. may apply in the following performa 2 for seeking grant-in-aid under the scheme. Assistance will be provided only to those states who have a functional mechanism for enforcement of provisions of chepter IV-A of the Drugs and Cosmetics Act 1940 in-terms of State Drug Licensing Authority/Controller for ASU drugs and drug inspectors etc.

PROFORMA -2

PROFORMA OF APPLICANT FOR CENTRAL ASSISTANCE FOR RELEASE OF GRANTS AS REIMBURSEMENT OF EXPENDITURE INCURRED BY STATE DIRECTORATE OF ISM&H/STATE LICENSING AUTHORITIES FOR TESTING OF AYURVEDA, SIDDHA, UNANI AND HOMOEOPATHY DRUGS SAMPLES THROUGH NABL ACCREDITED/ OTHER APPROVED LABORATORIES FOR TESTING OF HEAVY METALS/PESTICIDE RESIDUE/ MICROBIAL LOAD/ IDENTIFICATION OF INGREDIENTS ETC.

1. Name and address of the State Government/Directorate of ISM&H (alongwith tel., fax nos.)
   OR other institution:
   (Attach detail regarding the State Drug Licensing Authority/Drug Controller/Drug Inspector for enforcement of ASU&H provisions)

2. Name of the Laboratory (with complete address)

3. No. of Samples tested – Ayurveda/Unani/Siddha/Homeo-pathy

4. Types of tests like heavy metals i.e. arsenic/cadmium/ mercury/lead etc./pesticide residue/ identification test etc.

5. Rates of per sample
   Total Charges of tested samples

6. Requirement of funds from Central Government (please use separate sheet)
7. Total fund requirement from Central Government for testing of samples of Ayurveda, Unani, Siddha and Homeopathic drugs from NABL accredited/approved laboratories.

8. Whether any assistance has been received from Central Government under this

Scheme/any other Department of Central/State/ UT Government for similar scheme. If so, please specify and attach a certificate.

9. How State Government/ Organization propose to increase the number of sample testing of Ayurveda, Siddha, Unani & Homoeopathy drugs.

10. How are the accounts of Organization being audited (Govt. Auditors/Chartered Accountant)

11. Name of the Schedule Bank where accounts are maintained

12. Names of two offices bearers responsible for jointly operating the accounts

13. Any other relevant information justifying the request for financial assistance under the Scheme

14. Recommendation of the Director, Department of ISM&H State Government/UTs or the Controlling Officer of the Organization.

15. In case of other institution – recommendation of Head of the Institution/Registrar of University

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

Date:
Place:

SCHEME NO. 3

REIMBURSEMENT OF EXPENDITURE INCURRED BY STATES FOR STRENGTHENING OF ENFORCEMENT MECHANISM OF AYURVEDA, SIDDHA AND UNANI DRUGS AT THE STATE LEVEL AND EXPENDITURE INCURRED IN TESTING OF ASU&H MEDICINES BY FUNCTIONAL ACCREDITED LABORATORIES.

As Ayurveda, Siddha, Unani and Homoeopathy is not a high priority with States, enforcement work relating to these systems is neglected and in many States there are no Drug Controller/Inspectors for these systems. With a view to encourage strengthening enforcement machinery for ASU&H drugs in States, it is proposed to provide an annual financial assistance of Rs.15.00 lakhs per year for the duration of the 11th Plan only. Expenditure incurred on the following items would be reimbursed:

i. Purchase of vehicle for State AYUSH Drug Controller after 1-4-2007.
ii. Expenditure on computerization of office of AYUSH Drug Controller/ Licensing Authority incurred after 1-4-2007.
iii. Expenditure on collection of statutory / survey samples (maximum Rs. 1.00 lakh per annum).
iv. Expenditure on training of technical staff at Pharmacopoeial Laboratory for Indian Medicine (PLIM) / HPL / NABL as per approved cost norms.

The above expenditure would be on reimbursement basis subject to the condition that there should be a functional Drug Testing Laboratory and a separate functional Enforcement Mechanism for ASU&H drugs and further that concerned States will prepare a data base of manufacturing units and their products and introduce dossier based licensing system for ASU&H medicines and also submit medicinal plants

consumption/supply data of units in their States to the National Medicinal Plants Board and undertake minimum number of per unit drug testing as mentioned above. To facilitate the States, an advance of Rs.5.00 lakh will be released in the month of April every year and the remaining expenditure will be reimbursed on the basis of Statement of Expenditure authenticated by Director (ISM&H). The grantee institute/State Govt. may apply in the following performa 3 for seeking grant-in-aid under the scheme.

PROFORMA-3

APPLICATION FORM FOR GRANT-IN-AID FOR STRENGTHENING OF STATE DRUG CONTROLLER OF AYURVEDA, SIDDHA, UNANI & HOMOEOPATHY ENFORCEMENT MECHANISM.

1. Name and address of the State Government/ Directorate of ISM&H (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 year.

7. Statutory samples collected, tested and prosecuted under the Drugs and Cosmetics Rules during the last year.

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) Provision of vehicle for the State Drug Controllers/State Licensing authorities of ASU&H drugs.

    (b) Expenditure on computerization/ fax etc.

    (c) Expenditure of ASU&H drugs samples to a maximum of Rs. 1.00 lakhs.

    (d) Expenditure on training of enforcement staff by PLIM/HPL/NABL accredited Labs as per guidelines

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.

Signature,
Name & Designation of the
Incharge of Laboratory/
Institution with seal

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:

SCHEME NO. 4

ASSISTANCE TO AYURVEDA, SIDDHA & UNANI (ASU) DRUG MANUFACTURING UNITS TO ESTABLISH AN IN-HOUSE QUALITY CONTROL LABORATORY FOR THE PURPOSE OF QUALITY CONTROL TESTING OF ALL RAW MATERIALS/FINISHED PRODUCTS AS PER PHARMACOPOEIAL PARAMETERS INCLUDING TESTING OF INGREDIENTS/HEAVY METALS/PESTICIDE RESIDUE/MICROBIAL LOAD ETC.

Assistance to ASU&H drug manufacturing units having an annual turnover of upto Rs. 20.00 crores for acquisition of prescribed essential quality control equipment for in-house Quality Control Lab shall be limited to Rs. 30.00 lakhs or 30% of expenditure incurred on the basis of a MoU between the manufacturing unit / State Drug Controller and Department of AYUSH with a condition that the quality control equipment purchased with Government of India assistance shall not be disposed of and that Government of India will have lien on such equipment in case of company going into liquidation. The acquisition of quality control equipments would be as per **Annexure** for setting up an in-house quality control laboratory for testing of all ingredients and finished products as per Pharmacopoeial and other standards laid down by Deptt. of AYUSH / WHO from time to time. In the 10th Plan an assistance of upto Rs.5.00 lakh as back-ended subsidy was allowed to all ASU manufacturing units for becoming Good Manufacturing Practices compliant. However, the off take in the scheme was negligible on account of assistance being very meager. Further, it has been felt that Good Manufacturing Practices notified under Schedule 'T' of the Drugs & Cosmetics Act, 1940 and Rules, 1945 does not provide for a mandatory in-house

laboratory for every manufacturing unit as a result of which most of the manufacturing units have obtained Good Manufacturing Practices on the basis of having a tie up with an outside laboratory. **For all practical purposes testing of all raw material and finished products is not commercially viable unless a manufacturing unit has an in-house laboratory. Development of quality control laboratory is highly capital-intensive. Acquisition of equipments like Atomic Absorption Spectrometer, High Performance Thin layer Chromatography Spectrometer, etc for an in-house quality control laboratory entails heavy expenditure. Small and medium units find it very burdensome to obtain loans without any subsidy.** The Parliamentary standing Committee of Ministry of Health & Family Welfare has also recommended substantial increase in assistance to manufacturing units for becoming Good Manufacturing Practices compliant. The grantee institute/State Govt. may apply in the following performa 4 for seeking grant-in-aid under the scheme.

Annexure

LIST OF EQUIPMENT RECOMMENDED FOR IN-HOUSE QUALITY CONTROL SECTION OF AYUSH MANUFACTURING UNITS

(A) Chemistry Section (Area: 600+600 sq. ft.)	**Tentative Cost**
1. Alcohol determination apparatus (complete set)	Rs. 4,000.00
2. volatile Oil Determination Apparatus	Rs. 4,000.00
3. Boiling Point Determination Apparatus	Rs. 2,000.00
4. Melting Point Determination Apparatus	Rs. 10,000.00
5. Refractometer	Rs. 15,000.00
6. Polarimeter	Rs. 20,000.00
7. Viscometer	Rs. 20,000.00
8. Tablet Disintegration Apparatus	Rs. 20,000.00
9. Moisture Meter	Rs. 20,000.00
10. Muffle Furnace	Rs. 20,000.00
11. Electronic Balance	Rs. 75,000.00
12. Magnetic Stirrer	Rs. 10,000.00
13. Hot air Oven	Rs. 20,000.00
14. Refrigerator	Rs. 20,000.00
15. Glass / Steel Distillation Apparatus	Rs. 20,000.00
16. LPG Gas Cylinders with Burners	Rs. 5,000.00
17. Water Bath (Temperature Controlled)	Rs. 10,000.00
18. Heating Mantles / Hot plates	Rs. 10,000.00
19. TLC Apparatus with all accessories (Manual)	Rs. 10,000.00

20. Paper Chromatography Apparatus with accessories	Rs. 10,000.00
21. Sieve Size 10 to 120 with Sieve Shaker	Rs. 10,000.00
22. Centrifuge machine	Rs. 25,000.00
23. De-humidifier	Rs. 25,000.00
24. pH Meter	Rs. 10,000.00
25. Limit Test Apparatus	Rs. 10,000.00
26. GLC	Rs. 30,00,000.00
27. Atomic Absorption Spectrometer with Graphite furnace with Hydride generator	Rs. 40,00,000.00
28. HPTLC	Rs. 40,00,000.00
29. HPLC	Rs. 70,00,000.00
30. ICPMS Liquid Chromatography-Mars Spectrophotometer	Rs. 1,00,000,00.00

(B) Pharmacognosy Section (600 Sq.ft.)	
1. Microscope Binocular	Rs. 1,00,000.00
2. Dissecting Microscope	Rs. 50,000.00
3. Physical Balance	Rs. 10,000.00
4. Aluminum Slide trays	Rs. 10,000.00
5. Stage Micrometer	Rs. 35,000.00
6. Camera Lucida (Prism and Mirror Type)	Rs. 10,000.00
7. Chemicals, Glass-ware etc.	Rs. 50,000.00

(C) Microbiology Laboratory (300 Sq.ft.)	
1. Laminar flow clean air bench	Rs. 50,000.00
2. Autoclave	Rs. 25,000.00
3. colony counter	Rs. 20,000.00
4. BOD incubator	Rs. 30,000.00
5. incubator	Rs. 20,000.00
6. glassware, media	Rs. 50,000.00
7. temperature bath	Rs.10,000.00
Total	Rs. 1,58,00,000.00

Note: Purchase of Atomic Absorption Spectrometer with Graphite furnace with Hydride generator for testing of heavy metals and HPTLC/ HPLC for chemical analysis shall be mandatory for availing of assistance under the scheme by manufacturing units for setting up in-house quality control laboratory, if they do not have such equipments. Those AYUSH units who already have these equipments can utilize this assistance for more sophisticated equipments like ICPMS/ LC-MS etc. Any other equipment may be added in this list on the recommendation of Pharmacopoeial Laboratory of Indian Medicine and Pharmacopoeial Laboratory for Homeopathy, Ghaziabad.

PROFORMA-4

APPLICATION FORM FOR GRANT-IN-AID UNDER THE SCHEME TO ASSIST AYURVEDIC, SIDDHA AND UNANI DRUGS MANUFACTURING UNITS TO ESTABLISH IN-HOUSE QUALITY CONTROL LABORATORY FOR TESTING OF ALL RAW MATERIALS/FINISHED PRODUCTS AS PER PHARMACOPOEIAL PARAMETERS INCLUDING TESTING OF INGREDIENTS/HEAVY METALS/PESTICIDES RESIDUE/MICROBIAL LOAD ETC..

1. Name and address of manufacturing unit. (License Certificate should be attached).

2. Number and year of registration under Companies/ Societies Registration Act with Trading Profit/Loss Account/ Sales Tax returns of last 5 years.

3. Present Infrastructure:
   (a) Manpower

   (b) Machinery/equipment (Please attach in separate sheet).

   (c) List of trained manpower and quality control equipments at the time of application.

   List of trained manpower and quality control equipment proposed to be added with the assistance under the scheme

4. Name of the Bank/Govt. Financial Organization from where the loan is to be taken alongwith the DPR and Bank's appraisal report.

5. A Certificate given by the sanctioned authority of the Schedules Commercial Bank Manger stating that the amount has been sanctioned and would be disbursed upon sanction of

the proposal by Govt. of India. (Subsidy will be released through the bank only in disbursement of loan and setting up of Quality Control Laboratory).

6. Whether any other financial assistance has been taken by the applicant from Deptt. of AYUSH/Deptt. of Science & Technology/DBT/Deptt. of Chemicals in the last 5 years with details.

7. Signature & name of the Managing Director with Seal

8. Recommendation of the State Drug Controller/Director, Pharmexcil.

9. Copy of the G.M.P Certificate.

Place
Date

(Signature, Name, Designation)
Tel./Fax No. with Office Seal

Undertaking by the applicant that the unit will be kept operational after getting the assistance under the scheme from the Govt. of India and would not dispose off the equipment purchased with the assistance and that testing facilities would be made available to other units within a radius of 100 Kms. on payment of user charges mutually agreed upon which shall not be more than 75% of similar charges of the nearest accredited NABL laboratory. In case of dispute, PLIM/HPL will fax user charges.

(Signature with office seal
of the applicant)

SCHEME NO. 5

ASSISTANCE TO ASU MANUFACTURING UNITS HAVING A TURNOVER OF UPTO RS.20.00 CRORES FOR ACQUIRING US FDA/EU GOOD MANUFACTURING PRACTICES CERTIFICATION FOR THEIR UNITS.

Most of the countries are insisting on a higher Good Manufacturing Practices like US FDA/EU Good Manufacturing Practices for granting market authorization to products made by ASU manufacturing units. This may entail substantial expenditure on infrastructure development in addition to establishment/strengthening of in-house testing laboratories. Any applicant manufacturing unit desirous of obtaining assistance under this component shall make an application alongwith a Project Report duly appraised by a scheduled commercial bank indicating the various items of expenditure to be incurred. The application may be forwarded by the State Directorate of ISM&H or PHARMEXIL. ASU manufacturing units having a turnover of upto Rs. 20.00 crores shall be provided with assistance of 30% or Rs. 30.00 lakh, whichever is less for upgradation of the facilities to US FDA / EU Good Manufacturing Practices certification standards. This would be released through the scheduled commercial bank on receipt of report of disbursement of loan by the Bank and certificate issued by PLIM/ PHARMEXCIL to the effect that the expenditure has been already incurred and US FDA/EU Good Manufacturing Practices certificate has been obtained by the firm.

An Ayurveda, Siddha and Unani (ASU) manufacturing unit shall be entitled to assistance either for in-house quality control component or the higher Good Manufacturing Practices upgradation component **but not both**.

Eligibility Criteria

(i) ASU manufacturing unit should have a valid manufacturing license and a Good Manufacturing Practices and be registered under the Companies Act and in case of Societies like IMCOPS under the Societies Registration Act for at least last five years.

(ii) Application in the prescribed format would be submitted alongwith trading Profit & Loss Accounts or Sales Tax return showing turnover for the last five years.

(iii) Appraisal report of the scheduled commercial bank alongwith certificate regarding sanction of the loan for purchase of equipment for in-house quality control laboratory/infrastructure upgradation for obtaining US FDA/EU Good Manufacturing Practices.

(iv) In case of upgradation assistance for US FDA/EU Good Manufacturing Practices an independent appraisal by an international consultant regarding the feasibility of the applicant unit obtaining US FDA/EU Good Manufacturing Practices certification after upgradation.

(v) Subsidy of Rs. 30 lakhs or 30% of the expenditure incurred would be released on the basis of certificate issued by Director, Pharmacopoeial Laboratory for ndian Medicine, Ghaziabad and or Director, PHARMEXCIL that the in-house testing laboratory is fully operational and that all the equipments for which reimbursement is being sought have actually been installed and are being

utilized for at least 90 days and that trained manpower is available in the unit or that the unit has obtained US FDA/EU Good Manufacturing Practices certificate. Subsidy will be released through the bank account of the scheduled commercial bank which sanctioned the loan. The grantee institute/State Govt. may apply in the following performa 5 for seeking grant-in-aid under the scheme.

PROFORMA-5

APPLICATION FORM FOR GRANT-IN-AID UNDER THE SCHEME TO ASSIST AYURVEDIC, SIDDHA AND UNANI DRUGS MANUFACTURING UNITS HAVING A TURNOVER OF UPTO RS. 2.00 CRORE FOR ACQUIRING US FDA/EU GMP CERTIFICATION FOR THEIR UNITS.

1. Name and address of manufacturing unit. (License/GMP Certificate should be attached).

2. Number and Year of registration under Companies/Societies Registration Act with 5 year Trading Profit & Loss Account/Sales Tax return as proof of turnover.

3. Detailed Project Report indicating current infrastructure status and infrastructure/ manpower requirement to obtain US FDA/EU GMP accreditation independently evaluated by an accreditation/ certification agency notified for this purpose by US FDA/EU GMP/PHARMEXCIL.

4. Appraisal of the Scheduled Commercial Bank alongwith undertaking that the loan has been sanctioned and would be disbursed on sanction of the project by Govt. of India.
(Subsidy to be released only after disbursal of loan and accreditation).

5. Name of regulatory agency whose certification has to be obtained e.g. WHO, US FDA/EU, etc. and proof of initiation of contact with that agency.

6. Details of any assistance taken from Deptt. of AYUSH/Deptt. of Science & Technology/DBT/ Deptt. of Chemicals in the last 5 years with details.

7. Signature & name of the Managing Director with Seal

8. Recommendation of the State Drug Controller/Director (ISM&H)/ PHARMEXCIL

Place
Date

(Signature, Name, Designation)
Tel./Fax No. with Office Seal