Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)

(For compliance to WHO/ international GMPs)

DETAILED PROJECT REPORT

Introduction

Pharmaceutical sector is one of the most promising sectors of the Indian industry, which is growing at more than 10% annum. Being knowledge based industry; it requires to be highly regulated, more particularly, when it relates to health concerns. One of the key regulations on the industry is Good Manufacturing Practices (GMP) with a view to ensuring quality production and putting in place pollution and environmental control measures. Thesestringent regulations are being enforced both at the State andCentral levels through State Drug Controllers and Central Drug Standard and Control Organization(CDSCO). Particularly, the developed countries like USA, Europe, Japan, Australia etc. have adopted more stringent regulations, which are being enforced by their regulatory bodies. Other developing countries generally follow World Health Organization (WHO)/GMP norms.Any export of drugs from India to such countries must adhere to these regulations.

As per the extant regulations, no enterprise can manufacture drugs without obtaining Schedule 'M' Compliance i.e. GMP certification in India. Of late, all government procurements insist on a minimum of WHO-GMP certification for the manufacturers to qualify for participation in tenders. Hence,small and medium enterprises (SMEs) have to be WHO-GMP compliant, if these enterprises wish to compete with other giants/ MNCs in the domestic as well as International markets. The market share of small and medium enterprises in domestic market is 40%, which is quite substantial. It is also worth mentioning that the investments on making the units WHO-GMP compliant would definitely improve the quality, efficiency and efficacy of drugs. But, the returns on such investments may not yield the revenue to compensate for the cost of such funding. Ministry of Micro Small and Medium Enterprises (MSME) has already launched a Scheme called Credit Linked Capital Subsidy Scheme (CLCSS) which caters to the requirement of SSI units.Therefore, a new scheme viz. Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)is being proposed to assist medium enterprises (MEs) in terms of soft loan at the interest rate of 5% per annum for making these units WHO-GMP compliant.

2. Background

2.1 Statutory requirement of Schedule 'M' Compliance.

During the Eleventh Plan period, Department of Pharmaceuticals had submitted a scheme to Planning Commission to provide financial assistance to pharmaceutical small and medium enterprises (SMEs) for technology upgradation to Schedule 'M' Standards as laid down under the Drugs & Cosmetics Rules, 1945. Schedule 'M' standard is the minimum statutory requirement to be adhered to by the Pharmaceutical units to function. These standards are also known as Good Manufacturing Practices (GMP) in India. Planning Commission had accorded 'in principle' approval to this Scheme on 5.12.2007 subject to some conditions. As per recommendations of Planning Commission, the then Department of Chemicals & Petro Chemicals appointed National Productivity Council (NPC) for assessment of number of units likely to be benefitted by the PTUAS Scheme.After receiving report of National Productivity Council on 7.7.2008, Draft Empowered Finance Committee (EFC) Memo for PTUAS was circulated on 6.8.2008 to concerned Government Departments and Financial institutions. A revised EFC Memo incorporating the comments of various stake holders was circulated on 16th October, 2008 and the same was discussed with Planning Commission on 8th December, 2008. However, this proposed scheme was tweaked/ merged with the existing Credit Linked Capital Subsidy Scheme (CLCSS) of M/o MSME as per decision of EFC in its meeting held on 02.03.2009. Based on the observations of the EFC, Department of Pharmaceuticals finalized the list of equipments for assistance under the CLCSS Scheme and Guidelines wereaccordingly notified by MSME on 13.7.2009.The CLCSS Scheme provides financial assistance to only SSI units in the form of 15% capital subsidy limited to the project cost of up to Rs.1.00 crore i.e. capital subsidy with upper limit of Rs.15 lakh per SSI unit.

2.2 Awareness Generation Workshops for CLCSS

D/o Pharmaceuticals organized various awareness generation workshops during the months of October and November 2009 throughout the country (i.e. Goa, Mumbai, Baddi(H.P.), Ahmedabad, Bengaluru, Chennai, Hyderabad, Indore (M.P.) and Dehradun) for Implementation of Plan for "Scheme for Schedule 'M' Compliance for SSI Pharmaceutical Units to be implemented by dove-tailing/ tweaking with CLCSS Scheme of MSME.

2.3.Status under CLCSS Scheme of MSME

Under CLCSS Scheme, 294 drug and pharmaceutical units availed subsidy of Rs.19.76crore up to 31.3.2012 since inception of CLCSS Scheme in October, 2000.The

scheme provided assistance to small enterprises to make them Schedule ‘M’ compliant / WHO-GMP/ International norms compliant. However, WHO-GMP and other international GMP compliance is not practicable under the CLCSS Scheme as maximum loan available under the said Scheme is Rs.1.00 crore per unit as against the minimum financial requirement of Rs.2.00 crore per unit..

2.4.Procurement for Jan Aushadhi Scheme

Making quality drugs at affordable prices has always been the prime objective of the Department of Pharmaceuticals. In this direction, a major initiative in the form of Jan Aushadhi Scheme has already been taken in the year 2008. A new Business Plan is also being proposed to take it further and open 3000 (approx.) Jan Aushadhi Stores in the next four years. One of the prime concern in sourcing medicines from Small and Medium Enterprises would be of quality. Hence, it has been proposed that manufacturers, supplying drugs for Jan Aushadhi Scheme, must be WHO-GMP compliant. Thus, the proposed scheme of assisting Medium Enterprises would supplement the efforts of the department in making quality drugs available for common masses at affordable prices.

2.5.Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) Scheme-genesis

Department of Pharmaceuticals proposed a new Pharmaceutical Technological Upgradation Assistance Scheme (PTUAS) to assist the Pharmaceutical Medium Enterprises (MEs), which were not covered by the CLCSS Scheme of MSME. Though CLCSS provided for financial assistance to SSI units for WHO-GMP/ International norms compliance, it is only the medium enterprises, which can truly leverage the advantage of WHO-GMP/ international norms by exploring the possibilities of exports because of their sheer volume of production. Hence, there is a need to assist primarily the medium enterprises (MEs) in bridging the gap between Schedule ‘M’ and WHO-GMP/ other advanced international norms. The purpose of the new PTUAS Scheme was to assist Pharma MEs to enable them to cope with the fast changing technology and globalized nature of Pharmaceutical industry.Thus, it was feltthat critical assistance should be provided to Pharmaceutical MEs to meet the new challenges of quality production of medicines to the substantially higher standard i.e. WHO-GMP and other international norms.

3. Consultations with Planning Commission and SIDBI

D/o Pharmaceuticals prepared a modified PTUAS for Medium Enterprises and communicated the same vide its letter dated 15.6.2010 for comments to SIDBI, MSME, Ministry of Health & Family Welfare. In the meantime, the department submitted a proposal for PTUAS Scheme to Planning Commission on 16.6.2010 for getting 'in principle' approval. Further, Department of Pharmaceuticals also convened a meeting on 22.10.2010 with various Pharma associations i.e. SME Pharma Industries Confederation (India), Indian Drug Manufacturers Association, Confederation of India Pharmaceutical Industries (SSI), Federation of Pharma Entrepreneurs, FICCI (SME wing) and Indian Pharmaceutical Alliance with a view to get their suggestions and comments on the proposed PTUAS Scheme. The earlier proposal was to render assistance to ME in the form of reimbursement of 5% point of interest of loan taken from scheduled banks/ financial institutions. The comments received from SIDBI, MSME and M/o Health & Family Welfare were also shared with Planning Commission in the meeting held on 8.12.2011.

Department of Pharmaceuticals made a presentation on 08.12.2011 in a meeting with Planning Commission in connection with approval of PTUAS Scheme to assist MEs for making them WHO-GMP Compliant by providing financial assistance by way of reimbursement of 5% point of interest on the loan taken from the schedule Banks/ Financial Institutions. In this connection, Planning Commission circulated minutes of the meeting vide their letter dated 11.1.2012 and advised Department of Pharmaceuticals that "Instead of subsidy route, SIDBI could be approached directly by Medium sized pharma units for soft loan." It was also decided that a view on the proposed scheme will be taken only after Department of Pharmaceutical has taken up the issue with SIDBI and other financial institutions and outcome of the exercise made available to the Planning commission.Accordingly, Department of Pharmaceuticals approached SIDBI for needful action as suggested by Planning Commission.

SIDBI vide its letter dated 10.12.2012 submitted their comments on Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) for providing need based soft loan at concessional rate of 5% p.a. to Pharma MEs and proposed Rs.500 crore interest free Corpus Fund to be kept with them for disbursement of loan to 250 MEs at the rate of Rs. 2.00 crore per unit. Department of Pharmaceuticals submitted the comments of SIDBI to Planning Commission on 8.1.2013 and in response to this Planning Commission instructed the department to submit proposal in EFC format vide their letter dated 30.1.2013. Keeping in view the recommendations and guidelines made available by

SIDBI, a new time bound soft loan scheme viz. Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) is being proposed.

4. WHO-GMP and other international GMP norms

4.1 WHO-GMP Compliance

WHO-GMP standards are in existence since 1975 as a means of exchanging information between regulatory authorities in importing and exporting countries. The objectives are:

a) To provide assurance that a given product has been authorized to be placed on the market in the exporting country and if not, to explain why authorization has been withheld, or has not been requested.

b) To provide assurance that the plant in which the product is manufactured is subject to inspections at suitable intervals and conforms to the requirements for good practices in the manufacture and quality control of drugs, as recommended by WHO.

c) To provide for exchange of information on the implementation of inspections and controls by the authorities in the exporting country. In the case of serious quality defects, inquiries may also be made.

4.2. World-wide recognized quality standards

The following types of quality standards, which are recognized world-wide, exist in production of drugs.

a)WHO GMP norms, which are essential for export of drugs to a large number of countries, are also followed by WHO in their medicine procurement scheme for developing countries.

b) The more stringent GMP norms being followed by highly regulated markets in developed countries like USA (USFDA), Europe (EMEA), UK (MHRA), Australia (TGA), South Africa (MCC), Japan etc.

c) All developed countries are making common GMP guidelines like International Conference on Harmonization (ICH) Q7 applicable for bulk drugs or active pharmaceutical ingredients worldwide. Also, the common guidelines are being drafted for formulation industry. Meanwhile, Europe has been insisting from Indian Pharma industries to produce WHO-GMP certification with a commitment to follow the European Union GMP guidelines for export of medicines in Europe market.

d) USA (US-FDA) and Australia (TGA) require FDA inspection for Indian Manufacturing sites to qualify for export of medicines to these countries.

5. Scope of the proposed PTUAS scheme

As per information provided by the office of Deputy Director General (Chemical &Petro Chemical), dated 21.9.2011, on the basis of reports received from State Drug Controllers (SDCs), there are 752 MEs units functioning in India.Out of these, 153 MEs have got WHO-GMPcertification from the office of Central Drug Standard and Control Organization(CDSCO) and State Licensing Authority. It is further projected that around 50 units may graduate from SSI Pharmaceutical units to MEsduring the12th and 13th Five Year Plan (FYP) period.

As per the definition given in Section 2(g) of the Micro, Small and Medium Enterprises Development Act, 2006), an enterprise has to have capital investment in plant and machinery between Rs.5 crore to Rs.10 croreto be in the category of a ME. It is proposed to assist MEs in making their manufacturing facilities WHO-GMP compliant by providing soft loan upto Rs.2.00 crores per unit to eligible MEs at a concessional rate of interest of 5% p.a. through SIDBI or any other financial institution, duly authorized by SIDBI. With corpus fund of Rs. 500 crore, it is possible to extend benefit to around 250 MEs in the 12th Plan period and around 400 MEs in the 13thPlan period out of the revolving fund generated through repayment of loansincluding interest earnings on the soft loan/ deposits.

The soft loan will be provided by SIDBI as per their operational guidelines. For availing the benefit, the eligible Medium Enterprises will have to approach SIDBI or other financial institutions notified by SIDBI. An MOU/Tripartite Agreement has to be signed by MEs with the Nodal Agency (SIDBI) and the lending Banker (Scheduled Banks)

6. Specifications& benchmarking of Technology Upgradation

Technology upgradation would ordinarily mean induction of the state-of-the-art technology required for the WHO-GMP compliance. In the widely varying mosaic of technology obtaining in the Indian Pharmaceutical Medium Enterprises (MEs) Sector, at least a significant step up from the present technology level to a substantially higher one would be essential. Accordingly, technology levels are benchmarked in terms of specified machinery for the pharmaceutical industry. Machinery with technology levels lower than that specified will not be permitted for funding under the Scheme.

Technology up-gradation under the Scheme would primarily aim at complying with the Good Manufacturing Practices as per WHO-GMP and other international GMP norms of premises, plant and equipment for pharmaceutical products.The up-gradationalso includes laboratory (both instrumentation and microbiological), pollution treatment devices, controls, training, documentation, information technology, energy generation (DG), energy saving equipment and automation in production activities.

The list of such well-established& improved technologies that are relevant & essential for upgradation of MEs in drugs & pharmaceuticals so as to comply with the WHO-GMP and other international GMP norms is at Annexure-I. Installation of the types of machinery indicated in **Annexure I** in existing MEs by way of replacement of existing machinery and / or expansion will be eligible for coverage under the scheme. Under the Scheme, procurement of only new machinery will be permitted.

7. Other eligible items

The following items will also be eligible to the extent necessary for the plant and equipment to be installed for Technology Upgradation and the total of such investments will not normally exceed 25% of the total investment in such plant and machinery:

(1) Renovation of factory building and electrical installations;

(2) Preliminary and pre-operative expenses;

(3) Investments in the installation of the following facilities including necessary equipment:

(a) Energy saving devices;

(b) Effluent treatment plant (ETP)

(In case of an individual unit or an independent unit setting up Effluent Treatment Plant for its own use or substantively for a group of willing pharmaceuticals enterprises in that area, it will be eligible for coverage under PTUAS on stand-alone basis.)

(c) Water treatment plant for captive industrial use;

(d) In-house R. & D. including Pilot Plant

(e) Information technology devices/equipments

(f) Total quality management (TQM)

(g) Equipments for uninterrupted power supply.

(h) Training on disaster management and safety

(i) Documentation

The list would be updated from time to time based on the recommendations of a Technical Committee, depending on the changing requirements of the pharmaceutical industry under the WHO-GMP norms and other international GMP norms.

The Technical Committee would consist of Chairman & Managing Director, Indian Drugs & Pharmaceuticals as chairman, a representative each from Small Industries Development Bank of India (SIDBI), Drugs Controller General of India(DCGI), Development Commissioner (MSME) and other technical experts as nominated by the Government from time to time. Benchmarking of the cost of machinery will also be done by the committee. This committee shall also look into all possible disagreements between lending institutions, enterprises and SIDBI regarding eligibility and the cost of equipment/machinery.

8. Eligibility criteria of Medium Enterprises:

All registered existing Medium Enterprises, which require compliance to WHO-GMP and other international GMP norms would be eligible for soft loan under the scheme provided they fulfill the following eligibility criteria.

a)As per Section 2 (g) of the Micro, Small and Medium Enterprises Development Act – 2006, a Medium Enterprise,which is a manufacturing unit,is defined as an Enterprise where the investment in plant and machinery is more than **five crore rupees** but not more than **ten crore rupees.**

b) All MEs willing to avail soft loan should produce a certificate of Schedule 'M' compliant as laid down under the Drugs & Cosmetics Rules, 1945.

c) A Medium Enterprise will remain eligible under the scheme even after its investment in plant and machinery exceed to Rs.10.00 crore after availing the benefit.

d) A SSI unit graduated to ME after taking benefit of CLCSS Scheme of MSME would also be eligible under this Scheme; if it has attained the assistance under the CLCSS for Schedule 'M' compliance.

e)The medium enterprise should be in operation during the lending period.If the medium enterprise closes down/ becomes NPA, the unit would not be eligible for soft loan. However, the enterprises, which are closed temporarily for maintenance work / seasonal requirements, will be exempted from the requirement provided the period of closure of the unit does not exceed 2 months in a year. Similarly, benefit of soft loan will not be available for the period during which the account of the unit remains NPA in the books of the lending agency.

f)A Medium Enterprise can undertake one or more activities under Technology upgradation. However, multiple activities can be undertaken only in an integral manner, i.e., by way of forward or backward integration. For example; for formulation activities, packing in various forms shall be considered as integral activities.

g)The Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) is totally independent of other similar Schemes. MEs are permitted to avail of benefits of other schemes, in addition to PTUAS, unless specifically provided otherwise. In case of any doubt, the matter may be referred to the Steering Committee for clarification.

9. Structure of Scheme

9.1 Corpus Fund

An interest free Corpus Fund of Rs.500 crores,to be kept with SIDBI for disbursement of soft loan as per terms set forth herein-after,would be created by the Government. Disbursement of need based loan to MEs up to Rs.200 lakhs per unit at concessional rate of interest of 5% p.a. would be made to 250 MEs in 12th Plan period out of this corpus fund.

The corpus fund would grow by interest earnings and cash inflow, received through repayment of loanand the fund would be utilized as revolving fund during the 13th Plan period for extending benefit to around 400 units. It is estimated that around 650 ME units would be benefitted during the 12th and 13th Plan period under this Scheme.

SIDBI may keep the unused funds of the corpus fund from time to time in fixed deposits and the interest earned thereon will be added to the corpus fund

SIDBI would be required to return the Corpus Fund to Government of India along with the interest credited to the Corpus Fund after completion of 10 years from the launch of the Scheme, in 5 equal annual installments.

9.2 Terms and Conditions for Soft Loans under the scheme

Under the scheme, soft loans would be provided by SIDBI or by lending agencies such as Financial Institutions and Scheduled banks as notifiedby SIDBI subject to terms and conditions given below:

a) Quantum of assistance

Need based assistance in terms of soft loan for technology upgradationshall be maximum of Rs.2.00 crore per unit.

b) Promoter's contribution

The Promoters contribution will be minimum 20% of the outlay on technology upgradation which will be disbursed pro-rata basis alongwith soft loan.

c) Rate of Interest

The loan up to Rs.2.00 crore per unit will carry a concessional rate of 5% p.a. Any higher amount of loan will carry interest rate as per the norms of SIDBI.

d) Repayment period

The loan shall be repayable within a period of 5 years including one year moratorium, in monthly installments. The moratorium period is optional and is subject to willingness of manufacturers..

e) Foreign Currency loan

Foreign currency loan will also be arranged by SIDBI, as per rule, in case new machinery is imported for the purpose of the scheme.

f) WHO-GMP and other international GMP certificate

All MEs, to whom benefit of soft loan is extended, must obtain WHO-GMP certification, as stipulated in the PTUAS Scheme, within 2 years of the drawl of the soft loan, failing which soft loan will be converted to a normal loan by SIDBI.

g) Non-performing asset (NPA)

If an account becomes a non-performing asset (NPA), the credit risk would lie with SIDBI. In case the account becomes NPA or unit does not implement the scheme as envisaged or do not adhere to the guidelines of the schemes, the soft loan would be converted into normal loan from the date of NPA/ date of non-adherence to the guidelines and would attract normal rate of interest.

10. Implementation of the Scheme

The Credit Co-ordination Group, Mumbai, SIDBI, would operate the scheme and issue operational guidelines to its branches, Financial Institutions /State Financial Corporations (SFCs), State IndustrialDevelopment Corporations (SIDCs)/ Commercial/Cooperative Banks for operation and management of the Scheme. SIDBI would monitor the soft loan benefit extended to eligible MEs through these financial institutions by developing appropriate accounting/ reporting and auditing of their accounts.SIDBI wouldalso be represented in Technical Committee, constituted for resolving technical issues for admissibility of items for the soft loan.

SIDBI, the nodal financial institutions of the scheme,may co-opt assistance of other All India Financial Institutions (AIFIs)/ state financial corporations (SFCs) / state industrial development corporations (SIDCs) and scheduled banks in the scheme for sanction and disbursement of soft loan so as to have a better reach to the eligible MEs in the country.

However, there will be no erosion in the concessional rate of the interest of 5% p.a. available to the borrower on account of such linkages

Applications for assistance under the Scheme may be submitted in the prescribed form available from the concerned financial institutions or co-opted AIFIs/SFCs/SIDCs/commercial/ co-operative banks, as the case may be.

A special cell will be set up by SIDBI (the nodal agency) for expeditious processing of soft loan proposals.

The financial institutions will furnish periodically (quarterly) information in respect of sanction and disbursement of the loans and other related information to the SIDBI/ Department of Pharmaceuticals. Such information in respect of the co-opted AIFIs/ SFCs / SIDCs/ commercial/co-operative banks will be co-ordinated and furnished by the SIDBI.In respect of the co-opted financing institutions, the SIDBI will be responsible for verifying the soft loan disbursement claims.

SIDBI would prescribe/ devise appropriate application form for availing soft loan benefit under the scheme and set up suitable accounting procedure/ guidelines for reporting by the FIs and branches of SIDBI for proper monitoring and appraisal of the benefit under the scheme.

The annual account pertaining to the Corpus fund would be got audited by SIDBI by a Chartered Accountant/ independent agency and the report would be submitted to D/o Pharmaceuticals for review by Steering Committee.

11.Administrative Expenses of the Scheme

SIDBI would be allowed to retain a reasonable portion of interest earning from MEs towards its administrative and transaction cost (say 1% to 1.5% of soft loan disbursement). Such fee would be payable to the SIDBI (nodal agency) in lieu of its services rendered for implementation of the scheme and for bearing the entire burden of credit risk of NPA.However, SIDBI may share its fee earning with other FIs (say 0.1% to 0.5% of soft loan disbursement) in line with banking parlance/ guidelines as per discretion of SIDBI.

11.2Publicity Campaign

D/o Pharmaceuticals would bear the initial advertisement/ Publicity expenditure of Rs.50.00 lakhs out of the total budgeted amount for the year 2013-14 before launch of the Scheme. The publicity/ advertisement expenditure in the subsequent yearswill be arranged by SIDBI from out of its administrative cost component.

12.Monitoring/ Appraisal mechanism of the Scheme

12.1 Inter-Ministerial Steering Committee

AnInter-Ministerial Steering Committee, under the Chairmanship of Secretary(Pharma) would be constituted to lay down norms for monitoring and appraisal mechanism for effective implementation of the Scheme. This Steering Committee shall have members each from SIDBI, NIPER, MSME and DoP. The Steering Committee would also periodically review the functioning of the scheme and may make such modifications/ changes in it as may be deemed essential.

The Inter-ministerial Steering Committee may also set up appropriate machinery to lay down such norms for a monitoring and appraisal mechanism for effective implementation of the scheme.

12.2 Technical Committee

A Technical Committee would be constituted under the Chairmanship of CMD, IDPL with a representative from Small Industries Development Bank of India (SIDBI), DCGI and other Technical Experts to be nominated by the Government for advising the Steering Committee for updating the list of eligible machinery depending on requirement of the Pharmaceutical industries under the WHO -GMP norms and other international GMP norms. The Technical Committeewill also advise Steering Committee on all technical matters.

12.3 GrievanceRedressal Committee

In order to sort out the dispute/ complaint and grievances of the beneficiary under the Scheme, Steering Committee would constitute a forum in the form of Grievance Redressal Committee to be represented by Technical Committee Members including SIDBIand headed by DS/ Director in Department of Pharmaceuticals.

12.4 Mid-term review of the Scheme

A mid-term review of the Scheme would be conducted immediately after completion of 2 years of the launch of the scheme. For this purpose, D/o Pharmaceuticals may engage the services of institutes of repute such as National Council for Applied Economic Research or any other independent agency for conducting the said review. The review report would be submitted to the Steering Committee for taking a view for continuation/ amendment of the Scheme.Another review would be done after the completion of the 12th Plan period.

13. Expected outcomes of PTUAS

Pharmaceutical MEs, which are already GMP compliant, are further proposed to be incentivized to upgrade their manufacturing facility to substantially higher standards of

production, at par with WHO-GMP certification. The expected benefits of the scheme are;

(i) To ensure quality of medicines to international standards by using state-of-art manufacturing technology for indigenous production and supply of medicines

(ii)To maintain production of medicine in the most hygienic environmenttoensure highest standard of efficacy, purity, stability and safety of the medicines for consumption of general population in the country.

(iii) To augment competition among the MEs in their production and marketing with a view to reduce price of medicines through economy of scale in production and by practicing healthy competition.

(iv) To encourage the MEs to become the member of an elite group of WHO-GMP compliant unit, which is generally a pre-condition for eligibility for offering bids for bulk supply of medicines..

(v) WHO-GMP certification would provide a suitable platform to MEs to compete in domestic market with other Pharmaceutical giants for bulk supply of drugs to Government hospitals/ Institutions and State Government sponsored NGOs.

(vi) WHO-GMPcertification would make the MEs to compete in global markets for export of their products.

14. Conclusion

It has always been the endeavor of the Department of Pharmaceuticals in the Ministry of Chemicals & Fertilizers to make available **quality drugs** available at affordable prices to masses. Drug security has also been one of the major concerns. In this context, the proposed scheme viz. PTUAS would go a long way in improving quality, efficacy and efficiency of drugs manufactured by Medium Enterprises. It will also strengthen the presence of small and medium enterprises in domestic as well as international markets given the globalized nature of pharmaceutical industry. The PTUAS Scheme would also stimulate continuous technological upgradation and trigger healthy competition among the Pharma MEs towards improving quality of drugs by availing soft loan assistance.It is expected that by the end of 13th Five Year Plan, all Medium Enterprises would have state-of-the-art manufacturing facilities conforming to WHO-GMP / international norms.

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I. Specific Requirements for formulations			
(A) Tablet and capsule section			
Sl.No.	**Activity**	**Technology**	**Approximate Cost** ***(Rs. in lakh)***
1	2	3	4
1.	Dispensing Booth	Reverse laminar flow equipment	1.5-2
2.	Weighing	Automatic electronic balance 300 kg.; 150 kg, 1 kg and 200mg.	0.5 to 2.0 depending on the model
3.	Mixing and granulation	Rapid mixer granulator capacity as per requirements	3.0 to 8.0
		Double cone blender/ Octa blender capacity depending of the requirement of the unit	1.0 to 2.0
4.	Dry granulation	Roller compactor	3.0 to 5.0
5.	Drying	Fluidized bed dryer capacity as per the requirement of the unit	4.0 to 8.0 (both steam and electric)
6.	Size reduction	Clitzmill or Cadmill	0.5 to 2.0
		Oscillating granulator	0.15-.25
7.	Sifter	Vibrating sifter	.8-1.4
8.	Coating suspension	1.Colloid mill 2.Auto Coator	1.5 t 3 5 to 8.
9.	Powder Mixing	Blender	2.0 to2.5
10.	Mass Mixing	RMG	3 -5
11.	Reaction	Reactor	2-3

12.	Compression	Rotary tablet machine	2.0 to 5.0
13.	De- dusting of tablets	On-line de duster	0.3 to 0.5
		Metal Deductor	0.5 to 1.50
14.	Thermostatically controlled hot air	TD	2-3
15.	Exhaust System	Dust Extractor	0.3-0.5
16.	Capsule filling	Semi-automatic capsule filling machine	6.0-9.0
17.	Capsule polishing	Automatic polishing machine	2.0-3.0
18.	Inspection	Tablet /capsule inspection unit	1.0-2.0
19.	Packaging	Packing machines for blister/strip /Alu- Alu packs	6.0-9.0
20.	Printing of packaging cartons	Semi-automatic printing Machine	1.0 to 2.0
21.	Water generation	RO water plant	6.0-8.0
22.	Stirring	Agitator	1.0 to 2.0
23.	Storage	Storage Vessel	2.0 to 4.0
24.	Bottle Washing	Automatic Rotary line	4.0 to 5.0
25.	Homogenization/Colloidal Milling	Colloid mill	1.0 to 2.0
26.	Liquid Transfer	Transfer pump	1.0 to 2.0
27.	Filtration	Filter	0.75 to 1
28.	Filling machine	4 head Automatic machine	3.0 to 5.0
		Automatic liquid filling composite line	10.0 to 20.0
29.	Pill Proof Capping	Capping Machine	1.0-1.2

30.	Clarity Testing	Inspection Unit	0.2-0.3
31.	Mixing	Reactor	4-8
32.	reaction	Reactor	2-3
33.	Distillation	Distillation Unit/ Ion Exchange DM Water	4.0 to 5.0 2.0 to 4.0
34.	Bottle Filling machine	Automatic filling machine as per the requirement	2.0-5.0
(C) Injectable Section			
35.	Distillation	Distillation unit	4.0 to 5.0
36.	Filtration	Filter cartridges	0.5 to 2.0
37.	Integrity of the membrane filter	Bubble point apparatus	0.75-1.5
38.	Sterilization	Double door autoclave	6.0-11.0
		Sterilization tunnel	10.0 to 25.0
39.	Washing vials/Ampoules	Washing Vials/Ampoules machine/Vial washer	7.0 to 10.0
40.	Vial filling machine	Automated filling machine with sealing facility	5.0-7.0
		Rubber plug processor	5.0 to 6.0
41.	Bung Processor	Bung Processor	15.0 to 20.0
42.	Dynamic pass box	Dynamic pass box	.75 to 1.25.0
43.	Labeling	Automated labeling machine with printing	2.0 to 4.0
(D) Dry Syrup Section			
44.	Turn table	Turn table	.08 to 1.20
45.	Filling machine	Automated dry powder filling	3.0-10.0

		machine/ line	
46.	Sealing	Sealing machine	1.5 to 3.0
47.	Packing	Packing Belt	0.7 to 1.30
48.	Labeling	Automated labeling machine with printing	2.0 to 4.0
(E) External Preparations			
49.	Mixing & Storage	Reactor	3.0 to 4.0
50.	Reaction	Reactor	2.0 to 02.5
51.	Mixing	Vessel	3.0 to 3.5
52.	Planetary Mixing	Mixture	3.0 to 3.5
53.	Colloidal Milling	Emulsifier	1.0 to 2.0
54.	Milling	Ointment Mill	1.0 to 2.0
55.	Liquid Filling	Filling Machine	2.0 to 2.5
56.	Tube filling	Tube filling machine	4 to 5
57.	Filling	Jar Filling Equipment	1.5-2.0
(F) Ophthalmic Preparations			
58.	Heating	Tep Controlled Oven	4.0 to 5.0
59.	Reaction	Reactor	2.0 to 3.0
60.	Mixing	Reactor	4.0 to 8.0
61.	Colloidal Milling	Ointment Mill	1.0 to 1.2
62.	Tube Filling	Crimping Equipment	1.0 to 4.0
63.	Cleaning	Tube cleaning	0.8 to 1.0
64.	Automatic washing	Tube washing machine	1.0 to 3.0
65.	Drying	Oven	2.0 to 4.0

66.	Automatic vial washing	Vial washing machine	2.0 to 4.0
67.	Sealing	Rotary Sealing machine	3.0 to 4.0
68.	Washing	Rubber bungs washing	2.0 to 3.0
69.	Filter	Cartridge candle filter	1.5.0 to 3.0
70.	Liquid Filling	Liquid Filling machine	2.0 to 5.0
71.	Sterlization	Ventilator autoclave	2.0 to 6.0
(G) Parental preparations in Plastic containers			
72.	DM Water	Ion exchange unit	2.0 to 4.0
(H) Solution Preparation area			
73.	Sterile filling	Sterile filling machine	2.0 to 3.0
II. Bulk Drugs			
S. No.	**Activity**	**Equipment and Machinery**	**Appx Cost** *(Rs in Lakh*)
74.	Reaction Vessel	MS, SS, MS/GL Lead/ RL linned reaction vessel	25 .0 to 40.0
75.	Filtration	Centrifuge, Nutch filter, Vacumm filter SS, MS/GL	15.0 to 25.0
76.	Distillation Unit	SS	15.0 to 20.0
77.	Dryer	TD, VTD, Nauta dryer Rotatory Vacuum	10
78.	Storage tanks	MS, SS, MS/RL	10
79.	Pumps	Centrifugal, Rotopump Multistage	5.0 to 10.0
80.	Powder Processing	Multimill, vibrator, blender, Coating	10
81.	Scrubber	Glass/MS/RL	5
82.	Laboratory Equipments	HPLC, FTIR, UV, Digital balances Kf	15.0 to 35.0

		testing, HTTLC	
83.	AHU	Air conditioning & Rh control	25
84.	Utilities	Cooling water, Chilled Water Chilled brine, air, water	20
85.	Pollution Control	Water, air, solid waste management	15.0 to 20.0
86.	Documentation	SOP, Validation etc DMF filling etc	5.0 to 10.0
III. General Requirements			
(A) Quality Control Department			
87.	Air Compressor	Air Compressor	2 to 4
88.	Vacuum Pumps	Vacuum Pumps	2 to 4
89.	Boiler	Boiler	2 to 3
90.	Drug assay and testing	HPLC	12.0 to 15.0
		HPTLC	11.30 to 15.0
		FTIR	12.0 to 15.0
		Gas Chromatograph	3.0 to 5.0
		automatic titrator	12.0 to 15.0
		Ph meter	.5 to 1.0
		Melting point Karl Fisher instrument	3.0 to 4.0
		Dissolution test Apparatus	0.5 to 0.8
		Disintegration test apparatus	8.0 to 10.0
		UV Spectroscope	10.0 to 12.0
		Laminar Flow benches	1.5 to 2.0
91.	Stability testing	Stability chambers	3.0 to 10.0

(B) Quality Assurance			
92.	Documentation	SOP, STP, Calibration, Validation, Stability testing, Trouble shooting	5.0 to 10.0
(C) Information Technology			
93.	SCADA	Online indicator, recording, retrieving, controlling	50.0 to 100.0
(D) Environment Control Devices			
94.	Air conditioning and humidity control of all types of areas	Air conditioning, Humidity control equipment (Dehumidifier)	10.0-30.0
95.	Air handling for parenteral (Sterile) area	Air handling unit with HEPA filters, Ducting with insulation; Chilled water piping; electrical cabling and panels; Chilled water pump; Chilled water control	15.0-40.0
96.	Air handling other for parenteral area	Air handling unit with five micron filters / AF (0.4lu)	10.0-15.0
97.	Pollution control	Effluent Treatment Pollution Control machinery	10.0 - 15.0
98.	Miscellaneous fittings	Ducting with insulation; chilled water piping; electrical cabling and panels; chilled water pump; chilled water control	5.0-6.0
99.	Energy Generation	DG	2.0-12.0l