



Implementation of Scheme for Schedule M Compliance for SSI Pharma Units

1. INTRODUCTION

- i. As per the second supplement of the Revised Guidelines issued by MSME on the Credit Linked Capital Subsidy Scheme (CLCSS) for Technology Up-gradation of Micro, Small and Medium Enterprises by the Ministry of MSME on 13th July, 2009 the pharma SSI units will now be able to avail the benefits of CLCS Scheme for financial assistance for an expanded list of products from 32 to 179.
- ii. As per the CLCSS Scheme of the MSME, 15% Capital Subsidy would be provided on capital investment of up to Rs One Crore. The scheme is available for 179 machinery and equipment as per Annex-I. It will be implemented in the same manner as the CLCSS scheme. SIDBI and other nominated banks would be implementing the scheme as in the case of CLCSS. List of banks is at Annex-II.
- iii. The scheme will involve collaboration with the following:
 - I. Development Commissioner, Micro Small, Medium Enterprises, Ministry of Micro Small, Medium Enterprises
 - II. Certification agencies (CDSCO / SRA)
 - III. Banks and Financial institutions like SIDBI
 - IV. State government officials in Departments of Health and Industry
- iv. 1.4 Implementation Methodology: The implementation of the Credit Linked Capital Subsidy Scheme (hereinafter referred to as 'Scheme') comprises inter alia the following stages:
 - I. Awareness Building
 - II. Organizational arrangements
 - III. Implementation processes
 - IV. Involvement of all stakeholders
 - V. Periodic Review and Monitoring

2. AWARENESS BUILDING

For this a three fold strategy is proposed to be adopted:

Awareness Building Workshops

Dissemination of Scheme brochures and related material

Media support

2.1 Awareness Building Workshops (ABW):

2.1.1 Workshop Location:

Workshops at 10 SSI Cluster locations as per following schedule would be organized:

Workshops at 10 SSI Cluster locations as per following schedule would be organized

Sl.No.	Venue	Date	Nodal Industry
1.	Goa	05.10.09 (tdursday)	SPIC
2.	Mumbai	06.10.09 (Tuesday)	IDMA & SPIC
3.	Baddi (H.P)	13.10.09 (Tuesday)	FOPE/NIPER, Mohali
4.	Ahmedabad	16.10.09 (Friday)	NIPER (PERD)/IDMA
5.	Bengaluru	22.10.09 (tdursday)	KAPL/SPIC
6.	Chennai (T.N.)	23.10.09 (Friday)	CPI/IDPL
7.	Hyderabad (A.P.)	27.10.09 (Tuesday)	NIPER/Pharmexcil
8.	Indore (M.P.)	30.10.09 (Friday)	SPIC
9.	Dehradun	12.11.09 (tdursday)	FOPE

The aim of the ABWs would be to spread awareness and deepen the understanding of Pharma SSI manufacturers/entrepreneurs about the implementation of the scheme involving interalia, substantially expanded list of 179 machineries/Equipments required for Schedule 'M' Compliance. The choice of these locations takes into account the concentration of SSI pharma units in these locations.

2.1.2 Workshop Personnel:

DDG Shri Ashok Vishan Dass and DIA (Shri Mathur) together would co-ordinate these ABWs. JS (Pharma), Shri Devendra Chaudhry would be present in the important workshops, preferably at larger clusters, as an 'Observer'.

2.1.3 Workshop assisting Organizations:

NIPERs: Ahmedabad, Mohali, Hyderabad

KAPL: Bangalore

NPC: all through

Banks including SIDBI

IDMA, SPIC, FOPE, CIPI, and other Industry associations will be required to assist in getting in organizing and convening the industry at every location.

SMPIC - Small, Medium Pharma Industry Centre at NIPER Mohali may also render technical advise to assist pharma SSIs units. This would also go a long way in capacity building.

2.1.4 Scheme Brochure:

A detailed Scheme Brochure will be made available to the potential beneficiaries to understand the various facets of the scheme and its implementation methodology.

2.1.5 Media:

Two advertisements, one each in vernacular and English languages would be made in the prominent newspapers of the states wherever the ABWs will be held. These advertisements will be released through DAVP.

3. **ORGANISATIONAL ARRANGMENTS**

Scheme Implementation Committee (SIC)

The Scheme Implementation Committee would be set up to be guided by JS DC. DDG AVD will be Member Convenor with other members from SIDBI, NPC and selected industry nominees. SIC would lay down monitoring and evaluation formats developed with support from NIC for effective reporting on the progress of the Scheme. The Committee would meet every month to ensure proper implementation of the Scheme.

4. **IMPLEMENTATION PROCESS**

4.1 Technical and Certification Support:

As a number of Pharma SSI units are not well conversant with the technical requirements of the compliance regulators in terms of physical implementation processes, capacity building with the help of NIPER will be done. This will sensitise the SSI units of the implementation issues and increase their commitment to the project. The ABW would be one day event.

4.2 Other Activities planned:

- i. Cluster survey of the status of the implementation of Schedule M
- ii. Status Report on the standards implementation status
- iii. Gap identification
- iv. Plan to implement for compliance
- v. Capacity building of the potential beneficiary

The requirements of Schedule 'M' compliance include documentation - a very essential part. Accordingly, these units will be provided technical advice by NIPERs to secure the necessary

certification from the concerned state Regulatory Authority.

4.3 Project Approval Support

Each unit would be required to prepare Detailed Project Plan (DPP) for application to the Bank for financial assistance including loan and subsidy. For SIDBI would coordinate and monitor all the applications made seeking assistance under the Scheme.

There will be weekly monitoring of applications filed and sanctioned as well as disbursements of loan and adjustment of subsidy in the loan amount. A close team led by DDG will have to coordinate with the Bank and beneficiary as well as MSME.

5. **MONITORING & EVALUATION**

Scheme Oversight Committee (SOC)

A Scheme Oversight Committee would be set up in the Chairmanship of the Secretary Pharma with DC MSME, JS DC, DDG AVD, Senior Officer of NPC and concerned GM of SIDBI, Heads of IDMA, CIPI, FOPE as members. SIDBI would be Member-Convenor. Based on the monthly Scheme Implementation Committee (SIC), the Oversight Committee would provide periodic guidance for successful implementation of the scheme including policy issues. The SOC would meet every two months.

Annexure-I

Second Supplement of the Revised Guidelines on the Credit linked Capital Subsidy Scheme (CLCSS) for Technology Up gradation of Micro and Small Enterprises approved by the Technical Sub-Committee on the CLCSS (TSC) in its 7th meeting held on the 13th day of July, 2009 under the chairmanship of the Additional Secretary & Development Commissioner (MSME)

Office of the Development Commissioner (MSME),
Ministry of Micro, Small and Medium, Enterprises
Government of India,
Nirman Bhawan,
New Delhi.

iv: Drugs & Pharmaceuticals:

- a. List of Machineries/ Equipments Recommended for Drug and Pharmaceutical Products, Sub-Sector-wise (including the Existing Technologies in the CLCSS) Required for Schedule 'M' Compliance and Indian/International Standards for inclusion at S. No. IV in the Credit Linked Capital Subsidy Scheme for Technology Upgradation.

Surgical Dressing Ophthalmic Preparations Peccaries and Suppositories

Surgical Dressing Ophthalmic Preparations Peccaries and Suppositories

S.No.	Activity	Approx. Cost (Rs. Lakh)	Technology Need	Advantages
	External Preparations			

1.	Mixing and Storage	Reactor	3-4.0	WHO-GMP Compliance Better Quality
2.	Reaction	Reactor	2-2.5	--do--
3.	Mixing	Vessel	3-3.5	--do--
4.	Planetary Mixing	Mixture	3-3.5	--do--
5.	Colloidal Milling	Emulsifier	0.6-0.9	--do--
6.	Milling	Ointment Mill	1-1.5	--do--
7.	Liquid filling	Filling Machine	2-2.5	--do--
8.	Filling	Jar Filling Equipment	1.5-2.0	--do--
In Oral Liquid Preparation				
9.	Stirring	Agitator	0.3-0.5	--do--
10.	Colloidal Milling	Colloidal Mill	0.3-0.5	--do--
11.	Filtration	Filter	0.3-0.5	--do--
12.	Pill Proof capping	Capping machine	1-1.2	--do--
13.	Clarity testing	Inspection unit	0.2-0.3	--do--
14.	Mixing	Reactor	4-8	--do--
15.	Reaction	Reactor	2-3	--do--
16.	Bottle Filling	4 head filling machine	2-3	--do--
17.	Distillation	Distillation unit	4-5	--do--
Tablets				
18.	Dispensing	Reverse laminar flow equipment	1.5-2.0	Safety of personnel
19.	Storing	Storage Cabinet	0.5-0.8	Storage
20.	De-Dusting of	On-line de-duster	0.4-0.6	GMP

	Tablet			
21.	Dissolution test	Lab testing apparatus	1-1.2	Quality testing
22.	Sifter	24 Dia Sifter	0.8-1.0	WHO-GMP Compliance
23.	Powder Mixing	Blender	2-2.5	--do--
24.	Mass Mixing	RMG	3-5	--do--
25.	Granulation	Roller Compactor	1.5-3	--do--
26.	Weighing	Balance	0.8-1	--do--
27.	Thermostatically controlled hot air	TD	2-3	--do--
28.	Tablet compression	16 station rotary tablet machine, 27 station rotary tablet machine	2.0-3.0, 3.25-4.0	Increased Productivity --do--
29.	Tablet Inspection	Inspection Table	1-1.2	--do--
30.	In Process testing	Lab instruments	2-2.5	--do--
31.	AHU	AHU	15-17	GMP
32.	Strip/blister packing	Strip/blister packing machine	6-9	Production
33.	Leak testing	Vacuum leak tester	1-1.2	Analysis
34.	Table Counter	Counter	0.3-0.5	Packing
35.	AHU	Dehumidifier	8-10	GMP
36.	Reaction	Reactor	2-3	WHO-GMP compliance
37.	Coating	Coating Pan	1.5-3	--do--
38.	Exhaust System	Dust Extractor	0.3-0.5	--do--
39.	AHU	Dehumidifier	8-10	GMP
40.	Weighing	Balance	0.8-1	GMP

41.	Disintegration	Multi mill	1-1.5	Production
42.	Powder Mixing	Blender	2-2.5	--do--
43.	Sifter	24" Dia Sifter	0.8-1.0	--do--
44.	Vessels	SS vessels & scoops	0.2-0.9	--do--
45.	Filling	Filling machine	4-6	--do--
46.	Weighing	Balance	0.8-1	--do--
Capsules				
47.	Mixing	Blender	2-2.5	Production
48.	Filling	Capsules filling machine	8-15	--do--
49.	Counter	Capsules counter	1-1.2	--do--
50.	Weighing	Balance	0.8-1	--do--
50.	Weighing	Balance	0.8-1	--do--
51.	Disintegration	Disintegration Tester	0.4-0.6	--do--
52.	Capsules polishing	Polishing equipment	2-3	--do--
52.	Rolling	Roller Machine	2-2.5	--do--
53.	Trimming	Trimming Machine	1-2	--do--
54.	Trimming	Trimming Machine	1-2	--do--
55.	Cutting	Cutting equipment	1-2	--do--
56.	Folding & Pressing	Folding & pressing machine	2-3	--do--
57.	Mixing	Medicating processing tanks	2-3	--do--
58.	Heating	Dry steam sterilizer	10-15	--do--
59.	Air heating	Oven	1-2	--do--
60.	Working place	Tables	1-2	--do--
61.	Steam Sterilization	DHS	10-18	--do--

62.	Heating	Temp. controlled oven	4-5	WHO-GMP compliance
63.	Reaction	Reactor	2-3	--do--
64.	Mixing	Reactor	4-8	--do--
65.	Colloidal milling	Ointment mill	1-1.2	--do--
66.	Tube filling	Crimping Equipment	1-4	--do--
67.	Cleaning	Tune cleaning	0.8-1	WHO-GMP Compliance
68.	Automatic washing	Tube washing machine	1-3	--do--
69.	Drying	Oven	2-4	--do--
70.	Automatic vial washing	Vial washing machine	1-3	--do--
71.	Washing	Rubber bungs washing	2-3	--do--
72.	Filter	Cartridge candle filter	1.5-3	--do--
73.	Liquid filling	Liquid filling machine	2-5	--do--
74.	Sterilization	Ventilator autoclave	2-6	--do--
75.	AHU	Dehumidifier	8-10	GMP
76.	AHU	Laminar air flow unit	1-1.5	Sterility
77.	Mixing	Reactor	1-1.5	--do--
78.	Moulding	Moulding equipment	1-1.2	--do--
79.	Weighing	Balance	1-1.5	--do--
80.	Mixing	Reactor	1-2	--do--
81.	Measuring	Graduated measuring equipment	1-2	--do--
82.	Sealing	Sealing machine	1-1.2	--do--
Repacking of Drugs & Pharmaceutical Chemicals				

83.	Powder disintegration	Powder disintegrator	1-1.2	--do--
84.	Sieving	Sifter	1.5-2	--do--
85.	Scoops	Scoop	0.2-0.3	--do--
86.	Weighing	Balance	1-1.5	--do--
87.	Filling	Filling Machine	2-2.5	--do--
88.	Pill proof capping	Capping machine	1-1.2	--do--
89.	Sealing	Sealing machine	0.3-0.5	--do--
90.	Water lines	SS pipes	3-5	--do--
Parental preparation				
91.	De-ionization	Ion exchange unit	12-15	--do--
92.	Distillation	Triple effect evaporators	4-5	Sterility
93.	Water storage	Thermal controlled reactor	3-5	--do--
94.	Pumping	Pump	2-3	--do--
95.	Piping	SS lines for water	4-6	--do--
Container & closer preparation				
96.	Automated Rotary	Ampoule washing machine	5-7	--do--
97.	Washing	Closure washing machine	2-3	--do--
98.	Storage	Storage cabinet	2-3	--do--
99.	Storages benches	SS benches	2-3	--do--
100.	Automatic vial washing	Vial washing machine	4-5	--do--
101.	Rubber bung washing	Rubber bung washing machine	1-3	--do--

Solution preparation				
102.	Stirring	Agitator	0.3-0.5	--do--
103.	Filtration	Filter	2-3	--do--
104.	Pumping	Pump	2-3	--do--
105.	Benches	SS benches	1-2	--do--
106.	Preparation Tank	Reactor	2-4	--do--
Filling capping				
107.	Ampoule filling	Ampoule/vial filling machine	3-5	--do--
108.	Gas lining	SS pipes	2-4	--do--
109.	Benches	SS benches	1-2	--do--
110.	Pressure leak testing	Pressure leak test equip	1-1.2	--do--
111.	Steam Sterilizer	Autoclave	10-12	--do--
112.	Dry heat sterilizer	DHS	14-18	--do--
113.	Quarantine area	Room storage	4-7	--do--
114.	Platforms	SS Platforms	2-4	--do--
115.	Visual inspection	Belt type inspection table	1-3	--do--
116.	Benches	SS benches	1-1.5	--do--
Parental preparations in Plastic containers				
117.	DM water	Ion exchange unit	12-15	--do--
118.	Distillation	Triple effect evaporators	4-5	--do--
119.	Water Storage	Thermal controlled reactor	3-5	--do--
120.	Pumping	Pump	2-3	--do--

121.	Water transportation	SS lines for water	4-6	--do--
121.	Water transportation	SS lines for water	4-6	--do--
Solution preparation area				
122.	Pumping	Pump	2-3	--do--
123.	Water storage	Thermal controlled reactor	3-5	--do--
124.	Filtration	Membrane filter	1-2	--do--
125.	Sterile filling	Sterile filling machine	2-3	--do--
126.	Filling	Plastic filling machine	2-3	--do--
127.	Batch Coding	Batch coding machine	1-1.2	--do--
128.	Labeling	Labeling machine	2-3	--do--
129.	Batch coding	Batch coding machine	1-1.2	--do--
130.	Labeling unit	Labeling machine	2-3	--do--
131.	Automatic vial washing	Vial washing machine	4-5	--do--
132.	Vial drying	Oven	2-4	--do--
133.	Autoclave	Autoclave	4-5	--do--
134.	Laminar flow	Laminar air flow unit	1-1.5	Sterility
135.	AHU	HVAC	10-15	

Bulk Drugs

(vii) Plastic Moulded/Extruded Products and parts

Sl. No.	Activity	Technology need	Cost (in Rs. Lakh)	Advantages
1.	Weighing	Automatic electronic balance 300kg.;150kg and 1kg.	0.5-2.0 depending on the model	Accurate weighing of raw materials; increased productivity
2.	Reaction	MS SS MS/Cl Lead/DI lined	25	Suitable for

2.	REACTION	MS,SS,MS/GL Lead/RL lined Reaction Vessel	25	Suitable for process
3.	Filtration	Centrifuge, Nutch filter, Vacumm filter, filter press, Pressure filter SS, MS/GL	15	Suitable for process
4.	Distillation Unit	SS Distillation Unit	15	Solvent Quality Reusable
5.	Dryer	TD,VTD, Nauta dryer, Rotatory Vacuum, SS Dryer with modern facilities, spray/ flash	15	Quality upgradation
6.	Storage tanks	MS, SS, MS/RL Storage tanks	10	Avoid mixing
7.	Pumps	Centrifugal, Totopump	5	Process
		Multistage		Handling
8.	Powder Processing	Multimill, vibrator, blender coating	10	Quality Requirements
9.	Scrubber	Glass/ MS/RL	5	Environmental Improvement
10.	Laboratory Equipments	HPLC, FTIR, UV, KF testing, HTTLC	35	Quality Requirements
11.	Mixing	Blenders	5	For uniformity of the product
12.	Micronisation	Jet mill, Pulverizer	25	For better dissolution rate
13.	Compacting	Roll compacter	15	For increasing bulk density of the product
14.	Distillation	SS Condensers	10	For improving recovery of solvents and uniform reaction
15.	Raw material and finished product weighing	Electronic Weighing machine	0.15	<ol style="list-style-type: none"> 1. Saving of time 2. Saving of labour 3. No loss of material

				4. Increase in the profitability
16.	Quality control	Laboratory Equipment of latest technology, spectrophotometer, Gas Chromatograph & others. ITR,	10	<ol style="list-style-type: none"> To get the best possible precise results. less time consuming & immediate results display
17.	Pulverisation.	Latest technology pulverisers impact	4	<ol style="list-style-type: none"> Quality of products improves due to finest particles. Physical loss of material is very less
18.	Heating	Boilers	10	For heating
19.	Power	DG Set	10-15	For uninterrupted power during process
20.	Chilling	Chilling units, cooling towers. WAS systems	25-50	To maintain process parameters
21.	Instrumentation	Online PH meters, temperature meters	5	To maintain process parameters
22.	AHU	Air conditioning & Rh control	25	Quality up gradation
23.	Chilling	Cooling water, chilled water chilled brine, air water VAS System	30-45	To maintain process conditions parameters

24.	Accurate Weighing	Digital balances,	1	For accuracy
25.	Non-reactive Storage Tanks	Storage Containers Numbers & size to depend on operation	1-8	For handling of pharmaceuticals in-process
26.	Containers	Storage Containers Number & size to depend on operation	1-5	Material handling
27.	Process Instruments	Measuring temperature, pressure	2-5	Process Control
28.	Pumps	Centifugure, vacuum	5	Atomization
Quality Control Department				
29.	Dispensing	Reverse laminar flow equipment	1.5-2	Safety o personnel
30.	Weighing	Automatic electronic balance 300kg.; 150 kg. and 1kg	0.5-2.0 depending on the model	Accurate weighing of raw materials; Increased productivity
31.	Drug Assay and testing	HPLC, HPTLC, FTIR, automatic titration, PH meter, melting point, karl fisher instrument Gas chromatograph, small rato evaporator system with vacuum pump tablet hardness tester, dissolution test apparatus, disintegration test apparatus, UV spectroscope, laminar flow benches, TLC/FID detector	20-40	Accurate drug analysis
33.	Stability chambers	Two stability chambers at 40 \ddot{Y} & 25 \ddot{Y} with alarm bell and printer	7	
Environment Control Devices				
34.	Weighing	Automatic electronic balance 300kg. 150kg. & 1kg.	0.5-2.0 depending on the model	Accurate weighing of raw

				materials; increased productivity
35.	Air conditioning and humidity control of all types of areas	Air conditioning Humidity control equipment (dehumidifier)	10-30	Improve product stability, enhance personal comfort
36.	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	15-40	Improve product quality, enhance personal safety
37.	Air handling other for parenteral area	Air handling unit with 5 micron filters,	10-15	Improve product quality, enhanced personal safety,
38.	Miscellaneous fittings	Ducting with insulation; chilled water piping; electrical cabling and panels; chilled water pump; chilled water control	5-6	Improves product quality, enhanced personal safety
39.	Energy Generation	DG	2.0-12.01	For continuous Production
40.	Pollution control	Effluent Treatment Pollution Control Machinery	10-15	Biochemical treatment of effluent removes 90 to 95% of soluble organic matter in the waste
41.	Recovery	Reverse osmosis plant, scrubbers	10	To improve discharge or waste water
42.	Pollution control	Incinerators	20	For solid waste disposal
43.	Cleaning	Vacuum cleaner and scrubbers	2	For maintaining cleanness as required Schedule M

Annexure –II

Addresses of Nodal Agencies for CLCSS

Addresses of Nodal Agencies for CLCSS

S.No.	Title
1.	CHIEF Manager, Bank of India, 70/80,M.G.Road, Post Box No. 238, Mumbai-400001.
2.	Chief General Manager, National Bank of Agriculture & Rural Development, Block-C-24, G Block, 5th Floor, B Wing, Bandra Kurla Complex, Bandra East Mumbai-51.
3.	Dy. General Manager, Small Industries Development Bank of India, SIDBI Tower, 15, Ashok Marg, Lucknow -226001. (U.P.)
4.	Chief Manager, State Bank of India, Commercial Branch, Corporate Operation Division, N.G.N.Vaidya Marg, Mumbai.
5.	Chief Manager (SME Division), Punjab National Bank, H.O., Atma Ram House, 1, Tolstoy Marg, New Delhi.
6.	AGM, Canara Bank Corporate Credit Wing, 112, J.C. Road, Head Office, Post Box N. 6648, Bangalore-560002.
7.	GM (SME Banking), Bank of Baroda, Baroda Corporate Centre, Plot No. C- 26, G Block, Bandra Kurla Complex, Bandra (East). Mumbai-400051
8.	Dy. General Manager (IC), The Tamilnadu Industrial Investment Corporation Ltd. 692, Anna Salai, Nandanam, Chennai – 6000035.
9.	AGM, Andhra Bank, Head Office Dr. Pattabhi Bhawan, 5-9-11, Saifabad, Hyderabad – 500004.
10.	Chief Manager (C&I), State Bank koff Bikaner & Jaipur, Head Office, Tilak Marg, Jaipur – 302005.

[Website Policies](#)
[Contact Us](#)
[Disclaimer](#)
[Visitor Analytics](#)

[Help](#)
[Feedback](#)
[Terms & Conditions](#)
[Pension Revision Status](#)



Website Content Managed by **Department of Pharmaceuticals**
 Designed, Developed and Hosted by **National Informatics Centre (NIC)**
 Last Updated: **09 Feb 2017**