



# Pharma Web

A Newsletter of  
Tamilnadu Pharmaceutical  
Sciences Welfare Trust

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# Pharma Web

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Sciences Welfare Trust

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## **CHAIRMAN'S MESSAGE**



It is my proud privilege and pleasure to introduce this newsletter for the benefit of Pharmacy professionals, industrialists, academicians as well as the student community.

The Tamilnadu Pharmaceutical Sciences Welfare Trust was established during 1989 with the motive of sharing knowledge and also to uplift the student community in order to improve their professional skills. It is a known fact that quality of medicines produced in this country improved in various aspects, including cGMP, in the last four decades. The state-of-art in manufacturing, quality control and quality assurance of pharmaceuticals has been envisaged through various legislations as well as professional organizations. It is also pertinent to bear in mind that the consumer at large is demanding finest quality of drug formulations and hence it is imperative to widen the knowledge of professionals, which we hope to achieve through this newsletter.

As a service to the pharmacy profession, the Trust has established a library facility with latest books on various subjects and also journals and periodicals, etc. Of late, it was observed that, due to various engagements and time constraints, professionals have not been able to make full utilization of the library. Hence, for the convenience and benefit of the readers, the trustees felt the need for such a newsletter, which can reach their organizations free of cost, on a quarterly basis.

I trust this newsletter will serve the community of professionals to upgrade their knowledge. This is the first issue, being released during the meeting of Indian Pharmaceutical Association, Tamilnadu branch. In the next and future issues, we will be publishing much more useful articles and information.

Wishing you all the best.

G. RANGACHARI



## **EDITORIAL**



**Dear Readers,**

The Tamilnadu Pharmaceutical Sciences Welfare Trust was established in the year 1989 after organizing a successful Indian Pharmaceutical Congress in Chennai. The Governing Body consists of many professional persons. After having served for the society of professionals, the Trust is trying to stimulate the professionals to learn and gain knowledge through the library established. The Trust had conducted various technical seminars/workshops through various professional organizations, particularly Indian Pharmaceutical Association, Tamilnadu branch. The Trust also organized in this year a GMP workshop for the benefit of various technical personnel involved in pharmaceutical manufacture. These two days of "workshop" was very successful. We are bringing some of the lectures delivered by eminent professionals through this newsletter.

This is the first inaugural issue of this newsletter. This first issue is being released during the meeting of Indian Pharmaceutical Association, Tamilnadu branch. The newsletter contains various activities of our Trust and also GMP lectures delivered by various professionals. We are also publishing in this newsletter various amendments notified in the Drugs and Cosmetics Act by Government of India for the benefit various regulatory authorities including industrial regulatory bodies etc. The first edition of this newsletter also consists of various news items and

the data of Pharmacy Colleges in Tamilnadu.

This newsletter will be published on quarterly basis and circulated free of cost to all Pharmaceutical industries, colleges, professional associations and Drugs Control departments.

The future newsletter will have various scientific papers and also useful information like statistical data of import and export of drugs and pharmaceuticals etc.

We have able persons associated in the editorial board and also in the advisory board. I am very much thankful to these persons for guiding me to prepare the first issue of this newsletter. The editorial as well as the advisory board will be meeting soon to chart out the future issues of newsletter. I hope this newsletter will be beneficial to all the persons dealing in the pharmacy profession.

I would like to thank Mr. N. Sreenivasen, Hon. Gen. Secretary of the Trust for giving encouragement for starting this newsletter. I also thank the office executives of the Trust, particularly, Mrs. Pratima Mathur, Deputy Director, Pharma information Centre for the compilation of various news items as well as activities of the Trust for this newsletter.

Best regards,  
**R. Narayanaswamy**

## ACTIVITIES OF TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST (TNPSWT)

The Tamilnadu Pharmaceutical Sciences Welfare Trust was established in the year 1989 after successfully organizing Indian Pharmaceutical Congress in Chennai, with the objective of promoting and developing Pharmaceutical education and profession in all its aspects by awarding scholarships for students and sponsoring lectures, seminars, etc. for Pharmacy professionals.

### Library

In 1999, The Trust established a reference library facility with a range of resources including Pharmacopoeias, Pharmaceutical and Medical reference books, journals and scientific CD ROMs. The library is well utilized by students, researchers and technical personnel of pharmaceutical manufacturing units. Useful titles are added to the library every year.

### Pharma Information Centre (PIC)

Recognising the growing need and enquiries for up-to-date information, the Trust has established a Pharma Information Centre (PIC) which was inaugurated by the then Drugs Controller General (India), Mr. Ashwini Kumar. The main objective of PIC is to provide crucial, in-depth and unbiased information to Industrial Pharmacy professionals, academicians, researchers, students, medical and related health-care professionals. Technical guidance is given to help them in literature search for their projects at various levels.

### Document Delivery Facilities

The Trust also has document delivery facilities to provide any type of scientific documents such as abstracts, journal articles, patents, book chapters, conference papers, etc. ensuring copyright compliance.

### Scholarships

In order to motivate the student community, for the past eleven years the Trust has been awarding scholarships to M. Pharm

students of Tamilnadu, selected on the basis of their best projects. Every year, an amount to the tune of Rs. 1.5 Lacs has been earmarked for this.

### Sponsorship

To promote the interest in learning and development of pharmaceutical profession, the Trust is sponsoring various professional organisations like Indian Pharmaceutical Association for conducting scientific sessions, seminars, lectures, etc.

### Foreign Travel Grant

The Trust encourages and assists academicians in their research activities by providing foreign travel grants to academicians from Pharmacy colleges of Tamilnadu for presenting research papers in international conferences/seminars.

### Training programmes

The Trust is also conducting various training programmes for the benefit of students and pharmacy professionals. In August 2008, the Trust organized a 2-day training programme for technical personnel of various departments of Pharmaceutical industry. Eminent speakers from Chennai and out-station contributed to this programme that was attended by 20 participants.

### Newsletter

The quarterly newsletter of the Trust "PHARMA WEB" is circulated free of cost to academic institutes, Pharma Industries, offices of regulatory authorities and professional organisations of Tamilnadu, to provide useful and technical information on various topics.

### Infrastructure

The Trust functions from its own premises in a prime locality. It has a library / conference room which can accommodate 30 persons. The Pharma Information Centre is equipped with computers with Internet facilities for providing scientific information to the target audience.

## M. Pharm Scholarships (for best projects) awarded by Tamilnadu Pharmaceutical Sciences Welfare Trust for the year 2008- 2009

The eleventh year of scholarship award by Tamilnadu Pharmaceutical Sciences Welfare Trust to M. Pharm students of various colleges of Tamilnadu received 189 applications in seven branches from 17 colleges.

186 were sent to Dr. Balaraman, Professor and Head Department of Pharmacy and his

team of The MS University of Baroda, Vadodara for evaluation. Scholarships have been awarded to 43 students (10 - first ranks, 14 - Second ranks and 19 - third ranks). The awards and certificates were handed over to the students during the National Pharmacy week Celebrations of the respective colleges.

Subject	Applications	First	Second	Third
Pharmaceutics	45	1	1	1
Pharmaceutical Chemistry	24	1	1	4
Pharmaceutical Analysis	22	4	2	3
Pharmacology	34	1	2	4
Pharmacognosy	26	1	3	4
Pharmacy Practice	28	1	3	2
Biotechnology	7	1	2	1
<b>TOTAL</b>	<b>186</b>	<b>10</b>	<b>14</b>	<b>19</b>

College-wise break-up	Applications evaluated	Awards
1. SRIPMS, Coimbatore	: 40	13
2. J. S. S. College of Pharmacy, Ooty	: 41	9
3. Madras Medical College, Chennai	: 16	*
4. S. R. M. College of Pharmacy, Chennai	: 13	6
5. C. L. Baid Metha College of Pharmacy, Chennai	: 12	2
6. Periyar College of Pharmaceutical Sciences, Trichy	: 11	1
7. K. M. College of Pharmacy, Madurai	: 10	3
8. Swamy Vivekanandha College of Pharmacy, Thiruchengode	: 8	*
9. Adiparashakthi College of Pharmacy, Melmaruvathur	: 7	1
10. Vel's College of Pharmacy, Chennai	: 7	2
11. K. M. C. H. College of Pharmacy, Coimbatore	: 5	3
12. P. S. G. College of Pharmacy, Coimbatore	: 4	*
13. R. V. S. College of Pharmacy, Coimbatore	: 4	1
14. Madurai Medical College, Madurai	: 3	1
15. The Erode College of Pharmacy, Erode	: 3	1
16. Ultra College of Pharmacy, Madurai	: 1	*
17. Arulmighu Kalasalingam College of Pharmacy, Sriviliputhur	: 1	*
<b>TOTAL</b>	<b>186</b>	<b>43</b>

The details of the awards are as follows:

#### **PHARMACEUTICS**

<b>Rank</b>	<b>Name</b>	<b>Institute</b>	<b>Amount</b>
First	Mr. Mohammed Hussain	C. L. Baid Metha College of Pharmacy, Chennai	Rs. 6,000/-
Second	Mr. Wagh Kunal Prakash	The Erode College of Pharmacy, Erode	Rs. 4,000/-
Third	Mr. C. Arther Paul	SRIPMS, Coimbatore	Rs. 2,000/-

#### **PHARMACEUTICAL CHEMISTRY**

<b>Rank</b>	<b>Name</b>	<b>Institute</b>	<b>Amount</b>
First	Ms. A. Manjula	SRIPMS, Coimbatore	Rs. 6,000/-
Second	Mr. Gajendra Kumar	SRM College of Pharmacy, Chennai	Rs. 4,000/-
Third	Mr. Ankit Kumar Sitoke	SRM College of Pharmacy, Chennai	Rs. 2,000/-
Third	Ms. S. Shakila Banu	SRIPMS, Coimbatore	Rs. 2,000/-
Third	Mr. Gurdeep Singh Saluja	SRM College of Pharmacy, Chennai	Rs. 2,000/-
Third	Mr. Mukesh Soni	JSS College of Pharmacy, Ooty	Rs. 2,000/-

#### **PHARMACEUTICAL ANALYSIS**

<b>Rank</b>	<b>Name</b>	<b>Institute</b>	<b>Amount</b>
First	Ms. K. S. Kokilambigai	KM College of Pharmacy, Madurai	Rs. 6,000/-
First	Ms. M. Muthulakshmi	KM College of Pharmacy, Madurai	Rs. 6,000/-
First	Ms. Rigno Boni Freeda	CL Baid Mehta College of Pharmacy, Chennai	Rs. 6,000/-
First	Mr. Nageswara Rao Pacha	Adhiparasakthi College of Pharmacy, Melmaruvathur	Rs. 6,000/-
Second	Mr. Manikanta Kumar Alavala	SRIPMS, Coimbatore	Rs. 4,000/-
Second	Mr. S. Vijayaraj	SRIPMS, Coimbatore	Rs. 4,000/-
Third	Ms. Dhanya K. Nair	SRIPMS, Coimbatore	Rs. 2,000/-
Third	Ms. N. Bharathi	SRIPMS, Coimbatore	Rs. 2,000/-
Third	Mr. P. Senthil Nathan	RVS College of Pharmacy, Coimbatore	Rs. 2,000/-

#### **PHARMACOLOGY**

<b>Rank</b>	<b>Name</b>	<b>Institute</b>	<b>Amount</b>
First	Mr. Nandu Rangnath Kayande	SRM College of Pharmacy, Chennai	Rs. 6,000/-
Second	Mr. Nikunj Sethi	JSS College of Pharmacy, Ooty	Rs. 4,000/-
Second	Mr. R. Sankar Anand	SRIPMS, Coimbatore	Rs. 4,000/-
Third	Mr. Mahesh Bhanudas Narkhede	SRIPMS, Coimbatore	Rs. 2,000/-
Third	Ms. S. Suganya	JSS College of Pharmacy, Ooty	Rs. 2,000/-
Third	Mr. Sachin Sadanand Joshi	KMCH College of Pharmacy, Coimbatore	Rs. 2,000/-
Third	Mr. Maruthi Prasanna	JSS College of Pharmacy, Ooty	Rs. 2,000/-

#### **PHARMACOGNOSY**

<b>Rank</b>	<b>Name</b>	<b>Institute</b>	<b>Amount</b>
First	Ms. P. Susithra Selvam	SRM College of Pharmacy, Chennai	Rs. 6,000/-
Second	Ms. Priya Abraham	JSS College of Pharmacy, Ooty	Rs. 4,000/-
Second	Mr. Borole Rahul Nandkumar	JSS College of Pharmacy, Ooty	Rs. 4,000/-
Second	Ms. B. Uma Maheswari	Madurai Medical College, Madurai	Rs. 4,000/-
Third	Ms. A. Vijayalakshmi	Vel's College of Pharmacy, Chennai	Rs. 2,000/-
Third	Mr. Umesh B. Telrandhe	Vel's College of Pharmacy, Chennai	Rs. 2,000/-
Third	Mr. Diptanu Biswas	SRM College of Pharmacy, Chennai	Rs. 2,000/-
Third	Mr. Baskar Ananda Raj	JSS College of Pharmacy, Ooty	Rs. 2,000/-



**PHARMACY PRACTICE**

Rank	Name	Institute	Amount
First	Ms. K. Shailaja	KM College of Pharmacy, Madurai	Rs. 6,000/-
Second	Ms. Jenny Mariam Varghese	JSS College of Pharmacy, Ooty	Rs. 4,000/-
Second	Mr. K. M. Binu	SRIMPS, Coimbatore	Rs. 4,000/-
Second	Mr. T. Darwin	JSS College of Pharmacy, Ooty	Rs. 4,000/-
Third	Ms. R. Jothi	Periyar College of Pharmaceutical Sciences, Trichy	Rs. 2,000/-
Third	Ms. Lini Elizabeth Chacko	SRIMPS, Coimbatore	Rs. 2,000/-

**BIOTECHNOLOGY**

Rank	Name	Institute	Amount
First	Ms. M. Nancy Rita	SRIPMS, Coimbatore	Rs. 6,000/-
Second	Mr. T. R. Arun Raj	SRIPMS, Coimbatore	Rs. 4,000/-
Second	Ms. B. Krithika Devi	KMCH College of Pharmacy, Coimbatore	Rs. 4,000/-
Third	Ms. A. Sulthana	KMCH College of Pharmacy, Coimbatore	Rs. 2,000/-



## **AN OPEN INVITATION TO**

- ♦ **THE PHARMACEUTICAL MANUFACTURERS**
- ♦ **PHARMACY ACADEMIC INSTITUTIONS**
- ♦ **OTHER PHARMACY RELATED PROFESSIONALS**

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# **GOOD MANUFACTURING PRACTICES - NON-COMPLIANCES**

**By**  
**Mr. S. S. V. Krishnan, Rtd. Drugs Controller of Kerala at the GMP**  
**training programme on 09.08.2008 organized by the Tamil Nadu**  
**Pharmaceutical Sciences Welfare Trust .**

## **GMP REQUIREMENTS**

While discussing GMP non-compliances, it is essential to examine the GMP requirements. GMP is the totality of the quality control and assurance systems of a unit. It comprises of different factors.

### **Components of GMP**

1. Infrastructure facilities comprising of plant, machineries & equipment and personnel.
2. Control Procedures.
3. Documentation.

Insufficiency or defect in any of these components affecting directly or indirectly the quality control and assurance could amount to non-compliance.

## **INFRASTRUCTURE FACILITIES**

### **Plant Machineries and equipment:**

The requirements of these components are detailed in the law. The actual requirement of the individual component depends upon the nature of the activity. The design, installation, performance and operation shall be proportionate to the needs of the operation. Insufficient or excessive or poorly designed space, poor environment controls, unsuitable capacity or design or performance or improper installation or operation of an equipment would directly affect the quality of the product. Apart from the requirements of space and equipment specified in the Schedule M, there are other facilities required for carrying out the activities

of the production sections and these are generally known as 'Utilities'. These include space and equipment. Some of these are mentioned as ancillary areas in the Schedule and include washing area, change-room etc. The utility equipment are many of which some are essential while some are optional. These include Pass-boxes, S S trays, Cross-over-benches, Air-curtains, work tables, Drain-traps, Punches and dies storage cup-boards, ladder etc.

### **Personnel**

\* This includes technical and non-technical staff: skilled and unskilled labour. Personnel are required to be duly qualified and experienced to execute the works involved and are in sound physical and mental frame work. The personnel are also required to be adequately trained to perform the works involved accurately and precisely.

\* The personnel shall be, in numbers, adequate for carrying out the operations in the designed manner. Insufficient and excessive numbers would be detrimental to the proper execution of the work and could affect the quality control and assurance systems.

## **CONTROL PROCEDURES**

SOPs are required for all activities that influence directly or indirectly the quality control and assurance systems. Lack or insufficiency of an SOP would affect the quality of a product in one way or other. These include:

1. SOPs for the plant, machineries and equipment.

2. SOPs for materials.
3. SOPs for personnel.
4. SOPs for operations.
5. SOPs for validations of processes, cleaning and methods.
6. Master formulae.
7. Documentation.
8. Other matters such as rejections and returns, disposals of rejected/ returned materials, semi-processed & processed materials and products, Self-audit, Actions on non-conformities, sanitation and pest control procedures etc.

## **DOCUMENTATION**

Documents are important to check and ensure proper execution of works. All activities are required to be documented in accordance with the statutory norms or as per the in-house norms prescribed in the Control procedures. Documentation shall be on-line processes done at all levels as and when activities are planned or initiated or progressing. Every person executing an activity is required to maintain a record of the activity in such form as is prescribed and every such record is to be duly authenticated by the competent person.

## **GMPCOMPLIANCE**

GMP compliance is not a one time matter like securing a drugs licence. It is a continuous process and requires periodical reviews, updating and upgrading activities. GMP compliance can not be decided merely by checking the infrastructure facilities provided or the procedures prepared for adoption. GMP compliance can be effectively checked by internal or external audits by verifying the proper maintenance and utilization of the facilities and by verifying and ensuring that the control procedures prescribed are 100% in order and that they are adopted and implemented in letter and spirit. Procedures may require timely modifications or replacements and such changes are to be done without

any delay if proper GMP compliance is to be ensured.

## **NON-COMPLIANCES GENERALLY OBSERVED IN PLANTS**

The presentation here under is not to inform the exhaustive list of non-compliances. Those seen generally are outlined here and these may or may not be applicable in individual cases and there could be additional ones also.

### **Poor design qualification:**

This occurs in most places where the old unit was modified resulting in poor design for flow or movement of materials and personnel, improper doors and windows, improper electrical fittings, improper or inadequate water supply, sanitation, environment conditions etc. Such situations are seen in materials handling areas and in other ancillary areas for activities such as dress change including toilets, hand wash etc, refreshment areas for the staff, washing areas for equipments, utensils etc, de-cartoning area, air locks, holding areas for semi- processed materials, areas for spares and accessories etc.

### **Materials handling:**

- » Lack of properly covered Receipt area, de-dusting area, quarantine, sampling area, rejected materials store, approved materials storage area and dispensing area. The receipt bays and de-dusting areas are unclean areas and providing access for personnel to these areas from other areas is poor designing that defeats the purposes of controls in other places.
- » The usual defect seen is that the receipt bay is not sufficient to handle materials properly protected from dust, direct sun light and rain. Very little space is provided making it impossible to unload and keep materials in bulk or in heavy containers such as drums

- » Providing for or carrying out de-dusting activity in the receipt bay itself is not a proper design or control as the level of contamination in the receipt bay is generally high. The de-dusting area is also required to be of sufficient space and provided with the equipments necessary to execute the works involved. Most SSIs cannot afford RLAF facility for the activity and do the work by vacuum cleaning only. If properly executed, this is a proper compliance, but very often the procedures adopted are inadequate to make the activity a purposeful exercise.
- » Providing door to the quarantine area is a poor design as workers very often tend to move through the door to and from the cleaner areas. Tunnels, trap doors, pass-doors for materials etc with proper sops serve the purposes better.
- » It is desirable to have a separate quarantine and ware house area adjacent to the de-dusting area for materials in heavy drums and other containers. Separate quarantine is needed for packaging materials also.
- » Trolleys used in materials receipt area are used to move materials to other areas resulting in carrying of contaminants to clean areas.
- » Materials such as sugar that are procured in gunny bags or in other containers that may shed fibers and particles are not transferred to dedicated clean factory containers and are carried as such to production areas.
- » Liquid materials in drums are carried in such drum containers to production areas. Transfer to factory containers if at all done is done in a crude way by placing the drum in an elevated place and pouring into open containers instead of using dedicated transfer pumps.
- » Dedicated facility is not provided for inflammable materials.
- » Sampling areas are deficient in environment controls. Dedicated sampling equipments and containers are not provided.
- » Sufficient space, storage pallets, racks etc are not provided in the approved materials ware house.
- » Sampling and dispensing are done in one area. While this is permitted if the quantum of operation permits such an arrangement, dedicated areas sampling and dispensing of  $\beta$ -lactum drugs and other high risk materials are lacking. Dedicated tools and equipments are also lacking.
- » The design of the factory premises being defective in permitting parallel entries other than the designated ones for personnel and materials and thereby allowing administrative staff, management staff and visitors entering the production or ancillary areas unregulated.

#### **Production Areas:**

- » Insufficient environment controls in general.
- » Use of old equipment such as tray driers, filters, water purification and supply system that do not meet GMP norms. Not using dedicated bags for each product for the FBD. Non-availability of equipment for tablets inspection.
- » Use of trolleys that do not meet GMP norms and also those used in the materials handling area.
- » Pipelines and wirings lying on the floor and acting as sources of contamination.



- » Poor washing facilities for equipments that cannot be moved from installed locations or washing of heavy movable equipments within the production area.
- » Poor drainage systems in the production areas.
- » Poor dust extraction and disposal systems wherever heavy dust generation activities take place.
- » Lack of dedicated production area / facility including primary packaging equipment for B- lactum drugs.

#### **Ancillary Areas:**

- » Personnel Entry: Lack of adequate Number of air locks, space & facilities for keeping footwear used outside; insufficient facilities for washing hands, feet etc, full size mirror for self checking of proper dress wear; lack of physical barriers in the form of cross over bench. Lack of separate entry for visitors.
- » Washing areas: Insufficient space; insufficient lighting; Absence of dust control.
- » Corridors: Fresh, clean air systems are poor. Insufficient (or absence of) emergency exit especially in first and higher floors.
- » Absence of de-cartoning areas or lack of environment controls in de-cartoning areas.
- » Insufficient space and facilities for packaging materials especially empty hard gelatin capsules, foils, etc.
- » Absence or insufficiency of hazard control equipments such as fire extinguisher, flame-proof lamps etc.
- » Absence of or insufficient facilities for keeping accessories, spares and change parts.

- » Absence of essential utilities such as proper pass-boxes, air-curtains etc are also lacking in some places.
- » IPQC areas and equipment required to carry out in-process checks are either absent or poorly developed.

#### **Quality Control:**

- » Improper lay out: Most SSIs require a laboratory that has Physico chemical, Instruments and Microbiology sections. The layout shall include sufficient spaces for these sections. Ancillary sections namely stores for chemicals, reagents, spare glass-wares and equipments, Control samples storage area, Reference and working standards, area for library & records and utility area are also required. Facilities for stability studies are absent in most places.
- » Hazards control/ management facilities such as body & eye wash facilities, emergency exit, fire extinguisher are lacking in most places.
- » IR Spectrophotometer, HPLC and other such essential equipment are lacking.
- » Vibration free surfaces for sensitive instruments are lacking.
- » IQ, OQ and PQ norms are not observed generally.

#### **Surroundings:**

- » Proper maintenance of the surroundings of a production unit is as important as the interior. While some importance is given for maintenance of the front of the main building in a neat and tidy manner, the other surroundings are either neglected or poorly maintained.

- » Plant and animal wastes shall be removed regularly.
- » Waste disposal management is poorly executed. Obsolete equipment, vessels, packaging materials products or material wastes are dumped in the surroundings. Littering, chewing & spitting, smoking, disposal of articles of food and their package materials etc. in the surroundings are to be prohibited. Waste pits for solid and liquid wastes and effluents are usually open and become breeding places for insects and rodents.
- » Vehicles driving and parking are not regulated. Vehicles moving at appreciable speed on soil surface would cause floating of dust particles. Vehicles shall be parked in places well away from the production blocks to eliminate pollution & contamination.
- » Revalidations are required in the event of changes in Facilities, Equipment, Documentation, Utilities and Personnel (FEDUP). Revalidation is necessary in the event of changes in materials also.
- » SOPs for logging use of production and ancillary areas are not maintained. Log books of equipments, if at all maintained, do not present the profile of the equipment including preventive maintenance, dismantling and re-assembling procedures, calibration & validation wherever applicable, IQ, OQ & PQ, and details of maintenance, lay off etc.
- » Procedures for equipment and areas in the forms of 'Dos and Don'ts' in vernacular are not displayed for the respective areas and equipment.

#### **Control Procedures:**

- » SOPs are in house-norms that are to be tailor made for each activity, equipment, area personnel etc.. and are to be prepared by competent persons within the unit. In many places, SOPs prepared elsewhere are copied and maintained.
- » Most are in vague terms instead of being detailed and precise. SOPs for house-keeping, materials handling, inventory controls and management, production activities, QC activities, validation, re-validation, self audit, complaints and returns, recovery and reprocessing, recruitment and redeployment/rotation of personnel, hazards control and management etc. are either absent or insufficient.
- » Validations are prescribed in the law for processes, cleaning and methods. Validations, if at all done for these, are not supported by data and or not based on proper SOPs.
- » Vendor validation has limitations as far as SSIs are concerned. But in most cases no attempt is made for this purpose.
- » SOPs for use of factory clothing, personal hygiene etc. are insufficient. In most places the clothes do not cover the skin, hair, foot etc. completely and the situation is mostly due to lack of clear norms and control procedures. Use of goggles while handling sensitive and hazardous materials is not insisted. The footwear used is restricted to use of slippers that do not cover the foot properly.
- » Norms for induction training and training while in service are absent. Apart from training, it is essential to create awareness of the GMP requirements among the staff. Persons who have no or poor knowledge of the GMP requirements cannot be expected to meet those requirements properly.
- » Norms and procedures for checking, restricting, and regulating entry of personnel of one department into another, visitors, administrative staff, representatives of managements entering the critical and non-critical areas are absent.

- » Specific SOPs are required for the activities of the QC. Apart from the routine SOPs of house-keeping etc., sops for outsourcing tests, norms for procurement of chemicals, reagents, glasswares and equipment, preparation, preservation and use of standard solutions and reagents, procurement and preservation of reference substances, working substances, proficiency testing etc. are also lacking.
- » SOPs for Pest control, sanitation, water supply, preventive maintenance etc., if at all available, are not put into proper use.
- » SOPs are required to be for specified period and are to be reviewed as per the procedure prescribed for that purpose. Having an obsolete SOP will amount to not having an SOP at all and further, an outdated SOP that has no or only partial relevance to the needs could even lead to faulty execution of the activity resulting in quality problems.
- » Self Audit is an important activity that is seldom complied with by SSIs. The statutory audit by regulatory officials and external audits by experts are mostly random or sample audits where in-depth study of each activity or procedure is not possible. Internal audit enables the management and the staff to study all facilities, procedures and activities in depth and also timely rectification of defects. It also would enable planning of developments and upgradations.

## **DOCUMENTATION**

- » The general principle of documentation is that all activities for which control procedures are prescribed shall be monitored and documented. Documentation shall be in such format as prescribed in the control procedure. Every document shall be authenticated by the person competent to do it and every person who is assigned to perform the activity shall also sign or put initials in respect of the relevant entry.
- » Site Master File is the document that gives a complete profile of the unit. In some places this document does not give a true or correct presentation of the status of various situations and activities. This document is to be updated periodically as per the in-house norms.

## **Factors that contribute to the non-compliance of GMP norms**

- » Apprehensions & Negative mindset: These were the principal reasons in the early days of transition to new GMP norms. Many were of the views that these were unnecessary or not practical or the implementation of the new requirements could be stalled or deferred or modified. Even now many have apprehensions as to what would be the future of their establishment and whether the investments made could be recovered and commitments met.
- » Lack of resources: Those who were willing to the change-over or who were resigned to accept the change-over lacked either financial or technical resources and the resultant situation was that they could not draw proper road map and plan for implementation.
- » Inadequate guidance and support: The regulatory agencies and the organisations of the producers could not give the kind of guidance that the individual unit needed and the focus were more on the time frame of implementation or change over and to achieve the statutory formality of issuing or securing a GMP compliance certificate.

## GMP Requirements WHO Requirements & Indian

Materials Handling:			
Area	WHO	Indian	Remarks
Materials receipt bay:	Completely covered	Completely covered	Partial coverage is inadequate and no cover is deficient.
De-dusting/ Cleaning	Transfer tunnel with vacuum cleaning facility	Vacuum cleaning.	Just wiping the surface is deficient
Quarantine	Well defined area with electronic quarantine system with proper storage conditions applicable to the drug	Well demarcated area.	
Sampling	1. Classified area with separate entry for men and material; dedicated area for washing drying and storing tools; AHU with HEPA filter, AC and dehumidifier; separate areas for APIs, excipients, high risk materials and primary packaging materials. 2. Double gowning. 3. Sampling of inflammable materials to be done with special devices suitable for the purpose.	Separate room with AHU 5 $\mu$ filter, AC & humidity control	Common booth for Sampling and dispensing with appropriate SOPs and controls for one activity at a time and Separate area for $\beta$ Lactum, hazardous materials etc. is deemed sufficient.
Rejected materials	Separate area and appropriate storage facilities	Demarcated area; separate area etc..	
Approved materials store (Ware house)	1. Separate areas for hazardous materials, $\beta$ Lactum materials, inflammables etc.. Cold Storage, AC, humidity control appropriate to the nature of the material; Storage racks, cup boards, pallets etc., Ambient temperature for materials that can be stored at NRT, though Ac would be the most appropriate one. Electronic / computer inventory controls	Separate areas for hazardous materials, $\beta$ Lactum materials, inflammables etc.. Cold Storage, AC, humidity control appropriate to the nature of the material; Storage racks, cup boards, pallets etc.; ambient temperature for materials that can be stored at NRT.	
Dispensing	Classified area with separate entry for men and material; dedicated area for washing drying and storing tools; AHU with HEPA filter, AC and dehumidifier; separate areas for APIs, excipients, high risk materials and primary packaging materials. 2. Double gowning	Separate room with AHU 5 $\mu$ filter, AC & humidity control	Common booth for Sampling and dispensing with appropriate SOPs and controls for one activity at a time and Separate area for $\beta$ Lactum, hazardous materials etc.



Area	WHO	Indian	Remarks
<b>Production areas:</b>			
<b>Entry:</b>	Regulated entry. Separate for personnel and materials	Regulated entry. Separate for personnel and materials	
<b>Personnel entry:</b>			
<b>Change rooms</b>	Black → Grey → White → Factory → Section*	Outside → Factory → Section	* Entry in to the factory
<b>Tablets/ Capsules:</b>			
<b>Environment</b>	HEPA filtered air/ 5 $\mu$ with filter in the return air duct; AC, humidity controlled	Capsules: 5 $\mu$ filtered air, AC and dehumidified. Tablets: Ambient/ AC, AHU, humidity controlled.	
<b>Doors &amp; windows</b>	S.S. Double door	Any non-fiber/particle shedding material; double door	
<b>Flooring</b>	Any hard, firm, smooth, non-chipping, non-cracking material capable of withstanding heavy loads such as Kota slabs.	Kota slabs with Epoxy joints	
<b>False ceiling</b>	Seamless smooth surface - Aluminium, E Board etc.	Aluminium, E Board etc. with smooth surface	
<b>Partitions</b>	Panels; seamless/ jointless; smooth washable surface	Panels; seamless/ jointless; smooth washable surface	
<b>Dust Collection</b>	Dust extractor with HEPA filter if the return air is to be re-circulated/ Dust Extractor + Damper + Collection bag. 100% fresh air + 5 $\mu$ filter	Dust extractor with HEPA filter if the return air is to be re-circulated/ Dust Extractor + Damper + Collection bag. 100% fresh air + 5 $\mu$ filter	

Area	WHO	Indian	Remarks
<b>Coating</b>	Inlet: HEPA filter + Blower with Scrubber, flame proof.	Hot air blower + filter 5 $\mu$ (Where the blower is inside or HEPA filter if the blower is outside), flame proof.	
<b>Compression</b>	HEPA filtered air/ 5 $\mu$ with filter in the return air duct; AC, humidity controlled	Ambient/ AC, AHU, humidity controlled.	
<b>Washing</b>	Separate AHU with pressure difference with the corridor.	Common AHU with the corridor.	
<b>Clean equipments storage, punches, dies, capsule hand counter etc.</b>	Separate room, AHU with 5 $\mu$ .	Separate clean room	
<b>Liquid orals:</b>			
<b>Syrup preparation</b>	Separate sugar handling room and syrup preparation room. 100% fresh & HEPA/ 5 $\mu$ filtered air.	Separate syrup preparation room. 100% fresh 5 $\mu$ filtered air.	
<b>Manufacturing &amp; filling.</b>	HEPA filtered air/ 5 $\mu$ with filter in the return air duct; AC.	5 $\mu$ with filter in the return air duct; AC.	
<b>Washing &amp; drying area</b>	Independent AHU, 5 $\mu$ filtered air.	Common AHU with the corridor, 5 $\mu$ filtered air.	
<b>Floors, doors, windows.</b>	Same as solid dosage form, washing area floor: Epoxy.	Same as solid dosage form.	
<b>Pipelines and Service lines.</b>	Pendants.	Surface mounted.	
<b>External applications</b>			
<b>Base preparation</b>	Terminal HEPA/ Independent AHU, 5 $\mu$ filtered air AC + 100% exhaust	AHU, 20 $\mu$ filtered air, AC	
<b>Manufacturing &amp; filling.</b>	Terminal HEPA/ Independent AHU, 5 $\mu$ filtered air AC + 100% exhaust	AHU, 20 $\mu$ filtered air, AC	
<b>Floors, doors, windows.</b>	Same as solid dosage form, washing area floor: Epoxy.	Same as solid dosage form.	
<b>Pipelines and Service lines.</b>	Pendants.	Surface mounted.	

<b>Sterile products:</b>			
<b>Airlocks</b>	Four: Entry → Black → Grey → White;	Three; Black → Grey → White;	
<b>Airlocks</b>	Common AHU for the 1st and 4th and separate AHUs for the 2nd & 3rd; air shower in the final airlock. Grades: 1st: D; 2nd, 3rd and 4th: C; Air changes: 30 - 40-40-higher	Separate AHUs; 1st: D; 2nd and 3rd: C	Last air lock shall be of the same class as that of the preparation/filling area.
	Separate set of air three locks of class D for solution preparation area/ components preparation area.	Separate set of air three locks of class D for solution preparation area/ components preparation area.	
<b>Corridor</b>	As clean as the filling area	One class below the filling area	Pressure difference for β-lactum etc. shall be reverse.
<b>Filling background</b>	LAF with continuous monitoring of bacterial count.	LAF with daily monitoring.	
<b>Optical check</b>	Mechanical (Laser)	Manual	
<b>Flooring</b>	Epoxy/PU	Kota with Epoxy seamless joints	
<b>QC Lab:</b>			
<b>Entry:</b>	Through change room		
<b>Environment:</b>	HVAC/AHU with or without AC as per the needs of the area.	Ambient/AC as needed.	
<b>Microbiology</b>	Entry & Environment similar to production areas for sterile products; airlock cum change room: one. Separate areas for media preparation, media cooling, general tests area & sterile testing area; area for incubators; area for washing, sterilization, drying etc..	Entry & Environment similar to production areas for sterile products; airlock cum change room: one. Separate areas for media preparation, media cooling, general tests area & sterile testing area. area for incubators; area for washing, sterilization, drying etc..	

<b>Safety measures</b>	Smoke detector, Eye wash, Shower, fire extinguisher, emergency exit.	Eye wash, Shower, fire extinguisher, emergency exit.	
<b>Validation:</b>			
	Process Validation Cleaning validation Testing (Method) validation	Process Validation Cleaning validation Testing (Method) validation	
<b>Validation Master Plan (VMP)</b>	Shall be in place	Shall be in place	
	Predefined Protocols	Predefined Protocols	
	Report: Observations, Conclusion & Reconciliation	Report: Observations, Conclusion & Reconciliation	
	Resources: In-house/ Outsource	Resources: In-house/ Outsource	
<b>Process validation:</b>	Prospective for all processes of critical parameters.	Retrospective validation supported by concurrent validation of critical parameters.	10 to 25 batches as per WHO norms.
<b>Qualification:</b>	URS (User's Resources Specification), DQ, IQ, OQ, PQ.	DQ, IQ, OQ, PQ.	
<b>Revalidation criteria:</b>	1. Change in raw materials 2. Transfer of processes to other places, 3. Change of primary packaging, 4. Change of manufacturing process etc..		

- \* The WHO requirements mentioned above are those provided during the workshop conducted by the CDSCO for audits of manufacturing units and observed currently.
- \* There may be variations in the requirements specified for deciding compliances under Indian requirements from those specified in Schedule M. What is stated above the specifications currently observed for audits as decided during the workshop mentioned above.
- \* The above table is not an exhaustive one and there may be activities not covered by these and the norms observed by the CDSCO apply for them.



## **EVENTS**

### **Honour for Dr. B. Suresh, our Trustee**

- » Re-elected as President, Pharmacy Council of India
- » Elected as President, Indian Pharmaceutical Association, (Central), Mumbai
- » Assumed charge as Vice-Chancellor of JSS University, Mysore.
- » Re-nominated as a syndicate member, as Governor nominee, Bharathiyar University, Coimbatore.

WE WISH HIM ALL THE SUCCESS!

### **D. Sc conferred on Prof. K. Chinnaswamy, our Trustee**

The Tamilnadu Dr. M. G. R. Medical University, Chennai, in recognition of his contribution to the profession of Pharmacy for the last four decades, has conferred honorary degree of Doctor of Science (D.Sc.) on Prof. K. Chinnaswamy during its Eighteenth Convocation on 20th September 2008. Guest of Honour was Shri M. Hamid Ansari, His Excellency - The Vice-President of India.

Dr. Chinnaswamy is synonymous with the development of profession of pharmacy in the country and rendered selfless service as office bearer of various bodies like Indian Pharmaceutical Association, Indian Pharmaceutical Congress Association, Indian Hospital Pharmacy

Association, Indian Pharmacy Graduates Association. Dr. Chinnaswamy was also the President of Association of Pharmaceutical Teachers of India, Indian Pharmacy Graduates Association and Indian Pharmaceutical Association Tamilnadu Branch.

Dr. Chinnaswamy has served in the Tamilnadu Dr. M.G.R. Medical University, Chennai, in various capacities and in particular as the Senate Member, Governing Council Member and President, Faculty of Pharmacy. He is presently the Executive Committee Member of Pharmacy Council of India, New Delhi and Tamilnadu Pharmacy Council.

### **Shri. N. P Mathur Memorial Lecture**

The Indian Pharmaceutical Association, Tamilnadu Branch organized Shri N. P. Mathur Memorial Lecture (Sponsored by M/s. TNPSWT, Chennai) on 22nd October, 2008 at Hotel Palmgrove, Chennai. Dr. D. Roy, Ph.D, Dy. Drugs

Controller I/c, CDSO (South Zone), Min. of Health, Govt. of India spoke on the topic "Comparative Review of Revised Schedule M (GMP) with other International GMP norms". The lecture was well appreciated by the participants.

### **National Pharmacy Week Celebrations**



TNPSWT sponsored the 47<sup>th</sup> National Pharmacy week celebrations for the year 2008 through Indian Pharmaceutical Association, Tamilnadu Branch. The theme of this year's celebrations was "ASK YOUR PHARMACIST: FOR SAFE USE OF PRESCRIPTION MEDICINES". The function was organized on 25<sup>th</sup> November 2008 at Vel's College of Pharmacy, Chennai. Chief Guest Dr. S. P. Thyagarajan, Director and Chief Advisor (Former Vice Chancellor, University of Madras) delivered a lecture on "Current Trends in

Pharmaceutical R & D in India". Dr. Ishari K. Ganesh, Vice Chancellor, Vel's University was the Guest of Honour. Mr. R. Narayanaswamy, President, IPA, Tamilnadu branch and former Deputy Drug Controller of India, New Delhi delivered a lecture on the theme. Mr. R. Sabapathy, Executive Director, M/s. Medopharm, Chennai and immediate past President of IPA, Tamilnadu branch has been honoured as

"Pharmacist of the year 2008". On this occasion, scholarships instituted by Tamilnadu Pharmaceutical Sciences Welfare Trust were awarded for their best projects to 43 M. Pharm students of various Pharmacy colleges of Tamilnadu. The function was well attended by pharmaceutical professionals including Pharma industry and regulatory personnel, pharmacists, scientists, students, etc..

### **60<sup>th</sup> Indian Pharmaceutical Congress, New Delhi**

The 60<sup>th</sup> Indian Pharmaceutical Congress (IPC), Diamond Jubilee Congress was organized by Indian Pharmacy Graduates' Association, Delhi branch from 12<sup>th</sup> to 14<sup>th</sup> of December 2008 at Netaji Subhas Institute of Technology, Sector 3, Dwarka, New Delhi. This year, the theme of the Congress was "Pharma Vision 2020 - Regulations for Better Healthcare". It was attended by more than 8,000 delegates. Dr. K. Chinnaswamy was awarded as Eminent

Pharmacist of the year, 2008. Wide ranging topics from scientific, regulatory and technology to professional were covered to meet the sectoral interests of all. An exhibition displaying Pharma manufacturing machineries, analytical instruments and book stalls of pharmacy book dealers was organized at the venue. Shri.N.Sreenivasen and Shri.R.Narayanaswamy, Trustees were nominated and attended the Congress.

### **GMP Training Programme**



The GMP training programme was organized by this Trust in order to give latest GMP aspects like Clean Room Concepts, Water System for Pharmaceutical Use and Stability Studies of Pharmaceuticals, etc.. The programme was attended by 20 professionals who are working in Pharmaceutical industries in Tamilnadu.



The programme was held in the Trust building itself on 8<sup>th</sup> & 9<sup>th</sup> of August 2008. Mr.G.Rangachari, Chairman of our Trust welcomed the participants and also all the resource persons. Mr. S. V. Veerramani, CMD of Fourrts Indian Ltd., Chennai inaugurated the programme. Mr. Sanjay Dasmohapatra,

Vice-President (Technical), M/s Medopharm, Chennai gave an elaborate talk on the subjects of Validation, Water System for Pharmaceutical Use and Quality Assurance and Quality Control functions. Dr. G. L. Jain, GMP expert and Consultant, Centre for Active Learning and Guidance & Solutions, Udaipur gave an excellent talk on Clean Room Concepts and HAVC System. The consultants of M/s Doshicon Pvt. Ltd., Indore explained the trainees on Construction, Layout and Building Design of a Pharma unit in accordance to the latest GMP standards. Dr. M. D. Nair, Pharma Consultant, Chennai briefed the participants with regard to various challenges facing the Pharma industry including high cost of R & D of drugs and pharmaceuticals and merger of various Pharma industries and also healthcare system in our country and globally. Mr. Bhaskaran, Deputy

Director of Drug Control of Tamilnadu gave a lecture on the latest GMP Requirement as per Schedule M of Drugs & Cosmetics Acts and Rules. Dr. M. S. P. Sastry, Senior Vice President, R & D, M/s. Tablets (India) Ltd., Chennai delivered a lecture on Stability Studies of Pharmaceuticals. Mr. S. S. V. Krishnan, Rtd. Drugs Controller of Kerala and Mrs. Santhi Gunasekaran, Asst. Drugs Controller, CDCSO, South Zone, Chennai gave the detailed talk on the subject of Non-compliances observed during GMP Inspection and WHO GMP Certification Scheme respectively.

The programme was coordinated by Shri. R. Narayanaswamy and moderated by Mr. Prafulla Chandra, GM Production, M/s Cheminnova Pvt. Ltd. Hyderabad.



### **FORTHCOMING EVENTS OF INDIAN PHARMACEUTICAL ASSOCIATION, TAMILNADU BRANCH**

All-India seminar on Packaging February 2009

Meeting on Herbal Drugs March-April 2009

Seminar on Clinical Research of Pharmaceuticals June July 2009

Seminar on drug regulatory system September October 2009

Meeting on QA & QC and Documentation December 2009

## MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

### NOTIFICATION

New Delhi, the 13<sup>th</sup> August, 2008

G. S. R. 592(E). – Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), at page 3 to 4 in the Gazette of India Extraordinary, Part II, Section 3, Sub-Section (i) dated the 2<sup>nd</sup> February 2007 under the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health), number GSR 62 (E), dated 2<sup>nd</sup> February, 2007 inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on 09-2-2007.

And whereas the objections and suggestions received from the public on the said draft rules were considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the said Act, the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics rules, 1945, namely:-

1. (1) These rules may be called the Drugs and Cosmetics (II Amendment) Rules, 2008.  
(2) They shall come into force on the date of their publication in the Official Gazette.
2. In the Drugs and Cosmetics Rules, 1945, (hereinafter referred to as the said rules), in rule 2, Clause (j) shall be omitted.
3. In rule 75 A of the said rules, in sub-rule (1), -
  - (a) in the Explanation, for the word and figures "Form 28" occurring at the end, the words, figures and letter "Form 28 and Form 28 D" shall be substituted;
  - (b) after sub-rule (2), the following proviso shall be inserted, namely:-

"Provided that if an item is a notified drug under rule 68 A, the manufacturing unit undertaking manufacture on behalf of the loan licensee shall have a valid manufacturing license approved by the licensing Authority and its manufacture on loan license shall not affect the quality of the drug."

4. In rule 78 A of the said rules, in sub-rule (1) for the word and figures "Form 28" occurring after the words "owned by the licensee in", the words, figures and letter "Form 28 and Form 28 D" shall be substituted.
5. In rule 94 of the said rules, in sub-rule (1), -
  - (a) in the proviso, for the words "blood products, Narcotic and Psychotropic Substances" the following words shall be substituted, namely:-

"or blood products defined under rule 122 EA";

(b) after the proviso, the following proviso shall be inserted, namely:-

"Provided further that where a drug classified as Narcotic Drug or Psychotropic Substance is to be exported under a code number, the same may be permitted by the said Licensing Authority on the following conditions, namely:-

- (i) each consignment of export shall be accompanied with requisite import license from the importing country;
- (ii) the applicant shall obtain a no objection certificate from the Drugs Controller, India for manufacture of such formulations to be exported with code number against each export order along with certificate from the regulatory of the Importing country controlling Narcotics drugs and Psychotropic Substances that they do not have any objection for the import of the drug with code number;
- (iii) the State Licensing Authority shall issue the manufacturing license for these formulations on each export order on the basis of a no objection certificate from Drugs Controller, India;
- (iv) a no objection certificate shall be obtained from the Drugs Controller, India for export of each consignment; and
- (v) a no objection certificate shall be obtained from the Narcotic Commissioner of India, Gwalior for export of each consignment of the drug"

6. In rule 96 of the said rules, in sub-rule (1),--

- (a) for clause (Viii), the following shall be substituted, namely:- (Viii) drugs specified in Schedule C(I) and their preparations including combinations in other drugs shall bear on their labels (a) the date of manufacture, and (b) date of expiry of potency fixed by the manufacturer:";
- (b) after clause (xi), the following clause shall be inserted, namely:- (xii) Drugs and their preparations including combinations with other drugs imported into the country shall also bear on the label, the license number under which the drug is imported, preceded by the words "Import License " and the name and address of the importer.'.

7. In the said rules , in Schedule A, --

- (a) in Form 17 A, in the opening paragraph, for the figures "19", occurring in the first line after the words "day of ", the figures "20", shall be substituted ;
- (b) in Form 35, for the entries under the heading, the following entries shall be substituted, namely :-  
"[ see rules 65, 67 G, 74, 74 A, 74B, 78, 78 A, 85 H, 122 P, 142, 142 B, 150E, 158 and 158A]"

8. In the said rules, in Schedule K,--

- (i) in item number 5, under column 'Extent and conditions of Exemption', after the entry number (3), the following shall be inserted, namely:-  
(4) No drug shall be supplied or dispensed after the date of expiration of potency recorded on its container, label or wrapper or in violation of any statement or direction recorded on such container, label or wrapper.";
- (ii) in item number 5A, under column 'Extent and conditions of Exemption' after the entry number (4), the following shall be inserted, namely:-  
(5) No drug shall be supplied or dispensed after the date of expiration of potency recorded on its container, label or wrapper or in violation of any statement or direction recorded on such container, label or wrapper.";
- (iii) in item number 31, under column 'class of drugs',-



- (A) in sub-item (b), for the words and figures "in 15gm. Tube", the words and figures "in 25gm Tube" shall be substituted;
- (B) after sub-item (d), the following sub-item shall be inserted, namely:-  
"(e) All Biochemic and its combinations (1 to 28), in tablet forms, in sealed original packaging of the manufacture."
9. In the said rules, in Schedules S, under the heading 'Standards for cosmetics in finished form', after item number 28 and the entry relating thereto, the following item and entry shall be inserted namely:-  
"29. Bathing Bars IS: 13498:1997".

[F. No. X 11014/7/2005-DFQC]  
DEBASISH PANDA, Jt. Secy.

Ref: THE GAZETTE OF INDIA: EXTRAORDINARY

[Part II – Sec 3(i)]

**Brief Note on the above Amendment:**

In nutshell, the above amendment comprises of the following:-

1. The Drugs and Cosmetics rules 75A and 78A now allow loan licence for manufacture of Large Volume Parenterals, Sera and Vaccines. The manufacturing unit who is undertaking the manufacture on behalf of the loan license shall have valid manufacturing licence approved by the licensing authority.
2. Narcotic and Psychotropic substances / drugs are allowed to be exported under neutral code i.e they need not mention the name and address of Indian manufacturer with the conditions as stipulated in amendment.
3. The label of all imported drugs shall bear import license number and name and address of the importer.
4. The Drugs and Cosmetics rules allow manufacturing and marketing of bathing bar as per the standards of BIS.

## **CONTACT DETAILS OF PHARMACY COLLEGES OF TAMILNADU**

### **College Of Pharmacy**

#### **Madras Medical College**

Park Town, Chennai 600 003.  
Phone: 2256 3131 / 2256 4764

### **College of Pharmacy**

#### **Madurai Medical College**

Madurai 625 020  
Phone: 0452 2496 0151 / 2253 3535

### **J. S. S. College of Pharmacy**

"Rockland's" Bombay Castle  
P. B. No.20, Elkhill Road  
Udagamandalam 643 001.  
Phone No: 0423 244 3393 / 244 3847  
Fax No: 0423 244 2937  
E - mail: jaspharm@hotmail.com  
Website: www.jsspharma\_ooty.com  
**Courses Offered:** B. Pharm, M. Pharm, Ph. D,  
Pharm D, Pharm D (Baccalaureate)

### **C. L. Baid Metha College of Pharmacy**

Old Mahabalipuram Road, Jyothi Nagar  
Thorapakkam, Chennai 600 096.  
Phone: 2496 0151 / 2496 04251  
E - mail: clbmcpl@md4.vsnl.net.in,  
principal@clbaidmethacollege.com  
Website: www.clbaidmethacollege.com

**Courses Offered:** D. Pharm, B. Pharm, M. Pharm,  
Ph. D

### **K. M. College of Pharmacy**

Melur Road, Uthangudi  
Madurai 625 107.  
Phone No: 0452 2423312 / 2423454  
Fax No: 0452 2423415  
E-mail: kmcp@sancharnet.in  
Website: www.kmcp.ac.in  
**Courses Offered:** D. Pharm, B. Pharm, M. Pharm

### **College of Pharmacy**

#### **Sri Ramakrishna Institute of Paramedical Sciences**

395, Sarojini Street Coimbatore - 641 0440.  
Phone No: 0422 4500164 / 4500194  
Fax No: 0422 2210521  
E-mail: pha\_sripms@yahoo.com  
**Courses Offered:** B. Pharm, M. Pharm, Pharm D

### **Sri Ramachandra College of Pharmacy**

#### **Sri Ramachandra University**

Porur,  
Chennai 600 116.  
Phone No: 044 24762003  
Fax No: 044 24767008/24765995  
E-mail: profcumr@yahoo.co.in  
Website: www.srmc.edu  
**Courses Offered:** B. Pharm, M. Pharm, Pharm D

### **Periyar College of Pharmaceutical Sciences for Girls**

Periyar Centenary Educational Complex  
Sathanoor Main Road  
Trichirapalli - 620 021.  
Phone No: 0431 245 9911  
Fax No: 0431 - 245 6677  
E - mail: pcgharm@md2.vsnl.net.in,  
pcpsgirls@yahoo.com  
Website: www.pcpsg.in  
**Courses Offered:** D. Pharm, B. Pharm, M. Pharm,  
Ph. D

### **Swamy Vivekanandha College of Pharmacy**

Elyampalayam  
Kumaramangal Post 637 205.  
Tiruchengodu Taluk, Namakkal District.  
Phone No: 04288 234674  
Fax No: 04288 234891  
E-mail: principal.svcp@gmail.com  
Website: www.vcpfarm.org  
**Courses Offered:** D. Pharm, B. Pharm, M. Pharm

### **Nandha College of Pharmacy**

29/4, Koorapalayam Pirivu  
Pichandampalayam, Erode 638 052.  
Phone No: 04294 226405 / 224611, 221405  
Fax No: 04294 224622  
E-mail: Nandha\_pharmacy@yahoo.co.in  
Website: www.nandhainstitution.org  
**Courses Offered:** D. Pharm, B. Pharm, M. Pharm,  
Ph.D

**S. R. M. College of Pharmacy**

S. R. M. Nagar, Potheri  
Kattankolathur 603 203.

Kancheepuram District

Phone No: 04114 27453160

Fax No: 04114 27455717

Website: [www.srmuniv.ac.in](http://www.srmuniv.ac.in)

**Courses Offered:** B. Pharm, M. Pharm, Ph. D,  
Pharm. D

**Adiparashakthi College of Pharmacy**

Melmaruvathur 603 319.

Kancheepuram District

Phone No: 2752 9093

Fax No: 27529196

E-mail: [vetrisel@yahoo.com](mailto:vetrisel@yahoo.com)

Website: [www.apcp.in](http://www.apcp.in)

**Courses Offered:** B. Pharm, M. Pharm, Ph. D

**K. M. C. H. College of Pharmacy**

Kovai Estate, Kalapatti Road

Coimbatore 641 035.

Phone No: 0422 2627784 to 90

Fax No: 0422 2627196

E-mail: [kmch@md2.vsnl.net.in](mailto:kmch@md2.vsnl.net.in)

Website: <http://www.kmchcop.ac.in/>

**Courses Offered:** B. Pharm, M. Pharm

**Vinayaka Mission's College of Pharmacy**

Yercaud Main Road

Kondappa Naickenpatty

Salem 636 308.

Phone No: 0427 2400174

Fax No: 0427 - 2400174

E-mail: [vmcpharm@yahoo.co.in](mailto:vmcpharm@yahoo.co.in)

Website: [vmu@vinayakamission.com](http://vmu@vinayakamission.com)

**Courses Offered:** D. Pharm, B. Pharm, M. Pharm

**Arulmigu Kalasalingam College of Pharmacy**

Anand Nagar, Krishnankoil

Kunnur Post 626 190.

Srivilliputhur (Via), Virudhunagar District

Phone No: 04563 289006

E-mail: [akcprrl@yahoo.com](mailto:akcprrl@yahoo.com)

Website: [www.akcpharmacy.org](http://www.akcpharmacy.org)

**Courses Offered:** D. Pharm, B. Pharm, M. Pharm.

**J. K. K. Munirajah Medical Research Foundation College of Pharmacy**

Ethirnedu, Valayakaranur

Post, P.B. No.70

B. Komarapalayam 638 183.

Namakkal District

Phone No: 04288 260588 / 260032

E-mail: [senthilkumarjkk@gmail.com](mailto:senthilkumarjkk@gmail.com)

Website: [www.jkkmparmacy.com](http://www.jkkmparmacy.com)

**Courses Offered:** D. Pharm, B. Pharm, M. Pharm,  
Ph. D

**R. V. S. College of Pharmaceutical Sciences**

242-B, Trichy Road, Sullur

Coimbatore 641 402.

Phone No: 0422 - 268 7421 / 268 7480 / 2687 687

Fax No: 0422 - 268 7604

E-mail: [rvscas@eth.net](mailto:rvscas@eth.net)

Website: [www.rvshs.ac.in](http://www.rvshs.ac.in)

**Courses Offered:** D. Pharm, B. Pharm, M. Pharm

**Padmavathi College of Pharmacy**

3/77C, Anaikuttam Road,

Sivakasi, Virudhunagar (Dist)

Phone No: 04562 231918, 232088

Fax No: 04562 272329

E-mail: [sbpharmacycollegesvk@dataone.in](mailto:sbpharmacycollegesvk@dataone.in)

Website: [www.sbcollegeofpharmacy.com](http://www.sbcollegeofpharmacy.com)

**Courses Offered:** D. Pharm, B. Pharm, M.  
Pharm(Pharmaceutics)

**Ultra College of Pharmacy**

4/235, College Road

Thasildar Nagar, Madurai 625 020.

Phone No: 0452 253 4593/2534701

E-mail: [ultratrust@rediffmail.com](mailto:ultratrust@rediffmail.com)

Website: [www.ultracollegeofpharmacy.ac.in](http://www.ultracollegeofpharmacy.ac.in)

**Courses Offered:** D. Pharm, B. Pharm, M. Pharm

**J. K. K. Natarajah College of Pharmacy**

P.B No. 151, Natarajapuram

N.H - 47, Salem to Coimbatore

Komarapalayam 638 183.

Namakkal District

Phone No: 04288 - 261726

Fax No: 04288 - 265793

E-mail: [jkkncp@yahoo.com](mailto:jkkncp@yahoo.com)

Website: [www.jkknataraja.org](http://www.jkknataraja.org)

**Courses Offered:** B. Pharm, M. Pharm

**The Erode College of Pharmacy**

Veppampalayam, Perunthurai Main Road  
Vallipurathanpalayam  
Vallipurathanpalayam (Post)  
Erode 638 112.  
Phone No: 0424 2339929, 2339103  
Fax No: 0424 2339539  
E-mail: ecperode@hotmail.com  
Website: www.ecperode.in  
**Courses Offered:** B. Pharm, M. Pharm

**Sankaralingam Bhuvaneswari College of Pharmacy**

3/77C Anaikuttam Road  
Sivakasi, Virudhunagar (Dist)  
Phone No: 04562 231918/232088  
Fax No: 04562 272329  
E-Mail: sbpharmacycollegesvk@dataone.in  
Website: www.sbcollegeofpharmacy.com  
**Courses Offered:** D. Pharm, B. Pharm, M. Pharm  
(Pharmaceutics)

**P. S. G. College of Pharmacy**

Peelamedu Coimbatore - 641 004.  
Phone No: 0422 - 4345841, 2570170, 2570170  
Fax No: 0422 2594400  
E-mail: principal@psgpharma.ac.in  
Website: www.psgpharma.com  
**Courses Offered:** B. Pharm, M. Pharm, Pharm D

**K. K. College of Pharmacy**

1/161, K.R.A. Campus, Sankaralinganar Road  
Gerugambakkam  
Chennai 602 101.  
Phone No: 044 32546162  
**Courses Offered:** D. Pharm, B. Pharm, M. Pharm  
(Pharmaceutics)

**Jaya College of Pharmacy**

C.T.H. Road  
Thiruninravur 602 024.  
Thiruvallur Dist, Tamilnadu  
Phone No: 044 29038239  
Fax No: 044 26340953  
E-mail: karthiga\_mahe@yahoo.com  
Website: www.jcp.org  
**Courses Offered:** D. Pharm, B. Pharm

**Kamalakshi Pandurangan College of Pharmacy**

Ayyampalayam  
Tiruvannamalai 606 603.  
Phone No: 04175 236215  
Fax No: 04175 236215  
E-mail: principal@kp-collegeofpharmacy.com  
Website: www.kpcollegeofpharmacy.com  
**Courses Offered:** D. Pharm, B. Pharm

**Thanthai Rover College of Pharmacy**

Rover Campus, Perambalur  
Trichy 621 212.  
Phone No: 04328 277835  
Fax No: 0431 278114  
Website: www.thrtc.ac.in  
**Courses Offered:** D. Pharm, B. Pharm

**Mohammed Sathak A. J. college of Pharmacy**

Medavakkam Road  
Sholinganallur  
Chennai 600 119.  
Phone No: 044 - 2496 2573  
Fax No: 044 24502572  
E-mail: msajcpharm@gmail.com  
Website: www.msajcpharm.in  
**Courses Offered:** B. Pharm

**Maharaji College of Pharmacy**

No.1, 7th Avenue  
Besant Nagar, Chennai 600 090.  
Phone: 2491 7646 / 2491 8844  
Fax: 2491 8622  
E-mail: principal@maharajicollege.com  
Website: www.maharajicollege.com

**Pallavan Pharmacy College**

Iyyangarkulam  
Kanchipuram 631 502.  
Kanchipuram District.

**Fathima College of Pharmacy**

103, Main Road, Krishnapuram  
Kadayanallur 627 759.  
Tirunelveli District  
Phone No: 04633 242648  
E-mail: fcpkdnl@fcp.in  
Website: www.fcp.in  
**Courses Offered:** B. Pharm

**Annai Veilankanni's Pharmacy College**

81, V.G.P. Salai  
Saidapet, Chennai 600 015.  
Phone: 044 - 2485 1172  
Fax No: 044 - 2471 0820  
E-mail: dev@annaiveilankannis.com  
Website: www.annaiveilankannis.com  
**Courses Offered:** B. Pharm

**Cheraan's College of Pharmacy**

521, Siruvani Main Road  
Telungupalayam Pirivu  
Coimbatore 614 039.  
Phone No: 0422 2343380  
**Courses Offered:** B. Pharm

**E. G. S. Pillay College of Pharmacy**

Nagore Main Road,  
Nagapattinam 611 002  
Phone No: 04365 251260  
Fax No: 04365 251968  
E-mail: principal@egsp.org  
Website: www.egsp.org  
**Courses Offered:** D. Pharm, B. Pharm

**S. A. Raja college of Pharmacy**

Raja Nagar, Vadakankulam 627 116.  
Tirunelveli District  
Phone No: 04637 230257  
Fax No: 04637 230111  
E-mail: info@raju.edu  
Website: www.raja.edu  
**Courses Offered:** D. Pharm, B. Pharm

**S. Chattantha Karayalar College of Pharmacy**

Karayalar Nagar, Tenkasi Taluk  
Kodikurichi 627 804.  
Tirunelveli District.

**Pearl Peace Medical Mission**

College of Pharmacy  
MDT, Hindu college Campus  
Pettai, Tirunelveli 627 010.

**Karpagam College of Pharmacy**

Othakkalmandapam Village  
Coimbatore - 641 032.  
Phone No: 0422 2619038/2619039  
Website: www.karpagamuniversity.com  
**Courses offered:** B. Pharm

**Aadhi Bhagawan College of Pharmacy**

Rantham Village  
Cheyyar to Arcot Road  
Cheyyar Taluk  
Thiruvannamalai District 604 407.  
Phone No: 04182-248211 / 248379, 248378  
E-mail: aadhibhagawan@gmail.com  
Website: www.abcparmacy.co.in  
**Courses offered:** B. Pharm

**P. G. P. College of Pharmaceutical Sciences & Research Institute**

NH-47, Namakkal - Karur Main Road  
Namakkal District 637 207.  
Phone No: 04286-267722  
Fax No: 04286 267722  
E-mail: pgppharmacy2007@yahoo.co.in  
Website: www.pgp.edu.ac.in  
**Courses Offered:** B. Pharm

**K. R. S. Pallavan College of Pharmacy**

Mannur Villagae  
Valapuram Post  
Sriperumbudur Taluk  
Kanchipuram District 602 105.

**Reference:** Tamilnadu MGR Medical University  
website

## **OFFICES OF DRUGS CONTROL ORGANISATIONS IN TAMILNADU**

### **TAMILNADU DRUG CONTROL DEPARTMENT**

#### **Director of Drugs Control**

Office of the Director of Drugs Control  
Administration  
Government of Tamilnadu  
No. 359, Anna Salai  
DMS Compound  
Teynampet, Chennai 600 006  
Phone No.: 24310687

#### **Director of Drugs Control**

Office of the Director of Drugs Control  
Administration  
Government of Tamilnadu  
No: 359, Anna Salai  
DMS Compound  
Teynampet, Chennai 600 006

#### **Zone 1**

The Assistant Director of Drugs Control  
Zone - I  
No; 359, Anna Salai  
D DMS Compound  
Teynampet, Chennai 600 006  
Phone No.: 24328734

#### **Zone 2**

The Assistant Director of Drugs Control  
Zone - II  
No; 359, Anna Salai  
DMS Compound  
Teynampet, Chennai 600 006  
Phone No.: 24310687

#### **Zone 3**

The Assistant Director of Drugs Control  
Zone - III  
No. 359, Anna Salai  
DMS Compound  
Teynampet, Chennai 600 006  
Phone No.: 24351581

#### **Zone 4**

The Assistant Director of Drugs Control  
Zone - IV  
No. 4/14, Kalyana Nagar  
Third Street, Muduchur Road  
Tambaram  
Chennai 600 045  
Phone No.: 22266876

#### **Thiruvallur Zone**

The Asst. Director of Drugs Control  
Thiruvallur Zone  
No. 201, First Floor, J. N. Road  
Thiruvallur 602 101  
Phone No.: 27666698

#### **Coimbatore Zone**

The Assistant Director of Drugs Control  
Coimbatore Zone  
No. 219, Race Course road  
Coimbatore 641 018  
Phone No.: 0422 2210350

#### **Madurai Zone**

The Assistant Director of Drug Control  
Madurai Zone,  
Plot No. 5, Ramaiah street  
Shenoy Nagar  
Madurai 625 020  
Phone No.: 0452 2533699

#### **Tirunelveli Zone**

The Assistant Director of Drugs Control  
Tirunelveli Zone  
No. B. 74, 17th Cross  
Maharaja Nagar  
Tirunelveli 627 011  
Phone No.: 0462 2573138



**Vellore Zone**

The Assistant Director of Drugs Control  
Vellore Zone  
No. 3 Ekambaram Street  
Pulavar Nagar  
Rangapuram, Sathuvacherry  
Vellore 632 009  
Phone No.: 0416 2252120

**Salem Zone**

The Assistant Director of Drugs Control  
Salem Zone  
No. 7 Thiruvalluvar Street  
Subramaniapuram  
Salem 636 005  
Phone No.: 0427 2335823

**Thanjavur Zone**

The Assistant Director of Drugs Control  
Thanjavur Zone,  
No 7C/17, Selvam Nagar,  
Medical College Road  
Thanjavur 613 007  
Phone No.: 04362 231171

**Trichy Zone**

The Assistant Director of Drugs Control  
Trichy Zone  
No. 19, A. V. Arcade,  
9th Cross Street, Thillai Nagar  
Trichy 620 018  
Phone No.: 0431 2741526

**Virudhunagar Zone**

The Assistant Director of Drugs Control  
Virudhunagar Zone  
No. 80, P. S. C. Nadar Street  
Virudhunagar 626 001  
Phone No.: 04562 243731

**CENTRAL DRUG STANDARDS CONTROL ORGANISATION****Deputy Drugs Controller, India****Central Drugs Standard Control Organisation**

South Zone, 2nd Floor, Shastri Bhawan Annexe  
26, Haddows Road, Chennai 600 006.  
Phone No.: 8278186. Gram: ZONEDRUG-  
CHENNAI.  
Tele Fax: 044-28213079.

**Assistant Drugs Controllers at Ports**

Asstt. Drugs Controller (India) Port  
Room No. 23, IV Floor, Annexe Bldg.  
Custom House, Chennai 600 001.  
Phone No.: 25212041. Gram: DRUGCONIND.

**Astt. Drugs Controller (India)**

Central Drugs Standard Control Organisation  
Air Cargo Complex, Meenambakkam Airport  
Chennai 600 027.  
Phone No.: 2256 0698.

**Central Drugs Laboratory (CDL) - Kolkata**

The Director - Central Drugs Laboratory  
3, Kyd Street, Kolkata 700 016.  
Phone: 033-22299541  
Gram: BIOSTANLAB  
Fax: 033-22299380

**Central Drugs Testing Laboratory (CDTL) Chennai**

Director-In-charge - Central Drugs Testing Laboratory  
Govt. of India, 37, Naval Hospital Road  
Periamet, Campus G.M.S.D., Chennai 600 073.  
Phone: 044-25610402/25610205  
Gram: DRUGSLAB  
Fax: 044-25610906  
E-mail : cdtl@dataone.in

## **DETAILS OF VARIOUS COUNCILS AND ASSOCIATIONS**

### **The Indian Pharmaceutical Association (IPA) - Tamilnadu Branch**

Secretary's Office: Sri Devi Temple Towers  
Survey No. 135/1B Sembakkam II Main Road  
Sembakkam, Chennai - 600 073.  
Phone No. : 22275994, 2227 5961 Fax: 22275965  
E-mail: tnipa@rediffmail.com

#### **OFFICE BEARERS**

##### **President**

Mr. R. Narayanaswamy

##### **Vice President**

Mr. M. M. Yousuf

##### **Hony. Secretary**

Mr. J. Jayaseelan

##### **Joint Secretary**

Mr. D. Babu Ananth

##### **Treasurer**

Mr. Rajesh H. Bhandari

##### **E. C. Members Elected**

Mr. G. Anandaselvam

Prof. V. Ravichandran

Prof. R. Meenakshi Sundaram

#### **CHAPTERS**

##### **Chairman -Community Pharmacy Division**

Mr. T. Ilango

##### **Chairman-Regulatory Affairs**

Mr. S. Manivannan

##### **Chairman -Education**

Dr. B. Jayakar



### **NEW BOOKS ADDED TO TNPSWT LIBRARY DURING 2008-2009**

1. British Pharmacopoeia - 2008 ED
2. Martindale - The Complete Drug References - 35<sup>th</sup> ED (2007)
3. Indian Pharmacopoeia - 2007 ED
4. Stockley's Drug Interactions - Edited by Karen Baxter - 8<sup>th</sup> ED (2008)
5. Herbal Pharmacy : Scientific Research - 1<sup>st</sup> ED (2007)
6. Quality Standards of Indian Medicinal Plants (6 Volumes) - 8<sup>th</sup> ED (2008)

**NOTE:** List of all books available at Trust website [www.pictrust.com](http://www.pictrust.com)

## **Tamilnadu Pharmacy Council**

Block E, First Floor  
Bharathiyar Complex  
100 Feet Inner Ring Road  
Vadapalani, Chennai 600 026.  
Phone No.: 24728747  
Fax No.: 2470061  
E mail: enquiry@tnpc.ac.in  
Website: www.tnpc.ac.in

### **MEMBERS OF COUNCIL:**

Dr. B. Suresh	President
Dr. V. Ravichandran	Vice-President
Dr. K. Chinnaswamy	Member
Dr. N. Narayanan	Member
Director of Drugs Control	Member
Joint Director of Drugs Control	Member
Director of Medical and Rural Health Services	Member
Government Analyst (Drugs)	Member
Dr. B. Jayakar	Executive Member
Mr. A. Balakrishnan	Member
Prof. R. Meenakshi Sundaram	Member
Prof. M. Thamizh Mozhi	Member
Joint Director of Medical Education (Pharmacy)	Member
Prof. of Pharmacognosy, Madras Medical College, Chennai	Member
Member, Tamilnadu Medical Council, Chennai	Member

### **Office Staff:**

Mr. T. Ilango	Registrar
Mr. B. V. Prasad	Assistant Registrar



## **“ FOR THE BENEFIT OF REGISTERED PHARMACISTS ”**

### **Procedure for transfer of his / her registration from one state to another state**

Registered Pharmacists of the Tamilnadu Pharmacy Council transferring their registration to other State Pharmacy Councils should apply directly to the State Pharmacy Council where he/she intends to transfer his/her registration with following documents:

- 1) Should surrender the original Tamilnadu Pharmacy Council Registration Certificate along with Identity Card and Service Book (if obtained)
- 2) Original HSC Certificate with a copy
- 3) Original Diploma/Degree in Pharmacy with copy
- 4) Original Mark sheets of Diploma/Degree in Pharmacy
- 5) Original Course-cum-Conduct Certificate issued by the Pharmacy College with a copy
- 6) Original Transfer Certificate with a copy
- 7) Original Practical Training Certificate with a copy, in the case of D. Pharm
- 8) A Demand Draft for Rs. 100/- [Rupees one hundred only] drawn on Tamilnadu Pharmacy Council payable at Chennai, towards the fees for issue of No Objection Certificate to the respective Council
- 9) Registration and Renewal Fees as applicable in the respective State Pharmacy Council
- 10) Recent passport-size photographs as required by the respective State Pharmacy Council
- 11) Any other documents as required by the respective State Pharmacy Council

**Note:** Procedure of fresh registration from Tamilnadu Pharmacy Council is available at [www.tnpc.ac.in](http://www.tnpc.ac.in)

Source TNPC

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