ISSUE No. 7

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

July. - Aug. - Sep. 2010

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ISSUE : 7 **July - Aug. - Sep. 2010**

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EDITORIAL

Dear Readers,

This is the 7th Issue of our quarterly newsletter since inception. In the last issue we partially covered some programs of IPA Convention held at Chennai. In this present issue we have covered other lecture programs held during this convention. As many of our pharmaceutical manufacturers indented to enrich their knowledge on stability study, the articles pertains to the same have been published. The article like stability study of pharmaceutical which are having tests result out of specification and also impact of pharmaceutical and biopharmaceutical stability on the specifications for the drug substances.

The Govt. of India (Ministry of Health) at last issued the draft notification of "collection, Storage and Issue of umbilical cord blood". I request all our readers may go through the notification and give their comments to this Trust office so as to enable us to send their comments in consolidated form. The Govt. of India also notified import registration guideline for import of cosmetics which is effective from April 2011. This notification will be published in our next issue of our newsletter.

Indian Pharmaceutical Association TN, branch conducted a worthwhile symposium on the subject of **"Management of Expired Drugs".** Many allied association members and dignitaries attended this workshop and given their suggestions for proper handling date expired medicines.

The Annual General Body meeting of our Trust was held on 17the June 2010 at Presidency club, Chennai. All the trustees attended the meeting and actively participated. The Trust is going to conduct series of workshops on the subject of **Export of Drugs and Pharmaceuticals, Marketing Management of Drugs and Pharmaceuticals and 'Drug awareness and importance of Pharmacy Profession.**

We request all our readers including our drug manufacturers to forward the vacancies for the placement of pharmacy graduates. Our Trust is interested to help the needy graduates to get proper placement.

We have covered many important news items including various pharmacy college functions as well as our professional news items.

I am thankful to all the members of the editorial board and the Advisory board for helping me to publish this issue in a time bound manner. I hope the readers will be benefited from this bulletin.

With best regards

Mr. R. Narayanaswamy

ARTICLES

Impact of Pharmaceutical and Biopharmaceutical Stability on the Specifications for Drug Substances and Drug Product

By Dr. Ravi S. Harapanhalli, Ph.D.
Principal Consultant and Practice Lead for Late Stage Development Consulting
PAREXEL Consulting, Bethesda, MD, USA
At the Satellite Workshop on **Stability Testing for Global Submission**
Organised by IPA Regulatory Affairs Division & IPA, Tamilnadu Branch
in association with American Association for Pharmaceutical Scientists (AAPS)

Talk Outline

- Dynamics of stability testing
- Impurities versus degradation products
- Setting specifications for degradation products
- Standard versus Reduced Stability Testing
- Functionality tests affected by stability
- Extractables and leachables
- Global expectations for stability testing
  - Climate zones
  - Long term testing
  - Accelerated and Stress testing
  - Temperature cycling
  - Significant temperature excursions
  - Shipping, handling, and cold chain management
- Recalls due to stability failures- revisiting specifications

Stability

- The capacity of a drug substance or a drug product to remain within specifications established to ensure its identity, strength, quality, purity, and potency throughout the retest period or expiration dating period, as appropriate

Dynamics of Stability Testing

Chemical stability	Oxidation, reduction, hydrolysis, racemization, polymerization, etc.
Physical stability	Appearance, hardness, moisture, emulsion phase separation (synerisis), viscosity, redispersibility, pH, etc.
Microbiological stability	Sterility, apyrogenicity, microbial quality/load, preservative effectiveness, etc.
Therapeutic stability	Change in dissolution profile, Bioavalability
Toxicological stability	Increase in type and amount of degradation products or extractable

Impurities and Degradation Products

- ICH Q3A(R2)- Impurities in DS
- ICH Q3B(R2)- Degradation products in DP
- Impurities
  - Drug-related process impurities
  - Residual solvents
  - Inorganic impurities
- Degradation products
  - DS degradation due to hydrolysis, oxidation, racemization, decarboxylation, rearrangement, breakdown, etc
  - Reaction of DS with excipients
    - E.g. Maillard reaction of amines with lactose
  - Breakdown of excipients in the DP
    - Hydroxypropyl methyl cellulose phthalate (HP-55) breakdown to free phthalic acid and its secondary reactions with DS

Setting Specifications

- Name of a test, analytical procedure, and acceptance criteria
- Table of specifications includes a set of individual specifications
- Specifications cover batch release testing and stability over the claimed shelf life
- Stability-indicating test methods
- Identification of impurities/degradation products
  - Isolation versus synthesis

How Specifications are Set?

- Extent of toxicological testing and exposure levels in preclinical testing
- Level of qualification in clinical testing
- Manufacturing experience
  - (e,g, 3 X STD of mean)
- Stability projections to achieve a reasonable shelf life

Purpose of Stability Study

To establish, based on testing a minimum of three batches of the drug substance or drug product, a retest period or shelf life and a labeling storage statement applicable to all future batches of the drug substance or drug product manufactured, packaged, and stored under similar circumstances

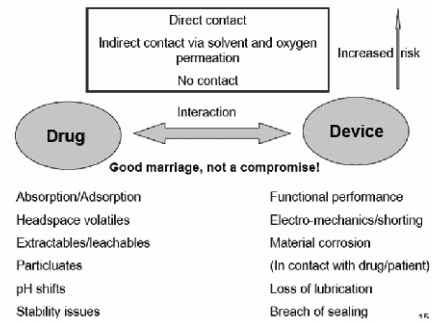
Stability Testing Begins with Formulation Development

- ICH Q8(R2)
- DS and excipient interactions
  - Binary, ternary, multiple mixtures
- Open dish experiments
- Stress testing (e.g. 50°C for days to weeks)
- Water activity studies
- Impact of impurities in the excipients

Container Closure System Linked to Stability Testing

Degree of Concern Associated with the Route of Administration	Likelihood of Packaging Component-Dosage Form Interaction		
	High	Medium	Low
Highest	Inhalation Aerosols and Solutions; Injections and Injectable Suspensions'	Sterile Powders and Powders for Injection; Inhalation Powders	
High	Ophthalmic Solutions and Suspensions; Transdermal Ointments and Patches; Nasal Aerosols and Sprays		
Low	Topical Solutions and Suspensions; Topical and Lingual Aerosols, Oral Solutions and Suspensions	Topical Powders; Oral powders	Oral Tablets and Oral (Hard and Soft Gelatin) Capsules

Drug-Device Combination Products



Pharmaceutical Development: Container Closure System

- ICH Q8 does not adequately address CCS
- CCS may potentially affect product's critical quality attributes.
- Controlling quality of CCS components upstream
- Change controls in the quality system to ensure vendors
  - manufacture components under GMP/ISO type standards
  - are amenable to audits and have reporting obligations
  - use optimized process to minimize use of additives, processing aids, etc, and to assure consistency
  - use effective cleaning processes designed to remove/minimize extractables

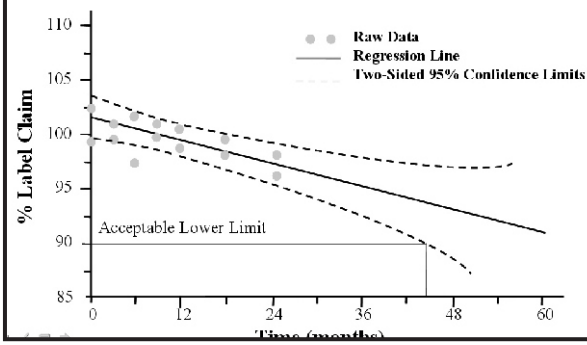
ICH Q1D

- Full design: a stability schedule in which samples for every combination of all design factors are tested at all time points as recommended in Q1A
- Reduced design: a stability schedule in which sample for every factor combination are not all tested at all time points

Value of Statistical Analysis

- Regression analysis with 95% confidence limits is a systematic approach to shelf life estimation
- Shelf life estimation assuming zero- or pseudo-zero-order kinetics (using linear regression) is valid for assay and degradants
- More scientifically valid when extrapolating beyond observed range

Shelf-Life Estimation for a Single Batch



"To Pool or Not To Pool?" Is the question

- Data from more than one batch or factor should not be pooled without statistical test
- ANCOVA is a systematic approach to testing different batches and other factors for poolability based on common slopes/intercepts
- Alternative approaches, e.g., testing equivalence in predicted shelf lives, recommended in Q1E

Reduced Designs

- Matrixing is of limited utility and bracketing is generally not applicable to drug substances
- Can be applied to most types of drug products
- Can be applied to IND, NDA, & postapproval changes, if appropriate
- Bracketing and matrixing are based on different principles; careful if used together.

Bracketing

- Factors that are characterized by a range of numeric values: e.g., strength, package size (i.e., container size and fill)
- Strength where formulation is identical or very closely related

Bracketing Contd..

- Package size where container size or fill varies while the other remains constant
- Package size where both container size and fill vary, if justified
- Select extremes based on dimensional or physical characteristics of container closure system

Matrixing

- Design of a stability schedule in which samples from a selected subset of all factor combinations are tested at a specified time point; a different subset will be tested at subsequent time point
- It assumes that the stability of the subset tested represents the stability of all factor combinations at a given time point

Factors for Matrixing

- Without further justification
  - Batch
  - Strength with identical or closely related formulation
  - Package size in the same container closure system
  - Intermediate time points (though time is considered a covariate)

Factors for Matrixing Contd..

- With further justification
  - Strengths where amount of active changes while each excipient or total weight remains constant
  - Container closure material
  - Container closure system
  - Container storage orientation
  - Drug substance manufacturing site
  - Drug product manufacturing site

Factors for Matrixing Contd..

- Factors that should not be matrixed
  - Strength with different formulations
  - Test attributes
  - Storage conditions
  - Initial and final time points

Stability Issues with Gelatin Capsules

- Tend to exhibit reduced dissolution rates upon aging
- Typically evident when a formulation is stored for 1-6 months under accelerated temperature and/or humidity
- Gelatin cross-linking and hydrogen bonding
- Promoters of cross-linking
  - Sulfonic acids, hydrogen peroxide, glucose, aldehydes, dyes
  - High temperature, high humidity, light

Remedying Cross-linking Problems

- USP Tier II test using enzymes pancreatin, pepsin
- Stress-testing the formulation before it is too late!
- Formaldehyde treatment
  - Addition of formaldehyde at various concentrations to filled capsules, which are exposed to ICH stability test conditions for days to months
- Efforts to aim define the limits of aldehydes to be controlled to avoid changes in dissolution
- Non-invasive and non-destructive ways to detect aldehyde levels in dosage units using NIR

A Case Study

- A peptide drug and an IR capsule
- The API equivalency and the primary stability batches manufacturing strategy for the NDA submission was changed at the last minute
- Out-Of-Specification (OOS) value observed at the one month time point under accelerated storage conditions (40°C/75% RH) for yellow/white and orange/white drug product capsules
- Formaldehyde from the dye used in desiccant canister label caused gelatin cross-linking and peptide oxidation

Stability Impacting Specifications for Biopharmaceuticals

- Limits for aggregates
- Sub-visible particulates (USP <788>) specification stratifying 1-10 um particles
  - Correlation between subvisible particulates in 1-10 um range and immunogenicity
- Conventional specification:
  - Particulates ≤ 10 um
  - Particulates ≤ 25 um

Extractables and Leachables in Pharmaceuticals

Risk-based Approaches to Extractables and Leachables

Safety Level	Supporting data	Dosage forms
1 Intended for respiratory track-compromised patients	USP Biological reactivity test data, extraction/tox evaluation, limits on extractables, batch to batch monitoring of extractables, stability monitoring of leachables (case-by-case)	Inhalation aerosols, solutions, suspensions, and Nasal sprays
2 Rapid and complete access to systemic circulation	USP Biological reactivity test data, extraction/toxicological evaluation, stability monitoring of leachables (case-by-case)	Injections, injectables, and opthalmics (required to be sterile)

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Assessing Extractables and Leachables

- Controlled Extraction studies:
  - Every batch of incoming CCS component is tested
  - Vigorous but not aggressive (worst case) and be representative of interaction through shelf life
  - Complete qualitative/quantitative profile of all potential leachables using complementary analytical methods
  - Identify extracts whenever possible
  - Determine which chemical species may migrate into the dosage form and at what concentration
  - Develop/validate routine extractables testing methods
- Toxicological evaluation of extracts:
  - Determine the safe level of exposure via the label-specified route of administration
- USP/ISO Tests as appropriate

PQRI Terminology for E/L

- **SCT**: negligible safety concerns from carcinogenic and noncarcinogenic toxic effects.
- **QT**: a given non-carcinogenic leachable is not considered for toxicological assessments unless it presents structure activity relationship concerns.
- **AET**: Analytical Evaluation Threshold
  - The converted SCT used by analytical chemists.
  - the threshold at or above which a chemist should begin to identify a particular leachable and/or extractable
  - report it for potential toxicological assessment.

Leachables in ONIDPs

- Even though primary containers may no show significant leachables, potential exists for migration of components of protective overwrap through LDPE container walls
- Safety concern threshold (SCT) for these products intended for daily use is 0.15 mcg/day and a Qualification Threshold (QT) of 5 mcg per day for an individual leachable in an OINDP.
- For parenterals, and for acute use, appropriate conversion factors (e.g.100) may be proposed.

Specifying Leachables in ONIDPs

Major Leachables via GC (n = 30 canisters)	
2,2,4,6,6-Pentamethyl hept-3-ene	NMT 300 mcg/inhaler
3,3'-Oxybispropionitrile	NMT 225 mcg/inhaler
Nonyl Phenol isomers	NMT 120 mcg/inhaler
Oleic acid	NMT 130 mcg/inhaler
Antioxidant 2248	NMT 160 mcg/inhaler
Hydrocarbon 1 related to 2,2,4,6,6-pentamethylhept-3-ene	NMT 18 mcg/inhaler
Hydrocarbon 2 related to 2,2,4,6,6-pentamethylhept-3-ene	NMT 55 mcg/inhaler
Total non-assigned leachables (> LOQ of 2 mcg/canister)	NMT 350 mcg/inhaler

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Leachables in ONIDPs Contd.

Major Leachables via LC (n = 6 canisters)	
Organox 259	NMT 500 mcg/inhaler
Irganox 245	NMT 20 mcg/inhaler
Silicone oil via AAS (n=5 canisters)	NMT 250 mcg/inhaler
Minor Leachables	
Acrylonitrile (n=15 canisters)	NMT 1.9 mcg/inhaler
Formaldehyde (n = 3 canisters)	NMT 0.4 mcg/inhaler
Total Nylon oligomers	NMT 2.8 mcg/inhaler
Total coated can leachables (n = 30 canisters)	NMT 9.0 mcg/inhaler

Leachables testing is not performed routinely since extractables are controlled in incoming container and closure system components.

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Leachables in ONIDPs Contd.

Extractables in rubber valves	
Acrylonitrile monomers	NMT 8 PPM (mcg/g)
Nitrosamines: NDMA, NDEA, NDBA, NPIP, NPYR, NMOR	Total: NMT 24 ppb Individual: NMT 5 ppb
PAHs: Acenaphthylene, Benxo(a)pyrene Pyrene, Acenaphthene Dibenzoanthracene, Anthracene Fluoanthene, Benzo(a)anthracene Chrysene, Benzo(b)fluoranthrene Flurene, Phenanthrene, Benxo(ghi)perylene, Naphthalene Benzofluoranthrene, Indeno(123 cd)pyrene)	Individual: NMT 1.0 ppm
Silicone oil	1.0 mg/Valve

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Leachables in Parenteral Containers

- **Large Volume Parenterals**
  - **Glass bottles**
  - **Plastic bottles**
  - **Plastic bags**
- **Small Volume Parenterals**
  - **Glass vials, ampoules, or syringes**
  - **Plastic syringes**

Plastics Used for LVP

- **Polycarbonate,**
- **Polyvinyl chloride**
- **Polypropylene**
- **Polystyrene**
- **Ethylene-propylene copolymer**

Flexible Plastic containers

- **Outer Layer**

  Polypropylene :styrene-ethylene-butylene-styrene (60:40)
- **Middle Layer**

  Polypropylene:polyester:ethylene vinyl acetate:styrene-ethylene-butylene-styrene (2:38:10:50)
- **Inner Layer**

  Polyvinyl chloride resin

  Plasticizer

  Lubricant
- **Overpouch**

  HDPE or laminated aluminum foil

Potential Plastic Extractables

- **Plastic components**
  e.g. vinyl chloride monomer for PVC
- **Antioxidants**
  sodium bisulfite, sodium hydrosulfite, butylated Hydroxyanisole (BHA), butylated Hydroxytoluene (BHT)
- **Plasticizers**
  DEHP (diethylhexyl phthalate), calcium phosphate.
- **Catalysts**
  triethylaluminum
- **Sealing solvents (e.g. cyclohexanone)**
- **Bloom/exudation components**
- **Hot stamp ink (solvents and ingredients)**
- **Heavy metals**
- **Solvents**
- **Clarifiers (e.g.NA-11, 2,2'-methylene-bis 4,6-di-t-butylphenyl)-phosphate)**

Potential Plastic Extractables

- **Clarifiers**
  (e.g.NA-11, 2,2'-methylene-bis 4,6-di-t-butylphenyl)-phosphate)
- **Stabilizers**
  (e.g. epoxidized linseed oil, zinc stearate, calcium stearate, and magnesium oxide)
- **Lubricants**
  (e.g.N,N'-ethylene bis-stearamide)

Extraction Studies

(new plastic bags)

- **Stress conditions**
  70°C/24 hours, 121° C/1 hour (water, USP)
- **Normal conditions**
  40°/up to 3 months and RT/24 months (dosage form)

Extractables in Glass containers

- **Metal oxides (e.g. calcium, boron, iron, silicates, etc.)**
- **Aluminum**

Aluminum

- **Toxicity**
  CNS toxin, of concern for renal-impaired patients and neonates
- **Source**
  Glass and plastic Containers --*leachable*
  Bulk drug substances--*impurity*

Regulations - Aluminum

(21 CFR 201.323 and 65 FR 4103)

- **LVP : NMT 25 ppb for LVPs used as TPN components**
- **SVP: measured and recorded actual level (not limited to 25 ppb)**
- **Labeling: specify the level**

***Based on the data accumulated.**

Extractables Issues

- **Extraction studies and tests**
- **Solution properties**
- **Acceptable levels**
- **Qualification**
  - **USP Physiochemical Tests for Plastics**
  - **Biological tests/cytotoxicity test**
  - **Pharma/tox consults**
- **Release and stability testing**

Leachables From Infusion Systems

- Liposomal formulation
- Extended peritumoral infusion in brain
- Adsorption, absorption, permeation, leaching and air/moisture transmission

Choosing Right LT Stability Testing Condition

- Meteorological data based on monthly mean values of temperatures and due points
- Identification of hottest and/or most humid place in a country/region
- Deciding on the appropriate LT stability testing conditions

Global Regulatory Requirements for Stability Testing

- Climate zones
- Long term testing
- Accelerated testing
- Stress testing
- Temperature cycling
- Significant temperature excursions
- Shipping, handling, and cold chain management

Climate Zones and Testing Conditions

CZ	Climate Definition	Criteria*	Testing Conditions
I	Temperate	≤15° C/≤11hPa	21° C/45% RH
II	Subtropical and Mediterranean	>15-22° C/>11-18hPa	25° C/60% RH
III	Hot and Dry	>22° C/≤15 hPa	30° C/35% RH
IV A	Hot and Humid	>22° C/15-27hPa	30° C/65% RH
IV B	Hot and Very Humid	>22° C/>27hPa	30° C/75% RH

*Mean Annual Temperature measured in open air and **Mean** Annual Partial Water Pressure

Ref: ICHQ1A/Q1F, USP <1150>Pharmaceutical Stability; WHO 40th Expert Committee on Specifications for Pharmaceutical Preparations, Geneva, 24-28 October, 2005

Stability Testing Safety Margin

- $Y_T = (T_S - T) - 100/T$
  - Y_T is % temperature margin of safety
  - T_S = Stability testing storage temperature
  - T = Measured or Mean Kinetic Temperature
- $Y_T > 0$ if $T_S > T$
- $Y_T = 0$ if $T_S = T$
- $Y_T < 0$ if $T_S < T$
- Required safety margin depends on
  - Impact of the environment (loading variability)
  - Ability of the formulation/batch-to-batch to resist heat and moisture (resistance variability)

Mean Kinetic Temperature (MKT)

- The single calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures.
- It is not a simple arithmetic mean
- MKT data sources:
  - Shipping studies, warehouse studies, and retail pharmacies

Contact Systems and Stability

- CCS as well as other materials in the fluid path such as reactors, transfer tubes, filters, chromatographic resins, desiccants, connectors, valves, etc.
- Metallic surfaces
  - Degradation of epinephrine-containing formulations
- Lewis acids from desiccants ($AlCl_3$, Silica, BF_3 ,etc.)
  - Degradation of inhalation anesthetics to generate hydrogen fluoride, carbon monoxide, etc.
- 21CFR 211.65(1): Material contact surfaces
  - should not be reactive, additive, or absorptive
  - Safety, identity, strength, purity, quality

Other Elements of Stability Testing

- Accelerated testing:
  - to support temperature excursions and to project stability under long term storage
- Intermediate storage testing:
  - as a fall back if accelerated testing fails
- Stress testing
  - To develop stability indicating test methods and to understand degradation pathways
  - Temperature (accl + 10C), humidity(75%), photolysis, hydrolysis, oxidation)
- Temperature cycling
  - To support temperature and humidity fluctuations during shipping, handling, and transit
- Cold chain management
  - Manufacturing site to pharmacy/warehouse to patient's drug cabinet

Significant Change Under Accelerated/Intermediate Testing

- DS:
  - Failure to meet specifications
- DP:
  - A 5% loss from the initial assay values
  - Any new or specified degradant exceeding its specification limits
  - Dissolution exceeding 12 unit specification limit
  - Failure to meet other specifications

Recalls due to Stability Failures

- Field alert reports
- Root cause analysis
  - Common cause versus special cause
- Risk analysis and communication
- Class A, B, C recalls
- Follow through actions- CAPAs
- Additional qualification studies to revise specifications

Relevant Guidance Documents

- ICH Q3A(R2) and Q3B(R2)
- ICH Q6A and Q6B
- ICH Q1A(R2), Q1B, Q1C, Q1D, Q1E, Q1F (withdrawn), and Q5C
- FDA Guidance on Stability
- FDA Guidance on Container Closure Systems
- EMEA Guidance on Pharmaceutical Stability
- WHO Guidance on Pharmaceutical Stability
- A Risk-Based Approach to Establish Stability Testing Conditions for Tropical Countries: Zahn et al, J. Pharm. Sc., 95, 2006, p 946-964

Investigating OOS (out of specification) Test Results for Pharmaceutical Production

By Saji Thomas
Par Pharmaceutical
At the Satellite Workshop on **Stability Testing for Global Submission**
Organised by IPA Regulatory Affairs Division & IPA, Tamilnadu Branch
in association with American Association for Pharmaceutical Scientists (AAPS)

Reference

- 21 CFR part 211.192
- Guide to inspection of quality control laboratories, FDA, July 1993
- FDA draft guidance, 1998
- FDA draft guidance ,2006

Why Investigate OOS Results?

- It's the law. 21 CR 211.192 states
  - The failure of a batch or any of it's components to meet any of it's specifications shall be **thoroughly investigated**, whether or not the batch has already been distributed. The investigation shall **extend to other batches** of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. A **written record** of the investigation shall be made and shall include the conclusion and follow up

The Barr Decision

- **United States District Court For the District of New Jersey**
- **United States of America, Plaintiff, v. Barr Laboratories, Inc., et al., Defendants - Page 1**
- Civil Action No. 92-1744
- ORDER
- In accordance with the Court's Opinion filed herewith,
- It is on this day of February, 1993,
- ORDERED that plaintiff's motion for a preliminary injunction directing defendants to comply with the Federal Food, Drug and Cosmetic Act is granted in part and denied in part; and it is further
- ORDERED that defendant Barr shall produce the data underlying its ***analytical validation*** studies relied upon during this proceeding within thirty (30) days of the date of this Order; and it is further
- ORDERED that defendant Barr shall submit to the Court and to plaintiff a proposed **schedule of *validation within ten (10) business days*** of the entry of this Order, provided, however, that defendant Barr shall complete all validation studies within one year of the date of this Order; and it is further
- ORDERED that plaintiff shall submit to the Court and defendant Barr a recommendation regarding the appropriate ***recall class for each batch Barr*** must recall, together with evidence supporting their position, within ten business days of the date of this Order, after which time the Court will issue further instructions on the mechanics of the required recall; and it is further
- ORDERED that plaintiff's motion is denied with respect to the individual named defendants.
-
- Alfred M. Wolin, U.S.D.J.

OOS Result- Product Failure

- Judge Wolin preferred to use the term "out-of-specification" (OOS) laboratory results rather than the term "product failure" .
- OOS result identified as a laboratory error by a failure investigation or an outlier test , or overcome by retesting is not a product failure.
- OOS results fall into three categories:
  - laboratory error
  - non-process related or operator error
  - process related or manufacturing process error

1993- The Barr Decision

- The ruling settled much of the debate between the industry and the FDA concerning
  - Investigations
  - Raw data
  - Validation
  - Data Integrity

Judge Wolin's Legal Ruling- Issues

- Averaging OOS values with "in specification" values to get passing results
- Ineffective program for process validation
- Discarding raw data
- Conducting multiple retesting with no-defined endpoint
- Performing inadequate failure investigation
- Lack of method validation

Decisions

- The history of the product should considered
- The exact cause is difficult to determine
- Restrictions on using outlier test
- The firm should have retest policy
  - The protocol must define the point which testing stops and evaluation occurs
  - Firm cannot conduct two retest

FDA Draft Guidance 2006- Scope

- This guidance applies to chemistry-based laboratory testing of drugs regulated by CDER.
- It is directed toward traditional drug testing and release methods.
- It applies to
  - active pharmaceutical ingredients,
  - excipients and other components,
  - in-process materials, and
  - finished drug products
- Excludes PAT approaches

Assessing OOS Test Results

- The source of the OOS result should be identified either as
  - an aberration of the measurement process
  - or an aberration of the manufacturing process.
- Even if a batch is rejected based on an OOS result, the investigation is necessary to determine if the result is associated with other batches of the same drug product or other products.
- Batch rejection does not negate the need to perform the investigation.
- The investigation should be thorough, timely, unbiased, well-documented, and scientifically sound

Assessing OOS Test Results

- Contract lab
  - The laboratory should convey its data, findings, and supporting documentation to the manufacturing firm's quality control unit (QCU), who should then initiate the full-scale OOS investigation
  - Quality Agreement

System Performance-Bracketing Std

- Failure of bracketing std response
  - Indicate that the system is not functioning properly
  - All of the data collected during the suspect time period should be properly identified and should not be used
  - The cause of the malfunction should be identified and, if possible, corrected before a decision is made whether to use any data prior to the suspect period

Obvious Errors

- If errors are obvious, such as
  - the spilling of a sample solution or
  - the incomplete transfer of a sample composite,
  - Chipped/broken tablets
  - floating tablets
- The analyst should immediately document what happened
- Analysts should not knowingly continue an analysis they expect to invalidate at a later time for an assignable cause (i.e., analyses should not be completed for the sole purpose of seeing what results can be obtained when obvious errors are known).

Supervisor's Responsibility

- Supervisor's assessment should be objective and timely.
- There should be no preconceived assumptions as to the cause of the OOS result.
- Data should be assessed promptly to ascertain if the results might be attributed to laboratory error, or whether the results could indicate problems in the manufacturing process

Responsibility of Laboratory Mgmt

- should ascertain
  - reliability of the individual value obtained
  - significance these OOS results to the laboratory quality assurance program.
- Trends
  - Alert to developing trends
  - Monitor these trends and ensure that any problematic areas are addressed

ROOT CAUSE ANALYSIS

Materials

Solvents	Dishwashing detergent
Reagents	Column
Vials	Any changes to anything relevant to testing
Caps of Vials	Changes to gases (GC)
Glassware	Pipettes/manual or automated

Methods

Changes to method	Normality, etc. calculated correctly
Any chemist observation	Validation report
Calculation checked	Any assumed steps"
Standards-RT/RF	Training of chemists

ROOT CAUSE ANALYSIS

Environment

Temp. control of lab	Humidity of lab

Equipment

Instrument type	Balance
Detector	pH meter
Injector	Burette size-able to measure differences?
Sonicator	Temperature control of column
Vortexer	

People

Chemist training	Chemist experiences
Glassware washing personnel changes	

Laboratory Error and CAPA

- Laboratory error should be relatively rare.
- Frequent errors suggest a problem that might be due to
  - inadequate training of analysts,
  - poorly maintained or improperly calibrated equipment,
  - or careless work.
- Whenever laboratory error is identified, the firm should determine the source of that error and take corrective action to prevent recurrence.
- To ensure full compliance with the CGMP regulations, the manufacturer also should maintain adequate documentation of the corrective action.

Phase 1- Investigation

- When
  - The analyst reports an OOS result
- Objective
  - To determine the assignable cause
  - To ascertain if the results might be attributed to laboratory error
  - whether the results could indicate problems in the manufacturing process.
- Assignable cause established to the testing Lab
  - Invalidate the initial result-retest as per the monograph
  - Corrective action
  - Preventive action

Phase 2 of the Investigation

- When- Assignable cause not established to the Lab
  - When the initial assessment does not determine that laboratory error caused the OOS result and testing results appear to be accurate
- Objective
  - To identify the root cause of the OOS result and take appropriate corrective and preventative action.
- A full-scale investigation should include
  - review of production and sampling procedures
  - and will often include additional laboratory testing
  - impact of OOS result(s) on already distributed batches.

Phase 2- Investigation

- The investigation should be conducted by the QCU and should involve all other departments
  - manufacturing,
  - process development
  - maintenance
  - engineering

Review of Production

- A full-scale OOS investigation should consist of a timely, thorough, and well-documented review. A written record of the review should include the following information.
  - A clear statement of the reason for the investigation.
  - A summary of the aspects of the manufacturing process that may have caused the problem.
  - The results of a documentation review, with the assignment of actual or probable cause.
  - The results of a review made to determine if the problem has occurred previously.
  - A description of corrective actions taken.

    If this part of the OOS investigation confirms the OOS result and is successful in identifying its root cause, the OOS investigation may be terminated and the product rejected.
  - However, a failure investigation that extends to other batches or products that may have been associated with the specific failure must be completed

Production-Follow Up

- OOS results may indicate a flaw in product or process design. For example,
  - a lack of robustness in product formulation, inadequate raw material characterization or control,
  - substantial variation introduced by one or more unit operations of the manufacturing process, or
  - a combination of these factors can be the cause of inconsistent product quality.
- In such cases, it is essential that redesign of the product or process be undertaken to ensure reproducible product quality

Retest

- The sample used for the retesting should be taken from the same homogeneous material that was originally collected from the lot, tested, and yielded the OOS results
- It is often important for the predefined retesting plan to include retests performed by an analyst other than the one who performed the original test.
- A second analyst performing a retest should be at least as experienced and qualified in the method as the original analyst.

Retest

- FDA inspections have revealed that some firms use a strategy of repeated testing until a passing result is obtained, then disregarding the OOS results without scientific justification.
- This practice of "testing into compliance" is unscientific and objectionable under CGMPs.
- The maximum number of retests to be performed on a sample should be specified in advance in a written standard operating procedure (SOP).
- The number may vary depending upon the variability of the particular test method employed, but should be based on scientifically sound principles.
- The number of retests should not be adjusted depending on the results obtained. The firm's predetermined retesting procedures should contain a point at which the additional testing ends and the batch is evaluated

Reporting of Results

- In the case of a clearly identified laboratory error, the retest results would substitute for the original test result
- If no laboratory or calculation errors are identified in the first test, there is no scientific basis for invalidating initial OOS results in favor of passing retest results. All test results, both passing and suspect, should be reported and considered in batch release decisions

Case Study

- Initial result
  - 89
- Retest
  - 90, 91
- Reported result
  - 90

While this average would meet specifications, the additional test results also tend to confirm the original OOS result

- Initial result
  - 80
- Retest
  - 85,105
- Reported result
  - 90

These results do not confirm the original OOS result but show high variability and may not be reliable.

In both examples, the individual results, not the average, should be used to evaluate the quality of the product.

Reporting of Results

- one sample ,one result
  - Multiple injections should be averaged as one result
- The use of replicates to arrive at a single reportable result, and the specific number of replicates used, should be specified in the written, approved test method.
- Acceptance limits for variability among the replicates should also be specified in the method.
- Unexpected variation in replicate determinations should trigger remedial action as required by § 211.160(b)(4).

Reporting of Results

- The QCU is responsible for interpreting the results of the investigation.
- In those instances where an investigation has revealed a cause and the suspect result is invalidated, the result should not be used to evaluate the quality of the batch or lot.
- A confirmed OOS result indicates that the batch does not meet established standards or specifications and should result in the batch's rejection, in accordance with § 211.165(f), and proper disposition
- in cases where an investigation (1) does not reveal a cause for the OOS test result and (2) does not confirm the OOS result — the OOS result should be given full consideration in the batch or lot disposition decision.

No assignable cause

- Initial results-89.5%
- Retest results-99.0, 98.9, 99.0, 99.1, 98.8, 99.1, and 99.0
- A comprehensive laboratory investigation (Phase 1) fails to reveal any laboratory error
- Review of the manufacturing process and product history demonstrates that the process is robust. The seven passing retest results are all well within the known limits of variability of the method used.
- Batch results from in-process monitoring, content uniformity, dissolution, and other tests are consistent with the passing retest results.
- After a thorough investigation, a firm's QCU might conclude that the initial OOS result did not reflect the true quality of the batch
- Incases of No assignable cause should we average the failing and passing results?

Outlier Test

- Statistical procedure for identifying from an array those data that are extremes
- An outlier may result from
  - Deviation from prescribed test method
  - Variability in the sample
- The possible use of outlier test should be determined in advance (SOP, protocol etc)

How many replicates?

- Distribution with mean μ and standard deviation σ
- Precision increases with √n (SD = σ÷√n)

n	√n
2	1.41
3	1.73
6	2.45
8	2.83
9	3
20	4.47

Averaging of Results

- In cases where a series of assay results (to produce a single reportable result) are required by the test procedure and some of the individual results are OOS, some are within specification, and all are within the known variability of the method, the passing results are no more likely to represent the true value for the sample than the OOS results.
- For this reason, a firm should err on the side of caution and treat the reportable average of these values as an OOS result, even if that average is within specification

Field Alert

- Unless the OOS result on the distributed batch is found to be invalid within 3 days, an initial FAR should be submitted.
- A follow-up FAR should be submitted when the OOS investigation is completed.

Preventing OOS Results

- Product development (QbD)
- Analytical methods
- Quality systems
- Scientifically sound stability program

Preventing OOS/OOT

- Product development
  - Good understanding of the physical and chemical attributes of the API
  - Understanding of critical process parameters and critical formulation attributes
  - Statistically designed process validation studies(DOE)
  - Evaluation of process validation results
  - Establish the design space based on Scientific understanding of the process

Preventing OOS/OOT

- Analytical Methods
  - Methods validated based on current guidances
  - Critical parameters of the method established by statistically designed Robustness studies
  - QC friendly method
  - Method transfer to QC
  - "Real time" QC testing instead of end product testing

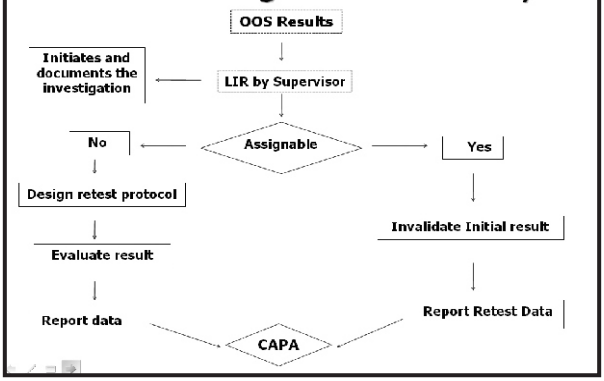
Preventing OOS

- Quality Systems
- Standard Operating Procedure(SOP)
  - Having well established procedure is the key to preventing OOS
  - In-house limits/Alert limits
- 3 Sets of SOP
  - OOT
  - OOS for developmental products
  - OOS for marketed products

Preventing OOS

- Stability Study
  - Appropriate storage conditions and packaging configuration
  - Evaluate all data for all attributes
  - Testing completed in reasonable timeframe

OOS Investigation- Summary



For the kind attention of Pharmaceutical manufacturers / Pharma educational institution

TRAINING / PLACEMENT VACANCIES FOR PHARMACY GRADUATES

TNPSWT is creating a database for placement of graduates / post-graduates in Pharmacy who require job opportunities like academics / industries (Production, QA & QC) / marketing / Research and Regulatory Affairs, etc.

You are requested to forward the details of positions available in your organisation to enable us to communicate to the appropriate candidates. The details may be emailed to us at pictrust@hotmail.com

NOTIFICATION

MINISTRE OF HEALTH AND FAMILY WELFARE

(Department of health)

NOTIFICATION

New Delhi, the 9th April, 2010

G.S.R. 304(E). – The following draft of certain rules to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, after consultation with the Drugs Technical Advisory Board, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act. 1940 (23 of 1940), is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of forty-five days from the date on which the copies of the Gazette of India containing these draft rules are made available to the public.

Objection or suggestions, if any, may be addressed to the Secretary (Health), Ministry of Health and Family Welfare, Government of India, Nirman Bhavan, New Delhi-110011;

Any objection of suggestion which may be received from any person with respect to the said draft rules before the expiry of the period as specified above will be taken into consideration of the Central Government.

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics 3rd Amendment) Rules, 2010.
(2) They shall come into force on the date of their final publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, (hereinafter referred to as the said rules):-
(i) in rule 122EA, in sub-rule (1),-

(a) for the words. "and in Part XIIB and Part XIIC", the words, "Part XIIB, Part XIIBI and Part XIIC", shall be substituted.

(b) after clause (f), the following clause shall be inserted, namey:-

"(ff) 'cord blood bank' means a place or organization or unit for carrying out and responsible for operations of collection, processing, testing, banking, selection and release of cord blood units."

(c) after clause (I), the following clause shall be inserted, namely:-

"(m) 'umbilical cord blood' is the whole blood including Hematopoietic Progenitor Cells (HPC) collected from placental and or Umbilical cord blood vessels after the Umbilical cord have been clamped."

(ii) in rule 122F, after the words "processing of human blood for components" and "processing of whole human blood for components" wherever they are occurring, the words and symbols, "collection, processing, testing, storage, banking and release of Umbilical cord blood stem cells/" shall respectively be inserted;

(iii) in rule 122G,

(a) after the words "processing of whole human blood for components' wherever they occur, the words and symbols "processing of whole human blood for components / collection, processing, testing, storage, banking and release of Umbilical cord blood stem cells" shall be substituted;

(b) in Explanation II, after the words, "Schedule F, Part XIIB", the words "Part XIIC", the words and letters", Schedule F, Part XIIB, Part XII-BI and Part XIIC shall be substituted;

(v) in Form 26G, in the heading after the words, "sale or distribution of its components", wherever occurring, the words " or collection, processing, testing, storage, banking and release of umbilical cord blood", shall be inserted;

(vi) in Form 27C, in the heading after the words, "preparation of Blood Components", wherever occurring, the words" or collection, processing, testing. storage, banking and release of umbilical cord blood", shall be inserted;

(vii) in Form 28C, in the heading after the words, "its components for sale or distribution", the words "or collection, processing, testing, storage, banking and release of umbilical cord blood", shall be inserted;

(viii) in Schedule F, after Part XIIB the following "Part XIIB1" shall be inserted, namely:-

"PART XII BI

REQUIREMENT FOR COLLECTION, PROCESSING, TESTING, STORAGE, BANKING AND RELEASE OF UMBILICAL CORD BLOOD DERIVED STEM CELLS

A. GENERAL REQUIREMENTS

1. ***Location, Surroundings and Building:*** The building (s) for storage of Umbilical cord blood shall be so situated and shall have such measures as to avoid risk of contamination from external environment including open sewage, drain, public lavatory or any factory which produces disagreeable or obnoxious odour or fumes, excessive soot, smoke, chemical or biological emissions.

2. ***Building and premises:*** The premises used for processing and storage shall be designed, constructed and adapted and maintained to ensure that the above operations and other ancillary functions are performed smoothly under hygienic conditions and in sterile areas wherever required. They shall also conform to the conditions laid down in the Factories Act, 1948 (63 of 1948)

   The premises shall be:

   (i) adequately provided with working space to allow orderly and logical placement of equipment, material and movement of personnel so as to maintain safe operations and prevent contamination.

   (ii) designed/constructed/maintained to prevent entry of insects, pests, birds, vermins and rodents. Interior surfaces (walls, floors and ceilings) shall be smooth and free from cracks, and permit easy cleaning painting and disinfection. In aseptic areas the surfaces shall be impervious, non-shedding, non-flaking and non-cracking. Flooring shall be unbroken and provided with a cove both at the junction between the wall and the floor as well as the wall and the ceiling.

(iii) provided with light fitting and grills which shall flush with the walls and not hanging from the ceiling to prevent contamination.
(iv) provided with doors of non shedding materials in aseptic areas preferably of aluminium or steel.
(v) if provided, with fire escapes, these shall be suitably fastened to the walls without any gaps.
(vi) provided with the furniture in aseptic areas which is smooth, washable and made of stainless steel or any other appropriate material other than wood.
(vii) provided with separate areas for processing and storage of products to prevent mix-ups, product contaminations and cross contamination.
(viii) provided with defined environmental conditions for temperature, humidity, ventilation and air filtration. Classifications shall be defined and, if appropriate, monitored.

A periodical record of cleaning and renovating of the premises shall be maintained.

3. Disposal of waste and infectious materials:

3.1 Waste materials awaiting disposal shall be stored safely.

3.2 The disposal of sewage and effluents from the facility shall be in conformity with the requirement of the Environment pollution control Board.

3.3 All Bio-Medical waste shall be dealt with in accordance with the provisions of the Bio-medical Waste (Management and Handling) Rules, 1996.

4. Health, Clothing and Sanitation of personnel:

4.1 All personnel shall undergo medical examination prior to employment and shall be free from infectious and contagious diseases. Thereafter they should be medically examined periodically at least once a year. Records shall be maintained thereof.

4.2 All personnel, prior to and during employment, shall be trained in practices which ensure personal hygiene. A high level of personal hygiene shall be observed by all those engaged in the collection, processing, banking of umbilical cord blood.

4.3 All persons shall wear clean body coverings appropriate for their duties before entering the Processing Zone. Change Rooms with adequate facilities shall be provided prior to entry into any specific zone.

4.4 Smoking, eating drinking, is prohibited inside the Laboratory.

4.5 All personnel working in the Laboratory shall be vaccinated against Hepatitis B virus.

5. Requirements for Processing, Testing and Storage Areas for Umbilical cord blood stem cells

5.1 Separate enclosed areas specifically designed for the purpose and the workload shall be provided.

5.2 There shall be separate areas for designated work purposes, viz:

i. Cord blood Reception: Cord blood reception area with space for transient storage of units and physical examination shall have adequate facilities for registration, data entry and generation of bar-coded labels.

ii Cord blood processing area: The room shall be clean and have an air handling System to provide a Class 10,000 environment. The room will house Class 100 biological safety cabinets for Umbilical cord blood processing. The temperature of the clean room shall be maintained 20 to 25°C and with a positive differential pressure of 10-15 pascals and Relative humidity of 50 - 60%

iii Haematology and Serology Laboratory: The laboratory shall be equipped and utilized for the purpose of testing of Umbilical Cord Blood for ABO grouping and Rh Typing, Total Nucleated Cell Count, Progenitor cell Count and viability test. The room shall be air-conditioned.

iv Transfusion Transmissible Disease Screening Laboratory: The Laboratory shall be equipped and utilized for screening tests on maternal blood for infectious diseases viz. HIV I & II; Hepatitis B & C virus, syphilis and malaria. The room shall be air-conditioned.

v Sterility Testing Laboratory : The laboratory shall be used for performing Sterility tests on Umbilical cord blood Unit. The premises may be classified depending on the testing method used. The room shall be air-conditioned.

vi HLA Typing Laboratory : The Umbilical cord blood Unit shall have arrangement for HLA typing and genetic disease testing. In house testing can be done by providing a well departed Laboratory from the processing area for evaluation of possible genetic disease and HLA typing. The area shall have Class 100,000 environment and air conditioned.

vii Sterilization-cum-washing: Appropriate facility shall be provided within the premises for proper washing and sterilization. This facility would be optional for Laboratories using entirely disposable items.

viii Records and Store Rooms: There shall be designated record room(s) and store room(s). The access to record room shall be permitted only to authorized persons. The room will have adequate protective facilities as the documents and records are to be preserved for long years.

ix Cryogenic Storage room: A minimum space of 200 sq feet shall be provided b the Licensee. the cryogenic storage room shall have provision for temperature monitoring of storage vessels, liquid nitrogen level in storage vessels and oxygen meter. The service space between each liquid nitrogen storage vessel, supply cylinders and connecting hose should be between 10 to 25 sq. feet. Separate storage space for other accessories required shall be provided. The room shall be air conditioned.

B. COLLECTION AND STORAGE OF PROCESSED UMBILICAL CORD BLOOD COMPONENT

1. Collection:

1.1 Umbilical cord blood specific for an individual will be collected after signing an agreement with the parents, whose to be infant's Umbilical cord blood is to be collected, and the specific Processing, Testing and Storing Authority, Private and Public Umbilical Cord Blood Banking to have different agreements.

1.2 Umbilical cord blood shall be collected from hospitals, nursing homes, birthing centers and from any other place where a consenting mother delivers, under the supervision of the qualified Registered Medical Practitioner responsible for the delivery.

1.3 The cord blood shall be collected aseptically in a disposable PVC bag containing adequate quantity of sterile, pyrogen free anticoagulant.

1.4 The Umbilical cord blood would be collected from a premises having a hygienic location to allow proper operation, maintenance and cleaning.

2. Transportation

2.1 Umbilical cord blood shall be transported from the birthing center to the designated laboratory under and as per procedure prescribed by the cord blood bank.

2.1 The Transportation procedure shall be validated to ensure optimum survival of the stem Cells.

2.3 The transportation temperature should be between 18 to 28°C.

2.4 The time period between Collection and processing shall not exceed 72 hours.

STORAGE:

a. The Umbilical cord blood shall be stored at room temperature between 20 to 25°C in the processing area.

b. Samples pending tests for the Specific Transfusion Transmittable Infectious agents shall be stored in a segregated manner.

Note:- Maximum allowable temperature range shall be between 4 to 37 degrees Celsius, for the whole time period of transit. The effects, of deviation of transit temperature from the optimum, on the product shall be adequately explained by the licensee in the client education booklet.

C. PERSONNEL

Cord blood bank shall have following categories of whole time competent technical staff:-

1. Medical Director. The operation of cord blood bank shall be conducted under the active directions and supervision of a Medical Director who is a whole time employee and is possessing a Post Graduate degree in Medicine - MD (Pathalogy/ Transfusion Medicine/ Microbiology) and has experience / training in cord blood processing and Cryogenic Storage.

2. Laboratory in-charge: The laboratory in-charge shall have Post Graduate qualification in Physiology or Botany or Zoology or Cell Biology or Microbiology or Biochemistry or Life Sciences, or Graduate in Pharmacy and one year working experience in pathological laboratory licensed by the local health authority or any microbiology laboratory of a licensed drug manufacturing / testing unit and or experience / training in cord blood processing and cryogenic storage.

3. Technical Supervisor (cord blood processing):- The technical supervisor shall have a:

3.1 Degree in Physiology or Botany or Zoology, Pharmacy or Cell Biology or Bio Sciences or Microbiology or Biochemistry or Medical Laboratory Technology (M.L.T.) with minimum of three year of experience in the preparation of blood components and / or experience / training in cord blood processing and Cryogenic Storage. or

3.2 Diploma in Medical Laboratory Technology (M.L.T) with five year's experience in the preparation of blood components. Experience / training in cord blood processing and Cryogenic Storage shall be essential.

4. Cord Blood Bank Technician(s):- The technicians employed shall have a:

4.1 A Degree in Physiology or Botany or Zoology or Pharmacy or Cell Biology or Bio Science or Microbiology or Biochemistry or Medical Laboratory Technology (M.L.T.) with six months experience and or training in cord blood processing and cryogenic storage, or

4.2 Diploma in Medical Laboratory Technology (M.L.T.) with one year experience in the testing of blood and/or its components and / or experience / training in cord blood processing and Cryogenic Storage.

D. AIR HANDLING SYSTEMS

1. Air handling for sterile areas shall be different from those for other areas. The filter configuration in the air handling system shall be suitably designed to achieve the grade of air as given in the Table I. The environmental microbiological monitoring of clean areas shall be in accordance to the recommended limits given in Table II.

2. The Processing area shall be air-conditioned and fitted with HEPA Filters having Grade C (Class 10,000) environment as given in Table I.

3. The entire Processing would be done under a Biosafety hood conforming to Grade A (Class 100) Standard of Air Quality.

TABLE I

AIR BORNE PARTICULATE CLASSIFICATIONS FOR MANUFACTURE OF STERILE PRODUCTS

Grade	Maximum number of permitted particles per cubic metre equal to or above			
	At rest (b)		In Operation (a)	
A	0.5 µm	5 µm	5 µm	5 µm
B (a)	3500	0	3500	0
C (a)	3,50,000	2000	35,00,000	20,000
D (a)	35,00,000	20,000	Not defined	Not defined

TABLE II

RECOMMENDED LIMITS FOR MICROGIOLOGICAL MONITORING OF CLEAN AREAS "IN OPERATION"

Grade	Air Sample cfu/m^3	Settle Plates (dia 90mm) cfu/2 hrs.	Contact plates (dia. 55mm) cfu per plate	Glove points (five fingers) cfu per glove
A	< 1	< 1	< 1	< 1
B	10	5	5	5
C	100	50	25	-
D	500	100	50	-

E. QUALITY CONTROL

Facilities shall be provided for Quality Control such as Haematological, Microbiological and Instrumental testing. Following duties shall be performed under the function of quality control :

1. To prepare detailed instructions for carrying out such tests and analysis.
2. To approve or reject raw materials and consumables, used in any step, on the basis of approved specifications
3. Haemotological Tests like Total Nucleated Cell Counts, Mononuclear Cell Count, Enumeration of the population of Stem Cells, Stem Cell viability shall be performed on samples of processed Umbilical cord blood Unit
4. Microbiological Tests shall be done on Maternal Blood samples for freedom from Hepatitis B Surface Antigen, Hepatitis C Virus antibody, HIV I and II antibodies. Syphilis and Malaria. Bacterial and Fungal Culture shall be done on the Umbilical Cord Blood Samples.
5. Instruments which would be used to process test and store the UCB unit would be validated before commissioning and calibrated from time to time to check their conformity to specific standards according to an approved and valid protocol.
6. The Environmental Monitoring of the Clean rooms would be done at periodic intervals according to an accepted and validated protocol.
7. All tests mentioned above shall be done in house except tests under item numbers 5, 6 and test for enumeration of Stem Cell Population, HLA typing and Genetic Disease Testing which may be outsourced to a competent third party.

F. SCREENING TESTS

1. The maternal Blood sample shall be tested for
   - i. Hepatitis B
   - ii. Hepatitis C
   - iii. HIV 1 & 2
   - iv. Syphilis
   - v. Malaria

2. The Umbilical Cord Blood shall be tested for
   i. Total Nucleated Cell Count
   ii. Total Monocuclear Cell Count
   iii. Progenitor Cell (Cd34+) enumeration
   iv. Cell Viability
   v. ABO Group and Rh Type
   vi. Sterility as regards Bacterial and Fungal contamination status
   vii. HLA Matching (Only for allogenic Cord Blood Units)

G. STORAGE

1. The Umbilical cord blood shall be cryopreserved using a controlled rate freezing or equivalent validated procedures. The frozen storage shall be at minus 196°C and shall not be warmer than minus 150°C.
2. There will be no shelf life for this class of product.

H. REFERENCE SAMPLES

1. At least two reference samples shall be collected from cord blood unit product prior to cryopreservation and stored at minus 196°C and shall not be warmer than minus 150°C.
2. At least one additional reference sample shall be stored at minus 76°C or colder for the purposes other viability analysis.

I. LAELLING

2. Initial Label placed during collection shall specify:
   i. Human Umbilical Cord Blood
   ii. Approximate Volume or weight of contents in the collection bag (UCB + Anticoagulant)
   iii. Mother's Name
   iv. Place of Collection
   v. Date & Time of collection
   vi. Collected by
   vii. To be Labelled in bold, "ROOM TEMPERATURE ONLY - DO NOT REFRIGERATE, DO NOT IRRAIATE"

2. Label at completion of processing and before issue - Cryogenic Storage Label (Statutory label) shall indicate the following
   i. Name of Product:- Human Progenitor Cell (HPC)- Cord Blood
   ii. Volume or weight of contents
   iii. Percentage of any other additive/preservant
   v. Date of Collection (Birth) .....
   vi. Date of Processing .....
   vii. Name of Manufacturer :- .....
   viii. To be stored continuously not less than - 196°C
   ix. Unique Traceability Number and / or BAR Code.

3. Issue Label at the time of release of Cord Blood Unit shall indicate the following
   i. Name of manufacturer
   ii Licence Number

iii. All details of the Cryogenic Storage Label
iv. The results of Total nucleated Cells, Progenitor Cell percentage (Cd34+), Viability.
v. Result of Transfusion Transmittable diseases testing on maternal blood.
vi. ABO Group and Rh Type.
vii. Result of HLA typing (allogenic)
ix. Statement "Properly identify intended Recipient and Product"
x. A statement indicating that leukoreduction filters should not be used.
xi. Statement "Do not irradiate".
xii. Name and address of receiving hospitals

J. RECORDS / DOCUMENTATION

1. The Licensee shall maintain the following records
   i. Client/donor enrollment/agreement record.
   ii. Collection of unit and transportation record.
   iii. Master record of stored unit.
   iv. HLA Matching record.
   v. Unit Release Register
   vi. Stock Register for Blood Collection Bag Cryoprotectant and Preservant, RBC Sedimentation Enhance.
   vii. Stock Register for Diagnostic Kits, Reagents and other consumables
   viii. Record on feedback after use of cord blood / adverse reaction record
   ix. List of Standard Operating Procedures:

2. Standard Operating Procedures for the following shall be maintained:
   i. Umbilical cord blood collection.
   ii. Transportation of the collected Umbilical cord blood unit.
   iii. Processing of Umbilical cord blood unit
   iv. Cryogenic Storage of processed Umbilical cord blood unit.
   v. Testing of maternal blood for transfusion transmittable infections
   vi. Testing of Umbilical cord blood unit for Total Nucleated Cell Count, Mononuclear Cell Court, Progenitor Cell (Cd34+) enumeration, and Viability.
   viii. Testing of Umbilical cord blood stem cell unit for Sterility.
   ix. Disposal of bio medical waste.
   x. Dispensation of Umbilical cord blood unit.
   xi. Preventive maintenance Protocol for all Instruments
   xii. Acceptance / Rejection procedure of consumables
   xiii. Environment monitoring of classified areas.

K. CORD BLOOD RELEASE

1. There shall be designated area with adequate space for procedures and records related to cord blood unit selection and release.
2. The cord blood bank shall obtain written or electronic request from the transplant physician or designee for shipment of the cord blood unit.
3. Accompanying documentation at the time of issue from the cord blood bank shall include indications, contra-indications, caution, instruction for handling and use of the cord blood unit

including short-term storage and preparation for transplantation.

4. Procedure for transportation of cryopreseved cord blood Unit within the facility shall be designed to protect the integrity of the unit and the health and safety of the personnel.
5. Cryopreserved cord blood unit stored at - 150°C or colder shall be transported in a liquid nitrogen cooled dry shipper that contains adequate absorbed liquid nitrogen and has been validated to maintain temperature below - 150°C for at least 45 hours beyond the expected time of arrival at the receiving facility."

[F.No. X. 11014/2/2008-DFQC]
VINEET CHAWDHRY, Jt. Secy.

Foot Note : The Principal rules were published in the Gazette of India vide notification No. F-28-10/45H (i), dated 21st December, 1946 and was last amended vide notification G.S.R. 45(E), dated 21-1-2010.

Note:

The salient features of this notification is as follows:

1. Govt. of India issued a draft notification as regard to collection, Storage and Issue of umbilical cord blood.
2. Many readers may be aware that after pregnancy the Umbilical cord was simply cut and thrown away. Presently the umbilical cord blood can be stored and stem cells are collected. These stem cells are very useful and also have therapeutic value for certain genetic disorders for the new born babies.
3. In our country many companies have started collection and storage centre of umbilical cord blood.
4. In order to streamline the regulatory requirement particularly safety of the stem cell from blood born virus like HIV, HBS Ag and HCV etc.
5. The umbilical cord blood has to be stored less than minus 150 degree Celsius.
6. There are prescribed qualification for the personnel appointed for this job.
7. The separation of stem cell from UCB have to be carried out at controlled temperature and sterile atmosphere.
8. The procedure of transportation of UCB also mentioned in this notification.

Fake drugs unearthed from stores

The Drug department of Tamilnadu Drugs Control has picked up Voveron 100mg from Pharmacies which were spurious. Inspectors called up manufacturer, Emcure and the company confirmed that the batch number did not tally with those manufactured in the companyThey said that they found there was a series of drug stores linked to this fake racket, just like the last timeThe drug department is investigating further in this matter.

Source: *The Times of India, Chennai 13th July 2010*

M. Pharm Scholarship 2009-2010 awarded by TNPSWT

Profile of 3rd Rank Projects

(Continuation from Issue 6)

PHARMACEUTICS

Project Title: Proniosomes as carrier for the delivery of salbutamol to lungs
Name: Mr. Nithyananth M.
PSG College of Pharmacy, Coimbatore
Guide's Name: Prof. V. Sankar

PHARMACEUTICAL CHEMISTRY

Project Title: Design, docking, ADME studies and synthesis of novel enoyl acyl carrier protein reductase inhibitors as anti tubercular agents
Name: Ms. Purnima S.
Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore
Guide's Name: Mrs. Sonia George

PHARMACEUTICAL ANALYSIS

Project Title: Validated analytical methods for the estimation of Amlodipine besylate, Valsartan and Hydrochlorothiazide in combined tablet dosage form by UV Spectrophotometry, RP-HPLC and in Plasma by Liquid Chromatography-Mass Spectrometry.
Name: Ms. Jothieswari D.
Adhiparasakthi College of Pharmacy, Melmaruvathur
Guide's Name: Mr. K. Anandakumar

PHARMACOLOGY

Project Title: Behavioral and biochemical investigation of Adhatoda vasica Nees on diabetic encephalopathy in wistar Rats.
Name: Mr. Patil Mohan Yashawant
J. S. S. College of Pharmacy, Udhagamandalam
Guide's Name: Prof. R. Vadivelan

PHARMACOGNOSY

Project Title: Evaluation of some indigenous plants for psoriasis treatment
Name: Ms. Priyanka Dwarampudi L.
J. S. S. College of Pharmacy, Udhagamandalam.
Guide's Name:.Dr. S. P. Dhanabal

PHARMACY PRACTICE

Project Title: A clinical evaluation of oral glutamine in prevention of oral mucositis induced by radiation theraphy in patients with head and neck malignancies.
Name: Ms. Sarumathy S.
Periyar College of Pharmaceutical Sciences for Girls, Trichy
Guide's Name: Prof. A.M. Ismail

PHARMACEUTICAL BIOTECHNOLOGY

Project Title: Evaluation of anti-cancer activity of selected medicinal plants
Name: Mr. Patel Viralkumar Laxmanbhai
J. S. S. College of Pharmacy, Udhagamandalam.
Guide's Name: Dr. P. Vijayan

TRAINING / PLACEMENT FOR PHARMACY PROFESSIONALS

Tamilnadu Pharmaceutical Sciences Welfare Trust is creating a database for the placement of graduates and post-graduates in Pharmacy who require job opportunities in Pharmacy field like academics / industries (production, QA & QC) / marketing / research and regulatory affairs, etc. The application format is available at our website www.pictrust.com. Persons who are fresh graduates or experienced in pharmacy field may fill the same and send it to us online.

NEWS

DCGI joins with Commerce Ministry to re-examine spurious drugs definition

Drugs Controller General of India in association with Union Ministry of Commerce & Industry has started an exercise to re-examine the definitions of spurious drugs in the wake of recent seizures of Indian generic drugs by the EU authorities.

The decision came in after the 58th meeting of the DTAB. During the meeting, a proposal from the Commerce Ministry was considered to re-examine the definite of spurious, adulterated and misbranded drugs provided under Section 17 of the D&C Act. The re-definition needs to be in the context of current scenario and trade practices followed in the national and international markets, according to a DCGI circular.

The circular issued to the Pharma industry and its associations through a government order No. 18-3-2010-DC dated February 2010 has sought formation of an expert committee to examine the definitions of the spurious, misbranded and adulterated drugs under the D&C act and suggest amendments.

The expert committee includes Director of Ministry of Commerce, Dr. K. Sathyanarayana, Scientist, 'G' and Head P&P, ICMR, H. G. Koshia,, Commissioner, FDCA, Gujarat, Dr B. R. Jagshetty, Karnataka Drugs Controller, D. G. Shah, Secretary General, IPA and presidents of IDMA and OPPI.

The Ministry of Commerce and Industry pointed out in its strategy document 2008 that Indian Pharma industry has on occasions failed to adhere to the regulatory framework, including compliance and enforcement. Further, it viewed that there are different definitions for counterfeiting spurious drugs by regulated markets which had led to seizure and award of punitive damages against many Indian Pharma exporters.

Source: *Chronicle Pharmabi, 20th May 2010*

Drug Regulator cracks whip on Chinese APIs

The country's Drug regulator has banned import of raw materials from ten Chinese drug companies for supplying products without having the mandatory drug manufacturing standards, people familiar with the matter said.

The move could lead to shortage of few drugs which are manufactured from inputs largely supplied by these companies, industry officials said asking not to be named. The Drug Controller General of India (DCGI) cancelled the registration of Chinese forma last week that effectively stops any import of products manufactured by them in India.

The raw materials include Clotrimazole, Mefenamic acid and Sulphadoxine that are used to make anti-infective and painkillers. “A limited number of Chinese companies supply some of the active Pharmaceutical ingredients (APIs) so there can be shortage for that particular lot” an industry executive said.

“This will give a chance to local PAI companies to increase sales”, Lalit Kumar Jain, Chairman at SMPI, an association of small drug makers said. Indian drug companies largely depend on imports from China for APIs, the basic chemical used to make medicines and intermediates. Local drug makers use these

APIs and intermediates to make finished products which are sold in India and overseas markets. There are concerns among India companies that a large laps in manufacturing standards can be blown up by foreign drug makers to question the standards of drugs made in India.

At present, India exports medicines worth Rs. 42,000 crore every year while another Rs. 58,000 crore are sold in the country. "We have to ensure that drugs made in India are of top quality if we have to become the pharmacy of the world in the next decade or so," a senior health ministry official said.

As per a senior industry official, DCGI found during scrutiny that the Chinese companies had not submitted proper Good Manufacturing Practices (GMP) certificates. "The drug regulator cancelled registration of around half a dozen Chinese companies and a few others themselves surrendered their licenses to supply products into India as they also did not submit proper certificates that are mandatory," said the industry executive.

This is probably the first time the DCGI has taken action against Chinese companies and is stepping up vigil against imports of APIs and intermediates from China. It plans to send drug inspectors to China to audit facilities in that country to ensure drugs sold in India are made at units that meet the regulatory standards.

Source: *The Economic Times, 15th June 2010.*

Kenya may permit generic drugs

Admits Passing Anti-Counterfeit Law was a Mistake: Important Victory for India

The Kenyan health ministry has conceded that the country should not have passed the anti-counterfeit law last year and said it would try and make changes to ensure that imports of legitimate generics were not affected.

This marks an important victory in India's sustained efforts in Africa to counter propaganda by multinational Pharma companies against cheap generic drugs.

"The Kenyan health ministry has revealed at the recent WHO health assembly that the anti-counterfeit legislation passed by the country was pushed by its industry ministry and it had no clue about its ramifications," a commerce department official told ET. The official added that Kenya has said it will try to make changes to ensure that generics are not affected.

The government now plans to focus on countries such as Uganda, Nigeria, Zambia and Malawai that are planning similar anti-counterfeit legislation.

Generics are copies of drugs that do not have patent protection in India, allowing any manufacturer to produce them. The competition among manufacturers helps bring down prices substantially.

India is one of the world's largest producers of generics with yearly exports of an estimated Rs. 30,000 crore, a sixth of which goes to Africa.

Kenya's anti-counterfeit law could render genuine generics imported from countries like India illegal if a company holding a patent to the formulation in any country files a complaint. This could happen despite the fact that the drug is off patent in the exporting countries. Kenya now seems to have realised that the legislation could hamper access to cheap life-saving drugs.

The International Intellectual Property Agreement (TRIPS) under the WTO allows exports of generics to countries with insufficient production capacities on public health grounds

even if patents are held by companies in other parts of the world.

The commerce department had earlier written to the Kenyan government pointing out the downsides of the anti-counterfeit legislation and had also held several meetings on the issue.

Indian officials have also met government representatives from other countries that are planning similar legislations including Uganda, Nigeria and Tanzania to sensitise them about the importance of generics for the poor.

"We have to intensify our efforts in such countries", the official said.

One of the reasons behind anti-counterfeit legislation being considered in a number of African countries is an attempt by global Pharma companies to create confusion between counterfeits (genuine drugs that are made in violation of patents) and fake or spurious drugs that are harmful, the official said.

Generics eat into the profits of large pharmaceutical companies holding patents to those medicines in the Western countries as they can't make inroads into poor countries that prefer to buy the cheap yet effective copies of the original drugs.

Source: *The Economic Times, 3rd June 2010.*

Medicines may get more costly

Govt. Lets Firms Charge More for Non-Chemical Ingredients in Drugs

Country's drug price regulator plans to allow Pharma companies to charge more for non-chemical ingredients used in making medicines which could increase retail prices of drugs.

National Pharmaceutical Pricing Authority (NPPA) asked companies to submit market prices of about 65 excipients - non-chemical ingredients such as sugar, starch, lactose and coatings – for price revision, in a meeting with industry stake holders on Tuesday. Excipient prices were last revised in 2007.

"Cost of some of excipients may increase while others may come down depending on the price movement observed in the last three years," S. M. Jharwal, Chairman NPPA told ET. Excipients are mostly added to give the form, consistency or carry the active ingredient.

A top executive from a local drugmaker said, "Excipient cost constitute about 5-10% of a drug, so the final increase in retail price of brands should be marginal." Since they are used more in liquid forms such as syrups, companies who have products in liquid forms will benefit most from the price hike, he said.

Many of the country's top selling brands are popular cough syrups and vitamin supplements that are sold in liquid form such as Pfizer's Corex, GSK's Zinetac, Pfizer's Becosules and Franco Indian's Dexorange.

But another industry executive said some brands could see significant price rise depending on the quantum of increase in excipients prices. "Inflation has been high over the last three years which could mean significant increase in few medicines," he said. Based on industry's submission and its own analysis, NPPA will then fix the cap on the cost of excipients. The process is expected to be completed by September.

NPPA regulates prices of medicines made using 74 bulk drugs in the country's Rs. 42,000 crore drug retail market. It also prevents drugmakers from increasing prices of medicines beyond 10% within any consecutive 12 months.

Source: *The Economic Times 19th May 2010.*

PCI permits 3 Pharmacy colleges in Kerala to start Pharm D this year

The Pharmacy Council of India has permitted three colleges in Kerala to start the internationally recognized Pharm D Course this academic year. This is the first time the Council permits colleges in Kerala to start the programme after the course was launched in the country in May 2008.

The colleges which got permission this year are Amrita School of Pharmacy, Ernakulam, National College of Pharmacy, Kozhikodu and Al Shifa College of Pharmacy, Perinthalmanna in Malappuram District.

A few more colleges in the state are likely to get the green signal soon as the PCI has asked them to submit signed copies of Memorandum of Understanding with major hospitals or the colleges should be attached with some medical colleges.

Amrita School of Pharmacy of the Amrita Deemed University will start two programs of the Pharma D simultaneously, Pharma D regular and Pharma D post-baccalaureate.

Despite permission of PCI for two programmes, the National College of Pharmacy in Kozhikodu faces difficulty in starting both the program as they are waiting for affiliation from Calicut University for their three year program (Pharm D regular) from June, sources from the colleges told Pharmabiz.

Al Shifa College of Pharmacy in Perinthalmanna, Malappuram is starting the six year Pharm D from this academic year for which the admission process has been started.

Dr. KG Revikumar, Director, Amrita School of Pharmacy said unlike in other colleges, which are offering these programmes, the students in his college will get a hospital environment from the first year onwards.

Source: *Chornicle Pharmabiz 20th May 2010*

Pondicherry to have exclusive Drug Control Dept

The Health Ministry of Pondicherry Government has drawn up a new plan to set up a separate Drug Control Department bifurcating the existing Food and Drugs Control Administration. The ministry hopes that separate department will revamp and streamline the functions of the drug control administration effectively, Health Minister E. Valsaraj told Pharmabiz.

From 1964, the Food and Drug Control Administrations have been working under one director with separate staffs and facilities using same offices in four regions of the union territory. With the establishment of separate drug control department, more posts would be created and the functioning would be strengthened. Separate administration for drug control was a long standing demand of the officials in the department.

The minister said he has made a statement about the bifurcation of FDA in the recent meeting of the legislative assembly. "Modalities are to be worked out to pave the way for separation. Steps have already been taken and the process is going on to realise it in the nearest future," he said. After the establishment of the new administration, it can function as a separate department with a director as HoD.

According to sources, the head office of the department will be functioning in the same premises of the health department in Pondicherry, while there will be three regional offices headed by assistant directors of drugs controller, each in Karaikal, Yanam and Mahe. The ADCs will function in the capacities of Licensing Authorities for the grant and renewal of sale licenses in each zone.

Source: *Chronical Pharmabiz 13 May 2010*

ASSOCIATION NEWS

Drugs Control Department Retired Officers' Association

In order to uplift and update the profession of pharmacy and to guide the public in the health care system the retired officials of the Drugs Control Department of both State and Central Govt. have formed an association called drugs control Department retired officers association. The association is a registered body at Chennai and the registration number is 113/2010.

Objectives:

1. Integrating all those retired officers settled in various parts of the state of Tamilnadu.
2. To organize meeting/seminars/conferences/workshops as and when required for safe medication.
3. To assist the Government wherever needs arise in the implementation of the Drug statutes with a
   view to have a better control over the quality of drop marketed.
4. To offer voluntary service on and when required by government.
5. To associate with other service organization for the betterment of the members and society.

In the General Body Meeting held in Chennai on 21.01.10 the following were elected as office bearers of the Association.

1.	Thiru. C.V. Ramiah	– President
2.	Thiru R. Narayanaswamy	– Vice President
3.	Tmt. R. Jothi Bai	– Vice President
4.	Thiru A. Arunachalam	– Secretary
5.	Thiru R. Natrajan	– Treasurer

The Association will fight against the marketing of spurious and date expired drugs. It will also assist the public to get in touch with appropriate authorities, if they have encountered any problem with regard to the purchase of medicines and drugs.

The inauguration of the association was held on 11th of July 2010 at The Presidency Club, Egmore, Chennai. The Chief Guest of the function was Thiru. S. Boothanathan, formerly District Judge, President, District Consumer Disputes Redressal Forum Thiruvalluvar.

Symposium on Management of Expired Drugs

Indian Pharmaceutical Association, Tamilnadu Branch & IPA - Industrial Pharmacy Division organised symposium on Management of Expired Drugs on Saturday, the 19th June, 2010 at 6.30pm in Hotel Deccan Plaza for Pharma professional from Industry, Regulatory, Wholesale & Retail.

Welcome Address was given by Mr. R Narayanaswamy, President IPA TN branch. Chief Guest was Mr. M. Baskararan, Director of Drugs Control (Tamilnadu). Three speakers gave lectures on various topics. "Systems for Handling Date-expired Products" by Mr. B Raj, President – Aspire Consultants , "SMS- based Expired Drug Tracking Solution – a Novel Approach" by Mr. Kishore Kar, Director Sales – PharmaSecure and "Managing Expired products – A Trade perspective" by Mr. R. Srinivasan, Founder President, PMA. Vote of thanks was proposed by Mr. J. Jayaseelan, Secretary, IPA, TN branch.

The Pharma Secure Company explained the novel solution can track expired drugs with SMS and gives the consumer a short narrative about the status of the drug, whether it is time barred, spurious or substandard or banned one, along with a warning to the user to contact his/her chemist for more information. This method will also check the date expiry of the products and it will help both the regulators and customers. The basis of the solution lies in attributing a unique identifier code on drug packing, and associating these with authentic manufacture data for instance date of expiry. Further this method of a SMS is offered at low cost.

The symposium was a grand success and was attended by more than 145 members.

EVENTS

College of Pharmacy, SRIPMS, Coimbatore

College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore had participated in the inter-collegiate meet, VIBRANTZ '10 organised by PSG College of Pharmacy and bagged many prizes.

It also celebrated its XVIII Graduation Ceremony on 7th April 2010, during which 10 Ph. D, 164 M. Pharmacy graduates and 267 B. Pharmacy graduates were awarded their graduation certificates. The Ellappa Rangammal Trust Gold medals for academic excellence in B. Pharmacy were given to Ms. P. Roshini (2002 – 2006), Mr. N. Venkatesh (2003 – 2007), Ms. E. Nishanthi (2004 – 2008) and Ms. Jayani J. Shah (2005 – 2009). First prizes for academic excellence in M. Pharma were given to Mr. L. Alagappan (2005 – 2007), Ms. N. Archana (2006 – 2008) and Ms. A. Manjula (2007 – 2009). During the occassion, the scientific journal "Drug Lines" and "Pharmacy Practice News Letter" were released. Dr. B. Suresh, Vice-Chancellor, J. S. S. University, Mysore was the chief guest.

On behalf of college's NSS Unit, Anti-terrorism Day was observed on 21st May 2010 inside the college campus. Oath against terrorism in any form was taken by all the staff and students of the institution.

Students of the third year B. Pharmacy went on an educational tour to Kottakal Arya Vaidya Sala, Kottakal and Arya Vaidya Sala Medicinal Garden, Kanjirapuzha on 10th June 2010 and got benefited.

School of Pharmaceutical Sciences, Vels University, Chennai

Department of Pharmaceutics organised a one day workshop on "Current Developments of Polymer Technology in Pharmaceuticals" on 17th April 2010. Dr. Sampathkumar, General Manager, Formulation R& D, Shasun Chemicals and Drugs Limited, Puduchery delivered a special lecture on "Biodegradable Polymers as Drug Delivery Systems", Dr. Ramkumar, Senior scientist, Orchid Healthcare Pvt. Ltd, Chennai delivered a special lecture on "Role of Polymers in Oral Drug Delivery Systems" and Dr. Sanjay Kumar Dasmohapatra, Vice-President-Technical, Medopharm, Chennai presented a lecture on "Communication skills and time management".

Vels University, School of Pharmaceutical Sciences and Indian Pharmaceutical Association, Education Division conducted a one day International Seminar and Orientation Program for Pharm. D faculty and post-graduate students on 12th May 2010. Prof. Rajesh Balkrishnan. Director, Center for Medication Use, Policy & Economics, School of Pharmacy, University of Michigan, USA delivered a special lecture on "Pharmacoeconomics in chronic diseases". Mr. Jayaseelan, Secretary. Indian Pharmaceutical Association, Tamilnadu branch & Managing Director, Delvin Formulation Pvt. Ltd., Chennai delivered a special lecture. Special address was given by Prof. Dr. S. Ramachandran, Vice-Chancellor, Vels University

A one day work shop on "Current Perspectives - Flavonoids" was organised by department of Pharmacognosy. The chief guest for the workshop was Dr. T. Ilango, Technical Advisor, Herbal Galanicals, Chennai. He delivered a seminar on "Role of Flavonoids in Health Care". It was followed by poster presentation on Flavonoids. Dr. U. V. Babu,

Head, Agrotech Department, Himalaya Drug Company, Bangalore, delivered a lecture on "Drug Discovery from Indian Medicinal Plants – The Present Opportunities and Future Perspectives". The Vice-Chancellor, Prof. Dr. S. Ramachandran, delivered the presidential address. The workshop was headed by Dr. V.Ravichandiran, Director, School of pharmaceutical sciences. More than 200 students participated in the workshop.

KMCH College of Pharmacy, Coimbatore

KMCH college of Pharmacy, Coimbatore, Tamilnadu, organized a AICTE sponsored Staff Development Programme on "Recent Advances in Novel Drug Delivery System" from 15th April to 28th April 2010. Dr. R. Manavalan, Professor and Head, Department of Pharmacy, Annamalai University, on 15th April 2010 inaugurated the SDP and released the book of abstracts in the presence of trustee madam Dr. Thavamani, Dr. D. Palaniswami, Principal, Dr. A. Rajasekaran, CEO, Dr. O. T. Buvaneswaran and course Co-ordinator Dr. K. S. G. Arulkumaran. During the inaugural address, Dr. R. Manavalan insisted that faculty members across the country should take part in this type of SDP to update the latest developments in the field of Pharmacy. During the 2 weeks SDP, eminent speakers from academic institutions and industries delivered lectures to the participants. Delegates also visited SKM Ayurvedic and Siddha manufacturing unit at Modakkurichi, Erode, Medicinal Garden, Ooty, Vaccine Center and Kovai Medical Center and Hospital, Coimbatore. The valedictory function was held on 28th April 2010, where Dr. T. K. Ravi, Principal, SRIPMS, Coimbatore and Dr. K. Valliappan, Professor, Department of Pharmacy, Annamalai University gave valedictory address and key note address respectively. After the feedback from the participants, certificates were distributed by the guests. The function concluded after vote of thanks proposed by Dr. K. S. G Arulkumaran.

Periyar College of Pharmaceutical Sciences for Girls, Trichy

The NSS team of Periyar College of Pharmaceutical Sciences for Girls and Thilak Hospital, Trichy jointly organised Ear, Nose, Throat Medical camp on 4th April 2010 at our college campus. Dr. S. Ganathilakan, Head, Thilak Hospital welcomed the gathering and Thiru. G. Sebastian, Correspondent of our college presided over the function. Dr. K. Veeramani, Founder, President of Periyar Centenary Educational Complex inaugurated and delivered the key note address. Dr. V. Justin, Director, Thilak Hospital, Prof. P. Subramanian, coordinator, Periyar Centenary Educational Complex and Dr. R. Senthamarai, Principal of our college felicitated the camp. Finally, Mr. M. Sakthivel, NSS Coordinator gave a vote of thanks. Nearly more than 200 public were benefited by this camp.

Indian Council of Medical Research sponsored National Seminar on "Prospects and Perspectives of Herbal Drug Technology" was conducted by Department of Pharmacognosy on 26th & 27th April 2010. These events were organised in order to give an idea of modern platforms and update their knowledge of research in herbal drug technology.

Arulmigu Kalasalingam College of Pharmacy, Krishnankoil

A national level scientific seminar was conducted on "Drug Discovery from Medicinal Plants" on 6th & 7th November 2009, sponsored by ICMR, Delhi. Lectures were given by Prof. Dr. R. Manavalan, Dr. S. Narayanan, Joint Director of Medical Education (Pharmacy) and Prof. A. Abdul Hasan. More than 250 students from various colleges participated in the seminar and presented oral and paper presentations.

During the months of March and April 2010, two lectures were organised. "Molecular Modelling and Drug Design" by Dr. Girija on 31st March and another on "Problems Faced in the Standardisation of Herbal Drugs and their Solutions" by Dr. V. Gopal on 3rd April 2010.

AGM OF TNPSWT - A REPORT

The 19th Annual General meeting of Tamilnadu Pharmaceutical Sciences Welfare Trust was held on Thursday, the 17th June 2010, at 7.00 P.M. at The Presidency Club (Pearl Room), Chennai - 600 105. In the absence of Chairman, Mr. G. Rangachary, Dr. K. Chinnaswamy chaired the meeting. Hon. Gen. Secretary. Mr. N. Sreanivasan presented the Secretary's report and briefed the members about the activities and progress of the Trust during the year 2009-2010. Treasurer, Mr. R. Thiruvengadam presented the annual audited accounts which were approved after discussion and deliberations. Mr. R. Sabapathy, Mr. R. Thiruvengadam and Dr. K. Chinnaswamy, retiring by seniority and being eligible for re-appointment were re-appointed as Governing Council Members of the Trust to hold office. The Budget for 2010 - 2011, proposed and tabled at the meeting, was approved and adopted. It was also decided that during the year, the Trust will be organising certification programmes for professionals from Pharma industry on topics such as Preparation of Documents for Export of Drugs and Pharmaceuticals and Pharmaceutical Marketing.

ADVERTISEMETNTS

The members of the Tamilnadu Pharmaceutical Sciences Welfare Trust desire to accept and publish important advertisements in Pharma Web, from Pharma and allied industries. Pharmacy colleges, etc. The following are the tariff:

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