Medical Education & Drugs Department
Government of Maharashtra- MANTRALAYA

• FOOD AND DRUG ADMINISTRATION-FDA
• Government Medical Colleges
• Attached hospitals
WELCOME TO FOOD AND DRUG ADMINISTRATION
MAHARASHTRA STATE
Computerization of Govt. Functions and our role

Key words in S/W DESIGNING & DEVELOPMENT

FEASIBILITY STUDY
SYSTEM REQUIREMENT ANALYSIS
Development / Coding
INTEGRATED Testing
TRAINING
Maintenance- Customisation
Source code & User Manual, Database & its use
Role of FDA

To ensure availability of:-

• Standard, Safe and Efficacious medicines

• In abundant quantity

• At reasonable and fair prices
Division of responsibilities
Amongst Central Govt. & State Govt.

Central Government:-

• Central Drugs Standard Control Organisation (CDSCO) in the Ministry of Health and Family Welfare - Headed by the Drugs Controller General India
• Control over Import
• Formulating Policy
• Legislative Changes
• Approval of New Drugs
• Weeding out of irrational combinations
Division of responsibilities

State Governments:

- Control over manufacture and sell of the Drugs
- Licensing of Manufacturing and Selling Establishments
- Observance for compliance of condition of the licences by periodic inspection
- Post marketing surveillance
- Penal action against defaulters
Statute Strength

• Drugs & Cosmetic Act, 1940 & Rules, 1945.
• Drugs Price Control Order, 1995
• Narcotic Drugs & Psychotropic Substances, 1985.
• Drugs & Magic Remedies (Objectionable Advertisements), Act 1954
• Prevention of Food Adulteration act
ORGANISATIONAL STRUCTURE AT
HEAD OFFICE

COMMISSIONER

Joint Commissioner

Joint Commissioner

Joint Commissioner

Joint Commissioner

Joint Commissioner

Assistant Commissioner

Assistant Commissioner

Technical Officer

Technical Officer

Technical Officer

Technical Officer

Food

Food

Vigilance

Law

Head quarter’s

Food

Drug control

Support Staff

Support Staff

Scientific Officers

Scientific Officers

Support Staff

Analyst
# Personnel Management System

List of employees working at GREATER MUMBAI as DRUG INSPECTOR

<table>
<thead>
<tr>
<th>No.</th>
<th>Cadre</th>
<th>Staff No.</th>
<th>Name</th>
<th>Date of Birth</th>
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<tr>
<td>1</td>
<td>DRUG</td>
<td>FDA00044</td>
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<td>SMT. JYOTI SARDESSAI</td>
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FDA MAHARASHTRA

- **DRUG and FOOD CONTROL LABORATORY** MUMBAI AND AURANGABAD
- **DRUG STORE LICENCING**
- **MANUFACTURING UNIT LICENCING**
- **PERSONAL MANAGEMENT SYSTEM**
1. Laboratory Division

1. Sample details
   This activity inputs
   Drug Sampling Process

---

Diagram:

- Drug Inspector
  - Samples

- Government Institutions
  - Samples

- Semi Government Institutions
  - Samples

1. Drug Sampling Process
  - Tested Samples
  - Sample Reports

DCL Sections
Sampling Process

1.1 Accept/Reject Samples

1.2 Codification Process
- Coded Samples
- Accept Samples

1.3 Sample Analysis Process
- Analysed Samples

1.4 Sample Decodification Process
- Decoded Samples
- Reports

1.5 Report Generation
- Accepted Samples

Drug Inspector
- Samples
- Rejected Samples

Sample Each, register File
- Checked Samples

DCL Sections
1.2.1 Check MOA & References Stds.

1.2.2 Generation of Code Nos.

1.2.3 Generation of Sample Labels

1.2.4 Change containers of samples

1.2.5 Sticking of labels on new sample containers

Coded Samples

Accepted Samples

Reference Std File

Method of Analysis (MOA) File

Code Register File

DCL Sections

Checked Samples

Coded Samples

Sample Labels

Coded samples in new containers

Samples in New Containers
Decodification Process [1.4]

Single Record Screen

1.4.1 Check mail details

1.4.2 Decoding of samples

1.4.3 Writing decoded mails

Lotus Notes Mail Server

Mail for decoding samples

Checked Mails

Decoded Sample Mail

DCL Section
Masters

DCL Management System
 TRANSACTION

DCL Management System
Sample information
Observation
### Analysis Details

- **Coded Sample Nos:**
- **Division Code:**
- **Assigned To:**
- **Sample Priority:**
- **Assign Date:**
- **Test(s) to be carried out from Division:**
- **Sample Description:**

### No Limit Test Details

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Start Date</th>
<th>Observation</th>
<th>Result</th>
<th>Completion Date</th>
<th>Analyst Name</th>
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### Limit Test Details

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<th>Start Date</th>
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<th>UOM</th>
<th>Claim Made</th>
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</table>
Drug Control Laboratory
Maharashtra State, Bandra (East), Mumbai - 400 051

FORM 34
[See Rule 131 and 150]

CERTIFICATE OF TEST OR ANALYSIS OF COSMETICS BY THE CENTRAL DRUGS
LABORATORY OR THE GOVERNMENT ANALYST

Report #: M/52/2005

Name of the Inspector from whom received: SMT. A. S. KAMBLI
FOOD AND DRUG ADMINISTRATION, (HEAD QUARTER) BANDRA-KURLA, COMPLEX, BANDRA-EAST, MUMBAI- 400051, MAHARASHTRA

Serial number and date of Inspector's memorandum: ASK/HO/2005/01/01 29/01/2005
Number of Sample: 1 x 150 GM
Date of receipt: 29/01/2005
Name of cosmetic purporting to be contained in the sample: TEIMS WHITE BEAUTY SOAP
Condition of seals on the package: Intact and tally with the specimen seal. Impression of the seal received separately.

Results of tests or analysis with protocol of test applied:

Batch No.: 01
Mfg. Date: 01/10/2004
Mfg. Lic No.: C-1198
Exp. Date: Not stated

Observation on labelling:

Container Label: TEIMS WHITE BEAUTY SOAP
TOILET SOAP
NET WT: 150 GMS. (INCL. OF ALL TAXES)
T.F.M. 70%

Manufactured by: IAZREM HEALTH CARE PVT. LTD.
Food and Drug Management System
Methodology of FDA For Quality Monitoring

• Prelicensing Screening :-
  a) Plan approval, b) Inspection before grant of licence,
  c) Assessing of expertise staff, d) Product approval.

• Post Licensing Control :-
  a) Periodic inspections for observance of condition of
     the licences, b) Administrative action.

• Post Marketing Surveillance :-
  a) Sampling, b) Recall of products, c) Penal action
Pre licensing Screening (For Quality Monitoring)

System of Plan Approval, as per Provisions of Sch. M :-

• Unidirectional and logical flow of men and materials.

• That minimum area specified for all sections.

• Provision of Clean and Controlled Air Conditions

• That cross contamination prevented by insisting separate section/building for sensitive products like Beta Lactum, Anticancer and Sex harmones
System of assessing expertise of Human resources:-

- Minimum qualification and experience prescribed for Competent Technical staff
- System of Approval of Competent Technical staff through interview by the panel
Post Licensing Controls

Conditions of licenses :-

• Manufacturing and Testing under supervision of approved Competent Technical persons.
• Compliance of Good Manufacturing Practices made mandatory to a licensee.
• Licensee responsible for maintaining quality of drugs, manufactured by him.
• Emphasis on self inspection and self regulation.
Post licensing Controls

• Manufacturing and Testing - To be done as per Master Formula Record
• Batch Manufacturing Records - To be maintained as per Schedule U
• Records of raw materials - To be maintained as per Schedule U
• Records must be signed by the Competent technical person
Post licensing Controls

Emphasis on

• Validation
• Stability studies
• Standard Operating Procedure and
• Exhaustive, elaborate system of documentation
Post licensing Controls

Compliance of Good Manufacturing Practices assessed through Periodic Inspections

Licensing Authorities empowered

• To direct compliance
• To suspend the licences
• To cancel the licences
Post Marketing Surveillance

- Through random sampling at manufacturer’s premises and from distribution outlets
- Licensee bound to recall substandard drugs from market
- Penal action taken by the licensing Authority against defaulters
**Manufacturer / Sales Details**

- **District:** ZONE-VII GREATER MUMBAI
- **Name:** AJANTA PHARMA
- **Code:** AE700000002
- **Type:** Retailer + Wholesaler
- **Constitution:** Proprietary
- **Class:** Others
- **Address:** 123, ECSA ROAD, BORIVALI-EAST
- **City:** MUMBAI
- **Pin Code:** 400087
- **State:** MAHARASHTRA
- **Phone:**
- **Fax:**
- **Email:**
- **Web:**
Initiatives

- Development of Comprehensive Software.
- Collection of Data.
- Use of the collected data for further improvement.
- Focused and planned sampling programme for effective post marketing surveillance.
Food and Drug Administration
Maharashtra State

FORM 20
[See Rule 61(1)]
Licence to sell, stock, or exhibit [or offer] for sale, or distribute drugs by retail other than those specified in [Schedules C, C(1) and X]

7-11 KHAZANA MEDICAL & GENERAL STORES is hereby licensed to sell, stock, or exhibit [or offer] for sale, or distribute by retail drugs other than those specified in [Schedules C, C(1) and X] of the Drugs and Cosmetics Rules, 1945, and to operate a pharmacy on the premises situated at

189, I. M. MERCHANT RD, BELOW BEG. MOHD. BAUG,
NEXT TO MEMON BANK, MUMBAI 400003 MAHARASHTRA

subject to the conditions specified overleaf and to the provisions of the Drugs and Cosmetics Act, 1940 and the rules thereunder.

The licence shall be in force from 06/01/1999 to 31/12/2002

Name(s) of qualified person(s) in charge

1 KAMLESH RAMESH JAIN 90345 REGD. PHARMACIST

Categories of drugs All type of drugs covered under this License

Date 03/06/2009 Licence No. Z-2/3/556

SHRI. S.K. CHOUDHARI
Licensing Authority
Assistant Commissioner ZONE-IIGr MUMBAI
Food and Drug Administration Maharashtra State

Conditions of Licence

his licence shall be displayed in a prominent place in a part of the premises open to the public:

he licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder for the time being in force.

he licensee shall report to the licensing authority any change in the qualified staff in charge within one month of such change.
For viewing data click on Reports button Select report as required. Complaints, Prosecution
Take the cursor to ‘District’, press ‘F9’ key on keyboard : List of the Districts will be displayed, select the district by ‘↑↓’button on the keyboard and click on or enter. [The selected district/zone will be displayed at the field of ‘District’.

Note : For doing fresh entry ensure you are not in query mode . i.e in query menu the cancel field in not highlighted.
• In the screen enter the start date and end date in the format DD/MM/YYYY. The dates are entered to view data of particular period.
• Select the name of complainant Name to view individual’s data or select % to view the data of all complainants for that period.
<table>
<thead>
<tr>
<th>Serial No</th>
<th>Sample Report No</th>
<th>Sample Date</th>
<th>Prosecution Charge</th>
<th>Accused Name</th>
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<tbody>
<tr>
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<td>1/5/1999</td>
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1. 6268 TO 70/97
7/01/1998

**UNDER SECTION 18[a] [i] R/W SECTION 17[E][d] & SECTION 16 OF DRUGS & COSMETICS ACT, 1940
USECTION 27 [c] R/W SECTION 34 OF THE SAID ACT.**

<table>
<thead>
<tr>
<th>Name of Complainant: SHRI. D. C. SHAIKH</th>
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<tbody>
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<th>Cust Sno</th>
<th>Prosecution Courname</th>
<th>Prosecution Launch Date</th>
<th>Prosecution Sample Remarks</th>
<th>Prosecution Case Result</th>
<th>Accused Address</th>
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THIAMINE HCL BP 93 [VITAMIN B1 BP 93], B.N.: T940905, M.D.: 3/95, NOT OF STANDARD QUALITY & SPURIOUS

30, OM DARIYA MAHAL, 30, NEPEAN SEA ROAD, MUMBAI-400 006
405, CHANDRALOKA' 97, NEPEAN SEA ROAD, MUMBAI-400 006.
405, CHANDRALOKA' 97, NEPEAN SEA ROAD, MUMBAI-400 006.
30, OM DARIYA MAHAL, 30, NEPEAN SEA ROAD, MUMBAI-400 006
190/3 B, MACALDAS BUILDING, MANGALDAS ROAD, MUMBAI-40:

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<tr>
<td>2. of Convicted: 0</td>
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<td>3. of Discharged: 0</td>
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THANK YOU

Disclaimer: The views express by me are no way connected with the organisation

Nivedita A. Golatkar
Special Project Officer
DIT, Mantralaya Maharashtra