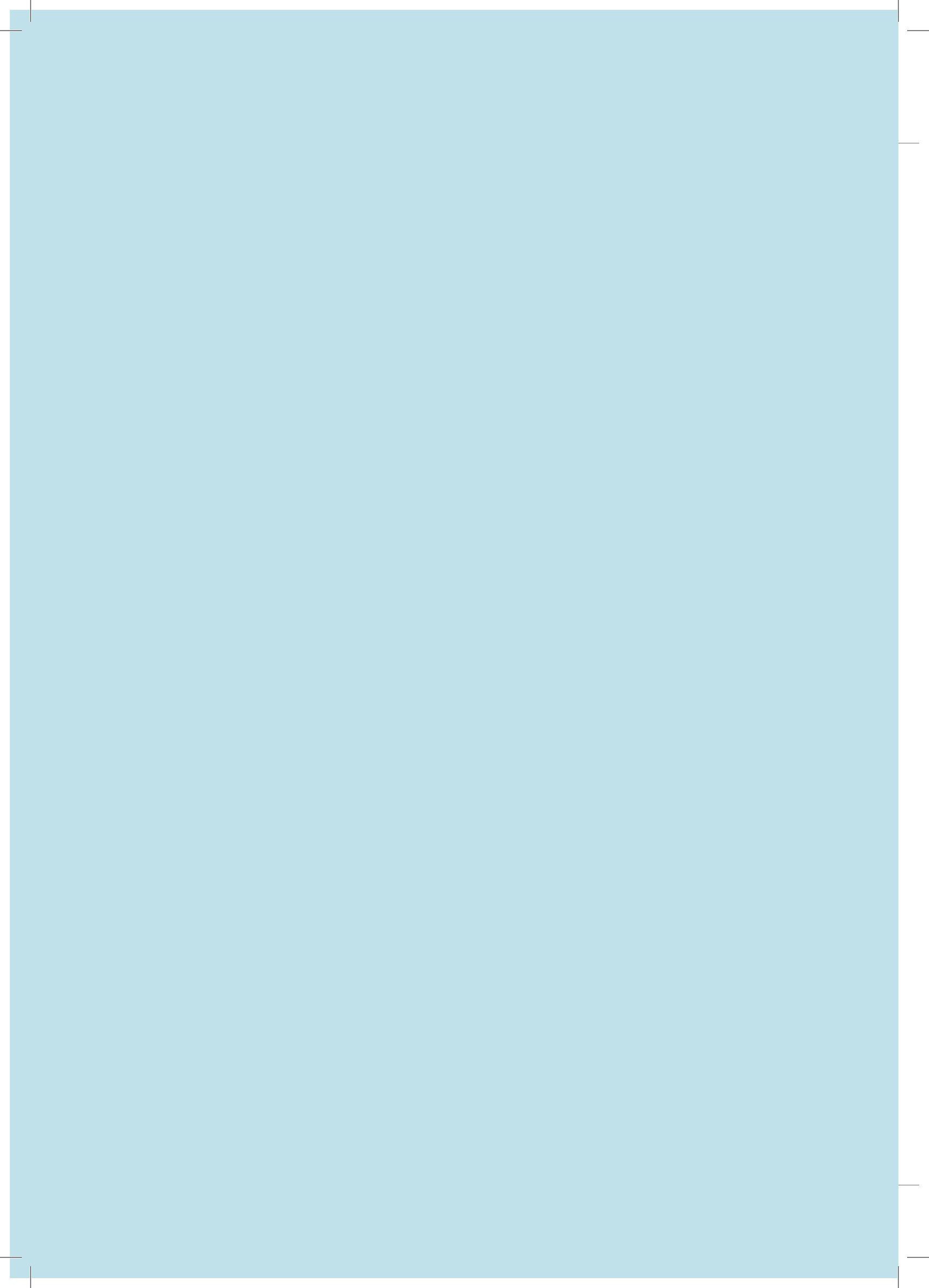


**NATIONAL
DRUG SURVEY
2014 - 2016**

Chapter 3

Unique Features





Unique Features

In many ways, this “Survey of Extent of Spurious and Not of Standard Quality Drugs in The Country” was first of its kind conceptualised to understand the quality of Drugs being sold in the domestic market. The outcome of the Survey would help in gathering evidence for regulatory purpose, better enforcement and coordination between Central and State Drug regulatory authorities. It should also show exact picture about the quality of medicines in domestic market and thereby offer opportunities for improvement. Above all, a periodic exercise of this type at state as well as national level based on methodology employed would instil confidence in consumers about quality of medicines.

The following are the unique features of this National Drug Survey:

Maximum Therapeutic Categories

15

National Drug Survey sampled Drugs relating to 15 major therapeutic categories from National List of Essential Medicines (NLEM) 2011 and fast moving molecules where there is a likelihood of products being Spurious or NSQ.

Sampled Largest Number of Drug Molecules

224

In the Drug Survey, formulations belonging to 224 Drugs molecules and selected fixed dose combinations were sampled across the country.

Variety of Dosage Forms

23

The present Survey covered 23 different dosage forms ranging from oral, semisolids, liquids and injectables available in the market.

Large Sample Size

47,954

The Survey undertook the never undertaken task of collecting 47,954 samples. Of these, 42,869 samples were collected from Retail and Government Sources whereas 5085 samples were from notified ports.

3 Stage Random Sampling Design

3 Stage

Survey scheme involved a 3-stage randomised sampling plan. In the first stage, Sources were selected, in the second stage molecules were selected and, in the third stage formulations were selected. Scheme was designed in such a way that all 224 molecules were treated uniformly and sampling efforts reduced drastically.

Mapped Entire Geographic Area

654 Districts

Primary focus of the Survey was to obtain estimates at the national level. Therefore, sampling design covered the entire length and breadth of the country and Drug samples were collected from 654 districts of all States and Union Territories.

Robust and swift Nationwide Training Program

1 800 Trainees
56 Trainers
28 Centers
2-4 Days

56 trainers underwent training who in turn cascaded training in 28 centres to approx. 945 Drugs inspectors and about equal number of representatives of Civil Societies/Pharmacy Council of India across the country in a short span of 2-4 days. A specially developed animated video was used for better understanding and easy recall of the processes. Hands on training was provided on use of software.

Validation of methodology Using Pilot Field Study

NCR Region
20 Teams
222 Samples

A pilot study was carried out at the National Capital Region to identify possible challenges in the physical conduct of Drug Survey, collection of samples and compilation of data, lab tests and analysis of the test results using AKS software.

Coverage of Legitimate Supply Chains

Retail Outlets
Govt. Supply
Ports

The National Drug Survey covered all three streams: (i) Retail Outlets, (ii) Government distribution points and (iii) notified ports (import from air and sea ports). Since, much of the imports is of active pharmaceutical ingredients (APIs), a separate sampling method was designed for APIs.

Sample Drawing Using Collaborative Approach



To instil credibility and transparency in the sample collection, Drugs Inspectors were accompanied by representatives of Civil Society /Pharmacy Council of India as observers. The timing and location of the sample collection was revealed just prior to the field visit.

Identification of suspects by Visual Inspection



All collected samples were subjected to visual inspection by trained Drug inspectors. An online format for visual inspection using software was designed to help Drug inspectors carry out a visual inspection to pick up suspects. All suspicious products with doubtful information were correlated with results of laboratory analysis.

Test/Analysis of All Samples



Instead of carrying out full-scale quality control analysis only for pre-selected sub-sample, the Survey carried out testing of 100% samples that were from list of 224 molecules.

Full-scale Pharmacopoeial Analysis



The laboratory analysis of all collected samples was carried out for specifications as applicable as mentioned in the monograph of the product in the relevant pharmacopoeia including IP or USP or BP or other pharmacopoeia.

Innovative In-house software



An in-house digital AKS software enabled online collection, collation and segregation of information, transmission of data to laboratory and interpretation of laboratory test and analysis of data.



To fulfil the objectives, the Survey design took into considerations all imaginable situations in the country as vast and diverse as India with large manufacturing base and distribution points. These features made the Survey unique which can serve as a model for conducting similar Surveys not only in India but countries across the globe and were taken into consideration while conceptualizing the Drugs survey.

