

Introduction



- Bharat Biotech was established in the year 1996 by Dr. Mr.Krishna M. Ella and Mrs. Suchitra K. Ella, with a vision to generate innovative technologies.
- Bharat Biotech is a pioneering biotechnology company known for its world-class R&D and Vaccine manufacturing capabilities.
- Bharat Biotech Successfully Completed 25 Years.



Introduction to Bharat Biotech



- Creating Innovative Vaccine and Biotherapeutics.
- Manufacturing Units are Located at Hyderabad, Bangalore, Pune, Ankleshwar & Bhubaneswar
- Over 3 billion vaccines delivered globally.
- More than 160 global patents.
- > Our manufacturing facilities are approved by KFDA and WHO.
- Supplying to over 125 countries.
- ➢ WHO-Approval, GMP-Certified Manufacturing Facilities.
- World first WHO-prequalification for Typhoid Conjugate Vaccine.
- World first WHO-Prequalified Rotavirus Vaccine from a naturally attenua strain.
- World's first WHO-Prequalified recombinant Hep-B Vaccine (free of Cosium chloride and this mercel)



Products list

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Recombinant Vaccines

- REVAC-B+ Recominant Hepatitis B vaccine
- REVAC-B mcf Mercury and Cesium Chloride free Recombinant Hepatitis B vaccine
- COMVAC 4 Diptheria, Tetanus, Pertussis
 - (whole cell), Hep B (rDNA) Vaccine
- COMVAC-5 Diptheria, Tetanus, Pertussis Pertussis (whole cell), Hep B (rDNA) and Hemophilis Type -B Conjugate Vaccine (Absorbed)

Bacterial vaccines

- TYPBAR TCV Typhoid Conjugate Vaccine
- COMVAC 3 Diptheria, Tetanus, Pertussis Vaccine
- BIOHIB Indegenously developed vaccine for haemophilus influenzae type-b bacteria (Hib)

Viral Vaccines

- INDIRAB Rabies Vaccine
- JENVAC Japanese Encephalitis Vaccine
- ROTAVAC Rotavirus Vaccine
- HNVAC -Influenza (H1N)
- BIOpOLIO Polio Vaccine
- COVAXIN Corona Virus Vaccine

Bio-therapeutics

- REGEN-D Recombinant Human
 - Epidermal Growth Factor
- SLVRGEN Recombinant Human
- EGF with Silver Sulfadiazine and
- Chlorhexidine Gluconate
- BIOGIT Gastrointestinal (GI) friendly probiotic yeast



Need for Track and Trace :

- DOC BHARAT BIOTECH Lead Innovation
- Implementation Guidelines for Coding & Labelling Pharmaceuticals and Drugs Using Global Supply Chain Standards to Meet Directorate General of Foreign Trade's (DGFT) Authentication, Track and Trace Requirements. Version 1.3 – August 2015 .

Ministry of Commerce and Industry Directorate General of Foreign Trade

UNICEF has recommended the use of GS1 standards on the secondary package of vaccines to improve product identification, labeling, and data exchange within the immunization supply chain. GS1 barcoding on the secondary packaging by latest 31 December 2021.





Advantages of Track and Trace:

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- Tracking products
- Product Authentication (prevents counterfeiting)
- Patient Safety
- Preventing medication errors, resale of medicines and sale of expired medicines



Strategy for Secondary & Tertiary level Barcoding:

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- Multipack coded with 2D barcode containing the following details along with Human Readable details
 - ➢ GTIN of in 14 digit format
 - > Batch No :
 - > Serial No :
 - ➢ MFG Date :
 - > Expiry Date :
- Inner corrugated box with multi cartons will be coded with two Linear 1D barcodes along with Human Readable details:
 - First GS1 barcode encoded with:
 - GTIN of in 14 digit format
 - Expiry date in YYMMDD format
 - Batch No.
 - Second GS1 barcode encoded with:
 - SSCC code Identifying the individual tertiary packing level packing as a logistic unit



Secondary level Barcoding

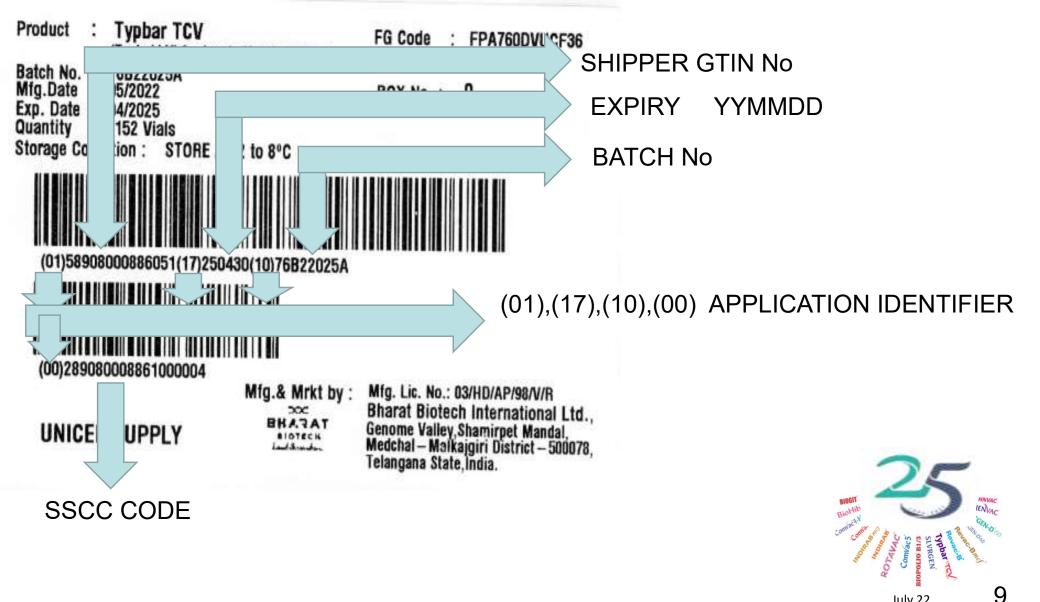
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Tertiary level Barcoding





Scope of product:



- Products prequalified by WHO
- Started with Typbar TCV, Biopolio B1/3 and Rotavac.



Project Team For Track and Trace :

- Project In charge
- IT dept.
- Packaging Development.
- QA dept.
- SAS dept.
- Regulatory.
- Engineering dept.
- Exports.
- Packing dept.
- Dispatch dept.

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Implementation team and responsibilities: BHARAT BIOTECH Lead Janovation

- Mr. Krishna Murthy Project In charge
- Mr. Anand IT dept.
- Mr. Karthi SAS dept.
- Mr. Rama Rao -Regulatory
- Mr. Subrahmanyam Engineering
- Mr. Apoorv Exports
- Mr. Madhu Packing dept.
- Mr. E.S. Rao Dispatch dept.
- Mr. Bharat Bhusan Prusty Packing dept
- Mr. Shrinivas Jadhav Packing dept.
- Mr.E Sreenivas Rao-Dispatch



Steps to Implementation For Track and Trace :

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- Step 1: Engage with GS1 member organization
- Step 2: Allocation of GTINs
- Step 3: Linking GTIN's in International Software Applications
- Step 4: Training and Education
- Step 5 : Implementation



Implementation :



• Vendor Identification:

Quotes & offers obtained, evaluated and vendor finalized

• Hard ware & Soft ware :

From approved vendor PROPIX we Procured Hard ware & Soft ware.

Installation & Qualifications :

- 1. Installation Qualification (IQ)
- 2. Operational Qualification (OQ)
- 3. Performance Qualification (PQ)

Qualifications are completed.

Packaging material.

The Art work of the cartons developed as per the machine feasibility.





Implementation :



• **SOP's**:

The below listed SOP are prepared

- 1. Generation of Product code and EAN code.
- 2. Generation of Finished goods code.
- 3. SOP of Level 3 application.

4. SOP of Level 1& 2 application at secondary and tertiary level.

• Trials:

Trials are taken for each and every product with presentation and packaging configuration wise.



Vendor Details:



- Propix Technologies pvt. Ltd.
- Cost of Project: USD 270,000

Rs. 2.0 crore (approx.)

- Details of Track and Trace Items Procured:
 - ➢ Plant Server.
 - ≻ Line Equipment's.
 - ➤ Ware House system.



Line Equipment system from Propix:

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- Functions:
 - Printing Bar code 2D matrix with Human Readable details on Multi carton
 - Scanning Barcode
 - Reject Multi carton packs with defected Barcode & Human Readable details
 - ➢ Printing labels for Tertiary level packing.



Training:



• Training :

Training given to the all BBIL packing employees

a) Importance of Track & Trace, Operating procedures.

b) Handling of line and trouble shooting.

• Commercial:

The system - Hardware and soft ware are now fully operational ````for commercial batches.







- Barcoding Details Approval Received from
- 1.GS1 India.
- 2.Unicef.
- 3.WH0

Barcode verification fees : We had paid Product wise fees to GS1 India for Barcoding Approval.

We paid 1 Product 1800 Rupees (Approx.)

or 30 USD



Operations :

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• Hardware:

The equipment manufactured by PROIX with configuration of Level 1 & 2. Hardware components are

- 1. Printer for 2D printing (Domino) : Cartons
- 2. Camera for inspection (Cognex) : Cartons
- 3. Printer for 1D printing (SATO) : Labels
- Software :

The supplied soft ware by PROPIX handle the operations like 1.Product Master,

2.Batch Master etc

3. These are Interlinked with all packing lines.



Ware House system from Propix :

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- Function:
 - Printing Barcoding label (SSCC) for Homogenous Packing
 - Printing Barcoding label (SSCC) for Heterogeneous Packing



Flow chart :

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Challenges :



1.Loose Vials Packing with Multi cartons.

2.Loose vials with multicartons packed with separate Box.

3.One batch with Different loose box club with one box in Dispatch.

Challenges resolved.

Discuss with Propix (VENDOR)soft ware to be upgrade.



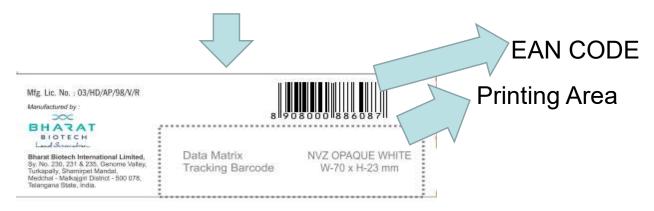
Carton Art Work Change

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• Before Track and Trace Implementation.

	Mfg. Lic. No. : 03/	/HD/AP/98/V/R	
Manufactured by:	Mig. Lic. No. : 03/	11D/A1/30/9/N	
BHARAT	Batch No. :		Drinting Area
Lead Irovation	Mfg. Date :	35x22 mm	Printing Area
Bharat Biotech International Ltd., Genome Valley, Shameerpet Mandal, Medchal District - 500 078 Telangana, India.	Exp. Date :		

• After Track and Trace Implementation





Future Plan: Bar coding on Primary packing

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Status: Under progress. DCVMN have extended Free Consultancy for Pilot study thro Propix

Scope of feasibility study:

- Pilot study by Propix which includesDesigning software & Hardware layout, Consultancy & Guidance for GS1 Registration, Artwork modification & designing,. On line & Onsite support.
 Documentation and preparation of SoPs
- Integrating primary and secondary barcoding systems
- Date of implementation: Jan 23





THANK YOU





www.bharatbiotech.com