



Biological E. Limited
Celebrating Life Every Day



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Capabilities at Bio E as per GS1 Standard

Tertiary Level
from
✓ 2012

Secondary
Level from
✓ 2012

Parent Child
relationship from
✓ 2015

Uploading data in
to DGFT portal
✓ 2015

PACKAGING LEVEL	BARCODING REQUIREMENT	Data Requirements	TIME LINE as per DGFT	STATUS
Tertiary Level	GS1-128 barcode Symbology encoded with: <ul style="list-style-type: none"> ▪ GTIN 14 ▪ Expiry Date ▪ Batch Number ▪ SSCC 	Information printed in human readable format: <ul style="list-style-type: none"> ▪ GTIN 14 ▪ Expiry Date ▪ Batch Number ▪ SSCC 	Implemented (2012 as per DGFT notification).	Implemente d from 2012
Secondary Level (Off Line printing of 2d Code)	GS1 DataMatrix or a GS1-128 barcode Symbology encoded with: <ul style="list-style-type: none"> ▪ GTIN 14 ▪ Expiry Date ▪ Batch Number ▪ Unique Sr. No. 	Information printed in human readable format: <ul style="list-style-type: none"> ▪ GTIN 14 ▪ Expiry Date ▪ Batch Number ▪ Unique Sr. No. 	Implemented (2012 as per DGFT notification).	Implemente d from 2012
Secondary & Tertiary Level Aggregation	Public notice No.:13/2015-2020 dated 22/05/2015 the dates for implementation of Track & Trace system for export of drug formulations along with maintaining the Parent-Child Relationship in packaging have been extended to 01/04/2016 for non SSI manufactured drugs and 01/04/2017 for SSI manufactured drugs.			Implemente d from 2015

PILOT STUDY –2D FOR ALL Packaging LEVELS

It's almost a decade, wherein we started serialization on Tertiary packaging, Secondary packaging levels. Now it's high time for primary packaging to be serialized to meet the end goal of the whole exercise.

There are two main aspects of serialization, Counterfeiting & Supply Chain transparency across the distribution channels.

We thank DCVMN for considering us as part of this consortium and keen to help vaccine industry to implement the Primary serialization including the financial support.

This is enabled us to take up this project during the pandemic time.

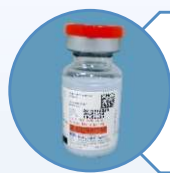


PILOT STUDY –2D FOR ALL Packaging LEVELS

Consultancy support for implementation of Barcoding Primary level.



Training and guidance from Consultant



Redesigning the artworks



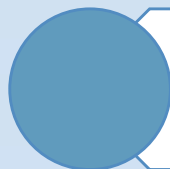
Technology selection for Printing



Vision inspection system selection & requirements.



GS1 Guidelines updates and complete Trainings



Understanding the L4 and L5 systems

Identifying SKU for Pilot Project – 15 mL Vial



15 mL – 20 Dose

Vial Label Size: 62 x 26 mm



5 mL – 10 Dose

Vial Label Size: 55 x 20 mm



3 mL – 1 Dose

Vial Label Size: 50 x 15 mm

As a best case scenario, we have proposed to implement 15 mL presentation



Target date for completion: *March 2022*

Identifying SKU for Pilot Project – 15 mL Vial



Forming Project Team :



Project Estimated Cost

Based on the subsequent discussions with the consultants and project meeting with all the members, we have Planned to implement the Primary serialization in 3 phases as below.

PHASE I - Feb 2022

Online 2D for Secondary Packaging Level

PHASE II - Feb 2022

Plan for Barcoding on Primary Level – Product level

Estimated Cost
100000







PHASE III - July 2022

Unique Barcode on Primary Level

Estimated Cost
150000

PILOT STUDY –2D FOR ALL Packaging LEVELS

Key Activities

-  Finalizing the Carton Coding Machine Technology
-  Preparing the URS and other Documentation
-  Ordering the Carton Coding Machine and other Integrated parts
-  Harmonization of Product GTINs across the company
-  Internal Trainings (For Integration and its requirements)
-  Mobile PCR integration with the Serialization database

PILOT STUDY –2D FOR ALL Packaging LEVELS

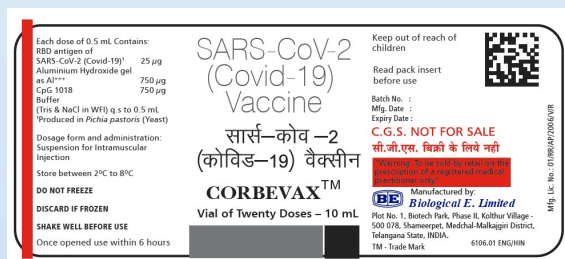
Implementation of unique 2D barcode on Primary Packaging.

⚙️ We have procured the Carton coding Machine with the capability of Serialization.

📐 Artworks revised with the unique product code as per the GS1 data matrix.

🔗 Artworks developed for CORBEVAX (COVID VACCINE) as per the requirement.

(Developed Label for 15 mL Vial of 20 doses presentation), we have chosen the best case scenario for pilot study based on label size in Phase-I (Bigger vial size of 15 mL for 20 Dose presentation with a Label size of 62x26 mm)



Label



2D Barcode with GTIN



Carton

Successfully Implemented in Feb 2022

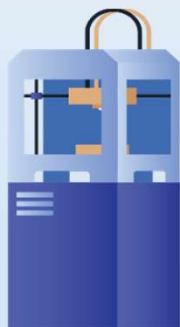
PILOT STUDY –2D FOR ALL Packaging LEVELS

Selection and Ordering of the below equipment's

Labelling Machine with online integration



Carton Coding Machine



Software Integration (PCR System)



Labelling Machine is expected to deliver by 15th July 2022

Expected to complete the project by Mid **August 2022**

Challenges Identified / Expected

Drug package is too small to fit the new mandated 2D barcode and human readable information on the traditional label for 3ml vials?



Example of linear barcode:

Current linear barcodes required by the regulatory bodies contain only the vaccine product identification information.



Example of 2D barcode:

A 2D, or data matrix, barcode can include product identification information as well as expiration date and lot number.



VVM requirement on Vial label also lead to the space issue for having Barcode

* Multilayer labels may be an option , but requires additional regulatory approvals.





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dcvmn



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thank you