



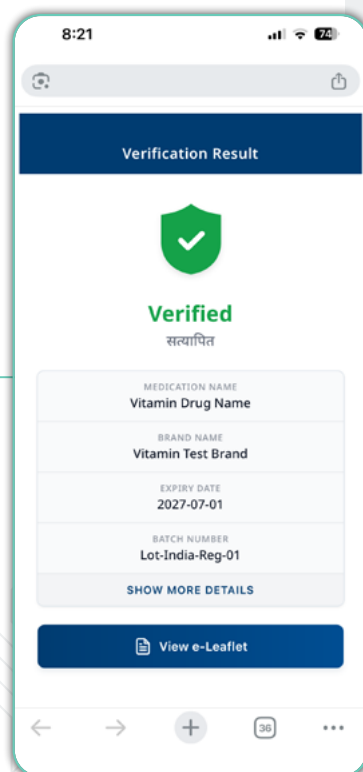
Meet India's QR Code Mandates with Confidence

Your Complete Guide to India's QR Code Rules



WHAT OUR SOLUTION DELIVERS

- Compliance support for India QR code regulations (API, Top 300, and Schedule H2 expansion)
- Cloud authentication powered by VerifyBrand™
- Scalable for high-volume QR scan demand
- Simple, readable verification interface
- Integration with OPTEL traceability solutions



QR CODE VERIFICATION

India's QR code requirements are already in effect and support track-and-trace, authentication, and anti-counterfeit programs.

1. API labels (in force since January 2022)

In January 2022, the Ministry of Health and Family Welfare amended the Drugs Rules, 1945, making QR codes mandatory for active pharmaceutical ingredients (APIs) manufactured in or imported into India. Each level of packaging must carry a QR code that stores data readable by software to support tracking and tracing.

REQUIRED API DATA (11 fields):

- Unique product identification code
- Name of the API
- Brand name (if any)
- Name and address of the manufacturer
- Batch number
- Batch size
- Date of manufacturing
- Date of expiry or retesting
- Serial Shipping Container Code (SSCC)
- Manufacturing licence number or import licence number
- Special storage conditions (if any)

2. Top 300 drug brands (in force since August 1, 2023)

For the notified Top 300 drug formulations/brands, manufacturers (including importers marketing in India) must print or affix a bar code or QR code on the label of the primary pack; if space is limited, it may be placed on secondary packaging. This requirement applies to batches manufactured on or after August 1st, 2023.

REQUIRED TOP 300 DATA (as specified in the notification/FAQs):

- Unique Product Identification Code
- Proper and generic name of the drug
- Brand name
- Name and address of the manufacturer
- Batch number
- Date of manufacturing
- Date of expiry
- Manufacturing licence number

3. Vaccines, antimicrobials, anti-cancer drugs, and narcotics/psychotropics (Schedule H2 expansion, notified June 2026)

The ministry of Health and Family Welfare has widened Schedule H2 beyond the Top 300 brand list. Vaccines, antimicrobials, anti-cancer drugs, and narcotic and psychotropic medicines now fall under the same QR code framework.

Compliance is phased. Vaccines, anti-cancer drugs, and narcotics/psychotropics take effect July 1st, 2027. Antimicrobials follow on July 1st, 2028.

Required data fields for this category are expected to mirror the existing Top 300 requirements, but the government has not published a separately itemized field list the way it did for API and Top 300.

OUR SOLUTION TO MEET INDIA'S QR CODE REQUIREMENTS (API, Top 300, and Schedule H2 expansion)

Powered by VerifyBrand™, our downstream serialization and traceability software, OPTEL's QR Code Verification solution helps customers meet applicable regulatory requirements.

The Ministry of Health and Family Welfare requires barcodes/QR codes for notified Top 300 drug brands to help combat counterfeiting, diversion, and unauthorized sales.

QR codes must be printed on or affixed to the primary packaging; if space is limited, the code may be placed on the secondary packaging.

OPTEL's QR Code Verification solution enables high-confidence authentication via a scalable cloud platform. It allows customers to verify the authenticity of a scanned product quickly and consistently.



ABOUT OPTEL

OPTEL is a leading global provider of track-and-trace and vision systems, leveraging innovative technologies to create secure, efficient, and transparent supply chains. With more than 30 years of experience in track-and-trace compliance, the company is a pioneer in vision inspection and traceability solutions for the life sciences industry and more. Its solutions track billions of products annually for leading brands. Founded in 1989, it is headquartered in Canada, with facilities in Germany, Ireland, India, and Brazil.

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