BioSpectrum
the business of Bi
24 years of leveraging the business of Bio
www.biospectrumindia.co

HiMedia Labs secures CDSCO manufacturing licenses for advanced Hepatitis B & C detection kits

19 August 2025 | News

Developed indigenously as part of the Make in India initiative to tackle two of the most significant viral infections



Mumbai-based HiMedia Laboratories, a global leader in diagnostics and life sciences, has received manufacturing licenses from the Central Drugs Standard Control Organization (CDSCO) for two advanced molecular diagnostic kits:

- Hi-PCR® Hepatitis B Virus (HBV) Detection and Quantitation Probe PCR Kit
- Hi-PCR® Hepatitis C Virus (HCV) Detection and Quantitation Probe PCR Kit

These regulatory approvals empower HiGenoMB - HiMedia to manufacture these highly sensitive and specific diagnostic tools on a large scale, developed indigenously as part of the Make in India initiative to tackle two of the most significant viral infections impacting both the global and Indian populations. This achievement aligns strongly with HiGenoMB's vision to help make India hepatitis free by enabling early, accurate diagnosis and effective management of hepatitis B and C.

Hepatitis B and C are leading causes of chronic liver disease, cirrhosis, and liver cancer. Early diagnosis is vital for timely treatment and preventing transmission.

Hi-PCR® HBV Kit (MBPCR181)

- Detects HBV DNA across all genotypes (A–J) with 100% specificity.
- Analytical Sensitivity ?15 IU/mL
- Includes quantitative standards for precise viral load measurement
- Includes endogenous internal control
- Compatible with various RT-PCR instruments
- Based on TaqMan chemistry
- Quantitative standards calibrated against 5th WHO International Standard (NIBSC Code: 22/120)

Hi-PCR® HCV Kit (MBPCR182)

- Detects HCV RNA across all genotypes (1–7) with 100% specificity.
- Analytical Sensitivity ?43 IU/mL
- Includes quantitative standards for precise viral load measurement
- Includes endogenous internal control
- Compatible with various RT-PCR instruments
- Based on TaqMan chemistry
- Quantitative standards calibrated against 6th WHO International Standard (NIBSC Code: 18/184)

Both kits are validated for EDTA plasma samples and intended for *In vitro* diagnostic use by trained clinical laboratory personnel.

“This achievement underscores our commitment to delivering world-class affordable diagnostics from India to the world. These kits offer accuracy, speed, and accessibility, helping healthcare providers diagnose and manage hepatitis more effectively, even in resource-limited settings,” said Dr Rajas V. Warke, Director, Molecular Biology & Virology, HiMedia Laboratories.

With CDSCO approval, HiMedia will supply these kits to hospitals, diagnostic labs, and public health programs across India, ensuring improved testing availability in both urban and rural regions.