Indian Pharmacopoeia Commission (IPC) Organizes National Conference on Quality and Safety of Biosimilars: Strengthening India's Biopharma SHAKTI Vision

Conference Aligns with the Government's Biopharma SHAKTI Vision to Strengthen India's Biopharmaceutical Ecosystem through Innovation, Self-Reliance, Quality and Global Competitiveness

IPC Launches Indian Pharmacopoeia Reference Substance (IPRS) for Enoxaparin Sodium for bioassays

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The Indian Pharmacopoeia Commission (IPC), an autonomous institution under the Ministry of Health and Family Welfare, Government of India, organized a two-day National Conference on "Quality and Safety of Biosimilars: Strengthening India's Biopharma SHAKTI Vision" on September 10–11, 2026, at the Centre for Cellular and Molecular Platforms (C-CAMP), Bengaluru. The conference was attended by 160 participants from regulatory authorities, industry, academia, research organizations and other stakeholder groups.

The conference was organized by IPC in collaboration with the Indian Drug Manufacturers' Association (IDMA), with the Biotechnology Industry Research Assistance Council (BIRAC) and Centre for Cellular and Molecular Platforms (C-CAMP) serving as Knowledge Partners, and the Karnataka Drugs and Pharmaceuticals Manufacturers' Association (KDPMA) as the Associate Partner. The conference aligns with the Government of India's Biopharma SHAKTI Vision to strengthen India's biopharmaceutical ecosystem through innovation, self-reliance, quality and global competitiveness.

The conference addressed key scientific and regulatory challenges associated with the development, evaluation and safety of biosimilars, with emphasis on pharmacopoeial standards, critical quality attributes, analytical characterization, comparability assessment, immunogenicity, pharmacovigilance and evolving regulatory expectations.

A major highlight of the conference was the release of the Indian Pharmacopoeia Reference Substance (IPRS) for Enoxaparin Sodium for bioassays. Enoxaparin Sodium is a low-molecular-weight heparin and anticoagulant widely used for the prevention and treatment of thromboembolic disorders. The IPRS for Enoxaparin Sodium for bioassays may serve as an authenticated reference material for bioassay testing, supporting accurate, consistent, and comparable assessment of its biological activity. The release of the IPRS marks an important advancement in strengthening the availability of authenticated pharmacopoeial reference substances for bioassay-related testing of Enoxaparin Sodium, while contributing to the Atmanirbhar Bharat vision by strengthening India's indigenous pharmaceutical quality infrastructure.

The inaugural session was addressed by distinguished representatives from IPC, SLA-Karnataka, NIB, IDMA, C-CAMP, and BIRAC, who emphasized the importance of strengthening quality, safety, and regulatory confidence in biosimilars. The session also highlighted the need for sustained collaboration among regulatory authorities, pharmacopoeial institutions, industry, academia, and research organizations to support the development of a robust and globally competitive biopharmaceutical sector.

Addressing the participants, Dr. V. Kalaiselvan, Secretary-cum-Scientific Director, IPC, highlighted the importance of strengthening pharmacopoeial standards, reliable analytical evaluation, safety monitoring, and regulatory cooperation to ensure the quality and safety of biosimilars. He also emphasized the need to align Indian practices with evolving regulatory expectations, support biopharmaceutical innovation, and contribute to the vision of Viksit Bharat.

Technical sessions featured experts from IPC, SLA, WHO, USP, NIB, IDMA, BIRAC, C-CAMP, and leading biopharmaceutical organizations, providing perspectives spanning pharmacopoeial standard-setting, regulatory science, analytical development, safety monitoring, and innovation in biologics.

A dedicated Panel Discussion on the first day of the conference brought together senior experts from regulatory authorities, the biopharmaceutical industry, and academia to examine measures required to strengthen India’s biosimilar ecosystem. The discussion focused on enhancing quality assurance, analytical and regulatory capabilities, scientific capacity, and alignment with evolving national and global regulatory expectations. The conference also featured poster presentations, during which researchers and industry professionals presented their scientific work and shared insights on biosimilars.

In pursuit of the vision of Viksit Bharat, the conference seeks to advance harmonized standards and strengthen quality, safety, innovation, and regulatory excellence in the biopharmaceutical sector. The release of the IPRS for Enoxaparin Sodium for bioassays, together with the scientific deliberations, underscores IPC's continued commitment to strengthening India's pharmaceutical and biopharmaceutical quality infrastructure and fostering collaboration among regulators, industry, academia, and research institutions to support innovation and enhance regulatory confidence.

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