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US FDA grants QIDP designation to Venus Remediesâ?? Polymyxin B Formulation

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VRP-034 is a novel supramolecular cationic (SMC) formulation of polymyxin B sulphate



Venus Remedies Limited (NSE: VENUSREM, BSE: 526953), a Panchkula-based pharmaceutical company specialising in critical care injectables, has announced that its investigational product VRP-034 has been granted Qualified Infectious Disease Product (QIDP) designation by the United States Food and Drug Administration (US FDA) for the treatment of bloodstream infections caused by polymyxin B (PMB)-susceptible strains in adults.

Developed by Venus Medicine Research Centre (VMRC), the R&D division of Venus Remedies, VRP-034 is a novel supramolecular cationic (SMC) formulation of polymyxin B sulphate, uniquely developed to address the nephrotoxic effects associated with conventional polymyxin B therapy.

The QIDP designation, granted under the Generating Antibiotic Incentives Now (GAIN) Act, provides VRP-034 with significant regulatory benefits, including priority review, eligibility for fast track designation, and an additional five years of market exclusivity upon approval in the United States.

Venus Remedies has developed the novel polymyxin-B formulation, VRP-034, using its proprietary Renal Guard technology. The company utilised kidney-on-a-chip technology (based on Organ-on-a-Chip model) to study established kidney injury biomarkers, including KIM-1, cystatin C, NAG, and NGAL, in response to polymyxin-B, an antibiotic used against multidrug-resistant Gram-negative bacteria. These insights directly contributed to the refining of its Renal Guard technology, forming the foundation of the novel formulation, VRP-034, designed specifically to minimise nephrotoxicity while preserving therapeutic efficacy.

Polymyxins, particularly PMB and colistin, are among the last-resort antibiotics used against Multidrug resistance (MDR) infections. However, their clinical use is severely limited by nephrotoxicity, which affects up to 60% of patients. VRP-034 offers a novel solution by preserving the pharmacokinetics and pharmacodynamics of PMB while significantly reducing oxidative stress and renal cell injury, as demonstrated in multiple *in vitro* and *in vivo* studies.