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Kemwell gets FDA nod after cGMP audit

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Bangalore: Kemwell Biopharma's oral solids manufacturing facility located in Bangalore, India, has successfully completed a US FDA certified good manufacturing practices (cGMP) audit for a pre-approval inspection (PAI), which was triggered by a NDA filing.

"The approval from the US FDA confirms Kemwell's cGMP manufacturing capability and regulatory compliance, and our commitment to provide our customers the highest standards of quality. The facility has been approved by many global regulatory authorities including EMA, MHRA, Health Canada and TGA. We will continue to strive to provide excellent quality pharmaceutical products and deliver on the highest customer service expectations," said Mr Anurag Bagaria, CMD, Kemwell.

Applying Quality by Design (QbD) principles, Kemwell's R&D and manufacturing teams in conjunction with the customer, optimized tablet formulation, conducted process scale-up studies to define design space for manufacturing of tablet formulation and manufactured the validation and submission batches for this NDA filing.

The audit involved an in-depth review and evaluation of all systems, procedures and processes related to the development, validation and manufacture of oral solids at the Bangalore site.

The state-of-the-art facility started cGMP production in 2008 and is designed to produce five billion tablets and capsules annually. The facility has been built in with high flexibility to manage batch sizes from 10 kg to 1000 kg. Kemwell has been regularly shipping products to Europe and Australia from this facility, and will soon start commercial supplies to Canada and the US.