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Research Article

Real-time imaging as an emerging process analytical technology tool for monitoring of fluid bed coating process

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Abstract

A direct imaging system (EyeconTM) was used as a Process Analytical Technology (PAT) tool to monitor fluid bed coating process. EyeconTM generated real-time onscreen images, particle size and shape information of two identically manufactured laboratory-scale batches. EyeconTM has accuracy of measuring the particle size increase of $\pm 1~\mu m$ on particles in the size range of 50–3000 μm .

EyeconTM captured data every 2 s during the entire process. The moving average of D90 particle size values recorded by EyeconTM were calculated for every 30 min to

Real-time imaging as an emerging process analytical technology tool for monitoring of fluid bed coating process: Pharmaceuti... calculate the radial coating thickness of coated particles. After the completion of coating process, the radial coating thickness was found to be 11.3 and 9.11 µm, with a standard deviation of ±0.68 and 1.8 µm for Batch 1 and Batch 2, respectively. The coating thickness was also correlated with percent weight build-up by gel permeation chromatography (GPC) and dissolution. GPC indicated weight build-up of 10.6% and 9.27% for Batch 1 and Batch 2, respectively.

In conclusion, weight build-up of 10% can also be correlated with $10 \pm 2 \,\mu m$ increase in the coating thickness of pellets, indicating the potential applicability of real-time imaging as an endpoint determination tool for fluid bed coating process.

Q Keywords: Fluid bed coating process analytical technology real-time imaging pellet size and shape quality by design EyeconTM

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Disclosure statement

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

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