Evaluation of a robotic compounding system for the preparation of non-hazardous ready to administer sterile products in a tertiary care hospital

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What was done?

We evaluated productivity, dose accuracy and environmental monitoring of KIRO® Fill, a robotic compounding system (RCS). We also assessed the microbiological results of the sterility tests performed.

Why was it done?

Automated compounding emerges as an alternative for manual compounding, making possible the centralization of standardized compounded medications in hospital pharmacy aseptic services at a larger scale.
This provides sterile, high-quality, safe, traceable ready-to-administer products to clinical units. Additionally, it could free up nursing time for patient care instead of performing pharmaceutical work.

How was it done?

We implemented a RCS equipped with ISO 5 aseptic environment, horizontal airflow with HEPA filters and continuous monitoring of: air flow operation, non-viable particle counts (limits for ISO Class 5 are 0.5µm and larger size: not more than 3.520 particles/m3, and 5µm and larger size: not more than 20 particles/m3) and temperature (not more than 25°C).
Two automated units work in parallel handling transfer syringes to withdraw solutions from source containers (SC) and fill final containers (syringes or infusion bags) via Luer Lock connections.
This technology allows barcode/data matrix verification of source and final containers used and RFID for in-process tracking.

An integrated scale is responsible for gravimetric control of the compounded preparations within an acceptable ±5% error range.
Gri-Fill® filling system was used for the preparation of SC.
Drug verification was assured through drug workflow management system and datamatrix verification in RCS.
We performed sterility test of all batches and physicochemical stability studies were developed when not available in the literature.

Keywords:
Preparation and compounding>Automated production
Preparation and compounding>Compounding robots
Preparation and compounding>Dosing accuracy

What has been achieved?

Between January 2022 and September 2022, we have prepared with RCS 2.813 syringes of norepinephrine (base) 0,2 mg/ml in normal saline for critical care unit syringe pumps and 395 morphine hydrochloride 1 mg/ml normal saline 250 ml infusion bags for patient-controlled analgesia (PCA) administered in the surgical area.

The average dose accuracy errors for syringes and infusion bags were 0,23% and -0,09%, respectively. Environmental monitoring results and temperature controls met our standards at all times.

Results from sterility tests demonstrated the absence of microbial growth In all tested preparations.

Fig. 1. KIRO Fill device.

Fig. 2. Norepinephrine syringe.

Fig. 3. Morphine infusion bag.

What next?

Overall satisfactory results when compounding sterile preparations using KIRO® Fill and positive feedback received from nurses in clinical units, have lead us to incorporate new batches, such as morphine syringes for critical care unit syringe pumps, to the production with the RCS. Stability studies are currently being performed for this purpose.

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