Increasing the yield in the production of slow release pellets in the manufacture of solid oral dosage forms

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***Introduction*:**

Research and Development (R&D) in the pharmaceutical industry enhances Good Manufacturing Practice (GMP) by improving manufacturing processes currently being used and making them more economically viable.

***Aim*:**

To increase the yield in the production of slow release oral dosage forms by targeting and changing the factors which are currently causing a decrease in yield

***Method*:**

- **A total of 28 batches were assessed at a local company**
- **Data was collected from the Batch Manufacturing and Instructions Record (BMIR)**
- **Assessment of the active pharmaceutical ingredient (API) application on sugar spheres and the subsequent application of the slow release outer coating**
- **Identification of the parameters affecting the yield in the production of slow release pellets**
- **Rating of the surface roughness of pellets from 1 to 5 — 1 being the roughest and 5 the smoothest**
- **Statistical analysis was performed using SPSS version 17.0**

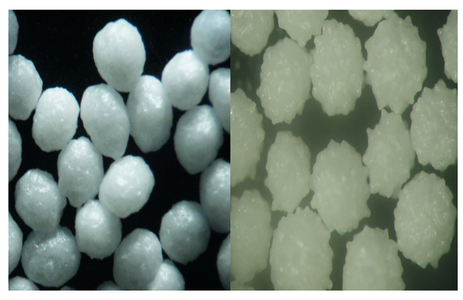

Fig 1: Photos of 2 different batch samples taken under a microscope. The surface rating of the picture on the left is 1 while that on the right is 5.

***Results and Discussion*:**

Statistical significance ($p<0.05$) was found for the following:

- **The temperature of the product was affected by the temperature of air entering the coating pan and the velocity of the pump. The temperature of the product changes by absorbing or losing heat into the environment and by the varied velocity of the pump.**
- **The time required to apply the API on sugar spheres depends on the velocity of the pump. The faster the velocity of the pump is, the less time is required to coat the sugar spheres.**
- **Two of the four types of waste, namely extraction and selection waste decrease the yield during the application of the API on sugar spheres. The extraction waste and selection waste account for 43.8% of the variation in the percentage yield of API. Extraction waste is affected by the negative pressure present inside the coating pan which is created by maintaining a high air outflow and a low air inflow.**
- **During the application of the second slow release coating, the spray pressure used affected the surface roughness of the pellets. On increasing the spray pressure the pellets' surface roughness decreased. When the spray pressure is high, the droplet size decreases. This leads to an increase in the rate of drying leading to an increase in the viscosity of the drops. High viscosity decreases the ability of the drop to form a uniform coating .[1,2,3,4]**

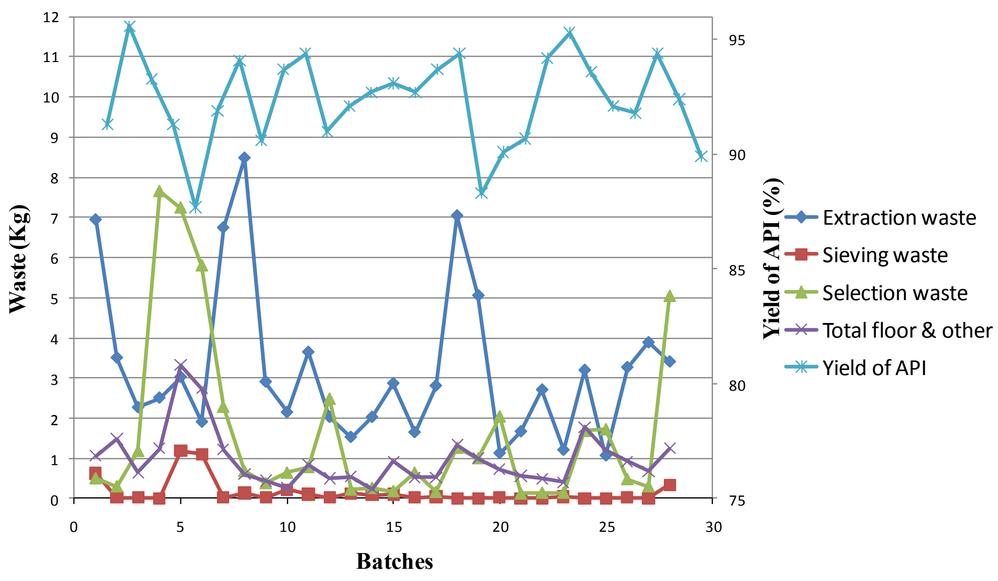

Fig 2: A graph showing the relationship between the four types of waste generated during the application of the API and the yield of API (Active Pharmaceutical Ingredient)

***Conclusion*:**

The results obtained from this study will enable pertinent modifications in the equipment and also a reduction in the waste which is currently being generated. These changes will make the process more pharmaceutically and economically viable.

References:

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