Technology Transfer of solid oral dosage form

In pharmaceutical industry, Technology transfer includes the transfer of data in the form of technology transfer dossier (TTD) from R&D to PDL and then finally to production for the commercial manufacturing of the dosage form. In the present study we followed the technology transfer of tablet dosage form which belongs to potent molecules i.e. the product was to be manufactured in a containment facility with full attention to personal protection.

The entire event of technology transfer involved the manufacturing of one scale up batch as per the recommendations of the technology transfer dossier for the optimization of process parameters.

After the successful completion of the scale up batch and evaluation of the analytical samples, exhibit batches were planned for the filing of the product as well as for the validation of the manufacturing process.

The test batch of API Tablets 2.5 mg involved monitoring of the manufacturing process of three test batches. The observations made during monitoring activity are summarized as follows

BLENDING:

Unit dose samples withdrawn at the stage of Pre lubrication and Final Blending show good blend uniformity. For the final blend individual results and the mean are well within the specified acceptance criteria of 90.0 - 110.0 %, with a maximum RSD of 1.37 %.

The results are reproducible and consistent for all sampling locations. The blend homogeneity is found to be independent of location of sampling.

Analytical results of representative In-Process sample of final blend are consistent. The results conform to the predetermined In-process Specifications.

The bulk blend was compressed on Tablet Compression Machine (Courtoy compression machine). Samples of tablets collected during compression run were subjected for evaluation of different physical parameters.

The observed data reveals that the physical parameters of the compressed tablets are consistent.

Further, the Uniformity of Dosage Units and Dissolution data of the tablets sampled at different stages of compression is satisfactory and conforms to the acceptance criteria i.e. acceptance value should be NMT 15, with a maximum Acceptance Value of 5.0

FILM COATING:

Film coating for tablets is carried out by using Film Coating Machine. The coating operation is smooth and the product is uniformly coated with the parameters specified in Master Formula. The final coat weight build up observed is 2.62 – 2.83 % w/w against the recommended limit of 2.50 % – 3.50 %w/w.

The batch representative samples of coated tablets tested for Dissolution show no significant variation between the batches. Tablets of all the batches comply to specification of NLT 80% of labeled amount of API is dissolved in 45 min.

The finished product results of the batches comply to the laid down Product Release Specifications.

Conclusion

The overall review of results shows consistency and reproducibility. These results demonstrate that the manufacturing process was under control throughout all the stages of manufacturing. The collated data clearly indicates Process Consistency and Reproducibility in yielding the product that meets predetermined attributes for the product.