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Short communication

Analytical method transfer for dissolution of Metformin hydrochloride in Metformin hydrochloride prolonged – release tablets

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Introduction

Analytical method transfer (AMT) is a systematic and documented process used to ensure that an analytical procedure developed in one laboratory can be successfully performed in another with comparable results (WHO,2011). It plays a key role in Pharmaceutical Quality Control, particularly during technology transfer, product lifecycle management and regulatory submissions (WHO, 2011).

This study describes the transfer of analytical method for dissolution testing of Metformin Hydrochloride tablets from Transferring Unit (TU), Research and Development where the method was developed and validated, to the Receiving Unit (RU) Quality Control Laboratory, where it is implemented and used.

A single batch of Metformin Hydrochloride tablets is analyzed in both laboratories. The process is carried out according to plan, protocol and an already validated analytical method (WHO,2011).

The aim of this study was to evaluate the analytical method transfer for dissolution testing of Metformin Hydrochloride prolonged-release tablets between laboratories, ensuring comparable performance and reliable results.

Materials and methods

For the determination of dissolution rate, a validated high performance liquid chromatography (HPLC) method was used.

The dissolution study was performed using USP Apparatus 1 (basket), with 1000mL dissolution medium (phosphate buffer pH=6.8), maintained at 37± 0.5°C. Samples were collected at 30 min, 1 h, 4 h, 6 h, 8 h, 10 h, 12 h. The basket rotation speed was 100 rpm.

The dissolution analysis was performed on 12 samples in both laboratories by different analysts, on different instruments and on different days.

The method used for transfer had been previously validated in accordance with ICH Q2 (R1) guidelines (ICH, 2005).

Results and discussion

The mean dissolution results obtained by the Transferring Unit (TU) and the Receiving Unit (RU) were compared at all-time points

The mean dissolution values of 12 samples were 34.29% (TU) and 32.73% (RU) at 1h, 70.73% (TU) and 68.38% (RU) at 4h and 97.22% (TU) and 94.53% (RU) at the final 12h time point.

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The absolute differences between the mean dissolution results obtained by the two laboratories were 1.56% at 1 h, 2.35% at 4 h, and 2.69% at 12 h.

All observed differences were below the predefined acceptance criterion of 5% for the difference between the mean dissolution results of the TU and the RU.

These results confirm that the RU is capable of performing the dissolution method with analytical performance comparable to that of the TU, fulfilling the predefined acceptance criteria for analytical transfer method.

Conclusion

Based on the obtained results from both laboratories, all evaluated parameters met the predefined acceptance criteria. Therefore, it can be concluded that the analytical method transfer for dissolution testing of Metformin Hydrochloride prolonged - release tablets was successfully completed, ensuring reliable performance for routine quality control and compliance with regulatory.

Analytical method transfer ensures that the dissolution method used in Quality Control of Finished products provides reliable and comparable results between laboratories, which is critical for consistent evaluation of prolonged- release tablets.

References

ICH guideline Q2 (R1), 2005. Validation of Analytical Procedures.

WHO Technical Report Series No. 961, Annex 7: Guidelines on Transfer of Technology in Pharmaceutical Manufacturing, 2011.