26th Congress of SCTM

Sept. 20-23, 2023, Metropol Lake Resort, Ohrid, N. Macedonia

Method Validation for *In Situ* Identification of Diazepam with Raman Spectroscopy in Pharmaceutical Industry

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Raman spectroscopy in its hand held version is one of the most advanced and used analytical techniques used for routine, *in situ* identification on incoming raw materials in the warehouses of the pharmaceutical industry.

The main objective of the validation of the analytical procedure is to demonstrate that the procedure is suitable for its intended purpose. This is performed according to the Guidance on validation of analytical procedures (CPMP/ICH/701/95) and USP Monograph ⟨1225⟩ Validation of Compendial Procedures.[1,2] In this study, the validation of the Raman spectroscopy identification method for diazepam active pharmaceutical ingredient (API) was performed on the parameters of specificity and robustness.

For testing method's specificity, Raman spectra were collected from three different positions in the same package from the same batch of diazepam API, in the original manufacturer's packaging. On the other hand, for testing the parameter robustness the effect of minor changes to the normal operating conditions was challenged, based on introduced changes in the polyethylene bag thickness. Also, the method robustness was assessed by analysis performed by different analyst using the same method parameters

The obtained results confirmed that the method is specific and robust in accordance with the validation criteria.

Keywords: validation, Diazepam, Raman spectroscopy, specificity, robustness, pharmaceutical industry

References:

1. ICH Guideline Q2(R1) Validation of Analytical procedures: Text and Methodology, November 2005.

2. United States Pharmacopoeia USP41, National Formulary 36. General Information/(1225) Validation of Compendial Procedures.