RFP 025689 Stability study of protein in an infusion system.

Appendix A.

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| --- | --- | --- | --- |
| Package | Volume variants | Time points | Tested conditio in total |
| A – stability in syringe | 1 | 1 | 1 |
| B – stability in infusion bags | 2 | 1 | 2 |

| **Table 1.**  Anali | |
| --- | --- |
| **Test** | **Odnośnik do metody analitycznej** |
|
| **IDENTITY** | |
| Western Blot | Ph.Eur.2.2.31  SDS-PAGE under reducing condition |
| **APPEARANCE AND DESCRIPTION** | |
| Clarity | Ph. Eur. 2.2.1, USP <855> Visual method |
| Colour | Ph. Eur. 2.2.2, USP <631> Visual method |
| Visible Particles | Ph. Eur. 2.9.20. |
| **PROCESS AND PRODUCT RELATED IMPURITIES** | |
| Purity by SE-HPLC | Ph. Eur. 2.2.29  SE-HPLC |
| HMW impurities by SE-HPLC |
| LMW impurities by SE-HPLC6 |
| Purity by IEX-HPLC | Ph. Eur. 2.2.29  IEX-HPLC |
| Charge variance by IEX-HPLC |
|
| Purity by RP-HPLC | Ph. Eur. 2.2.29  RP-HPLC |
| Hydrophobic variance by RP- HPLC |
|
| Purity by reducing SDS-PAGE (Coomasie stained) | Ph. Eur. 2.2.31.,  SDS-PAGE |
| Purity by non-reducing SDS-PAGE (Coomasie stained) |
| Impurities by non-reducing SDS-PAGE (Coomasie stained) |
| **QUANTITY AND POTENCY** | |
| Potency | Ph. Eur. 5.3,  Cell-based assay |
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| Protein concentration | Ph. Eur. 2.5.33. (Method 1), 2.2.25,  SoloVPE |
| **Process related impurities and Safety** | |
| Sterylity | Ph. Eur. 2.6.1 and USP <71> |
| **OTHER TESTS** | |
| Osmolality | Ph. Eur. 2.2.35,  Vapor pressure osmometry |
| pH | Ph. Eur. 2.2.3,  Potentiometric method |
| Bacterial endotoxins | Ph. Eur. 2.6.14. |
| Particulate contamination: sub-visible particles | Ph. Eur. 2.9.19, USP <787>, USP <788> |