3.2.P.8.1 Stability Summary and Conclusion

Stability testing was carried out on Sustanon 250 mg/mL solution for injection manufactured at EVER Pharma Jena GmbH, Germany. The samples were stored according to the stability protocol presented in section 3.2.P.8.2 and tested in accordance with the specifications provided in section 3.2.P.5.1.

3.2.P.8.1.1 Stability Testing

A summary of the batches tested is provided in Table 3.2.P.8.1 T-1 below.

Table 3.2.P.8.1 T-1: Details of Stability Batches

Batch Number	Pack type	Pack size	Date of Manufacture	Storage Condition	Data available
PB8033	Ampoule	1 Ampoule	23-Mar-2015	25°C ± 2°C /60 % r.H. ± 5% r.H. 30°C ± 2°C /65 % r.H. ± 5% r.H. 30°C ± 2°C /75 % r.H. ± 5% r.H.	36 months
				40°C ± 2°C /75 % r.H. ± 5% r.H.	6 months
PB8034	Ampoule	1 Ampoule	24-Mar-2015	25°C ± 2°C /60 % r.H. ± 5% r.H. 30°C ± 2°C /65 % r.H. ± 5% r.H. 30°C ± 2°C /75 % r.H. ± 5% r.H.	36 months
				40°C ± 2°C /75 % r.H. ± 5% r.H.	6 months
PB8035	Ampoule	1 Ampoule	25-Mar-2015	25°C ± 2°C /60 % r.H. ± 5% r.H. 30°C ± 2°C /65 % r.H. ± 5% r.H. 30°C ± 2°C /75 % r.H. ± 5% r.H.	36 months
				40°C ± 2°C /75 % r.H. ± 5% r.H.	6 months

Stability data tables are presented in section 3.2.P.8.3 Stability Data.

3.2.P.8.1.2 Discussion of Results

Appearance

The appearance of the 3 examined batches of Sustanon 250 mg/mL solution for injection complied with the specification (oily solution) over the time points and climatic conditions tested, thus no deviation is expected for further analyses in the stability study.

Colour (visual)

The colour of the 3 examined batches of Sustanon 250 mg/mL solution for injection complied with the specification (yellow) over all the time points and climatic conditions tested, thus no deviation is expected for further analyses in the stability study.

Clarity (visual)

The clarity of the solution of the examined batches of Sustanon 250 mg/mL solution for injection complied with the specification (clear) over all time points and climatic conditions tested, thus no deviation is expected for further analyses in the stability study.

Extractable volume

The extractable volume is only tested at the start and final test point due to the inert behaviour of the glass ampoule.

Particulate matter (sub-visible)

The amount of sub-visible particles (≥ 10 µm as well as ≥ 25 µm) was below the specification limit within the 3 examined batches over all time points and climatic conditions, as presented in section 3.2.P.5.1 Specifications. There is no indication of formation of particles during the analyses of all 3 batches, thus no deviation with respect to the specifications is expected.

Identity Testosterone esters

The identity of the four active ingredients is only tested for release (T0) as the identity is not considered a stability indicating parameter.

Assay Testosterone esters (HPLC)

The assay of Testosterone Propionate, Testosterone Phenylpropionate, Testosterone Isocaproate and Testosterone Decanoate complies with the shelf life specification for the three batches for each of the time-points and climatic conditions.

Impurities (HPLC)

The specified impurity Testosterone and all unspecified impurities were below the reporting levels specified in section 3.2.P.5.1 Specifications for all examined batches over all tested time

points and climatic conditions. As a result, there is no indication for any degradation reactions of the active pharmaceutical compounds. Each observed secondary peak was below the LOQ of the method as defined in section 3.2.P.5.3 Validation of Analytical Procedures.

All active compounds were characterised by an adequate stability, thus no deviation to the shelf-life specifications is expected for testing of impurities within further analyses of the current ICH stability study.

Sterility

Testing for sterility is performed every 12 months. The current sterility results of the 3 examined batches of Sustanon 250 mg/mL solution for injection complies with the specification at the climatic conditions tested, thus no deviation is expected for further analyses in the stability study.

Bacterial endotoxins

Testing for bacterial endotoxins is performed every 12 months. The current sterility results of the 3 examined batches of Sustanon 250 mg/mL solution for injection complies with the specification at the climatic conditions tested, thus no deviation is expected for further analyses in the stability study.

Conclusion

With respect to the actual results after 36 months of ICH stability studies, Sustanon 250 mg/mL solution for injection has been characterised by adequate stability, thus no significant changes in the product quality are expected over the course of the stability study.

Based on these results it can be seen that manufacture at the Ever Pharma Jena GmbH site has no effect on the stability of the finished product. Thus the currently registered shelf life may be applied to product manufactured in Ever Pharma Jena GmbH.