3.2.P.8.3 Stability Data (name, dosage form)

Results of the stability studies should be presented in an appropriate format (e.g. tabular, graphical, narrative). Information on the analytical procedures used to generate the data and validation of these procedures should be included.

Information on characterisation of impurities is located in 3.2.P.5.5.

Reference ICH Guidelines: [Q1A, Q1B, Q2(R1) and Q5C](http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html)

# Stability data <DrugProductName:Qdrug> <DosageForm:Injectable solution>

Table 1 Summary of GMP <DrugProductName:Qdrug> <DosageForm:Injectable Solution> <StabilityTesting:long term stability> testing for <Use:registration stability> use

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Batch Lot Number | API Lot | Use | Manufacture date | Fill Volume/ Vial Volume (mL) | Batch Size | Stability data/  Study condition | Stability Data tables |
| <B234> | <90338345> | Registration stability | <1/2/2016> | 0.5 mL fill/ 0.8 ml vial> | 1kg | <24 months at 5±3°C/ARH> | Table 2 |
| <B345> | <90338245> | Registration stability | <1/3/2016> | 0.5 mL fill/ 0.8 ml vial | 2kg | <24 months at 5±3°C/ARH> | Table 3 |
| <B456> | <90338245> | Registration stability | <1/4/2016> | 0.5 mL fill/ 0.8 ml vial | 2kg | <24 months at 5±3°C/ARH> | Table 4 |

Lorem ipsum dolor sit amet, consectetuer adipiscing elit. Maecenas porttitor congue massa. Fusce posuere, magna sed pulvinar ultricies, purus lectus malesuada libero, sit amet commodo magna eros quis urna

Table 2 Stability Data for <BatchNr:B234><StabilityTesting:long term testing> stored at <LongtermStorageDuration24M> at <LongtermStorageCondition5±3°C/ARH> for <Use:stability registration> use

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Test | Appearance | Identification by HPLC | Identification by UV | Assay | Related substances | Ethanol content | Moisture | Viscotity | Extractable volume | Particulate matter | Endotoxin | Sterility |
| Specification | A clear colorless to slightly yellowish liquid | Matches RRT of standard | Matches UV spectrum of the standard form PDA detector | 95.0 – 105.0% LC | - | 2.0 - 5.0 % w/w | ≥ 1% | 50 – 70 cP | ≥ 0.20 mL/Vial | ≤ 50 Part/mL ≥ 10 µm | ≤ 40 EU/mL | Sterile |
| <Initial (T0)> | Conform | Conform | Conform | 98.0 | - | 3.0 | 0.14 | 68.2 |  | 10 µm =0 | < 30 EU/mL | - |
| <4><M> | Conform | -a | -a | 96.6 | - | - | - | - |  |  | - | - |
| <6><M> | Conform | -a | -a | 99.1 | - | - | - | - |  |  | - | - |
| <9><M> | Conform | -a | -a | 98.4 | - | - | - | - |  |  | - | Sterile |
| <12><M> | Conform | -a | -a | 99.0 | - | 2.3 | 0.20 | 65.2 |  | 10 µm = 0 | < 30 EU/mL | Sterile |
| <18><M> | Conform | -a | -a | 99.2 | - | - | 0.22 | - |  | - | - | Sterile |
| <24><M> | Conform | -a | -a | 99.4 | - | 2.8 | 0.18- | 66.5 |  | 10 µm = 5 | < 15 EU/mL | - |

a -, test not conducted

m Months

Table 3 Stability Data for <B345><StabilityTesting:long term testing> stored at <LongtermStorageDuration24M> at <LongtermStorageCondition5±3°C/ARH> for <Use:stability registration> use

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Test | Appearance | Identification by HPLC | Identification by UV | Assay | Related substances | Ethanol content | Moisture | Viscotity | Extractable volume | Particulate matter | Endotoxin | Sterility |
| Specification | A clear colorless to slightly yellowish liquid | Matches RRT of standard | Matches UV spectrum of the standard form PDA detector | 95.0 – 105.0% LC | - | 2.0 - 5.0 % w/w | ≥ 1% | 50 – 70 cP | ≥ 0.20 mL/Vial | ≤ 50 Part/mL ≥ 10 µm | ≤ 40 EU/mL | Sterile |
| <Initial (T0)> | Conform | Conform | Conform | 98.0 | - | 3.0 | 0.14 | 68.2 |  | 10 µm =0 | < 30 EU/mL | - |
| <4><M> | Conform | -a | -a | 96.6 | - | - | - | - |  |  | - | - |
| <6><M> | Conform | -a | -a | 99.1 | - | - | - | - |  |  | - | - |
| <9><M> | Conform | -a | -a | 98.4 | - | - | - | - |  |  | - | Sterile |
| <12><M> | Conform | -a | -a | 99.0 | - | 2.3 | 0.20 | 65.2 |  | 10 µm = 0 | < 30 EU/mL | Sterile |
| <18><M> | Conform | -a | -a | 99.2 | - | - | 0.22 | - |  | - | - | Sterile |
| <24><M> | Conform | -a | -a | 99.4 | - | 2.8 | 0.18- | 66.5 |  | 10 µm = 5 | < 15 EU/mL | - |

a -, test not conducted

Table 4 Stability Data for <B456><StabilityTesting:long term testing> stored at <LongtermStorageDuration24M> at <LongtermStorageCondition5±3°C/ARH> for <Use:stability registration> use

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Test | Appearance | Identification by HPLC | Identification by UV | Assay | Related substances | Ethanol content | Moisture | Viscotity | Extractable volume | Particulate matter | Endotoxin | Sterility |
| Specification | A clear colorless to slightly yellowish liquid | Matches RRT of standard | Matches UV spectrum of the standard form PDA detector | 95.0 – 105.0% LC | - | 2.0 - 5.0 % w/w | ≥ 1% | 50 – 70 cP | ≥ 0.20 mL/Vial | ≤ 50 Part/mL ≥ 10 µm | ≤ 40 EU/mL | Sterile |
| <Initial (T0)> | Conform | Conform | Conform | 98.0 | - | 3.0 | 0.14 | 68.2 |  | 10 µm =0 | < 30 EU/mL | - |
| <4><M> | Conform | -a | -a | 96.6 | - | - | - | - |  |  | - | - |
| <6><M> | Conform | -a | -a | 99.1 | - | - | - | - |  |  | - | - |
| <9><M> | Conform | -a | -a | 98.4 | - | - | - | - |  |  | - | Sterile |
| <12><M> | Conform | -a | -a | 99.0 | - | 2.3 | 0.20 | 65.2 |  | 10 µm = 0 | < 30 EU/mL | Sterile |
| <18><M> | Conform | -a | -a | 99.2 | - | - | 0.22 | - |  | - | - | Sterile |
| <24><M> | Conform | -a | -a | 99.4 | - | 2.8 | 0.18- | 66.5 |  | 10 µm = 5 | < 15 EU/mL | - |

a -, test not conducted