| Parameter | Ph. Eur.* | | USP* | |
|---|---|---|---|---|
| | Specification | Test method | Specification | Test method |
| Identification | conforms | Ph. Eur.* (2.2.24, FT-IR) | conforms | USP* A(FT-IR) / B (GC) |
| Appearance of solution | conforms | Ph. Eur.* (2.2.1, 2.2.2) | — | — |
| Clarity of solution | — | — | A+B conform | USP* |
| Acidity | conforms | Ph. Eur.* | — | — |
| Related substances/ Organic impurities | conforms | Ph. Eur.* | conforms | USP* |
| o-cresol | ≤ 0.5% | Ph. Eur.* | ≤ 0.5% | USP* |
| p-cresol | ≤ 0.5% | Ph. Eur.* | ≤ 0.5% | USP* |
| any other impurity | each ≤ 0.1% | Ph. Eur.* | each ≤ 0.1% | USP* |
| total | ≤ 1.0% | Ph. Eur.* | ≤ 1.0% | USP* |
| Residue on evaporation | ≤ 0.1% | Ph. Eur.* | — | — |
| Assay | — | — | 98.0 – 102.0 % | USP* |

| Additional Parameters | | | |
|---|---|---|---|
| **Parameter** | | **Test method** | |
| Absorption (400 - 700 nm) | Max. 0.05 | UV-VIS Spectrometry (LSM 024) | |
| Endotoxins | ≤ 0.5 IU/mg | Ph. Eur.* / USP* / JP* (LAL, kinetic-turbidimetric method) | |
| **Parameter** | **ICH Q3C Specification** | **Additional Specification** | **Test method** |
| Toluene content | ≤ 890 ppm | ≤ 100 ppm | LSM 024* (GC) |

| Quality Assurance and Quality Control | |
|---|---|
| **Process/Operation** | **Standard / Requirement** |
| Production | Requirements defined from a HACCP study |
| Supply chain | WHO – GTDP Guidelines for Pharmaceutical Starting Materials |
| Analytical quality control | Full analysis of specification for each batch in a GMP qualified laboratory |
| Batch release | Qualified Person according to EU-GMP (2001/83/EC; Articles 48 & 49) |
| Packaging | Class D (100,000) clean room according to GMP (EU-GMP Part I Annex 1, US cGMP) |
| Blanketing | Product is blanketed with an argon layer |
| Primary packaging material | Specified packaging materials from audited suppliers: 100 mL, 1 L, 2.5 L Amber Glass Bottles |