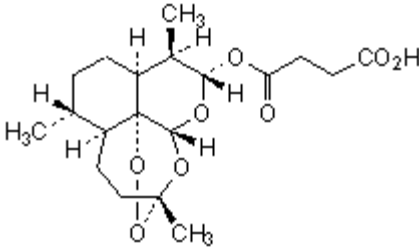

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## 1. General information/ specifications

Material	
Material type	<input checked="" type="checkbox"/> Active substance <input checked="" type="checkbox"/> GMP <input type="checkbox"/> non GMP
Material identification	<p>Name of the material: <i>Artesunatum</i>, Artesunate, Artesunate</p> <p>IUPAC: (3<i>R</i>,5<i>aS</i>,6<i>R</i>,8<i>aS</i>,9<i>R</i>,10<i>S</i>,12<i>R</i>,12<i>aR</i>)-decahydro- 3,6,9-trimethyl-3,12-epoxy-12H-pyrano[4,3-] 1,2-benzodioxepin-10-ol-hydrogensuccinat</p> <p>CAS No: 88495-63-0Material No (if applicable):</p> <p>Description (formula, molar mass, if applicable):</p> <div style="text-align: center;">  <p><math>C_{19}H_{28}O_8</math>, 384.4 g/mol</p> </div>
Supplier/ Manufacturer	In-house production
Storage/transport conditions	<p>Storage conditions: In a well-sealed container or sterile in a hermetically sealed container, protected from light.</p> <p>Transport conditions: n.a.</p>
Shelf life	<i>1 year</i>
Re-test interval	<i>After one year</i>

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## 2. Analytical data/ specifications

Parameter	Method statement [SOP-06-MA, Document No.]	Set point or range
<b>Content / Activity</b>		
Content	SOP-06-MA-015_Artesunate RS - Content determination by HPLC	96.0 % - 102.0% (calculated as anhydrous substance)
<b>Identity</b>		
IR spectroscopy	SOP-06-MA-003_Identity determination by means of ATR-FTIR	corresponds to the spectrum of the reference substance
<b>Purity</b>		
Related substances	SOP-06-MA-016_Artesunate RS - related substances	≤ 1.0% 10-epiartemimol and Imp A ≤ 0.5% Impurity Imp. B ≤ 0.2% Impurity C ≤ 0.2% any other single Impurity ≤ 2.0% sum of all impurities
<b>Additional characterisations</b>		
Specific optical rotation	SOP-06-MA-018_Measurement of specific optical rotation	$[\alpha]_D^{20^\circ C} =$ +4.5° to +6.5° (calculated as anhydrous substance)
Solubility	Practically insoluble in water soluble in dichloromethane <i>R</i> soluble in ethanol (abs.) <i>R</i> and acetone <i>R</i>	100 mg in >1L 1 g/mL 1 g/10mL
Heavy metals	External Laboratory LS	≤ 10 ppm cobalt ≤ 10 ppm lead ≤ 30 ppm arsenic ≤ 6 ppm mercury ≤ 4 ppm cadmium ≤ 20 ppm vanadium ≤ 40 ppm nickel ≤ 500 ppm lithium ≤ 180 ppm antimony ≤ 600 ppm copper
Sulphated ash	SOP-06-MA-012_Limit test for sulphated ash	≤ 1.0 mg/g
Water content	SOP-06-MA-038_Water determination by means of Karl-Fischer (volumetric)	≤ 5 mg/g
pH value	SOP-06-MA-001_pH-Messungen	3,5 – 4,5
Bacterial endotoxins	Ph. Eur. 10.0, chapter 2.6.14 External	≤ 2.5 IU endotoxin per mg substance
Sterility	Ph. Eur. 10.0, chapter 2.6.1 External	corresponds to

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Parameter	Method statement [SOP-06-MA, Document No.]	Set point or range
Residual solvent	Ph. Eur10.0, chapter 5.4 External	< 60 ppm chloroform < 3000 ppm methanol < 5000 ppm ethyl acetate
Residual solvent	Acetic acid kit according to VAL-031	< 5000 ppm acetic acid