

No.: BPAP-606-B-00/3.0

**CERTIFICATE OF ANALYSIS**

<b>Product Name</b>	Ropivacaine Hydrochloride	<b>CAS No.</b>	98717-15-8
<b>Batch No.</b>	P021160619B	<b>Mfg. Date</b>	Nov. 29, 2019
<b>Quantity</b>	150kg	<b>Retest Date</b>	Nov. 28, 2021
<b>Packing</b>	25kg/Drum	<b>Report Date</b>	Dec. 04, 2019
<b>Specification</b>	EP		

ITEM	SPECIFICATION	RESULT
<b>Appearance</b>	White or off-white crystalline powder.	Complies
<b>Solubility</b>	Soluble in water and in ethanol (96 %), slightly soluble in methylene chloride.	Complies
<b>Identification</b>	A. Conforms of Chloride reaction	Complies
	B. The infrared absorption spectrum of the sample shall be consistent with that of the reference substance.	Complies
<b>Specific Rotation</b>	-64.0°~-74.0°	-72.63°
<b>Color</b>	The absorbance at 405nm is not more than 0.030	0.001
	The absorbance at 436nm is not more than 0.025	0.001
<b>Clarity</b>	Solution should be clarified	Complies
<b>pH</b>	4.5~6.0	4.90
<b>Water</b>	5.0%~6.0%	5.58%
<b>Sulfated Ash</b>	≤0.1%	0.03%
<b>Heavy Metal</b>	≤10ppm	Complies
<b>Related Substances</b>		
- (S)-Bupivacaine	≤0.2%	Undetected
- 2,6-dimethylaniline	≤0.001%	Undetected
- Any Other Individual Impurity	≤0.1%	0.015%
- Total Impurities	≤0.5%	0.039%
<b>Enantiomeric</b>	≤0.5%	Undetected
<b>Assay (Anhydrous substance)</b>	99.0%~101.0%	99.65%
<b>Residual Solvents</b>		
- Acetone	≤0.5%	0.032%
- Methanol	≤0.3%	Undetected
- Methyl isobutyl ketone	≤0.45%	Undetected
- N-Methyl pyrrolidone	≤0.053%	Undetected

-Bromobutane	≤0.0076%	Undetected
-AceticAcid	≤0.5%	Undetected
<b>Bacterial Endotoxins</b>	≤0.05EU/mg	Complies
<b>Total Plate Count</b>	≤1000cfu/g	Complies
-Yeast & Mold	≤100cfu/g	Complies
-E.Coli	Absent in 1g	Undetected
<b>Conclusion</b>	Comply with the specification.	
<b>Storage</b>	Preserve in tight containers, protected from strong light and high heat.	

Analyst:

Reviewed by:

Approved by: