



## Certificate of Analysis

Rec02- SOP- QC086- 00

Inspection NO. QC- C04B1- 201908013

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Product name	Benzhexol hydrochloride	Product Specifications	API	Product code	C04B1
Product batch	19071301S	Manufacturing date	2019.07.13	Product weight	11.5KG
Packaging specification	1kg/bag				
Analysis date	2019.07.29	Report date	2019.08.09	Re- test date	2022.07.12
Analysis basis	< Benzhexol hydrochloride analysis operating procedures > (SOP- QC086) & < Promestriene quality standard > (SPS- C004)				

Test item specification Results

Conclusion

### Characters

Appearance	White, light crystalline powder, odorless	White, light crystalline powder, odorless	Complied
solubility	Dissolved in methanol, ethanol or chloroform, slightly soluble in water	Dissolved in methanol, ethanol or chloroform, slightly soluble in water	Complied

### Identification

Melting point	112~116℃	115.1~115.6℃	Complied
IR	Complied with that of the reference spectrum(NO.366 picture in the spectrum)	Complied with that of the reference spectrum	Complied
Chloride	Show the identification reaction of chloride	Show the identification reaction of chloride	Complied

### Test

Optical rotation	- 0.10 <sup>0</sup> to +0.10 <sup>0</sup>	+0.02 <sup>0</sup>	Complied
Chlorine content	10.3%~10.7% ( Calculated on dried basis )	10.4%	Complied
PH	5.0~6.0	5.4	Complied
Piperidine	According to the	0.34	Complied

phenylacetone	ultraviolet visible spectrophotometry, the absorbance shall not be greater than 0.5 at the wavelength of 247nm			
Related Substances	Single impurity NMT 0.5%, Total impurities NMT 1.0%	Single impurity NMT 0.03%, Total impurities 0.05%		Complied
Loss on drying	NMT 0.5%	0.1%		Complied
Residue on ignition	NMT 0.1%	0.08%		Complied
Heavy metals	NMT 20ppm	Complied		Complied
<b>Assay</b>	C <sub>20</sub> H <sub>31</sub> NO · HCL Calculated on dried basis NLT 98.0%	100.5%		Complied
<b>Microbial limit</b>	Total aerobic: NMT 10 <sup>3</sup> cfu/g; Total mould and yeast: NMT 10 <sup>2</sup> cfu/g; Escherichia coli: no detection	Total aerobic: NMT 10cfu/g; Total mould and yeast: NMT 10cfu/g; Escherichia coli: no detection		Complied

Test conclusion: According to < Benzhexol hydrochloride analysis operating procedures > (SOP- QC086) & < Promestriene quality standard > (SPS- C004), this product is analyzed, and the results are complied.

Reporter: Junwei Geng  
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Reviewer: Dongxue Liu

Director:

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