

# ROCHEM INTERNATIONAL, INC.

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## PRODUCT SPECIFICATION

### Liraglutide

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Version No: 400183-000

<b>Product Name:</b>	Liraglutide
<b>Batch Number:</b>	XXXXXXXXXXXXXX
<b>Batch Size:</b>	XXXXXXX
<b>Manufactured Date:</b>	XXXXXXX
<b>Expiry/Expiration/Retest Date:</b>	XXXXXXX
<b>CAS No.:</b>	204656-20-2
<b>ITEMS</b>	<b>SPECIFICATIONS</b>
<b>Appearance:</b>	White or Almost White
<b>Assay:</b> (Anhydrous substance)	95.0%-105.0%
<b>Identification:</b> A) Identification by HPLC B) Amino Acid Content	Retention Time is same with the reference substance Asp: 0.9 to 1.1 Ser: 2.7 to 3.3 Glu: 4.5 to 5.5 Gly: 3.6 to 4.4 His: 0.9 to 1.1 Arg: 1.8 to 2.2 Thr: 1.8 to 2.2 Ala: 3.6 to 4.4 Tyr: 0.9 to 1.1 Val: 1.8 to 2.2 Lys: 0.9 to 1.1 Ile: 0.9 to 1.1 Leu: 1.8 to 2.2 Phe: 1.8 to 2.2
<b>pH:</b>	5.5 to 7.0
<b>Specific Optical Rotation:</b>	-15.0° to -25.0°
<b>Related Substances: (HPLC)</b> <b>Impurity A:</b> <b>Impurity B:</b> <b>Impurity C:</b> <b>Impurity D:</b> <b>Impurity E:</b> <b>Any Other Impurity:</b>	NMT 0.3% NMT 0.5% NMT 0.5% NMT 0.5% NMT 0.3% NMT 0.2%

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<b>Total impurities:</b>	NMT 2.0%
<b>High Molecular Protein:</b>	≤ 1.0%
<b>Residual Solvents:</b>	Methylene Chloride: NMT 600 ppm Isopropylether: NMT 5000 ppm Methanol: NMT 3000 ppm Acetonitrile: NMT 410 ppm N,N- Dimethylformamide: NMT 880 ppm
<b>Acid Group Anion:</b>	Chloride Ion : NMT 5000 ppm Trifluoroacetic ion (TFA) : NMT 5000 ppm Phosphate Ion: NMT 5000 ppm
<b>Bicarbonate:</b>	NMT 20000 ppm
<b>Water ( Karl Fischer):</b>	NMT 8.0%
<b>Bacterial Endotoxins:</b>	Report Results

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