

## Annexure-I

### Specifications for DOTA-(Tyr3)-Octreotate GMP-grade

Amino acid Sequence: DOTA-DPhe-Cys-Tyr-DTrp-Lys-Thr-Cys-Thr-OH (Disulphide bridge: Cys<sup>2</sup>-Cys<sup>7</sup>)

#### Specifications & Appearance/Limits

Appearance: White to off-white lyophilized amorphous substance

Molecular mass: 1434.6 – 1436.6

Identity by HPLC: Co-elutes with reference standard +/- 0.5 minute (HPLC Chromatogram to be provided)

Amino Acid Contents:

Thr: 1.6-2.2,

Tyr: 0.9-1.1,

Phe: 0.9-1.1,

Lys: 0.9-1.1

Purity: ≥ 95% (Method to be described)

Related substances impurity

Any single impurity: ≤ 1%

Total of all impurities: ≤ 5%

Peptide content: ≥ 86%

Water content: ≤ 14% (w/w)

Acetate content: ≤ 5% (w/w)

Trifluoroacetic acid content: ≤ 1% (w/w)

Mass balance: 90-105%

Bioburden: ≤ 50 CFU/mg

Bacterial endotoxins: ≤ 6 EU/mg

Special Clause:

Batch specific COA mentioning purity levels from manufacturer end and all the above parameters are required to be provided.

A sample COA mentioning all the above parameters are required to be furnished along with quotation. During supply of material actual batch specific CoA to be provided.

Retest date/ Shelf life of the indented DOTATATE should be atleast 2 years from the date of release of purchase order.

Sample to be provided for analysis at R/No. 131/105, 1<sup>st</sup> floor, Radiation Medicine Centre, TMH Annexe, Jerbai Wadia Rd., Parel, Mumbai-4000012 in refrigerated condition along with quotation.



