3.2.P.5.6     JUSTIFICATION OF SPECIFICATIONS (2 MG/VIAL)

The release and shelf-life specifications for the drug product and their justifications are provided below.

**Appearance of lyophilizate**

Specification:      White to off-white lyophilized powder or cake

The physical characteristics of the lyophilized peptide are clearly described. Other colors or appearance can indicate impurities or a property change.

**Primary packaging material**

Specification:             Colourless 2R glass vial with grey rubber stopper, sealed with aluminum flip-top cap with blue (2 mg) or green (5 mg) plastic disc

The check of the appearance of the packaging materials ensures that the appropriate container is used.

**Identity of bulevirtide**

Specification:      A. The retention time of the main peak in the sample solution corresponds to the retention time of the main peak in the reference solution.

   B. The UV spectrum of the main peak in the sample solution corresponds to the UV spectrum time of the main peak in the reference solution.

The identification of bulevirtide is unambiguously ensured by the use of two independent specific analytical procedures i.e. HPLC and UV.

**Water content**

Specification:             ≤ 10% (Karl-Fischer titration)

The water content helps establish a uniform physical characteristic of the drug product. It is also ensured that water will potentially have no impact on purity during long term storage. Water content varies for each type of peptide but is typically ≤ 10%.