

Attachment 1 to Price Inquiry NUSI/124/PR113373/2025--QUALITY REQUIREMENTS

No.	SUBJECT OF THE PRICE INQUIRY	QUANTITY	UNIT	QUALITY REQUIREMENTS	REQUIRED DELIVERY DATE
NUSINERSEN SODIUM					
1.	Nusinersen sodium 5'-TCA CTT TCA TAA TGC TGG-3' A, T, G, C: 2'-O-methoxyethyl C: 5-Methyl-C All PS	10	g	sequence - conforms to standard substance sequence molecular weight - conforms to standard substance molecular weight retention time - conforms to standard substance retention time melting temperature - conforms to standard substance melting temperature $\pm 2,0$ °C water content - not more than 15% sodium content - in range 4.3-6.1% assay calculated on anhydrous and solvent free substance - in range 90.0-102.0% content of P=O(1) impurity - not more than 2.0% single unspecified impurity - not more than 0.50% purity - not less than 95.0% early eluting impurities - not more than 1.0% (impurities derived from the Nusinersen sequence due to removal of two or more nucleotides) late eluting impurities - not more than 1.0% (impurities consists of branched and cross-linked species) acetonitrile content - not more than 410 ppm other solvents - not more than 10% of ICH limit phosphates content - not more than 500 ppm chlorides content - not more than 5000 ppm acetates content - not more than 500 ppm no other anions present in the sample	not later than 21.07.2025