

## QUALITY VALIDATION FOR GENSULIN N 100 IU/ML PRODUCTS

**PRODUCT QUALITY TESTING RESULTS FOR THE PARAMETER. *CONTENT OF IMPURITIES OF MOLECULAR WEIGHT EXCEEDING INSULIN MOLECULAR WEIGHT\****

Examined parameter	Acceptance criteria (at release)	Results %	
		10 ml vial	3 ml cartridge
Content of impurities of molecular weight exceeding insulin molecular weight	no more than 1,0%	0.16 %	0.18%

Product quality for the selected parameter i.e. *Content of impurities of molecular weight exceeding insulin molecular weight* was presented based on values obtained for Gensulin N batches manufactured in 2017