

QUALITY VALIDATION FOR GENSULIN R 100 IU/ML PRODUCTS

RESULTS OF LONG-TERM STABILITY TESTING FOR KEY PARAMETERS PERFORMED AT THE TEMPERATURE OF 5°C ± 3°C FOR THE PERIOD OF 36 MONTHS*

Examined parameter	Acceptance criteria (in shelf life)	Results/Time points in which testing occurred (months)			
		0	12	24	36
Human insulin content	95.0-105.0 IU/mL	102.2 IU/mL	102.4 IU/mL	102.9 IU/mL	101.5 IU/mL
Content of impurities of molecular weight exceeding insulin molecular weight	≤2.0%	0.1%	0.2%	0.3%	0.5%
Related proteins: - A21-desamido insulin - Related proteins in total (without A21-desamido insulin)	≤2.5% ≤3.0%	0.1% 0.9%	0.1% 1.1%	0.1% 1.3%	0.1% 1.5%

* Presented based on results for Gensulin R batches tested between 2014 and 2017.

MEDICINAL PRODUCT IN-USE TEST (IN-USE STABILITY TESTING AT THE TEMPERATURE OF 25°C ± 2°C*)

Examined parameter	Acceptance criteria (in shelf life)	Results/ Time points in which testing occurred (weeks)		
		0	4	6
Human insulin content	95.0-105.0 IU/mL	101.6 IU/mL	100.9 IU/mL	99.9 IU/mL
Content of impurities of molecular weight exceeding insulin molecular weight	≤2.0%	0.1%	0.2%	0.3%
Related proteins: - A21-desamido insulin - Related proteins in total (without A21-desamido insulin)	≤2.5% ≤3.0%	0.2% 0.9%	0.4% 1.3%	0.3% 1.4%

* Presented based on results for Gensulin R batches tested in 2017.

**MEDICINAL PRODUCT IN-USE TEST (IN-USE STABILITY TESTING AT THE TEMPERATURE OF 30°C ± 2°C
RH=75%±5%*)**

Examined parameter	Acceptance criteria (in shelf life)	Results/ Time points in which testing occurred (weeks)		
		0	4	6
Human insulin content	95.0-105.0 IU/mL	101.6 IU/mL	100.9 IU/mL	99.9 IU/mL
Content of impurities of molecular weight exceeding insulin molecular weight	≤2.0%	0.2%	0.5%	0.6%
Related proteins: - A21-desamido insulin - Related proteins in total (without A21-desamido insulin)	≤2.5% ≤3.0%	0.2% 1.1%	0.4% 1.6%	0.3% 2.1%

* Presented based on results for Gensulin R batches tested in 2017.