2.1.P.5.1 Specification of Ivermectin 3 mg tablet

Ivermectin 3 mg tablet is tested according to the specification detailed below. The specification is for release and shelf-life.

Tests	*Methods*	*Acceptance criteria*	*Frequency*
Appearance	visual	White or almost-white biconvex tablet, "I" on one side	every batch
Identification[1] (Ivermectin)	*HPLC*	Identical	every batch
Dimensions diameter: height:		 6.0 ± 0.2 mm 1.5 – 2.2 mm	every batch
Average mass	*Ph.Eur. [2.9.5]*	60.0 mg ± 5 %	every batch
Uniformity of Mass	*Ph.Eur. [2.9.5]*	Average mass ± 10 % (18/20) Average mass ± 20 % (20/20)	every batch
Hardness	*Ph.Eur. [2.9.8]*	NLT* 25 N	every batch
Friability	*Ph.Eur. [2.9.7]*	NMT* 1.0 %	every batch
Disintegration	*Ph.Eur. [2.9.1]*	NMT* 15 min	every batch
Dissolution	*Ph.Eur. [2.9.3]*	NLT* 80% (Q) in 15 min	every batch
Assay:	*HPLC*	3.0 mg ± 5 %/tablet	every batch
Uniformity of dosage units[1]	*Ph.Eur. [2.9.40]*	AV≤15[§]	every batch
Related substances *HPLC* - impurity D - impurity with RRT 1.4 - Any individual unspecified impurity - Total impurities (except D)		 NMT*2.0 % NMT*2.7 % NMT*1.0 % NMT*6.0 %	every batch
Loss on Drying		NMT* 6.0 %	every batch
Microbiological purity	*Ph.Eur. [2.9.12]* *[2.9.13]*	TAMC ≤ 10^3 CFU/g TYMC ≤ 10^2 CFU/g Absence of Escherichia coli/g	every batch

[1] Test is not included in shelf-life specification.
* NLT: Not less than, NMT: Not more than
[§] The acceptance value of the first 10 dosage units is less than L1. If the acceptance value is greater than L1, test 20 additional dosage units and calculate the acceptance value. The final acceptance value is less than L1, and no individual content of the dosage unit is less than (1-L2x0.01)M, or more than (1+L2x0.01)M. L1 is 15, L2 is 25.