2.1.P.5.1 Specification

Hydroxychloroquine MEDITOP 200 mg film-coated 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, round, biconvex, film-coated tablets	every batch
Identification[1] (Hydroxychloroquine sulphate)	*HPLC*	Identical	every batch
Identification[1] (Hydroxychloroquine sulphate)	*IR*	Identical	every batch
Diameter		9.0 ± 0.2 mm	every batch
Thickness		4.0 – 4.7 mm	every batch
Average mass	*Ph.Eur. [2.9.5]*	315.0 mg ± 5 %	every batch
Uniformity of Mass	*Ph.Eur. [2.9.5]*	Average mass ± 5 % (18/20) Average mass ± 10 % (20/20)	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*	200.0 mg ± 5 %/film-coated tablet	every batch
Uniformity of dosage units[1]	*Ph.Eur. [2.9.40]*	AV≤15[§]	every batch
Related substances *HPLC*			every batch
- Impurity B		NMT*0.15 %	
- Impurity C		NMT*0.4 %	
- Any individual unspecified degradation product		NMT*0.10 %	
- Total impurities		NMT*0.6 %	

Tests	*Methods*	*Acceptance criteria*	*Frequency*
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

*NMT: Not more than, NLT: Not less 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.

[1] Test is not included in shelf-life specification.