2.1.P.5.4 Batch of Analyses

1 Description of Batches

Batch No.	Date of Manufacturing	Batch Size (dose units)	Manufacturing site
HI12001	02.2021	100 000	MEDITOP Pharmaceutical Ltd.
HI12002	02.2021	100 000	MEDITOP Pharmaceutical Ltd.
HI12003	02.2021	100 000	MEDITOP Pharmaceutical Ltd.

2 Results of Batch Analysis

Six batches were tested according to drug product specification.

Tests	Requirements	Results
		HI12001
Appearance	White or almost white, round, biconvex, film-coated tablet	complies
Identification (HPLC)	Identical	identical
Identification (IR)	Identical	identical
Diameter	9.0 ± 0.2 mm	8.96
Thickness	4.0 – 4.7 mm	4.40
Average mass	315.0 mg ± 5 %	314.3
Uniformity of mass	Average filling mass ± 5% (18/20) Average filling mass ± 10% (20/20)	311.0-318.5
Disintegration	NMT*15 min	10'36"
Dissolution	NLT* 80% (Q) in 15 min	99.31
Assay	200.0 mg ± 5 %/ film-coated tablet (95.0 % – 105.0 % of the label claim)	209.22
Uniformity of dosage units	AV≤15	complies
Related substances -Impurity B[1] -Impurity C[2] -Any individual unspecified degradation product -Total impurities	 NMT* 0.15 % NMT* 0.4 % NMT* 0.10 % NMT* 0.6 %	 0.02 0.08 0.04 0.22
Loss on Drying	NMT* 6.0 %	1.88
Microbiological purity	TAMC ≤ 10^3 CFU/g TYMC ≤ 10^2 CFU/g Absence of Escherichia coli/g	50 <100 negative

*NLT: not less than, NMT: not more than;

[1] 2-[[(4RS)-4-[(7-chloroquinolin-4-yl)amino]pentyl]-(ethyl)amino]ethyl hydrogen sulphate

[2] 2-[[(4RS)-4-[(7-chloroquinolin-4-yl)amino]pentyl]-(ethyl)amino]ethan-1-ol

Tests	Requirements	Results
		HI12002
Appearance	White or almost white, round, biconvex, film-coated tablet	complies
Identification (HPLC)	Identical	identical
Identification (IR)	Identical	identical
Diameter	9.0 ± 0.2 mm	8.92
Thickness	4.0 – 4.7 mm	4.39
Average mass	315.0 mg ± 5 %	314.0
Uniformity of mass	Average filling mass ± 5% (18/20) Average filling mass ± 10% (20/20)	310.5-318.0
Disintegration	NMT*15 min	8'54"
Dissolution	NLT* 80% (Q) in 15 min	99.95
Assay	200.0 mg ± 5 %/ film-coated tablet (95.0 % – 105.0 % of the label claim)	208.43
Uniformity of dosage units	AV≤15	complies
Related substances -Impurity B[1] -Impurity C[2] -Any individual unspecified degradation product -Total impurities	 NMT* 0.15 % NMT* 0.4 % NMT* 0.10 % NMT* 0.6 %	 0.02 0.09 0.04 0.22
Loss on Drying	NMT* 6.0 %	1.95
Microbiological purity	TAMC ≤ 10^3 CFU/g TYMC ≤ 10^2 CFU/g Absence of Escherichia coli/g	50 <100 negative

*NLT: not less than, NMT: not more than;
[1] 2-[[(4RS)-4-[(7-chloroquinolin-4-yl)amino]pentyl]-(ethyl)amino]ethyl hydrogen sulphate
[2] 2-[[(4RS)-4-[(7-chloroquinolin-4-yl)amino]pentyl]-(ethyl)amino]ethan-1-ol

Tests	Requirements	Results
		HI12003
Appearance	White or almost white, round, biconvex, film-coated tablet	complies
Identification (HPLC)	Identical	identical
Identification (IR)	Identical	identical
Diameter	9.0 ± 0.2 mm	8.94
Thickness	4.0 – 4.7 mm	4.40
Average mass	315.0 mg ± 5 %	314.8
Uniformity of mass	Average filling mass ± 5% (18/20) Average filling mass ± 10% (20/20)	211.8-322.8
Disintegration	NMT*15 min	10'13"
Dissolution	NLT* 80% (Q) in 15 min	99.83
Assay	200.0 mg ± 5 %/ film-coated tablet (95.0 % – 105.0 % of the label claim)	209.24
Uniformity of dosage units	AV≤15	complies
Related substances -Impurity B[1] -Impurity C[2] -Any individual unspecified degradation product -Total impurities	 NMT* 0.15 % NMT* 0.4 % NMT* 0.10 % NMT* 0.6 %	 0.01 0.09 0.04 0.20
Loss on Drying	NMT* 6.0 %	1.99
Microbiological purity	TAMC ≤ 10^3 CFU/g TYMC ≤ 10^2 CFU/g Absence of Escherichia coli/g	complies

*NLT: not less than, NMT: not more than;
[1] 2-[[(4RS)-4-[(7-chloroquinolin-4-yl)amino]pentyl]-(ethyl)amino]ethyl hydrogen sulphate
[2] 2-[[(4RS)-4-[(7-chloroquinolin-4-yl)amino]pentyl]-(ethyl)amino]ethan-1-ol