2.1.P.5.4 Batch of Analyses

1 Description of Batches

Batch No.	Date of Manufacturing	Batch Size (dose units)	Manufacturing site
IM15001	05.2021	100 000	MEDITOP Pharmaceutical Ltd.
IM15002	05.2021	100 000	MEDITOP Pharmaceutical Ltd.
IM15003	05.2021	100 000	MEDITOP Pharmaceutical Ltd.

2 Results of Batch Analysis

Three batches were tested according to drug product specifications.

Tests	Requirements	Results
		IM15001
Appearance	White or almost-white biconvex tablet, "I" on one side	complies
Identification (HPLC)	Identical	identical
Identification (IR)	Identical	identical
Dimensions	Diameter: 6.0 ± 0.2 mm Height: 1.5 – 2.2 mm	6.09 1.95
Average mass	60.0 mg ± 5 %	60.3
Uniformity of mass	Average mass ± 10% (18/20) Average mass ± 20% (20/20)	56.4-64.5
Hardness	NLT* 25 N	25 17-34
Friability	NMT* 1.0 %	0.51
Disintegration	NMT* 15 min	0'13"
Dissolution	NLT* 80% (Q) in 15 min	91.79
Assay	3.0 mg ± 5 %/tablet	2.94
Uniformity of dosage units	AV≤15	10.61
Related substances -Impurity D -Impurity RRT 1.4 -Any individual unspecified degradation product -Total impurities (except impurity D)	 NMT* 2.0 % NMT* 2.7 % NMT* 1.0 % NMT* 6.0 %	 0.19 1.78 0.54 3.10
Microbiological purity	TAMC ≤ 10^3 CFU/g TYMC ≤ 10^2 CFU/g Absence of Escherichia coli/g	<10 <10 negative

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

Tests	Requirements	Results
		IM15002
Appearance	White or almost-white biconvex tablet, "I" on one side	complies
Identification (HPLC)	Identical	identical
Identification (IR)	Identical	identical
Dimensions	Diameter: 6.0 ± 0.2 mm Height: 1.5 – 2.2 mm	6.09 1.91
Average mass	60.0 mg ± 5 %	60.3
Uniformity of mass	Average mass ± 10% (18/20) Average mass ± 20% (20/20)	56.2-63.7
Hardness	NLT* 25 N	28 19-48
Friability	NMT* 1.0 %	0.51
Disintegration	NMT* 15 min	0'11"
Dissolution	NLT* 80% (Q) in 15 min	94.66
Assay	3.0 mg ± 5 %/tablet	2.94
Uniformity of dosage units	AV≤15	11.08
Related substances -Impurity D -Impurity RRT 1.4 -Any individual unspecified degradation product -Total impurities (except impurity D)	 NMT* 2.0 % NMT* 2.7 % NMT* 1.0 % NMT* 6.0 %	 0.14 1.67 0.49 2.74
Microbiological purity	TAMC ≤ 10^3 CFU/g TYMC ≤ 10^2 CFU/g Absence of Escherichia coli/g	<10 <10 negative

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

Tests	Requirements	Results
		IM15003
Appearance	White or almost-white biconvex tablet, "I" on one side	complies
Identification (HPLC)	Identical	identical
Identification (IR)	Identical	identical
Dimensions	Diameter: 6.0 ± 0.2 mm Height: 1.5 – 2.2 mm	6.08 5.49
Average mass	60.0 mg ± 5 %	59.8
Uniformity of mass	Average mass ± 10% (18/20) Average mass ± 20% (20/20)	55.5-62.8
Hardness	NLT* 25 N	26 18-38
Friability	NMT* 1.0 %	0.51
Disintegration	NMT* 15 min	0'13"
Dissolution	NLT* 80% (Q) in 15 min	97.51
Assay	3.0 mg ± 5 %/tablet	2.91
Uniformity of dosage units	AV≤15	11.37
Related substances -Impurity D -Impurity RRT 1.4 -Any individual unspecified degradation product -Total impurities (except impurity D)	 NMT* 2.0 % NMT* 2.7 % NMT* 1.0 % NMT* 6.0 %	 0.14 1.33 0.50 2.73
Microbiological purity	TAMC ≤ 10^3 CFU/g TYMC ≤ 10^2 CFU/g Absence of Escherichia coli/g	<10 <10 negative

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