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Certificate of Analysis

Date of issue: 18/10/2024

Product Data

Product name: CIMETIDINA
Product code: 1040

Batch data

Batch number: 10402000022701 Manufacturing date: 19/09/2024 Retest date: 18/09/2029
Analysis: 890000006211

Specification	Result	Specification range	Unit	Method
Appearance	Complies	White or almost white powder		Appearance
Identification B (IR)	Positive	The spectrum of the major peak of the sample corresponds to that of the standard solution as obtained in Assay.		Identification by IR
Loss on drying	0.0	Max. 0.5	%	Loss on drying
Appearance of Solution	Complies	Must be clear and not more intensely coloured than Y5		Appearance of Solution
Sulphated Ash	0.0	Max. 0.2	%	Sulphated Ash
Assay (Titration)	99.4	98.5 - 101.5	%	Assay (Titration)
Impurity B	<0.05	Max. 0.2	%	Related Substances (HPLC)
Impurity C	<0.05	Max. 0.10	%	Related Substances (HPLC)
Impurity D	<0.05	Max. 0.10	%	Related Substances (HPLC)
Impurity E	<0.05	Max. 0.2	%	Related Substances (HPLC)
Impurity F	<0.05	Max. 0.2	%	Related Substances (HPLC)
Impurity G	0.1	Max. 0.2	%	Related Substances (HPLC)
Impurity H	<0.05	Max. 0.2	%	Related Substances (HPLC)
Any other impurity	0.05	Max. 0.10	%	Related Substances (HPLC)
Total impurities	0.1	Max. 1.0	%	Related Substances (HPLC)
Acetone	<3	Max. 1000	ppm	Residual Solvents (GC)
Ethanol	1950	Max. 5000	ppm	Residual Solvents (GC)
Isopropyl alcohol	99	Max. 500	ppm	Residual Solvents (GC)

METAPHARMACEUTICAL

N DE LOTE:

0251024

25/10/2024