

Certificate of analysis

Manufacturing site

Dipharma Francis S.r.l.
Via Bissone 5
20021 Baranzate MI
Italy
+39 02 382281

Issued QP

31.03.2023

Code

500340

Ref. DDT.

80014592

Ref. Order

10018461

Batch Nr.

2302779

Mfg. date

09.03.2023

Retest date

07.03.2028

Analysis nr.

40000060452

Buyer

30307

ITF -LABOMED FARMACEUTICA Ltda
Cerro El Plomo No.5420 of 1405
100011 SANTIAGO DE CHILE
Chile

End User

30307

ITF -LABOMED FARMACEUTICA Ltda

Product

TRIAMTERENE

TEST	UM	SPECIFICATIONS	REFERENCES	RESULTS
Description	-	Yellow crystalline powder.	EP/USP	Conform to description
Identification IR	-	Conform	EP/USP	Conform
Identification : HPLC	-	Conform	USP	Conform
Loss on drying	%	max 0,3	EP/USP	0,0
Residue on ignition	%	max 0,1	EP	0,0
Acidity or Alkalinity	-	Conform	EP	Conform
Nitrosotriaminopyrimidine (HPLC)	ppm	max 50	Company	< 0
4-Hydroxy (Imp.B EP) (HPLC)	%	max 0,1	Company	< 0,0
7-Hydroxy (IMP C EP) (HPLC)	%	max 0,1	Company	< 0,0
Each unknown impurity (HPLC)	%	max 0,10	Company	< 0,03
Total impurities (HPLC)	%	max 0,2	Company	0,0
Benzyl Cyanide (HPLC)	ppm	max 50	EP	< 10
Assay (potentiometric)	%	99,0 - 101,0	EP	99,6
Assay HPLC	%	98,0 - 102,0	Company	98,6
1-methoxy-2-propanol (GC)	ppm	max 200	Company	16
Nitrosotriaminopyrimidine (Imp. A EP) 4-Hydroxy = 2,7-diamino-4-hydroxy-6-phenylpteridine 7-Hydroxy = 2,4-diamino-7-hydroxy-6-phenylpteridine Benzyl Cyanide (Imp.D EP)				
Elemental impurities: none of the elemental impurity reported in ICHQ3D				

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TRIAMTERENE

TEST	UM	SPECIFICATIONS	REFERENCES	RESULTS
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is likely to be present

Name and Surname: Andrea Ferri
Title: Quality Control
Approved
Date: 24.03.2023 14:52:19

Name and Surname: MARTINA RUBES
Title: Quality Assurance
Approved
Date: 29.03.2023 09:37:36