

Siegfried

Siegfried Evionnaz SA
Route du Simplon 1,36
1902 Evionnaz
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+41 27 766 12 00
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CERTIFICATE OF ANALYSIS

Material No:	702089	Manufacturing date:	06-Sep-2019
Name:	Metolazone	Retest date:	06-Sep-2024
Quality:	USP, Ph. Eur.	Specification date:	28-Jan-2019
Lot No:	19344043		
CAS No.	17560-51-9		
Formula:	-		
Molecular Weight:	-		

Test	Method	Specification	Result
DESCRIPTION	14905__DEF00100	white to off-white crystalline powder	Complies
IDENTIFICATION UV	14905__DEF00300	UV : complies with reference	Complies
IDENTIFICATION IR(I)	14905__DEF00400	IR : complies with USP reference of gamma crystalline form	Complies
IDENTIFICATION HPLC	14905__DEF06100	RT complies with reference standard	Complies
DSC	14905__DEF11100	250 - 275 °C, only one peak	265.0 °C
LOSS ON DRYING	14905__DEF01200	max. 1.0 %	0.2 %
SOLUBILITY	14905__DEF00700	clear solution	Complies
HEAVY METALS	14905__DEF01600	max. 15 ppm	Complies
SULPHATED ASHES	14905__DEF01300	max. 0.1 %	0.0 %
ASSAY (HPLC)	14905__DEF03400	97.0 - 102.0 % (on the dried substance)	99.4 %
IMPURITIES (HPLC)	14905__DEF07300	Impurity A of EP / Meta-Metolazone of USP: max. 0.5 %	0.3 %
	14905__DEF07300	Impurity B of EP / Para-Metolazone of USP: max. 0.5 %	0.0 %
	14905__DEF07300	Impurity C of EP / Desmethylmetolazone of USP: max. 0.5 %	0.0 %
	14905__DEF07300	Impurity D of EP / Didehydrometolazone of USP: max. 0.5 %	0.0 %
	14905__DEF07300	Impurity E of EP / Metolazone benzamide of USP: max. 0.5 %	0.0 %
	14905__DEF07300	any unknown impurity: max. 0.10 %	0.00 %
	14905__DEF07300	sum of unknown impurities: max. 0.3 %	0.0 %
	14905__DEF07300	sum of all impurities: max. 1.0 %	0.3 %
BULK DENSITY	14905__DEF02600	indicative	291 g/L
PARTICLES SIZE	14905__DEF02500	D 90: max. 50 µm	27 µm
	14905__DEF02500	D 50: max. 25 µm	13 µm
	14905__DEF02500	D 10: max. 10 µm	4 µm
RESIDUAL SOLVENTS	14905__DEF18600	Ethanol: max. 2500 ppm	1384 ppm
	14905__DEF18600	Methanol: max. 100 ppm	0 ppm
	14905__DEF18600	Dichloromethane: max. 500 ppm	0 ppm

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Release comment: **meets specification**

Released On: **15-Oct-2019**
on behalf of Siegfried Evionnaz SA

Released By: **LAGE ANNE**
QA-Manager

This document was created electronically and is valid without signature.

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