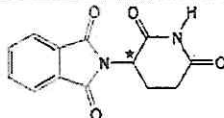


THALIDOMIDE CERTIFICATE OF ANALYSIS**V01**

1/2

		SPE n° CQ - 214, vs 21
C ₁₃ H ₁₀ N ₂ O ₄	CAS RN [50-35-1] – EINECS : 200-031-1	M.W. = 258.23 g.mol ⁻¹
(R,S) 1 <i>H</i> -Isoindole-1,3 (2 <i>H</i>)-dione, 2-(2,6-dioxo-3-piperidiny)-, (±)- (±)- <i>N</i> -(2,6-Dioxo-3-piperidyl)phthalimide α-(<i>N</i> -Phthalimido)glutarimide		

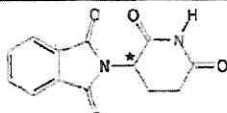
BATCH N°: NPBX-065

TESTS	METHODS / LABS	SPECIFICATIONS	RESULTS
APPEARANCE	Visual examination MOD n°: CQ - 215	White to off-white powder	White crystalline powder
IDENTIFICATION			
A : Infra-red spectrum	USP (197K) MOD n°: CQ - 215	Spectrum is consistent with Reference Standard "α-(alpha)-Thalidomide"	Comply
B : Identification HPLC	MOD n°: CQ - 215	The retention time of the major peak of the sample solution corresponds to that of the standard solution	Comply
PHYSICO-CHEMICAL TESTS			
Water content	USP (921) MOD n°: CQ - 215	≤ 0.5 %	0.3%
Limit of Glutamine	USP <466> MOD n°: CQ - 215	Individuals impurities ≤ 0.1%	<0.1%
Organic Impurities	USP <621> MOD n°: CQ - 215	Individuals impurities ≤ 0.1% Total impurities ≤ 0.3%	0.0% 0.0%
Assay (HPLC)	USP <621> MOD n°: CQ - 215	98.0% - 101.5% of C ₁₃ H ₁₀ N ₂ O ₄ calculated on anhydrous basis	100.4%
Residual Solvents	USP <621> MOD n°: CQ - 215	Methanol ≤ 3000 ppm Xylenes ≤ 2000 ppm Cyclohexanone ≤ 500 ppm Diethyleneglycol dibutyl ether ≤ 1000 ppm	44 ppm 43 ppm Not detected Not detected
		Dimethylformamide ≤ 880 ppm	747 ppm

Written by : Isabelle DORIN		Reviewed by : J. SEBILLOT	
Date : 30/01/2023	Visa : 	Date : 31/01/23	Visa : JSE

THALIDOMIDE CERTIFICATE OF ANALYSIS V01

2/2

		SPE n° CQ - 214, vs 21
C ₁₃ H ₁₀ N ₂ O ₄	CAS RN [50-35-1] – EINECS : 200-031-1	M.W. = 258.23 g.mol ⁻¹
(R,S) 1 <i>H</i> -Isoindole-1,3 (2 <i>H</i>)-dione, 2-(2,6-dioxo-3-piperidiny)-, (±)- (±)- <i>N</i> -(2,6-Dioxo-3-piperidyl)phthalimide α-(<i>N</i> -Phthalimido)glutarimide		

BATCH N°: NPBX-065

TESTS	METHODS / LABS	SPECIFICATIONS	RESULTS
Optical Rotation	CEBIPHAR Method n° MAN.287	0.00 (°) ± 0.05 (°) (20 mg.mL ⁻¹ , DMF, 25°C, 1 dm)	0.00°
Microbial Limit Tests	USP (61) / Ph. Eur. 2.6.12 USP (62) / Ph. Eur. 2.6.13 ACM Pharma	TAMC ≤ 10 ³ CFU/g TYMC ≤ 10 ² CFU/g	10 CFU/g <10 CFU/g

MANUFACTURING DATE	September 2022		
RETEST DATE	September 2027		
ANALYSES	Date : 01/12/2022 Pharma / CébiPhar	By: A.MANCEAU / C.COUPÉAU / Labservice / ACM	
CONCLUSION :	COMPLIANT WITH CURRENT SPECIFICATION		

Written by : Isabelle DORIN		Reviewed by : J. SEBILLO	
Date : 30/01/2023	Visa : 	Date : 31/01/23	Visa : JSE