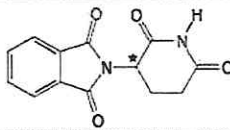


## THALIDOMIDE CERTIFICATE OF ANALYSIS

### V01

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

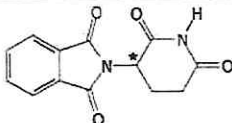
### BATCH N°: NPBX-065

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

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

### BATCH N°: NPBX-065

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

|                    |                                                                                        |
|--------------------|----------------------------------------------------------------------------------------|
| MANUFACTURING DATE | September 2022                                                                         |
| RETEST DATE        | September 2027                                                                         |
| ANALYSES           | Date : 01/12/2022<br>Pharma / Cébiphar<br>By: A.MANCEAU / C.COUPÉAU / Labservice / ACM |
| CONCLUSION :       | COMPLIANT WITH CURRENT SPECIFICATION                                                   |

|                                                                                                                 |                               |
|-----------------------------------------------------------------------------------------------------------------|-------------------------------|
| Written by : Isabelle DORIN                                                                                     | Reviewed by : J. SEBILLO      |
| Date : 30/01/2023<br>Visa :  | Date : 31/01/23<br>Visa : JSE |