

| Ciserano, 15/09/2020                                                                                                                                                                                                                            |                                       |                                                                                                                                      |                           |                               |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|---------------------------|-------------------------------|
| <b>ANALYSIS No. F602/2020</b>                                                                                                                                                                                                                   |                                       | <b>BATCH No. 102820018</b>                                                                                                           |                           |                               |
| Manufacturing date: <b>June 2020</b>                                                                                                                                                                                                            |                                       | Retest date: <b>June 2025</b>                                                                                                        |                           | Batch size: <b>1138,00 Kg</b> |
| <b>PRODUCT</b>                                                                                                                                                                                                                                  |                                       | <b>PROPRANOLOL HYDROCHLORIDE USP / PH. EUR.</b><br><b>CAS N. 318-98-9</b>                                                            |                           |                               |
| <b>Physical State:</b> crystalline powder<br><b>Colour:</b> white to off-white<br><b>Odour:</b> odourless<br><b>Solubility:</b> Soluble in water and Ethanol 96%, slightly soluble in Chloroform and practically insoluble in Ether and Heptane |                                       | <b>Molecular weight:</b> 295.81<br><b>Formula :</b> C <sub>16</sub> H <sub>21</sub> NO <sub>2</sub> .HCl<br><b>Method No.</b> 1028/1 |                           |                               |
| DETERMINATIONS                                                                                                                                                                                                                                  | RESULTS                               | LIMITS USP                                                                                                                           | LIMITS EP                 | IN-HOUSE LIMITS               |
| <b>IDENTIFICATION</b>                                                                                                                                                                                                                           |                                       |                                                                                                                                      |                           |                               |
| <i>I.R. spectrum</i>                                                                                                                                                                                                                            | Positive                              | Positive                                                                                                                             | Positive                  |                               |
| <i>HPLC</i>                                                                                                                                                                                                                                     | Positive                              | Positive                                                                                                                             |                           |                               |
| <i>Chlorides test</i>                                                                                                                                                                                                                           | Positive                              | Positive                                                                                                                             | Positive                  |                               |
| <i>Melting point</i>                                                                                                                                                                                                                            | 163.5 °C - 164.1 °C                   |                                                                                                                                      | min. 163°C<br>max. 166°C  |                               |
| <b>Acidity or alkalinity</b>                                                                                                                                                                                                                    | Conform                               |                                                                                                                                      | Conform                   |                               |
| <b>Clarity and colour of solution</b><br>(10% in methanol)                                                                                                                                                                                      | Clear<br>n.m.t. brown-yellow degree 6 |                                                                                                                                      | Clear<br>n.m.t. degree 6  |                               |
| <b>Loss on drying</b>                                                                                                                                                                                                                           | 0.10 %                                | n.m.t. 0,5%                                                                                                                          | n.m.t. 0,5%               |                               |
| <b>Sulphated ash</b>                                                                                                                                                                                                                            | 0.044 %                               | n.m.t. 0,1%                                                                                                                          | n.m.t. 0,1%               |                               |
| <b>ASSAY</b>                                                                                                                                                                                                                                    |                                       |                                                                                                                                      |                           |                               |
| <i>NaOH 0,1N (on dried substance)</i>                                                                                                                                                                                                           | 100.61 %                              |                                                                                                                                      | min. 99,0%<br>max. 101,0% |                               |
| <i>HPLC (on dried substance)</i>                                                                                                                                                                                                                | 99.74 %                               | min. 98,0%<br>max. 102,0%                                                                                                            |                           |                               |
| <b>Related substances (HPLC)</b>                                                                                                                                                                                                                |                                       |                                                                                                                                      |                           |                               |
| <b>Labelled Impurities</b>                                                                                                                                                                                                                      |                                       |                                                                                                                                      |                           |                               |
| <i>Diol</i>                                                                                                                                                                                                                                     | Not detectable                        |                                                                                                                                      | n.m.t. 0,10%              |                               |
| <i>Teramine</i>                                                                                                                                                                                                                                 | 0.02 %                                |                                                                                                                                      | n.m.t. 0,10%              |                               |
| <i>Bis ether</i>                                                                                                                                                                                                                                | 0.01 %                                |                                                                                                                                      | n.m.t. 0,10%              |                               |
| <b>Unknown Impurity Max</b>                                                                                                                                                                                                                     | 0.01 %                                |                                                                                                                                      | n.m.t. 0,10%              |                               |
| <b>Total Impurities</b>                                                                                                                                                                                                                         | 0.05 %                                |                                                                                                                                      | n.m.t. 0,2%               |                               |

  
 Qualified Person

  
 Quality Control Manager

|                                                                                                                                    |                  |                                                                           |                  |                                  |
|------------------------------------------------------------------------------------------------------------------------------------|------------------|---------------------------------------------------------------------------|------------------|----------------------------------|
| Ciserano, 15/09/2020                                                                                                               |                  |                                                                           |                  |                                  |
| <b>ANALYSIS No.</b> F602/2020                                                                                                      |                  | <b>BATCH No.</b> 102820018                                                |                  |                                  |
| Manufacturing date: <b>June 2020</b>                                                                                               |                  | Retest date: <b>June 2025</b>                                             |                  | Batch size: <b>1138,00 Kg</b>    |
| <b>PRODUCT</b>                                                                                                                     |                  | <b>PROPRANOLOL HYDROCHLORIDE USP / PH. EUR.</b><br><b>CAS N. 318-98-9</b> |                  |                                  |
| <b>Physical State:</b> crystalline powder                                                                                          |                  | <b>Molecular weight:</b> 295.81                                           |                  |                                  |
| <b>Colour:</b> white to off-white                                                                                                  |                  | <b>Formula :</b> C16H21NO2.HCl                                            |                  |                                  |
| <b>Odour:</b> odourless                                                                                                            |                  | <b>Method No.</b> 1028/1                                                  |                  |                                  |
| <b>Solubility:</b> Soluble in water and Ethanol 96%, slightly soluble in Chloroform and practically insoluble in Ether and Heptane |                  |                                                                           |                  |                                  |
| <b>DETERMINATIONS</b>                                                                                                              | <b>RESULTS</b>   | <b>LIMITS USP</b>                                                         | <b>LIMITS EP</b> | <b>IN-HOUSE LIMITS</b>           |
| <b>FOREIGN SUBSTANCES</b>                                                                                                          |                  |                                                                           |                  |                                  |
| <i>Powders</i>                                                                                                                     | n.m.t. 15 ppm    |                                                                           |                  | n.m.t. 15 ppm                    |
| <b>Particle size</b>                                                                                                               | 82.2 %           |                                                                           |                  | n.l.t. 50% passes 53 mcm         |
| <b>Bulk density</b>                                                                                                                | 0.29 g/ml        |                                                                           |                  | min. 0,25 g/ml<br>max. 0,45 g/ml |
| <b>Tapped density</b>                                                                                                              | 0.56 g/ml        |                                                                           |                  | min. 0,40 g/ml<br>max. 0,60 g/ml |
| <b>RESIDUAL SOLVENTS</b>                                                                                                           |                  |                                                                           |                  |                                  |
| <i>Acetone</i>                                                                                                                     | Not quantifiable |                                                                           |                  | n.m.t. 500 ppm                   |
| <i>Toluene</i>                                                                                                                     | Not detectable   |                                                                           |                  | n.m.t. 300 ppm                   |

We hereby certify that the material identified above has been analysed and found in accordance with the specifications of USP and Ph. Eur..

 **Qualified Person**

**Release date:** 16/09/2020

 **Quality Control Manager**