



## TECHNICAL DATA SHEET

002926-TDS-ENG-2024

| NADOLOL (EUR. PH / USP)  |   |                          |
|--------------------------|---|--------------------------|
| DESCRIPTION DCI: NADOLOL |   | DESCRIPTION DOE: NADOLOL |
| CAS Nº: 42200-33-9       | EC Nº: 255-706-3  | AEMPS CODE: 548A         |
| MOL. WEIGHT: 309,4       | MOL. FORMULA: C <sub>17</sub> H <sub>27</sub> NO <sub>4</sub> | ARTICLE CODE: 002926     |

| ATTRIBUTES             | SHOULD BE   |
|------------------------|---|
| Appearance             | White or almost white, crystalline powder   |
| Solubility             | Slightly soluble in water, freely soluble in ethanol (96 %), practically insoluble in acetone |
| Identification         | Complies  |
| Racemate Content       |   |
| Ratio Aa/Ab            | 0.72 - 1.08   |
| Racemate A content     | 40 - 60 %   |
| Related substances     |   |
| Impurity A             | <= 0.2 %  |
| Impurity C             | <= 0.2 %  |
| Impurity D             | <= 0.2 %  |
| Unspecified impurities | <= 0.10 %   |
| Total impurities       | <= 0.5 %  |
| Loss on drying         | <= 2.0 %  |
| Sulfated ash           | <= 0.1 %  |
| Assay                  | 98.5 - 101.0 %  |

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

Keep tightly closed, in a dry and cool place.

### REMARKS

Nadolol is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.