



# METAPHARMACEUTICAL

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10/01/2023

## QUALITY CONTROL DEPARTMENT

## INTERMEDIATE OF ANALYSIS

## FINISHED GOODS

Product Name : PROPRANOLOL HYDROCHLORIDE Ph.Eur.

|               |            |                                 |                     |
|---------------|------------|---------------------------------|---------------------|
| Batch No. :   | 22131PRR11 | Batch Size :                    | 523.80 KG           |
| Mfg Date :    | Aug/2022   | Expiry Date :                   | Jul/2027            |
| Retest Date : | NA         | A.R.No. :                       | IBD-224058          |
| Lims AR No.:  | 2102-12725 | LIMS Specification No.:         | 2102-14             |
| Page No.:     | 1 of 2     | Specification No./Revision No.: | TS/API/PR/COS/2.0/5 |

| Tests                        | Specifications                                                                                                                             | Results      |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| Character                    | A white or almost white powder.                                                                                                            | White powder |
| Character [Solubility]       | Soluble in water and in ethanol (96%), practically insoluble in heptane.                                                                   | Conforms     |
| Identification 1             | Infrared absorption spectrum of the sample and standard are concordant.                                                                    | Conforms     |
| Identification 2             | Conforms by reaction (a) of chlorides.                                                                                                     | Conforms     |
| Appearance Of Solution       | The solution is clear and not more intensely coloured than intensity 6 of the range of reference solutions of the most appropriate colour. | Conforms     |
| Acidity [Or] Alkalinity      | The solution is red. Add 0.4 ml of 0.01 M sodium hydroxide. The solution is yellow.                                                        | Conforms     |
| Related Substances [By HPLC] | Impurity A : NMT 0.10%                                                                                                                     | BDL          |
|                              | Impurity B : NMT 0.10%                                                                                                                     | BQL          |
|                              | Impurity C : NMT 0.10%                                                                                                                     | Not Detected |
|                              | Any Unspecified Impurity : NMT 0.10%                                                                                                       | BDL          |
|                              | Total Impurities : NMT 0.20%                                                                                                               | BQL          |

|                                |                   |                   |                   |
|--------------------------------|-------------------|-------------------|-------------------|
| Checked By (QC)                | Brijesh Kumar     | Approved By (QA)  | Rajendra Singh    |
| Checked On                     | 21/Sep/2022 17:44 | Approved On       | 22/Sep/2022 18:00 |
| Printed By :<br>Rajendra Singh | Printed on :      | 22/Sep/2022 18:15 | Copy No. : 1      |

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| QUALITY CONTROL DEPARTMENT                       |            |                                 |                     |
|--------------------------------------------------|------------|---------------------------------|---------------------|
| CERTIFICATE OF ANALYSIS                          |            |                                 |                     |
| FINISHED GOODS                                   |            |                                 |                     |
| Product Name : PROPRANOLOL HYDROCHLORIDE Ph.Eur. |            |                                 |                     |
| Batch No. :                                      | 2213IPRRII | Batch Size :                    | 523.80 KG           |
| Mfg Date :                                       | Aug/2022   | Expiry Date :                   | Jul/2027            |
| Retest Date :                                    | NA         | A.R.No. :                       | IBD-224058          |
| Lims AR No.:                                     | 2102-12725 | LIMS Specification No.:         | 2102-14             |
| Page No.:                                        | 2 of 2     | Specification No./Revision No.: | TS/API/PR/COS/2.0/5 |

| Tests                                                                  | Specifications                                             | Results      |
|------------------------------------------------------------------------|------------------------------------------------------------|--------------|
| Loss On Drying                                                         | NMT 0.5%w/w                                                | 0.23% w/w    |
| Sulphated Ash                                                          | NMT 0.1%w/w                                                | 0.04% w/w    |
| Assay                                                                  | 99.0% - 101.0% of<br>$C_{16}H_{22}ClNO_2$ (on dried basis) | 100.0% [odb] |
| REMARKS : The Sample CONFORMS with respect to the above Specifications |                                                            |              |

|                                                                                       |                   |                   |                   |
|---------------------------------------------------------------------------------------|-------------------|-------------------|-------------------|
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| Checked On                                                                            | 21/Sep/2022 17:44 | Approved On       | 22/Sep/2022 18:00 |
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