




## COA: PROPOFOL (EP, GMP-WC, CEP)

This product has been sourced by Ofipharma.

The product will be supplied in the **original manufacturers** packaging and with the original certificate of analyses, our promise of complete transparency. We are able to **repack** your products under **GMP** into pack sizes you need. If required we are able to sample - analyze this product according the latest Pharmacopea.

Country of origin: INDIA

| CERTIFICATE OF ANALYSIS  |   |  |                       |
|--|---|--|-----------------------|
| COS No.  | R0-CEP 2015-347-Rev 02  |  |                       |
| PRODUCT  | PROPOFOL E. P.  |  |                       |
| BATCH NUMBER   | PRF/004/2020-2021   | A. R. NUMBER   | HFC/PRF/2020-2021/004 |
| DATE OF MANUFACTURING  | FEBRUARY 2021   | EXPIRY DATE  | JANUARY 2024          |
| TOTAL QTY.MANUFACTURED   | 30.00 kg  | DRUG LIC. NUMBER   | 849                   |
| DATE OF RELEASE  | 10.03.2021  |  |                       |
| TESTS  | RESULTS   | SPECIFICATIONS / LIMITS  |                       |
| *Appearance  | Colorless clear liquid  | Colorless or very light yellow, clear liquid.  |                       |
| *Solubility  | Complies  | Very slightly soluble in water, miscible with hexane and with methanol.  |                       |
| Identification   | Complies  | The IR spectrum of sample is concordant with spectrum of propofol working standard.  |                       |
| Refractive Index   | 1.513   | Between 1.5125 and 1.5145.   |                       |
| Related substances (By HPLC) Method I  | Below disregard limit   | Impurity G : NMT 0.2 % (LOQ:0.0015%)   |                       |
|  | 0.001%  | Impurity E : NMT 0.01 % (LOQ:0.0010%)  |                       |
|  | 0.04%   | Any Unspecified Impurity: NMT 0.05 % (LOQ:0.0005%)   |                       |
|  | 0.04%   | Total Impurities: NMT 0.3%   |                       |
| Related substances (By GC) Method II   | Below LOQ   | Impurity J : NMT 0.05 % (LOQ: 0.005%)  |                       |
|  | Below LOQ   | Impurity K: NMT 0.05 %   |                       |
|  | Below LOQ   | Impurity L : NMT 0.05 %  |                       |
|  | Below LOQ   | Impurity O : NMT 0.05 %  |                       |
| Assay (By HPLC)  | 100.8%  | Between 98.0% & 102.0%   |                       |
| Residual solvents (By GC) Method I   | Below LOQ   | Methanol : NMT 3000 ppm  | LOQ 75 ppm            |
|  | Below LOQ   | Isopropyl alcohol: NMT 5000 ppm  | 63 ppm                |
|  | Below LOQ   | Toluene : NMT 890 ppm  | 11 ppm                |
|  | Below LOQ   |  |                       |
| Residual solvents (By GC) Method II  | Below LOQ   | Ethylene glycol : NMT 310 ppm  | LOQ 25 ppm            |
| <b>Remarks:</b> The batch complies as per E.P. and In-house Specifications.  |   |  |                       |
| <b>*Note:</b> These tests are for information only.  |   |  |                       |
| Prepared by<br><br>(Jr. Executive Q. A.)<br>Date : 18/02/22 | Checked by<br><br>(Dy. Manager Q. C.)<br>Date : 18/02/22 | Approved and Released by<br>For Harman Finochem Ltd.<br><br>(Manager Q. A.)<br>Date : 18/02/22 |                       |

Ofipharma is a reliable supplier with end-to-end knowledge.

We successfully meet supplier guidelines on an ongoing basis.

We are compliant with the Falsified Medicines Directive and we only approve suppliers that have successfully completed the supplier qualification process  
Free support when you need it, free advice to meet your specific requirements harma

All details as received from our supplier

The above information does not constitute a guarantee as to the suitability of the product for a specific purpose and shall not release the user from his inspection obligations including, without limitation, its obligation to conduct all necessary release testing to ensure that the products distributed comply with all legal requirements and regulations.

If you have additional questions, don't hesitate to contact us at:

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