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# Ipca Laboratories Limited

P.O. SEJAVTA, 457 001, DIST. RATLAM (M. P.)



## METAPHARMACEUTICAL

## QUALITY DIVISION CERTIFICATE OF ANALYSIS

N DE LOTE:

0050125

NAME OF THE PRODUCT : CETIRIZINE DIHYDROCHLORIDE Ph. Eur.

BATCH No. : 24046CZ6R11 BATCH SIZE : 247.00 Kgs  
MFG. DATE : Sep. 2024 A. R. No. : IBDA - 243788  
EXP. DATE : Aug. 2029 DATE : 27/11/2024

SPECIFICATION No. / REV. No. : TS/API/CZ6/COS / 2.0

CUSTOMER NAME / ITEM CODE : NA

| TESTS                                                           | SPECIFICATIONS                                                                                                                                                                                                                                                                                                                                                                                                                 | RESULTS                                                                                                                                                                       |
|-----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| CHARACTERS                                                      | A white or almost white powder<br>Freely soluble in water, practically insoluble in acetone and in methylene chloride.                                                                                                                                                                                                                                                                                                         | White powder<br>Conforms                                                                                                                                                      |
| IDENTIFICATION                                                  | 1 The infrared absorption spectrum of sample and standard are concordant.<br>2 It gives reaction (a) of chlorides.                                                                                                                                                                                                                                                                                                             | Conforms<br>Conforms                                                                                                                                                          |
| APPEARANCE OF SOLUTION                                          | Solution is clear and not more intensely coloured than reference solution BY <sub>7</sub> .                                                                                                                                                                                                                                                                                                                                    | Conforms                                                                                                                                                                      |
| pH                                                              | 1.2 to 1.8                                                                                                                                                                                                                                                                                                                                                                                                                     | 1.53                                                                                                                                                                          |
| RELATED SUBSTANCES (By HPLC)                                    | Impurity A : NMT 0.15%<br>Impurity B : NMT 0.15%<br>Impurity C : NMT 0.15%<br>Impurity D : NMT 0.15%<br>Impurity E : NMT 0.15%<br>Impurity F : NMT 0.15%<br>Impurity G : NMT 0.10%<br>Cetirizine methyl ester : NMT 0.10%<br>3-Chlorocetirizine : NMT 0.10%<br>Cetirizine N-oxide : NMT 0.10%<br>4-CBH : NMT 0.10%<br>4-Chlorobenzophenone : NMT 0.10%<br>Any Unspecified impurity : NMT 0.10%<br>Total impurities : NMT 0.30% | Not Detected<br>< 0.05%<br>< 0.05%<br>Not Detected<br>0.07%<br>< 0.05%<br>< 0.05%<br>< 0.05%<br>Not Detected<br>Not Detected<br>Not Detected<br>< 0.05%<br>0.07%<br>0.13% w/w |
| LOSS ON DRYING (at 105°C)                                       | NMT 0.5% w/w                                                                                                                                                                                                                                                                                                                                                                                                                   | 0.13% w/w                                                                                                                                                                     |
| SULPHATED ASH                                                   | NMT 0.2% w/w                                                                                                                                                                                                                                                                                                                                                                                                                   | 0.06% w/w                                                                                                                                                                     |
| RESIDUAL SOLVENTS                                               | *Acetone : NMT 5000 ppm<br>*Acetone being Class III solvent, is limited by the Test for Loss on Drying to a limit of NMT 0.5%.                                                                                                                                                                                                                                                                                                 | -<br>-                                                                                                                                                                        |
| ASSAY                                                           | 99.0% - 101.0% of C <sub>21</sub> H <sub>27</sub> Cl <sub>3</sub> N <sub>2</sub> O <sub>3</sub> (on dried basis)                                                                                                                                                                                                                                                                                                               | 99.9% (odb)                                                                                                                                                                   |
| REMARKS : The above sample CONFORMS as per above Specifications |                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                               |

PREPARED BY

DATE : 27/11/2024

Reviewed By QA

Sign/Date:

28/11/24

MANAGER QUALITY CONTROL

DATE : 28/11/24