

CERTIFICATE OF ANALYSIS

| PRODUCT : METHYLPHENIDATE HYDROCHLORIDE USP | | | |
|--|---|--|--|
| BATCH No. : | | A.R. No. : | |
| MFG. DT. : NOVEMBER 2008 | | RELEASE DATE : 30.11.08 | |
| EXP. DT. : OCTOBER 2011 | | PAGE : 01 of 01 | |
| Sr.No. | TEST | SPECIFICATION | RESULT |
| 1. | Description | White, odorless, fine, crystalline powder. | White, odorless, fine, crystalline powder. |
| 2. | Solubility | Freely soluble in water, and Methanol. Soluble in alcohol, slightly soluble in Chloroform. | Complies. |
| 3. | Identification | IR absorption spectrum of the sample in liquid paraffin dispersion shall be concordant with similarly recorded spectrum of Methylphenidate Hydrochloride working standard. | Complies. |
| | A) IR | | |
| | B) Test for Chloride | It responds to the tests for Chloride. | Complies. |
| 4. | Loss on drying | Not more than 0.50%w/w. | 0.22% w/w. |
| 5. | Residue on ignition | Not more than 0.10%w/w. | 0.05% w/w |
| 6. | Heavy metals | Not more than 0.001% w/w. | Complies |
| 7. | Limit of Erythro (R*,S*)] Isomer | Not more than 1.00% | Complies |
| 8. | Limit of α -Phenyl-2-piperidineacetic acid Hydrochloride | Not more than 0.60% | Complies |
| 9. | Assay | 98.0% to 100.5% w/w. (on dried basis) | 99.02% w/w |
| 10. | Organic volatile impurities | | |
| | a) Diethyl Ether | Not more than 5000 ppm | Not detected |
| | b) Methanol | Not more than 3000 ppm | 323 ppm |
| | c) Acetone | Not more than 5000 ppm | 163 ppm |
| | d) Chloroform | Not more than 60 ppm | Not detected |

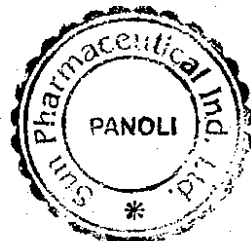
REMARKS: The product is **satisfactory** to the prescribed standards of quality in respect of the above mentioned tests as per USP specification.

Note: DATA REPRODUCED FROM ORIGINAL COA.

DATE OF ISSUE OF COA. : 09.03.09

PREPARED BY: *Hitin*

DATE: 09.03.09



VERIFIED BY: *[Signature]*

DATE: 09.03.09

Factory : 24/2, 25, Phase IV,
G.I.D.C., Panoli - 394116,
Dist. Bharuch, (Guj.) INDIA.
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CERTIFICATE OF ANALYSIS

| PRODUCT : METHYLPHENIDATE HYDROCHLORIDE USP | | | |
|--|---|--|---|
| BATCH No. : | | A.R. No. : | |
| MFG. DT. : DECEMBER 2008 | | RELEASE DATE : 03.01.09 | |
| EXP. DT. : NOVEMBER 2013 | | PAGE : 01 of 01 | |
| Sr.No. | TEST | SPECIFICATION | RESULT |
| 1. | Description | White, odorless, fine, crystalline powder. | White, odorless, fine, crystalline powder. |
| 2. | Solubility | Freely soluble in water, and Methanol. Soluble in alcohol, slightly soluble in Chloroform. | Complies. |
| 3. | Identification A) IR | IR absorption spectrum of the sample in liquid paraffin dispersion shall be concordant with similarly recorded spectrum of Methylphenidate Hydrochloride working standard. | Complies. |
| 4. | B) Test for Chloride Loss on drying | It responds to the tests for Chloride. Not more than 0.50%w/w. | Complies. 0.31% w/w. |
| 5. | Residue on ignition | Not more than 0.10%w/w. | 0.05% w/w |
| 6. | Heavy metals | Not more than 0.001% w/w. | Complies |
| 7. | Limit of Erythro (R*,S*)] Isomer | Not more than 1.00% | Complies |
| 8. | Limit of α -Phenyl-2-piperidineacetic acid Hydrochloride | Not more than 0.60% | Complies |
| 9. | Assay | 98.0% to 100.5% w/w. (on dried basis) | 99.75% w/w |
| 10 | Organic volatile impurities a) Diethyl Ether b) Methanol c) Acetone d) Chloroform | Not more than 5000 ppm Not more than 3000 ppm Not more than 5000 ppm Not more than 60 ppm | Not detected 1354 ppm 220 ppm Not detected |

REMARKS: The product is **satisfactory** to the prescribed standards of quality in respect of the above mentioned tests as per USP specification.

Note: DATA REPRODUCED FROM ORIGINAL COA.

DATE OF ISSUE OF COA. : 07.12.09

PREPARED BY : *Fliten*

DATE : 07.12.09

VERIFIED BY : *[Signature]*

DATE : 07.12.09

FOR AUTHORISED USE ONLY

Factory : 24/2, 25, Phase IV,
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CERTIFICATE OF ANALYSIS

| PRODUCT : METHYLPHENIDATE HYDROCHLORIDE USP | | | |
|--|---|--|--|
| BATCH No. : | | A.R. No. : | |
| MFG. DT. : NOVEMBER 2008 | | RELEASE DATE : 28.12.08 | |
| EXP. DT. : OCTOBER 2013 | | PAGE : 01 of 01 | |
| Sr.No. | TEST | SPECIFICATION | RESULT |
| 1. | Description | White, odorless, fine, crystalline powder. | White, odorless, fine, crystalline powder. |
| 2. | Solubility | Freely soluble in water, and Methanol. Soluble in alcohol, slightly soluble in Chloroform. | Complies. |
| 3. | Identification | IR absorption spectrum of the sample in liquid paraffin dispersion shall be concordant with similarly recorded spectrum of Methylphenidate Hydrochloride working standard. | Complies. |
| | A) IR | | |
| | B) Test for Chloride | It responds to the tests for Chloride. | Complies. |
| 4. | Loss on drying | Not more than 0.50%w/w. | 0.2% w/w. |
| 5. | Residue on ignition | Not more than 0.10%w/w. | 0.06% w/w |
| 6. | Heavy metals | Not more than 0.001% w/w. | Complies |
| 7. | Limit of Erythro (R*,S*)] Isomer | Not more than 1.00% | Complies |
| 8. | Limit of α -Phenyl-2-piperidineacetic acid Hydrochloride | Not more than 0.60% | Complies |
| 9. | Assay | 98.0% to 100.5% w/w. (on dried basis) | 99.14% w/w |
| 10. | Organic volatile impurities | | |
| | a) Diethyl Ether | Not more than 5000 ppm | Not detected |
| | b) Methanol | Not more than 3000 ppm | 1730 ppm |
| | c) Acetone | Not more than 5000 ppm | 269 ppm |
| | d) Chloroform | Not more than 60 ppm | Not detected |

REMARKS: The product is satisfactory to the prescribed standards of quality in respect of the above mentioned tests as per USP specification.

Note: DATA REPRODUCED FROM ORIGINAL COA.

DATE OF ISSUE OF COA. : 07.12.09

PREPARED BY : *Hiten*

VERIFIED BY :

DATE : 07.12.09

DATE : 07.12.09