# INTAS PHARMACEUTICALS LTD.

Factory : Plot No. 457, 458, Sarkhej-Bavla Highway, Matoda-382 210. Gujarat, India.
Phone : + 91 - 02717 - 661111, 661298 Fax : + 91 - 02717 - 661106


P1-10 (5) P1-10

INTAS

## QUALITY CONTROL DEPARTMENT
## CERTIFICATE OF ANALYSIS

Brand Name : PARAEFFER
Generic Name : PARACETAMOL EFFERVESCENT TABLETS 1000 mg
Composition : Each uncoated tablet contains:
Paracetamol Ph.Eur.....1000 mg
Analysis as per : INHOUSE (KENYA) Specification

Plant : INTAS PHARMA.LTD.,MATODA
Batch Size : 2800.00 Nos.
Receipt Dt. : 14.07.2016
Halb Batch Size : 1294595.000 nos
Report Dt. : 20.07.2016

Batch No. : T09262
AR Number : TE16/08905
Mfg. Dt. : 07/2016
Exp. Dt. : 06/2018
Spec. No. : PME0406-01
Halb Batch No. : T08905
Page No. : 1 / 2

| SR. NO. | TESTS | RESULT | LIMITS |
|---|---|---|---|
| 01 | Description | White, round, flat faced, beveled edged tablets plain on both sides. | White to off-white,round, flat faced, beveled edged tablets plain on both sides. |
| 02 | Average weight of tablets | 3658.9 mg | 3700.0 mg ± 3% (3589.0 mg to 3811.0 mg) |
| 03 | Uniformity of dosage units (By mass variation) | The acceptance value of the first 10 tablets is 2.1 | The acceptance value of the first 10 tablets should be less than or equal to 15.0. If the acceptance value is greater than 15.0, test next 20 tablets and calculate the acceptance value. The final acceptance value of the 30 tablets should be less than or equal to 15.0 and no individual content of the dosage unit should be less than (1-25.0x0.01)M or more than (1+25.0x0.01)M. |
| 04 | Identification | Paracetamol : A) By HPLC: The retention time of Paracetamol peak in the chromatogram of assay preparation corresponds to the paracetamol peak obtained with standard preparation as directed under assay.<br><br>B) By UV: The UV spectra of the test preparation in range of 200 to 400 nm exhibits maxima at same wavelength as that of standard preparation having same concentration. | Paracetamol : A) By HPLC: The retention time of Paracetamol peak in the chromatogram of assay preparation should correspond to the paracetamol peak obtained with standard preparation as directed under assay.<br><br>B) By UV: The UV spectra of the test preparation in range of 200 to 400 nm should exhibit maxima at same wavelength as that of standard preparation having same concentration. |

NATIONAL QUALITY CONTROL LABORATORY
16 AUG 2016
FAX: 2718073
P.O. Box 29726 - 00202, NAIROBI

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QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS

Brand Name : PARAEFFER

Batch No. : T09262
AR Number : TE16/08905
Halb Batch No. : T08905
Report Dt. : 20.07.2016 Page No. : 2 / 2

| SR. NO. | TESTS | RESULTS | LIMITS |
|---|---|---|---|
| 05 | Resistance to crushing | 210 N | Not less than 50 Newton |
| 06 | Disintegration time | 2 minutes | Not more than 5 minutes. |
| 07 | Clarity of solution | Slightly opalescent, not more opalescent than reference suspension II. | Clear to slightly opalescent, not more opalescent than reference suspension II. |
| 08 | pH of solution | 5.9 | Between 5.4 to 6.4 |
| 09 | Loss on drying at 75° C | 0.8% w/w | Not more than 1.0% w/w |
| 10 | Related substances | Not Detected | A) 4-aminophenol : Not more than 0.005% |
| | | Not Detected | B) 4-Chloroacetanilide: Not more than 0.001% |
| | | Below Disregard Level | C) Single unknown impurity: Not more than 0.10% |
| | | Below Disregard Level | D) Total impurities : Not more than 0.50% |
| 11 | Assay | 99.2% | 95.0% to 105.0% of label claim |
| 12 | Residual solvents | 432 ppm | Isopropyl alcohol : Not more than 3000 ppm |
| 13 | Microbial examination * | NA | A) Microbial enumeration tests :i) Total aerobic microbial count : Not more than $10^3$ cfu/g |
| | | NA | ii) Total combined Yeasts and Moulds count : Not more than $10^2$ cfu/g |
| | | NA | B) Test for specified micro -organism : i) Escherichia coli : Should be absent. |

Remarks : Conforms to INHOUSE (KENYA) Specification
* To be performed for validation /exhibit batches. For commercial batches it should be performed for first five batches followed by every fifth batch or one batch per year which ever is earlier.

Q.C.HEAD :
Rajendra D. Patel 26/07/16
SR. GM, QC

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## QUALITY CONTROL DEPARTMENT
## CERTIFICATE OF ANALYSIS

| | | | |
|---|---|---|---|
| Name of working standard | : PARACETAMOL | | |
| Evaluated with EP Batch No. | : 4 | Date of preparation | : 10/03/2016 |
| Working standard No. | : S PARA 161 | Valid Up to | : 10/03/2017 |
| Raw material Batch No. | : 1447/15-16 | Page | : 1 of 1 |
| Raw material A. R. No. | : 101603994 | | |
| Storage condition | : Keep container tightly closed and store below 25°C in amber colour vial. | | |

Reference : Ph.Eur & Inhouse specification.

| SR. NO. | TEST | RESULT | LIMITS |
|---|---|---|---|
| 01. | Characters | White, crystalline powder. | White or almost white, crystalline powder. |
| 02. | Identification | By IR: The IR spectrum of the substance being examined is concordant with the reference spectrum of Paracetamol EP reference standard. | By IR: The IR spectrum of the substance being examined should be concordant with the reference spectrum of Paracetamol EP reference standard. |
| 03. | Loss on drying | 0.3%. | Not more than 0.5%. |
| 04. | Related substances<br>A) Impurity J<br>B) Impurity K<br>C) Impurity F<br>D) Any other impurity<br>E) Total of other impurities | <br>A) Not detected.<br>B) 4 ppm.<br>C) Not detected.<br>D) 0.01%.<br>E) 0.01%. | <br>A) Not more than 10 ppm.<br>B) Not more than 50 ppm.<br>C) Not more than 0.05%.<br>D) Not more than 0.05%.<br>E) Not more than 0.1%. |
| 05. | Assay | 99.6%.<br><br>99.3% as such. | 99.0% to 101.0% calculated on dried basis.<br><br>Record. |

Remarks : The above material is compared with **EP** standard for above tests and is suitable to use as a working standard

PREPARED BY : 10/03/16 CHECKED BY : 10/03/16 APPROVED BY : 10/3/16
DATE : DATE : DATE :

NATIONAL QUALITY CONTROL LABORATORY RECEIVED 16 AUG 2016 P.O. Box 29726 - 00202, NAIROBI

INTAS PHARMACEUTICALS LTD. INTAS AHMEDABAD