## Manufacturing Site

Granules India Limited, H.No. 6-5 & 6-11, Temple Road, Bonthapally, Medak Dist. – 502 313. Andhra Pradesh, INDIA.



## CERTIFICATE OF ANALYSIS PARACETAMOL- IP

Batch No.

: APAP/13112090

Mfg. Date

: Nov.2013

Batch Qty.

: 5063 Kg

Exp. Date

: Oct.2018

A.R. No.

: PC-2346/1113

| TEST   | SPECIFICATION  | RESULT   |
|--|--|--|
| 1. Description   | White crystals or a white, crystalline powder.   | A white, crystalline powder.                     |
| 2. Solubility  | Freely soluble in ethanol (95%) and soluble in acetone; sparingly soluble in water; very slightly soluble in dichloromethane and in ether. | Complies   |
| 3. Identification  |  |  |
| A.IR Spectrum  | Test IR Spectrum should match with Std. IR Spectrum  | Complies   |
| 4. 4-Aminophenol   | Not more than 50 ppm   | Less than 50 ppm                                 |
| 5. Related substances (HPLC)   |  |  |
| Impurity J (P-chloroacetanilide) Impurity K(p-Amino phenol) Impurity F (p-Nitro phenol) Any Other impurity Total of other impurities | Not more than 10 ppm Not more than 50 ppm Not more than 0.05% Not more than 0.05% Not more than 0.1%                                       | Not Detected 2.09 ppm Not Detected 0.001% <0.01% |
| 6. Heavy metals  | Not more than 10 ppm   | Less than 10 ppm                                 |
| 7. Sulphated ash   | Not more than 0.1%   | 0.05%  |
| 8. Loss on drying  | Not more than 0.5%   | 0.17%  |
| 9. Assay (ODB)   | 99.0 to 101.0%   | 99.6%  |
| Report: The product complies wit   | th the specification of IP   |  |

Storage Condition: Preserve in tight, light –resistant containers, and store at room temperature. Protect from moisture and heat. (Ref. USP)

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|------------------------------|--------------------------------|-----------------------------|
| Prepared By                  | Approved By                    | Released By                 |
| 29/11/13                     | D 29/11/13                     | may 29/11/13                |
| K.Brahmaiah<br>Executive -QC | P.Harinath<br>Asst.Manager -QC | N.Ajaykumar<br>Executive-QA |