

# G. AMPHRAY LABORATORIES

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## CERTIFICATE OF ANALYSIS

Name of Product	:	PARACETAMOL BP	Date of Receipt	:	08.05.2008
Batch No.	:	003/08	Date of Analysis	:	08.05.2008
Date of Manufacture	:	May, 2008	Sample Size	:	100 Grams
Date of Expiry	:	April, 2013	Q.C.No.	:	G-08/093
Quantity	:	3,000 KGS			

## RESULTS OF ANALYSIS

TESTS	RESULTS	SPECIFICATIONS
Description	A white crystalline powder.	A white crystalline powder.
Solubility	Complies.	Sparingly soluble in water, freely soluble in alcohol, very slightly soluble in ether and in methylene chloride.
Identification	Second Identification : A. Melting Point : 171.8 ° C B. The specific absorbance at 249 nm : 884.85 D. Complies E. Complies	Between : 168 ° C to 172 ° C Between : 860 to 980 A violet colour develops which does not change to red. The reaction of Acetyl as per BP.
Heavy Metals	< 20 ppm	Not more than 20 ppm.
4 Aminophenol	02 ppm	Not more than 50 ppm.
Related Substances	< 0.005 %	Not more than 0.005 %
Loss on Drying	0.12 %	Not more than 0.5 %
Sulphated Ash	0.029 %	Not more than 0.1 %
Assay ( On Dried Basis )	99.78 % of C <sub>8</sub> H <sub>9</sub> NO <sub>2</sub>	Between 99.0 % to 101 %

### ADDITIONAL TEST

#### 1) Particle size on Tyler Machine:-

MESH	% PASSING THROUGH
50	100 %
60	97.08 %

2 Bulk density after 50 Tapped = 0.573 g/ml

REPORT: THE SAMPLE COMPLIES WITH THE PRESCRIBED STANDARDS OF QUALITY AS PER BP 2002

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AUTHORISED SIGNATORY

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## CERTIFICATE OF ANALYSIS

Name of Product	:	PARACETAMOL EP	Date of Receipt	:	08.05.2008
Batch No.	:	003/08	Date of Analysis	:	08.05.2008
Date of Manufacture	:	May, 2008	Sample Size	:	100 Grams
Date of Expiry	:	April, 2013	Q.C.No.	:	G-08/093
Quantity	:	3,000 KGS			

## RESULTS OF ANALYSIS

TEST	METHOD	RESULTS	LIMITS
Appearance	Organoleptic Test	Conforms	White odorless Crystalline Powder
Solubility	Visual Test	Conforms	Sparingly soluble in Water, freely soluble in alcohol, very slightly soluble in methylene chloride.
Identification A	EP 2002, 2.2.14	171.9 °C	The melting point is in the range 168° C to 172° C
Identification C	EP 2002, 2.2.24	Conforms	The Infrared Spectrum must correspond.
Loss on Drying	EP 2002, 2.2.32	0.19 %	≤ 0.5% (1 gm/ 105° C)
Sulphated Ash	EP 2002, 2.4.14	0.030 %	≤ 0.1% (1 gm)
Heavy Metals	EP 2002, 2.4.8	< 20 ppm	≤ 20 ppm
Assay	EP 2002, 2.2.20	99.80 %	99% to 101% (Dried Substance)
Related Substances <sup>1)</sup> § Impurity J <sup>2)</sup> § Impurity K <sup>3)</sup> § Impurity F <sup>4)</sup> § Unknown Single § Total Impurities 1 Disregard Limit 0.01 % 2 Chloroacetanilide 3 4-Aminophenol 4 4-Nitrophenol	EP 2002, 2.2.29	< 5 ppm < 5 ppm < 0.01 % < 0.01 % < 0.05 %	≤ 10 ppm ≤ 50 ppm ≤ 0.05 % ≤ 0.05 %, Individually ≤ 0.1 %

REPORT: THE BATCH MEETS THE REQUIREMENTS OF THE QUALITY OF EP SPECIFICATIONS.

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