

G. AMPHRAY LABORATORIES

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CERTIFICATE OF ANALYSIS

| | | | |
|--------------|-----------------------------|------------------|-------------------|
| Product | : NIACINAMIDE BP / USP / EP | Date of Analysis | : 03.03.2008 |
| Batch No. | : 156032008 / A | Exp. Date | : FEBRUARY, 2013. |
| Date of Mfg. | : MARCH, 2008. | Certificate No. | : 449 |
| Quantity | : 1,000 Kgs. | | |

RESULT OF ANALYSIS

| TESTS | OBSERVATION | SPECIFICATIONS |
|---|--|---|
| Characters / Description and Solubility. | Snow white, crystalline powder, odourless, free from black particles and has a bitter taste. Solution is neutral to litmus and Complies. | White, Crystalline Powder or colourless crystals, it is, odourless or practically so, and has a bitter taste. It's solutions are neutral to litmus. Freely soluble in water and in ethanol and soluble in glycerin, slightly soluble in ether. |
| Identification Test (A) IR Test (B) UV Ratio A ₂₄₅ /A ₂₆₂ C) Heating with NaOH (B.P.Method) D) Colour Test (B.P.Method) | Complies 0.66 Complies Yellow colour develops | The IR Absorption spectrum should be concordant with the spectrum of reference standard. Between 0.63 and 0.67 Heated with dilute sodium hydroxide solution, Ammonia is evolved. Treated with Cyanogen bromide solution, and aniline solution. A yellow colour develops. |
| Melting Range | 128.8 to 130.8 Deg. C | Between 128 to 131 Deg.C |
| Loss of Drying | 0.097 % W/W | NMT 0.5% w/w |
| Residue on ignition | 0.026 % W/W | NMT 0.1% w/w |
| Heavy Metals | Less than 5 ppm | NMT 30 ppm |
| Readily Carbonisable Substances | Complies | Test as per USP. |
| Related substances (TLC) | Complies | Test as per B.P. |
| PH of a 5 % w/v solution | 7.18 | Between 6.0 and 7.5 |
| Appearance of a 5 % w/v solution (B.P. Method) | Complies | Clear and not more intensely coloured than reference solution BY7. |
| Organic Volatile Impurities. | Complies | Test as per USP. |
| Assay a. By Titration (B.P. Method) b. By HPLC (USP Method) | 99.74 % w/w 99.83 % w/w | Not less than 99.0 % w/w Not more than 101.0 % w/w Calculated on dried basis. Not less than 98.5 % w/w Not more than 101.5 % w/w Calculated on dried basis. |

| | | | |
|-------------------|---------------|----------|--------------------------|
| Additional Test : | Particle Size | Mesh 40 | : 96.68 % Passes through |
| | | Mesh 60 | : 94.40 % Passes through |
| | | Mesh 100 | : 40.96 % Passes through |
| | | Mesh 200 | : 01.52 % Passes through |
| Bulk Density : | | Untapped | : 0.55 g / ml |
| | | Tapped | : 0.65 g / ml |

REPORT : IN MATERIAL COMPLIES WITH RESPECT TO B.P 2007 / USP 30 / EP 5 SPECIFICATIONS.

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AUTHORISED SIGNATORY