


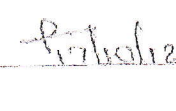

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|--------------------|------------------------------------|---------------|------------------------------------|
| Commercial batch # | : LAM/1210078 | Dispatch Qty. | : 100.00 Kg |
| In-house Batch # | : 4LAM3/12064 | Batch Qty. | : 360.30 Kg |
| Mfg. Date | : October - 2012 | Expiry date | : September - 2017 |
| Specification # | : QCD/SP/FP/LAM/001-R ₆ | Method # | : QCD/MH/FP/LAM/001-R ₆ |

| Sl. #. | TESTS | OBSERVATIONS | STANDARD LIMIT |
|--------|--|--|--|
| 1 | Characters - Appearance - Solubility | White powder Meets the requirement | White or almost white powder Very slightly soluble in water, Slightly soluble in anhydrous ethanol. |
| 2 | Identification by IR absorption | Meets the requirement | IR spectrum in KBR dispersion of sample should be concordant with that of reference/working standard. |
| 3 | Heavy metals | Less than 10 ppm | Not more than 10 ppm |
| 4 | Loss on drying at 105°C [at a pressure not exceeding 5.25 mmHg (0.7 kPa) for 3 hrs] | 0.04% | Not more than 0.5% |
| 5 | Sulphated ash | 0.01% | Not more than 0.1% |
| 6 | Related substances by HPLC - Impurity A - Impurity E - Impurity F - Impurity G - Schiff's base - Single unknown impurity - Total impurities | Below detection limit (0.01%) Below detection limit (0.01%) Below detection limit (0.01%) Below detection limit (0.01%) Below detection limit (0.03%) Below quantitation limit (0.03%) Not found | Not more than 0.10% Not more than 0.10% Not more than 0.10% Not more than 0.10% Not more than 0.10% Not more than 0.10% Not more than 0.2% |
| 7 | Assay by Potentiometry (dry basis) | 99.3% | Not less than 99.0% and Not more than 101.0%w/w |
| 8 | Additional tests | | |
| a) | Residual solvents - Isopropyl alcohol | Below detection limit (10 ppm) | Not more than 1000 ppm |
| b) | X-Ray diffraction | Meets the requirement | X-Ray diffraction pattern of sample should be concordant with that of reference / working standard. |
| c) | Particle size by Malvern Mastersizer - Less than 150 µm | 98% | Not less than 90% |

Remark: The product complies with above mentioned specification+ Customer's specification (CSO#CSO/481-R₁/12).

Storage condition: Store in airtight containers below 25°C.

Note: The values given in the parenthesis are for limit of detection and limit of quantitation of respective purity and residual solvents.

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|---|---|---|
| PREPARED BY :  | CHECKED BY :  | APPROVED BY :  |
| Date : 12/10/12 | Date : 12/10/12 | Date : 12/10/12 |

A Jubilant Bhartia Company

OUR VALUES



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