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United States Pharmacopeia Pharmaceutical Ingredient Verified

Certificate Number: VER-PI/EX-DFPC-001

Awarded: April 03, 2009 — **Expires:** April 03, 2012

Name of Pharmaceutical Ingredient: Isopropyl Alcohol

Pharmaceutical Ingredient Product Codes: 32500

Name of Holder: DEEPAK FERTILISERS AND PETROCHEMICALS CORPORATION LIMITED

Site(s) of Production:

Address: Plot K-1, MIDC Industrial Area, Talaja, 410208 District Raigad, Maharashtra, INDIA

DEEPAK FERTILISERS AND PETROCHEMICALS CORPORATION LIMITED voluntarily applied for verification of Isopropyl Alcohol under USP's Excipient Verification Program. During the verification process, USP conducted an on-site GMP audit of the production site(s) referenced above, reviewed the relevant manufacturing and quality control/quality assurance documentation, and performed laboratory testing of Isopropyl Alcohol as an excipient. After examining the information DEEPAK FERTILISERS AND PETROCHEMICALS CORPORATION LIMITED provided to USP during the verification process, USP finds that DEEPAK FERTILISERS AND PETROCHEMICALS CORPORATION LIMITED's quality system provides adequate assurance that Isopropyl Alcohol meets the applicable monograph requirements set forth in the current edition of the *United States Pharmacopeia-National Formulary*, or such other criteria deemed suitable by USP.

The submitted information represents randomly selected lots, produced in October 2008. In order to maintain verification status, manufacture of Isopropyl Alcohol must continue to take place in accordance with a suitable quality assurance system (e.g., GMP USP General Chapter <1078>) and under the same conditions submitted in the reviewed documentation.

USP is pleased to award this certificate to DEEPAK FERTILISERS AND PETROCHEMICALS CORPORATION LIMITED.

V. Srinivasan, Ph.D.
Vice President, USP Verification Programs

This certificate remains the property of USP. USP issues this verification certificate for a period of three (3) years from the date hereof or until any major change in production has taken place, as defined in the license agreement and/or the USP Pharmaceutical Ingredient Verification Manual Drug Substances. Failure to comply with the provisions of the manual or the license agreement shall render this certificate void, and the right to use the USP Verified Mark on the ingredient will be withdrawn. To check the validity of this certificate, call +1-301-816-8273 or visit www.usp.org.