PHARMACEUTICALS
ACTIVE PHARMACEUTICAL
INGREDIENTS
A Division of Taj Pharmaceuticals Ltd.

Taj Pharmaceuticals Ltd.
"WORKING FOR HEALTHIER WORLD"

NITRAZEPAM

CAS No. 146-22-5

99%

Nitrazepam IP/ BP

C15H11N3O3: 281.27

7-Nitro-5-phenyl-1,3-dihydro-2H-1,4-benzodiazepin-2-one

[146-22-5]

Nitrazepam, when dried, contains not less than 99.0z of $C_{15}H_{11}N_3O_3$.

Nitrazepam occurs as white to yellow crystals
or crystalline powder. It is odorless.

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or crystalline powder. It is odorless.

It is freely soluble in acetic acid (100), soluble in acetone and in chloroform, slightly soluble in methanol, in ethanol **(95)** and in ethanol **(99.5)**, very slightly soluble in *diethylether*, and practically insoluble in water.

Melting point: about 227 ^{0}C (with decomposition).

Identiˆcation

(1) To 3 mL of a solution of Nitrazepam in methanol (1 in 500) add 0.1 mL of sodium hydroxide TS: a yellow color is produced.

(2) To 0.02 g of Nitrazepam add 15 mL of dilute hydrochloric acid, boil for 5 minutes, cool, and ˆlter: the ˆltrate responds to the ***Qualitative Tests <1.09> for primary aromatic amines.***

(3) Neutralize 0.5 mL of the ˆltrate obtained in (2) with sodium hydroxide TS, add 2 mL of ninhydrin TS, and heat on a water bath: a purple color is produced.

(4) Determine the absorption spectrum of a solution of Nitrazepam in ethanol **(99.5) (1 in 100,000)** as directed under Ultraviolet-visible Spectrophotometry **<2.24>,** and compare the spectrum with the Reference Spectrum: both spectra ex- hibit similar intensities of absorption at the same wavelengths.

Purity :

(1) Clarity and color of solution—Dissolve 0.10 g of Nitrazepam in 20 mL of acetone: the solution is clear and pale yellow to light yellow in color.
(2) Heavy metals <1.07>—Proceed with 1.0 g of Nitrazep- am according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).
(3) Arsenic <1.11>—Prepare the test solution with 1.0 g of Nitrazepam according to Method 3, and perform the test (not more than 2 ppm).
(4) Related substances—Dissolve 0.25 g of Nitrazepam in a 10 mL of mixture of methanol and chloroform (1:1), and use this solution as the sample solution. Pipet 1 mL of the sample solution, add a mixture of methanol and chloroform (1:1) to make exactly 20 mL, pipet 2 mL of this solution, add a mixture of methanol and chloroform (1:1) to make exactly 50 mL, and use this solution as the standard solution. Per- form the test with these solutions as directed under Thin-lay- er **Chromatography <2.03>. Spot 10 mL** each of the sample so- lution and standard solution on a plate of silica gel with ‰uorescent indicator for thin-layer chromatography. Develop the plate with a mixture of nitromethane and ethyl acetate (**17:3) to a distance of about 10 cm, and air-dry the plate. Ex- amine under ultraviolet light (main wavelength: 254 nm)**: the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Loss on drying <2.41> 4 hours).

Residue on ignition <2.44>

Assay Weigh accurately about 0.4 g of Nitrazepam, previously dried, and dissolve in 40 mL of acetic acid (100). Titrate <2.50> with 0.1 mol/L W perchloric acid VS (potentiometric

titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L W perchloric acid VS

= 28.13 mg of $C_{15}H_{11}N_3O_3$

Containers and storage Containers——Tight containers.

Storage——Light-resistant.

Not more than 0.5z (1 g, 1059 C,

Not more than 0.1z (1 g).

Packing: 25kg /drum or on request.

A QUALITY PRODUCT FROM :- Taj Group (API) India.

Manufactured By: Group Subsidiary

PRODUCT CODE:TAJ API NTWAK 88765323

taj Taj Group **PHARMACEUTICALS ACTIVE PHARMACEUTICAL INGREDIENTS** A Division of Taj Pharmaceuticals Ltd.

TAJ TAJ GROUP PHARMA BUSINESS WORLDWIDE **Taj Pharmaceuticals Ltd.** INDIA "WORKING FOR HEALTHIER WORLD"

CHEMICAL PLANT
ADDRESS :PLOT NO. - 1019, ROAD NO. 10,
VILL. - SARIGAM,G.I.D.C. ,
DIST. - VALSAD,STATE OF GUJRAT.
INDIA

API PLANT
ADDRESS:- AT VILLAGE - KALGAM,
COASTAL HIGHWAY ROAD,
DIST. - VALSAD, GUJRAT - 396142.
INDIA

REGD. OFFICE : 434, LAXMI PLAZA, LAXMI INDUSTRIAL ESTATE,
NEW LINK ROAD, ANDHERI (W), MUMBAI - 400 053. (INDIA).
☎ + 91 - 22 - 2637 4592, + 91 - 22 - 2637 4593.
FAX: +91-22-2634 1274 MARKETING : 022-3060 1000
FACTORY : PLOT NO. 32/2B, VILLAGE-TONDALI, KHAPOLI PEN ROAD,
DIST. RAIGAD, MAHARASHTRA, FAX : 02192-278323 / 278324
e-mail : tajpharma@rediffmail.com/tajpharmaceuticals@rediffmail.com
web.: www.tajpharmaceuticals.com / www.tajapi.com