



Bharat Pharma

(A unit of Bharat Explosives Ltd.)

ABOUT US

WHO ARE WE

Bharat Pharma (A unit of Bharat Explosives Ltd.) is part of the well diversified Dalmia Group with business interests in Industrial Explosives, High Energy Fuels, Chemicals, Home furnishing, Yarn, Health Care products and IT enabled services.

WHAT WE DO

Bharat Pharma is cGMP and ICH Q7 compliant USFDA approved dedicated manufacturing facility for neat Nitroglycerin, Diluted Nitroglycerin IP/USP Drug substances in various formats, and Hand sanitizers which not only conforms but exceeds the standards of official monographs of IP and USP

WHERE WE ARE LOCATED

State of the art pharma manufacturing facility is located at Lalitpur, near Jhansi (U.P), India

OUR DIFFERENTIATORS

- ❑ USFDA approved Nitroglycerin and Diluted Nitroglycerin manufacturing facility
- ❑ Dedicated manufacturing facility, No cross contamination for Nitroglycerin Drug substances and Hand Sanitizers
- ❑ Only Indian company holding the Nitroglycerin manufacturing license, granted by PESO, for manufacturing of neat Nitroglycerin for its use in the manufacturing of Nitroglycerin Drug substance in various formats
- ❑ Unparallel Lowest Impurity Profile
(Total impurity ~ 1/10th of specified limits of USP and IP monographs)

CERTIFICATIONS AND DRUG MASTER FILES

USFDA

ISO 2001 : 2015

STATE GMP

Plant and machinery conforms to ICH Q7 guidelines

DRUG MASTER FILES SUBMITTED TO USFDA

- ❑ Nitroglycerin as in Diluted Nitroglycerin USP, DMF # 22435 (Incorporating the details of Neat Nitroglycerin for manufacturing of Diluted Nitroglycerin Drug substances in various formats)
- ❑ 17.7 % w/w Nitroglycerin in Solvated Adhesive, DMF # 22434 (for manufacturing of Transdermal patches)
- ❑ Diluted Nitroglycerin USP, DMF # 27609 (Incorporating the details of neat Nitroglycerin, Diluted Nitroglycerin USP (10% w/w Nitroglycerin in Lactose and 2% w/w Nitroglycerin in Lactose) for manufacturing of Tablets, Capsules, Ointments etc.

DRUG MASTER FILE SUBMITTED TO SINGAPORE AND MALAYSIAN DRUG REGULATORY AUTHORITIES

- ❑ Diluted Nitroglycerin USP, DMF # 27609 (Incorporating the details of neat Nitroglycerin, Diluted Nitroglycerin USP (10% w/w Nitroglycerin in Lactose and 2% w/w Nitroglycerin in Lactose) for manufacturing of Tablets, Capsules, Ointments etc.

BP/PR 002

PL 06

MB 02

TECHNICAL FEATURES

- ❑ Bharat Explosives Ltd has more than 26 years excellent track record in safe manufacturing of quality Nitroglycerin based industrial explosives for over 26 years.
- ❑ Fully automatic imported nitration plant
- ❑ Bharat Pharma is state of the art manufacturing unit. Main features are:
 - Semi automatic imported, Nitroglycerin manufacturing plant
 - Dedicated manufacturing facility for Nitroglycerin Drug Substances and Hand Sanitizers

26 YEARS
OF
TRUST



QUALITY CONTROL

- ❑ Quality control laboratory equipped with sophisticated instruments like HPLC, IR, GLC, TOC, Karl Fischer Titrator, Abel heat test apparatus etc.
- ❑ Microbiological laboratory equipped with
 - Double door autoclave
 - Automatic temperature controlled BOD incubators
 - Laminar flow work station
 - Pass Box
- ❑ In house Stability studies facility

OUR MOTTO
BEST QUALITY,
ONTIME,
EVERYTIME

PRODUCT RANGE

NITROGLYCERIN BASED DRUG SUBSTANCES

- ❑ Nitroglycerin diluted in Solvated Adhesive (with 15% /17.5 % / 17.7 % / 18% / 19% / 20% and or 22 % w/w Nitroglycerin concentration in Solvated Adhesive) for Transdermal Patches
- ❑ Diluted Nitroglycerin IP/UP (with 10% / 5% / 2% / w/w Nitroglycerin concentration in Lactose) for Tablets / Capsules and Ointment etc.
- ❑ Diluted Nitroglycerin USP (1.5% w/w Nitroglycerin in Lactose) for Tablets / Capsules and Ointment etc.
- ❑ Diluted Nitroglycerin IP/USP (with 10% / 5% / 2% / 1% w/w Nitroglycerin concentration in Propylene glycol) for injectables, Ointment and spray etc.

HAND SANITIZERS

Composition

- ❑ Isopropyl Alcohol I.P.: 75% v/v
Glycerol I.P.: 1.45% v/v
Hydrogen Peroxide Solution I.P.: 0.125% v/v (eq. to H₂O₂)
Purified Water: QS
- ❑ Ethyl Alcohol I.P.: 80% v/v
Glycerol I.P. 1.45% v/v
Hydrogen Peroxide Solution I.P.: 0.125% v/v (eq. to H₂O₂)
Purified Water: QS
- ❑ Isopropyl Alcohol I.P.: 70% v/v
Chlorhexidine Gluconate Solution I.P.:0.5% w/v (eq. to Chlorhexidine Gluconate)
Purified Water I.P.: QS
- ❑ Ethyl Alcohol I.P.: 70% v/v
Chlorhexidine Gluconate Solution I.P.: 0.5% w/v (eq. to Chlorhexidine Gluconate)
Purified Water I.P.: QS



PRODUCT PACKING

NITROGLYCERIN DRUG SUBSTANCES

- ❑ Nitroglycerin diluted in Solvated Adhesive (15% / 17.5% / 17.7% / 18% / 19% / 20% / 21% / 22% / w/w Nitroglycerin in Solvated Adhesive) in Composite containers (HDPE with MS covering) of 20 kg and 100 kg
- ❑ Diluted Nitroglycerin IP / USP (10% / 5% / 2% / 1% w/w Nitroglycerin in Propylene Glycol) in Aluminum / HDPE containers of 10 kg and 25 kg
- ❑ Diluted Nitroglycerin IP / USP (10% / 5% / 2% / 1.5% w/w Nitroglycerin in Lactose) in HDPE drums of 25 kg

HAND SANITIZERS

- ❑ Refill pack in 500 ml, 1 Liter, 5 Liters, 10 Liters and 20 Liters in HDPE container
- ❑ Dispenser pack in 200 ml, 500 ml and 1 Liter



QUALITY MANAGEMENT SYSTEM

In compliance with:

- ❑ Schedule M
- ❑ 21CFR Part 210 & 211
- ❑ ICH Q7
- ❑ ISO 9001:2015

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