

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20145/S006

CHEMISTRY REVIEW(S)

MAY 5 1995

DIVISION OF CARDIO-RENAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 20-145 CHEM.REVIEW #: 6 REVIEW DATE: 5/2/95

<u>SUBMISSION TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
<u>ORIGINAL</u>	12-10-85		
<u>SUPPLEMENT</u>	SLR-006 03-06-95	03-13-95	03-13-95
	SLR-007 04-20-95	04-25-95	04-27-95

AMENDMENTS

SUPPLEMENTS PROVIDE FOR:

SLR-006 Labeling changes. Delete picture instructions and add graphic "nitro-Dur" patch on front of package.
SLR-007 Added to ADVERSE REACTIONS section a warning regarding contact dermatitis

AMENDMENTS PROVIDE FOR:

None

NAME AND ADDRESS OF APPLICANT:

Key Pharmaceuticals, Inc.
2000 Galloping Hill Road
Kenilworth, NJ 07033

DRUG PRODUCT NAME:

Proprietary:	Nitro-Dur® Transdermal Infusion Systems
Nonproprietary/USAN:	None
Code Name/#:	NA
Chem.Type/Ther.Class:	3 S

Patent Status: There is no unexpired U.S. patent, to the knowledge of the applicant (01 0003).

PHARMACOL. CATEGORY/INDICATION:

Vasodilator (coronary)

DOSAGE FORM: Transdermal Patch

STRENGTHS: 0.1, 0.2, 0.3, 0.4 and 0.8 mg/hr

ROUTE OF ADMINISTRATION: Transdermal

DISPENSED: X Rx OTC

STRUCTURAL FORMULA, CHEMICAL NAME, MOLECULAR FORMULA, MOLECULAR WEIGHT:

CH₂-ONO₂

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CH₂-ONO₂

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CH₂-ONO₂

C₃H₅N₃O₉ M.W. - 227.09
CAS-55-63-0, Nitroglycerin;
1,2,3-Propranetriol, trinitrate

SUPPORTING DOCUMENTS:

See previous reviews.

RELATED DOCUMENTS (if applicable):

See prior reviews for this information.

REMARKS/COMMENTS:

See prior reviews for this information.

CONCLUSIONS & RECOMMENDATIONS:

These submissions are approved for use in the United States.

5/5/95
Joseph T. Piechocki, Ph.D.
Review Chemist

cc:
Orig. NDA 20-145
Dup.
HFD-110/Division File
HFD-110/JPiechocki/5-2-95
HFD-110/CSO

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Wolters
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