

RUSAN PHARMA LTD., DEHRADUN
PROCESS VALIDATION
FOR RESTRICTED CIRCULATION ONLY

Rusan



Protocol No.: PV/TDP-25,50,75,100 / 01			Issued By QA
Product Name: Fenstud Transdermal Patch			Page 1 of 47
Doc. No.	Issue Date	Effective Date	Supersedes No.
1.0	09-07-2011	11-07-2011	Nil

Location	Khasra No.122, MI Central Hope Town, Selaqui, Dehradun. Uttarakhand
Building/Department	Ground Floor/ Tablet Department
Product Name	Fenstud 25µg/hr Fenstud 50µg/hr Fenstud 75µg/hr Fenstud 100µg/hr
Generic Name	Fentanyl base
Label Claim	Each Transdermal Patch contains: For 25 mcg/hr; Fentanyl BP 3.00 mg For 50 mcg/hr; Fentanyl BP 6.00 mg For 75 mcg/hr; Fentanyl BP 9.00 mg For 100 mcg/hr; Fentanyl BP 12.00 mg
Mfg. Lic. No./Code No.	19/UA/2008
Shelf Life	2 Years
Batch Size	2897 g of casting solution

RUSAN PHARMA LTD. DEHRADUN
QUALITY ASSURANCE
MASTER COPY
Stamp No. Q/V01

RUSAN PHARMA LTD., DEHRADUN
PROCESS VALIDATION
FOR RESTRICTED CIRCULATION ONLY

Rusan

Protocol No.: PV/TDP-25,50,75,100 / 01			Issued By QA
Product Name: Fenstud Transdermal Patch			Page 2 of 47
Doc. No.	Issue Date	Effective Date	Supersedes No.
1.0	09-07-2011	11-07-2011	Nil



TABLE OF CONTENTS

Sr. No.	Content	Page No.
1	Process validation Pre-Approval	3
2	Objective	4
3	Scope	4
4	Validation Team	4
5	Responsibility	5
6	Revalidation Criteria	5
7	Batch Under Validation	5
8	Process Flow Chart and Process Overview	6
8A	Manufacturing	6
8B	Manufacturing Procedure	7-11
9	Master Formula record	11
10	List of Equipment and Tools	12
11	Experimental Design & Matrix for filling data recording [11A/11B]	13-15
12	Dispensing Batch Detail [12.A1/12.A.2/12.A.3]	16-18
13	Validation Process	19-43
14	Deviation Summary	44
15	OOS Result	44
16	Summary conclusion & Approval Report	45
17	Post Approval	46
18	List of Attachment	47

RUSAN PHARMA LTD. DEHRADUN
QUALITY ASSURANCE
MASTER COPY
Stamp No. QA/01

RUSAN PHARMA LTD., DEHRADUN
PROCESS VALIDATION
FOR RESTRICTED CIRCULATION ONLY

Rusan



Protocol No.: PV/TDP-25,50,75,100 / 01			Issued By QA
Product Name: Fenstud Transdermal Patch			Page 3 of 47
Doc. No.	Issue Date	Effective Date	Supercedes No.
1.0	09-07-2011	11-07-2011	Nil

1.0 Process Validation Pre-Approval:

	Prepared By	Checked By		Approved By
Name	Pankaj Singh	Mahesh Jadhav	J. Subudhi	Sheeraj Vals
Signature				
Date	07-07-2011	08-07-2011	08-07-2011	09-07-2011
Department	Q. A.	Head - QC	Head - Production	Head - QA

RUSAN PHARMA LTD., DEHRADUN
PROCESS VALIDATION
FOR RESTRICTED CIRCULATION ONLY

Rusan



Protocol No.: PV/TDP-25,50,75,100 / 01			Issued By: QA
Product Name: Fenstud Transdermal Patch			Page 4 of 47
Doc. No.	Issue Date	Effective Date	Supercedes No.
1.0	09-07-2011	11-07-2011	Nil

2.0 OBJECTIVE -

To provide guidelines on how to carry out process validation of Fentanyl transdermal patches to demonstrate that the proposed method of manufacturing is capable of consistently yielding product that meets the specifications.

3.0 SCOPE -

The protocol covers process, sampling and testing of three consecutive batches of Fentanyl transdermal patches at a batch size of 2897 g of casting solution to fully validate the proposed method of manufacturing at that batch size.

4.0 VALIDATION TEAM: A representative from following departments are responsible for the execution of this protocol. Validation team comprises of:

Name / Designation	Function Area	Signature	Date
P.K Singh.	Engineering	P.K Singh	11-07-2011
Mahesh Jadhav. Nidhish Bansal.	Quality Control	Nidhish Bansal	11-07-2011
J. Subudhi Om Shankar Tiwari	Production	Subudhi	11-07-2011
Dhruv Vats Lalit moham Singh	Quality Assurance	Dhruv Vats	11-07-2011