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(71) Applicant *(for all designated States except US)*: **ENALTEC LABS PVT. LTD.** [IN/IN]; 17th Floor, Kesar Solitaire, Plot No.5, Sector-19, Sanpada, Navi Mumbai 400 705, Maharashtra (IN).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BOBBA, Siva, Kumar, Venkata** [IN/IN]; Enaltec Labs Private Limited, Plot No.W-59 A, Addl MIDC, Dist-Thane, Ambernath 421 506, Maharashtra (IN). **TRIPATHI, Alok, Pramod** [IN/IN]; Enaltec Labs Private Limited, Plot No.W-59 A, Addl MIDC, Dist-Thane, Ambernath 421 506, Maharashtra (IN). **KODALI, Eswara, Rao** [IN/IN]; Enaltec Labs Private Limited, Plot No.W-59 A, Addl MIDC, Dist-Thane, Ambernath 421 506, Maharashtra (IN). **PATEL, Girish, Bansilal** [IN/IN]; Enaltec Labs Private Limited, Plot No.W-59 A, Addl MIDC, Dist-Thane, Ambernath 421 506, Maharashtra (IN). **VAIDYA, Sanjay, Dashrath** [IN/IN]; Enaltec Labs Private Limited, Plot No.W-59 A, Addl MIDC, Dist-Thane, Ambernath 421 506, Maharashtra (IN).

(74) Agent: **TAMBAT, Paresh, Shivnath**; Enaltec Labs Private Limited, Plot No.W-59 A, Addl MIDC, Dist-Thane, Ambernath 421 506, Maharashtra (IN).

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Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

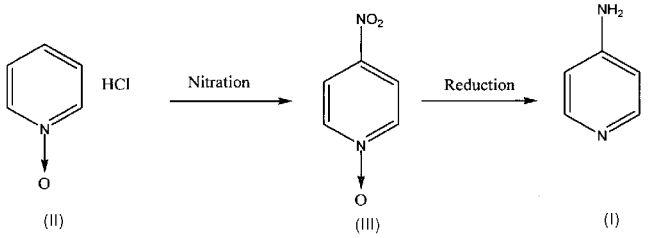
— *of inventorship (Rule 4.17(iv))*

Published:

— *with international search report (Art. 21(3))*

(88) Date of publication of the international search report:
29 March 2012

(54) Title: PROCESS FOR THE PREPARATION OF FAMPRIDINE



(57) Abstract: The present invention relates to a process for the preparation of substantially pure fampridine compound of structural formula (I), (II), (III) comprising nitrifying pyridine-N-oxide hydrochloride with suitable nitrating agent; reducing with suitable reducing agent and purifying by recrystallizing in water followed by treating with an alkyl acetate solvent.

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INTERNATIONAL SEARCH REPORT

International application No
PCT/IN2011/000134

A. CLASSIFICATION OF SUBJECT MATTER
INV. C07D213/73 A61K31/4409 A61P21/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
C07D A61K A61P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, CHEM ABS Data, WPI Data, BEILSTEIN Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	DATABASE CA [Online] CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; WANG, ZHIXIANG ET AL: "Improved preparation of 4-aminopyridine", XP002652907, retrieved from STN Database accession no. 2001:292472 cited in the application abstract & ZHONGGUO YIYAO GONGYE ZAZHI , 32(2), 83-84 CODEN: ZYGZEA; ISSN: 1001-8255, 2001, ----- -/--	1-5,8,9, 12

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 July 2011	03/01/2012

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Stix-Malaun, Elke

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IN2011/000134

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-5, 12(completely); 8, 9(partially)

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/IN2011/000134

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	MOSHER H.S. ET AL: "Pyridine-N-oxide", ORGANIC SYNTHESES, vol. 4, no. 33, 1 January 1953 (1953-01-01), - 1 January 1953 (1953-01-01), pages 828-830, XP009150355, page 828, paragraph 2 -----	1-5,8,9, 12

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-5, 12(completely); 8, 9(partially)

   Process for the preparation of Fampridine via nitration and reduction

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2. claims: 6, 7, 14, 15(completely); 8, 9(partially)

   Process for the preparation of crystalline Fampridine

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3. claims: 10, 11, 13

   Polymorphic Form A of Fampridine and Pharmaceutical Composition thereof

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