

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2024/079722

International filing date (day/month/year)
21.10.2024

Priority date (day/month/year)
27.10.2023

International Patent Classification (IPC) or both national classification and IPC
INV. A61K9/00 A61K9/20 A61K31/00 A61K31/4178

Applicant
ADAMED PHARMA S.A.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:



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Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Leitner, Nikolaus

Telephone No. -0



Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))
3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:
 - a. ☐ forming part of the international application as filed.
 - b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13*ter*.1(a)),
 - ☐ accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.
4. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established to the extent that a meaningful opinion could be formed without a WIPO Standard ST.26 compliant sequence listing.
5. Additional comments:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>1-17</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-17</u>
Industrial applicability (IA)	Yes: Claims	<u>1-17</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial
applicability; citations and explanations supporting such statement**

1 Prior Art

Reference is made to the following documents:

- D1 WO 2022/157357 A1 (ADAMED PHARMA S A [PL]) 28 July 2022 (2022-07-28)
- D2 US 2020/078337 A1 (BERDZIK-KALARUS SYLWIA [PL] ET AL) 12 March 2020 (2020-03-12)
- D3 WO 2018/069804 A2 (PRZED PRODUKCJI FARMACEUTYCZNEJ HASCO LEK S A [PL] ET AL.) 19 April 2018 (2018-04-19)

2 Novelty [Article 33(2) PCT]

The subject-matter of claims 1-17 is new in sense of Article 33(2) PCT.

- 2.1 **Document D1 discloses** (page 1, lines 5-6; example 1, tables 1-2, pages 29-35): a furazidin formulation in tablet form, where the mucoadhesive is Povidone K30 with a weight percentage of 3.5%, microcrystalline cellulose is used as filler, copovidone is used as disintegrant, the lubricant is magnesium stearate, and the dose strength of furazidin is between 50 and 150 mg, for use for treating urinary tract infections. The tablet is considered to be suitable for vaginal administration. Furthermore, a method for the preparation of the formulation with wet-granulation, in particular high-shear granulation, is disclosed.

D1 does not disclose: 1-15 weight percent furazidin.

The subject-matter of claims 1-17 is thus new over document D1.

- 2.2 **Document D2 discloses** (paragraph 52-54, page 4): a furazidin formulation for vaginal application, where the filler is lactose, and the lubricant is magnesium stearate.

Document D2 does not disclose: 1-15 weight % of Furazidin and a mucoadhesive polymer. Furthermore, the formulation is not in a granular form.

The subject matter of claims 1-17 is thus new over document D2.

- 2.3 **Document D3 discloses** (examples 9-15, pages 18-28; claims): discloses a Furazidin formulation with a weight percentage between of 0.5 – 20% for furazidin, povidone and lactose monohydrate are used as fillers, magnesium stearate as lubricant and the granulate is prepared by wet-granulation.

Document D3 does not disclose: a tablet for vaginal application; high shear granulation.

The subject matter of claims 1-17 is thus new over document D3.

3 **Inventive step [Article 33(3) PCT]**

The application does not meet the requirements Article 33(3) PCT, as claims 1-17 lack an inventive step.

- 3.1 **Any of documents D1 or D3 can be considered to represent the closest prior art. The following problem solution approach is made with document D1.**

The subject matter of claim 1 differs from the solution of D1 in that, the amount of furazidin in the composition is 1-15 % by weight, whereas in D1 the furazidin mass concentration is between 41.67-54.55 %.

There is no unexpected effect as a result of this differences. The examples of the application are inconclusive with regard to this feature.

The problem that can be recognized is: the provision of an alternative composition.

The solution offered by present claim 1 to the problem posed is obvious for the following reasons: adapting the dose of a pharmaceutical composition for optimal performance is part of common knowledge of the person skilled in the art and can be achieved with routine experimentation. Alterations in the dose strength is merely one of several options the skilled person would choose form in order to solve the problem posed.

Hence, the subject matter of claim 1 of the present application cannot be considered to involve an inventive step [Article 33(3) PCT].

The additional features of dependent claims 2-14 and 16 and independent claims 15 and 17 concern minor modifications and routine experimentation which lie in the normal practice of the skilled person e.g.:

the amount of furadizin in the composition (claim 2); the amount of polymeric mucoadhesive binder in the composition (claim 3); povidone as binder (claims 4 and 7); lactose and/or microcrystalline cellulose as filler (claims 5, 6 and 7); selection of the disintegrant (claim 8); the intragranular disintegrant and extragranular disintegrant are the same (claim 9); crospovidone as disintegrant (claim 10); magnesium stearate as lubricant (claim 11); the dose strength of Furazidin (claims 12 and 13); the granulate is prepared by wet-granulation (claim 14); a process for preparing a pharmaceutical composition of furazidin in the form of a mucoadhesive tablet for vaginal administration (claim 15); the use of a high-shear granulator in the process (claim 16); and a pharmaceutical composition of furazidin in the form of a mucoadhesive tablet for use in a method of treatment (claim 17).

3.2 A similar reasoning as in point 3.1 is applied if D3 is used for the problem solution approach.

4 Industrial Applicability [Article 34(4) PCT]

Claims 1-17 meet the requirements of Article 33(4) PCT.