CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

218197Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	May 26, 2023
Application Type and Number:	IND 118046 and NDA 218197
Product Name and Strength:	Truqap (capivasertib) tablets, 160 mg and 200 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	AstraZeneca Pharmaceuticals LP (AstraZeneca)
PNR ID #:	2022-1044724696 and 2023-1044725027
DMEPA 2 Safety Evaluator:	Tingting Gao, PharmD
DMEPA 2 Team Leader:	Ashleigh Lowery, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Truqap, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A, respectively. AstraZeneca did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

AstraZeneca previously submitted the proposed proprietary name, [(b) (4)]*** under IND 118046 on November 26, 2021. However, on January 24, 2022, we found the name, [(b) (4)]*** unacceptable due to misbranding concerns.[a] AstraZeneca subsequently submitted proposed proprietary name, [(b) (4)]*** under IND 118046 on February 18, 2022[b], and withdrew the name [(b) (4)]*** on May 20, 2022[c].

Thus, AstraZeneca submitted the name, Truqap, for review under IND 118046 on August 5, 2022[d] and under NDA 218197 on March 6, 2023[e].

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on March 6, 2023[e], and Prescribing Information received on March 28, 2023.

- Intended Pronunciation: TRUE-cap
- Active Ingredient: capivasertib
- Indication of Use: In combination with fulvestrant is indicated for the treatment of adult patients with HR-positive HER2-negative (defined as IHC 0 or 1+, or IHC 2+/ISH-) locally advanced or metastatic breast cancer following recurrence or progression on or after an endocrine-based regimen.
- Route of Administration: Oral
- Dosage Form: tablets

---

[a] Gao, T. Proprietary Name Review for [(b) (4)] (IND 118046). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2022 Jan 24. PNR ID No. 2021-1044724302.

[b] Proprietary Name Review for [(b) (4)] Wilmington (DE): AstraZeneca Pharmaceuticals LP. 2022 Feb 18. Available from: \\CDSESUB1\EVSPROD\ind118046\0278\m1\us\proprietary-names.pdf

[c] Re: IND 118046, Serial No.:0297, eCTD Sequence No.: 0297. Capivasertib (AZD5363). WITHDRAWAL OF APPLICATION TO REQUEST FOR PROPRIETARY NAME REVIEW. Wilmington (DE): AstraZeneca Pharmaceuticals LP. 2022 May 20. Available from: \\CDSESUB1\EVSPROD\ind118046\0297\m1\us\20220520-cover-letter-withdrawal-of-request.pdf.

[d] Proprietary Name Review for Truqap. Wilmington (DE): AstraZeneca Pharmaceuticals LP. 2022 Aug 5. Available from: \\CDSESUB1\EVSPROD\ind118046\0308\m1\us\proprietary-names.pdf.

[e] Proprietary Name Review for Truqap. Wilmington (DE): AstraZeneca Pharmaceuticals LP. 2023 Mar 6. Available from: \\CDSESUB1\EVSPROD\nda218197\0001\m1\us\proprietary-names-sn0001-pro-name-request-cmc-rolling-subm.pdf.

- Strength: 160 mg and 200 mg
- Dose and Frequency: 400 mg taken orally twice daily, for 4 days followed by 3 days off treatment. Continue treatment until disease progression or unacceptable toxicity occurs.
    - **Recommended dose modification for Adverse Reactions**

Recommended dose	Dose and Schedule
Starting dose	400 mg twice daily for 4 days followed by 3 days off treatment
First dose reduction	320 mg twice daily for 4 days followed by 3 days off treatment
Second dose reduction	200 mg twice daily for 4 days followed by 3 days off treatment

- How Supplied: (b) (4) bottle of 64 tablets
- Storage: Store in original package at 20°C to 25°C (68°F to 77°F)

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name, Truqap.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Truqap would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Truqap. The Division of Oncology 1 (DO1) concurred with the findings of OPDP's assessment for Truqap.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Truqap.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proposed proprietary name[f].

2.2.2 Components of the Proposed Proprietary Name

AstraZeneca did not provide a derivation or intended meaning for the proposed proprietary name, Truqap, in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e., a modifier, route of administration, dosage form, etc.) that can contribute to medication error.

[f] USAN stem search conducted on April 11, 2023.

2.2.3 Comments from Other Review Disciplines at Initial Review

On April 7, 2023, the Division of Oncology 1 (DO1) did not forward any comments or concerns relating to Truqap at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Eighty-nine practitioners participated in DMEPA's prescription studies for Truqap. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[g] identified 74 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	62
Low similarity name pair: combined match percentage score ≤54%	10

2.2.7 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 74 names contained in Table 1 determined none of the names will pose a risk for confusion with Truqap as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On May 25, 2023, DMEPA 2 communicated our determination to the Division of Oncology 1 (DO1).

[g] POCA search conducted on April 11, 2023 in version 5.2.

3 CONCLUSION

The proposed proprietary name, Truqap, is conditionally acceptable.

If you have any questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager, at 301-796-0942.

3.1 COMMENTS TO ASTRAZENECA PHARMACEUTICALS LP

We have completed our review of the proposed proprietary name, Truqap, and have concluded that this name is conditionally acceptable.

If any of the proposed product characteristics as stated in your submission, received on March 6, 2023, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [h]

[h] National Coordinating Council for Medication Error Reporting and Prevention. https://www nccmerp.org/about-medication-errors Last accessed 10/05/2020.

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@FDA, Cerner RxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.

- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[i]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign

[i] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

   Four separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions, verbal pronunciation of the drug name or during computerized provider order entry. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

   When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e., drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

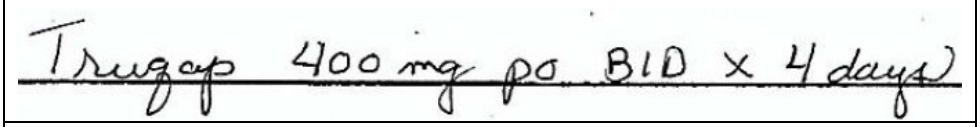
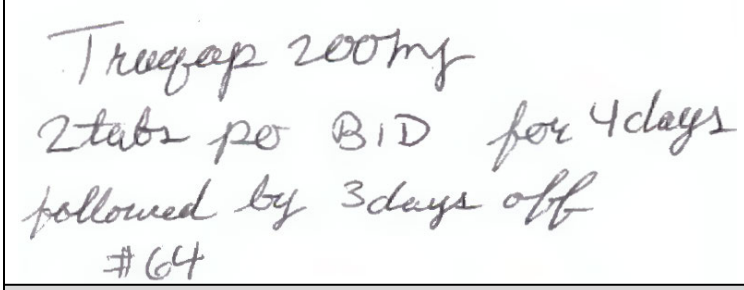
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Truqap Study (Conducted on March 21, 2023)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Truqap Two tablets by mouth twice daily for 4 days, followed by three days off. Dispense sixty-four
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Truqap	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Truqap

257 People Received Study

89 People Responded

Total **24** **23** **22** **20**

INTERPRETATION	INPATIENT	CPOE	VOICE	OUTPATIENT	TOTAL
TRAQAP	0	0	0	1	1
TREEFAP	0	0	0	1	1
TREEQAP	0	0	0	1	1
TRU CAP	0	0	1	0	1
TRUCAP	0	0	19	0	19
TRU-CAP	0	0	1	0	1
TRUECAP	0	0	1	0	1
TRUEFAP	0	0	0	3	3
TRUEFOP	0	0	0	1	1
TRUGAP	8	0	0	0	8
TRUQAP	14	23	0	12	49
TRUQAP 400MG	1	0	0	0	1
TRUQOP	1	0	0	1	2

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)

No.	**Proposed name:** Truqap **Established name:** capivasertib **Dosage form:** tablets **Strength(s):** 160 mg and 200 mg **Usual Dose:** 400 mg taken orally twice daily, for 4 days followed by 3 days off	POCA Score (%)	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Truqap	100	Name is the subject of this review.
2.	Tritop	72	Veterinary product

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	Propa P.H.	66
2.	Trusopt	66
3.	Protac	64
4.	(b) (4) ***	62
5.	Truvada	60
6.	Pro Tuss	59
7.	Procot	59
8.	Protuss	59
9.	Triphed	58
10.	Triumeq	57
11.	Crotan	56
12.	Tarka	56
13.	Triad	56
14.	Tricalm	56
15.	Tusstat	56
16.	Tyruko***	56
17.	Triacet	55

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Truqap **Established name:** capivasertib **Dosage form:** tablets **Strength(s):** 160 mg and 200 mg **Usual Dose:** 400 mg taken orally twice daily, for 4 days followed by 3 days off	POCA Score (%)	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Tetracap	62	Orthographically, Tetracap has an upstroke letter "t" on the 3rd position, whereas Truqap has a downstroke letter "q" in the fourth position. thus providing sufficient orthographic differences when scripted. Although many participants from the voice portion of the FDA prescription simulation study interpreted the ending syllable as "cap" in Truqap, phonetically, the first syllable (TRUE vs. te) and second syllable (cap vs. tra) of this name pair sound different when spoken. Additionally, Tetracap has three syllables whereas Truqap only has two syllables. Although the dose may overlap (2 pills), there is no overlap in strength (160 mg and 200 mg vs. 250 mg), and frequency (twice daily for 4 days, followed by 3 days off vs. twice daily or four times a day), which provides additional differentiating product characteristics when included on a prescription.
2.	Procan	60	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Truqap **Established name:** capivasertib **Dosage form:** tablets **Strength(s):** 160 mg and 200 mg **Usual Dose:** 400 mg taken orally twice daily, for 4 days followed by 3 days off	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
3.	Tranmep	59	Orthographically, Truqap has a downstroke letter "q" in the fourth position that is not seen in Tranmep, and the infix is shorter in Truqap when compared to Tranmep (6 letters in Truqap vs. 7 letters in Tranmep with the wider letter "m"), which provides some orthographic differences when scripted. Phonetically, the ending sounds of the first syllables (TRUE vs. tran), and the second syllables (cap vs. mep) of this name pair sound different when spoken. Although the dose may overlap (1 tablet or 2 tablets) and strengths overlap (200 mg), there are no overlapping frequency (twice daily for 4 days, followed by 3 days off vs. two, three, or four times a day).
4.	Trancot	58	This name pair has sufficient orthographic and phonetic differences.
5.	(b) (4)***	58	This name pair has sufficient orthographic and phonetic differences.
6.	Truxima	58	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Truqap **Established name:** capivasertib **Dosage form:** tablets **Strength(s):** 160 mg and 200 mg **Usual Dose:** 400 mg taken orally twice daily, for 4 days followed by 3 days off	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
7.	Turqoz***	58	Orthographically, the last letter (p vs. q) provides some minor differentiation. Phonetically, the ending sounds of the second syllables (cap vs. COZE) of this name pair sound different when spoken. Although the dose may overlap (1 tablet), there are no overlapping strength (160 mg and 200 mg vs. 0.3 mg/0.03 mg) and frequency (twice daily for 4 days followed by 3 days off vs. once daily). In the worst-case scenario where the name pair is confused orthographically on a written prescription: • If a prescription for "Truqap 200 mg 1 tablet PO BID x 4 days followed by 3 days off" is misinterpreted as Turqoz***, the strength "200 mg" and the additional instruction "4 days followed by 3 days off" will trigger the dispensing pharmacist to contact the prescriber because Turqoz*** is not available in a 200 mg strength and oral contraceptives are not dosed 4 days on 3 days off. We anticipate contacting the prescriber will clarify the order and prevent this risk of name confusion. • If a prescription for "Turqoz*** 1 tablet PO QD" is misinterpreted as Truqap, then the dispensing pharmacist will

No.	Proposed name: Truqap Established name: capivasertib Dosage form: tablets Strength(s): 160 mg and 200 mg Usual Dose: 400 mg taken orally twice daily, for 4 days followed by 3 days off	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
			have to contact the prescriber to clarify the strength (160 mg vs. 200 mg) or dose in milligram in order to dispense. We anticipate contacting the prescriber will clarify the order and prevent this risk of name confusion. Furthermore, while Truqap is proposed to be supplied in (b) (4) bottles of 64 tablets, Turqoz*** is an oral contraceptive available in a 28-day calendarized blister pack containing 21 active tablets and 7 inert tablets. In the rare event that the proprietary names are confused orthographically and not clarified between the prescriber and the dispensing pharmacy, it is likely that any such error would be intercepted given consumer familiarity with the calendarized dispensing packaging and labeling conventionally associated with oral contraceptives. Moreover, a prescription for Turqoz*** is likely to indicate a dispensing quantity of 1 to 3 packs, which is a common quantity specified for oral contraceptive packs. In contrast, a prescription for Truqap would require the specification of a quantity which would be greater than 1 to 3, and dispensing units (for example, 64 tablets). When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.

No.	**Proposed name:** Truqap **Established name:** capivasertib **Dosage form:** tablets **Strength(s):** 160 mg and 200 mg **Usual Dose:** 400 mg taken orally twice daily, for 4 days followed by 3 days off	POCA Score (%)	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
8.	Triban	57	This name pair has sufficient orthographic and phonetic differences.
9.	Triam	56	This name pair has sufficient orthographic and phonetic differences.
10.	Trovan	56	This name pair has sufficient orthographic and phonetic differences.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)
1.	Pro Otic	54
2.	Pro1tek	54
3.	Procet	54
4.	Procof	54
5.	(b) (4) ***	54
6.	Procomp	53
7.	Crofab	52
8.	Procrit	52
9.	Drotic	49
10.	Prosed	48

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Name	POCA Score (%)	Failure preventions
1.	Prostap 3	64	International product marketed in Denmark, Ireland, and United Kingdom.
2.	Propet	62	Veterinary product.
3.	(b) (4)***	60	Proposed proprietary name for IND 104187 found unacceptable by DMEPA (OSE# 2019-32766457 dated 12/18/2019). Subsequently, NDA 214622 is approved with the proprietary name Truseltiq (OSE # 2020-43182613 dated 12/23/2020).
4.	(b) (4)***	60	Proposed proprietary name for IND (b) (4) found acceptable by DMEPA (b) (4) Subsequently, the sponsor withdrew the name, (b) (4)***on (b) (4) and submitted an alternative name for review, (b) (4)***, on (b) (4) The proposed proprietary name, (b) (4)*** is denied (b) (4) for misleading concerns. No new names have been submitted to IND (b) (4)
5.	Tritec	60	Tritec is the brand name for ranitidine bismuth citrate. All prescription and nonprespcription anitidine drugs have been withdrawn from the U.S. market because of concerns over levels of the contaminant N-nitrosodimethylamine, which can increase with time and temperature, posing a risk of cancer.
6.	Truxade	60	Name identified in RxNorm database. Product is deactivated per Red Book with no generic equivalents available.
7.	Traxam	59	International product formerly marketed in the United Kingdom and Italy.
8.	Prodip	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
9.	Progan	58	International drug product formerly marketed in Australia.
10.	Propan	58	Name identified in RxNorm database. Product is deactivated per Red Book with no generic equivalents available.
11.	(b) (4)***	58	Proposed proprietary name for IND 121211 found unacceptable by DMEPA (OSE# 2017-13620885). NDA 210861 and NDA 211710 approved under the proprietary name Vitrakvi.

No.	Name	POCA Score (%)	Failure preventions
12.	(b) (4)***	56	Proposed proprietary name for IND 121211 found unacceptable by DMEPA (OSE# 2017-16491499). NDA 210861 and NDA 211710 is approved under the proprietary name Vitrakvi.
13.	Tri-Dec	56	Name identified in RxNorm database. Product is deactivated per Red Book with no generic equivalents available.
14.	Tri-Pase	56	Name identified in RxNorm database. Product is deactivated per Red Book with no generic equivalents available.
15.	Triumph	56	Veterinary product.
16.	Tropium	56	International product formerly marketed in the United Kingdom and Greece.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[j].

No.	Name	POCA Score (%)
1.	Proquad	65
2.	Bromtapp	60
3.	Uticap	60
4.	Bromapp	59
5.	Otrexup	58
6.	Prax	58
7.	Q-Tapp	58
8.	Bupap	57
9.	Requip	57
10.	Duract	56
11.	Dura-Tap Pd	56
12.	(b) (4)***	56
13.	Procapan	56
14.	Prostep	56
15.	Prulet	56
16.	Serutan	56
17.	Ultracaps	56
18.	Prozac	55
19.	Utrona-C	55

[j] Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

APPEARS THIS WAY ON ORIGINAL

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

TINGTING GAO
05/26/2023 09:16:10 AM

ASHLEIGH V LOWERY
05/26/2023 09:45:14 AM

CHI-MING TU
05/26/2023 01:00:57 PM