

Summary Report

Boric Acid

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Food and Drug Administration

Clinical use of bulk drug substances nominated for inclusion on the 503B Bulks List

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Table of Contents

| | |
|---|----|
| REVIEW OF NOMINATION | 4 |
| METHODOLOGY | 4 |
| Background information..... | 4 |
| Systematic literature review..... | 4 |
| Outreach to medical specialists and specialty organizations | 7 |
| Survey..... | 7 |
| CURRENT AND HISTORIC USE..... | 9 |
| Summary of background information..... | 9 |
| Summary of literature review | 9 |
| Summary of focus groups/interviews of medical experts and specialty organizations | 14 |
| Summary of survey results..... | 15 |
| CONCLUSION..... | 17 |
| APPENDICES | 18 |
| Appendix 1. References..... | 18 |
| Appendix 2. Survey instrument | 22 |

Table of Tables

| | |
|--|----|
| Table 1. Participating associations..... | 8 |
| Table 2. Associations that declined participation..... | 8 |
| Table 3. Currently approved products – US..... | 9 |
| Table 4. Currently approved products–select non-US countries and regions..... | 9 |
| Table 5. Types of studies | 9 |
| Table 6. Number of studies by country..... | 10 |
| Table 7. Number of studies by combinations..... | 10 |
| Table 8. Dosage by indication – US..... | 11 |
| Table 9. Dosage by indication – non-US countries..... | 12 |
| Table 10. Compounded products – US..... | 13 |
| Table 11. Compounded products – non-US countries | 13 |
| Table 12. Overview of interviewees..... | 14 |
| Table 13. Characteristics of survey respondents [21 people responded to the survey ^a]..... | 15 |
| Table 14. Types of products used, prescribed, or recommended | 15 |
| Table 15. Compounded use of boric acid in practice ^a | 16 |
| Table 16. Indications for which boric acid is considered a standard therapy | 16 |
| Table 17. Reasons for using a compounded product instead of any FDA-approved product..... | 16 |
| Table 18. Change in frequency of compounded boric acid usage over the past 5 years..... | 16 |
| Table 19. Do you stock non-patient specific compounded boric acid in your practice?..... | 17 |
| Table 20. Questions related to stocking non-patient specific compounded boric acid..... | 17 |

REVIEW OF NOMINATION

Boric acid (UNII code: R57ZHV85D4) was nominated for inclusion on the 503B Bulks List by ASP Cares for bacterial vaginosis, candida vulvovaginitis, and external otitis as a 150-600 mg otic capsule to be administered via an insufflator bulb.

The reasons provided for nomination to the 503B Bulks List is because there is no FDA-approved drug product that contains boric acid. There is also an advantage to otic therapy because a high concentration of the antimicrobial agent can be delivered to the infected tissue as compared with systemic therapy.

METHODOLOGY

Background information

The national medicine registers of 13 countries and regions were searched to establish the availability of boric acid products in the United States (US) and around the world. The World Health Organization, the European Medicines Agency (EMA), and globalEDGE were used to identify regulatory agencies in non-US countries. The medicine registers of non-US regulatory agencies were selected for inclusion if they met the following criteria: freely accessible; able to search and retrieve results in English language; and desired information, specifically, product trade name, active ingredient, strength, form, route of administration (ROA), and approval status provided in a useable format. Based on these criteria, the medicine registers of 13 countries/regions were searched: US, Canada, European Union (EU), United Kingdom (UK), Ireland, Belgium, Latvia, Australia, New Zealand, Saudi Arabia, Abu Dhabi, Hong Kong, and Namibia. Both the EMA and the national registers of select EU countries (Ireland, UK, Belgium, and Latvia) were searched because some medicines were authorized for use in the EU and not available in a member country and vice versa.

Each medicine register was searched for boric acid; name variations of boric acid were entered if the initial search retrieved no results. The following information from the search results of each register was recorded in a spreadsheet: product trade name; active ingredient(s); strength; form; ROA; status and/or schedule; approval date. Information was recorded only for products with strengths, forms and/or ROA similar to those requested in the nominations.

In addition to the aforementioned medicine registers, the DrugBank database (version 5.1.4) and the Natural Medicines database were searched for availability of over-the-counter (OTC) products containing boric acid. The availability of OTC products (yes/no) in the US and the ROA of these products were recorded in a spreadsheet. Individual product information was not recorded.

Systematic literature review

Search strategy

Two databases (PubMed and Embase) were searched including any date through January 25, 2019. The search included a combination of ("boric acid" [TIAB] OR "orthoboric acid" [TIAB]) AND (therapeutic*[TIAB] OR clinical[TIAB] OR therapy[TIAB] OR treatment[TIAB] OR vagin*[TIAB] OR infection[TIAB] OR antibacterial[TIAB] OR bacteri*[TIAB] OR antifung*[TIAB] OR candi*[TIAB] OR vulvo*[TIAB] OR fungal[TIAB] OR urin*[TIAB] OR yeast[TIAB] OR otitis[TIAB] OR ear[TIAB]) AND English[lang] AND humans[MeSH Terms] NOT autism. Peer-reviewed articles as well as grey literature were included in the search. Search results from each database were exported to Covidence®, merged, and sorted for removal of duplicate citations.

Study selection

Articles were not excluded on the basis of study design. Articles were considered relevant based on the identification of a clinical use of boric acid or the implementation of boric acid in clinical practice. Articles were excluded if not in English, a clinical use was not identified, incorrect salt form, or if the study was not conducted in humans. Screening of all titles, abstracts, and full-text were conducted independently by two reviewers. All screening disagreements were reconciled by a third reviewer.

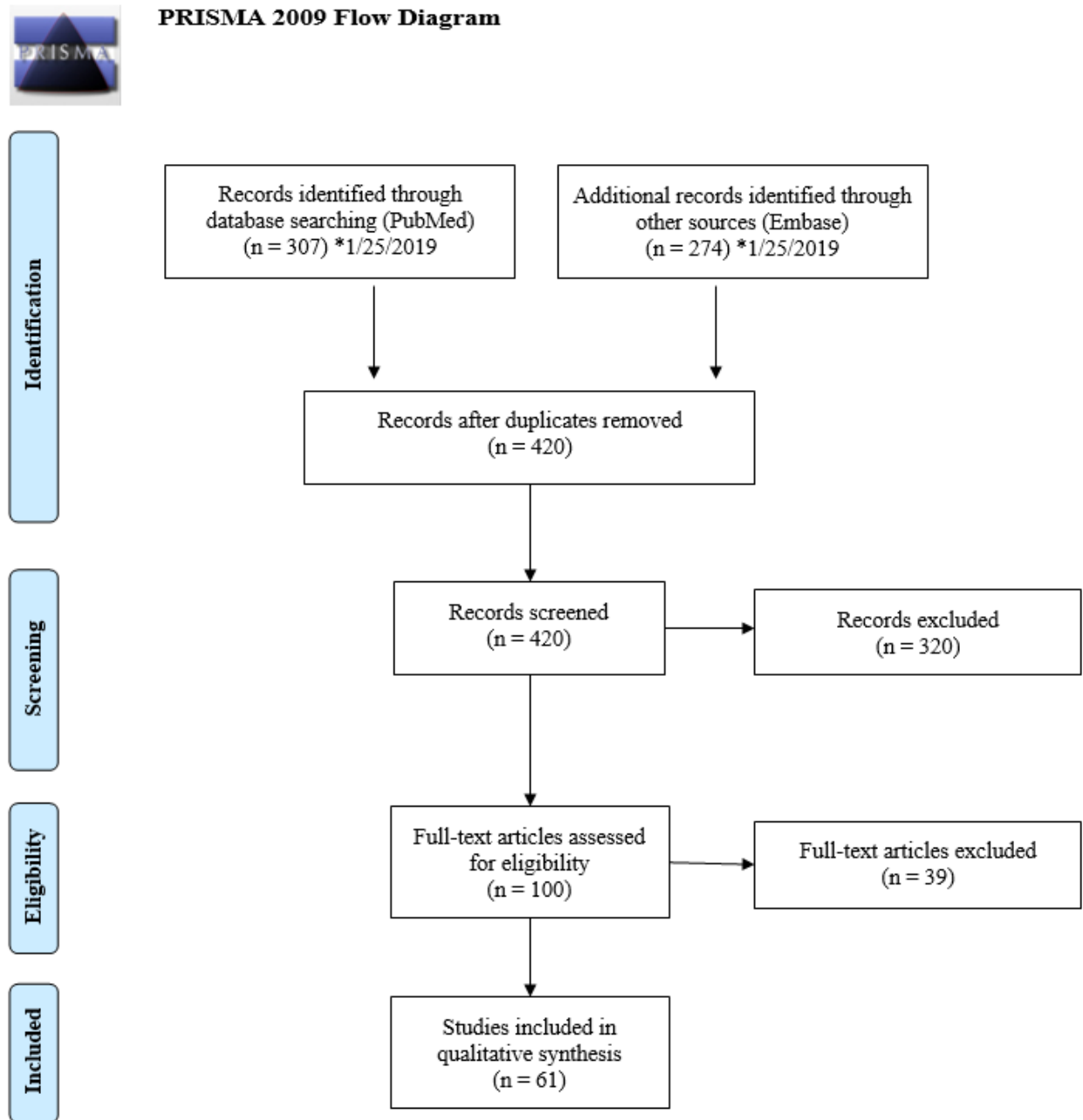
Data extraction

A standard data extraction form was used to collect study authors; article title; year published; journal title; country; indication for boric acid use; dose; strength; dosage form; ROA; frequency and duration of therapy; any combination therapy utilized; if applicable, formulation of compounded products; study design; and any discussion surrounding the use of boric acid compared to alternative therapies.

Results

Please refer to Figure 1.

Figure 1. Summary of literature screening and selection (PRISMA 2009 Flow Diagram)



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

Outreach to medical specialists and specialty organizations

Using the indications from the nomination and the results of the literature review, eight (8) medical specialties that would potentially use boric acid were identified: dentistry, dermatology, infectious disease, naturopathy, obstetrics and gynecology, oral medicine, otolaryngology, and wound care. Semi-structured interviews were conducted with subject matter experts within these specialties. Interviews lasted from 30-75 minutes and were conducted either via telephone or in-person. Criteria for selecting subject matter experts included recommendations provided by specialty professional associations, convenient geographic location, authorship within the specialty, or referral by an interviewee. Up to nine (9) interviews were conducted per substance. Four (4) experts were contacted for interviews, of which two (2) accepted. Two (2) medical experts, one specializing in dentistry and one in otolaryngology, failed to respond to the interview request. The interviews were recorded and transcribed via ©Rev.com. QSR International's Nvivo 12 software was utilized for qualitative data analysis. The University of Maryland, Baltimore IRB and the Food & Drug Administration R1HSC reviewed the study and found it to be exempt. Subject matter experts provided their oral informed consent to participate in interviews.

Survey

General professional medical associations and specialty associations for dentistry, dermatology, naturopathy, obstetrics and gynecology, oral medicine, otolaryngology, and wound care, identified from the nominations, literature review, and interviews, were contacted to facilitate distribution of an online survey. A Google™ search was conducted to identify relevant professional associations within each specialty. Associations were included if their members are predominantly practitioners, national associations, and organizations focused on practice within the US. Organizations without practicing physicians and state or regional organizations were excluded. The association's website was searched in order to identify the email of the executive director, regulatory director, media director, association president, board members, or other key leaders within the organization to discuss survey participation. If no contact information was available, the "contact us" tab on the association website was used.

An online survey was created using Qualtrics® software (Provo, UT). The survey link was distributed to 13 associations. If an association had more than one (1) substance with indications relevant to that specialty, substances were combined into one (1) survey with no more than 14 substances per survey. Table 1 highlights the associations that agreed to distribute the survey link and Table 2 includes the associations that declined to participate. Additionally, single substance surveys were created and posted on the project website which was shared with survey participants.

Participation was anonymous and voluntary. The estimated time for completion was 30 minutes with a target of 50 responses per survey. The Office of Management and Budget (OMB) approved this project.

Table 1. Participating associations

| Specialty | Association |
|------------------|--|
| Dermatology | American Academy of Dermatology (AAD) |
| | American Society for Dermatologic Surgery (ASDS) |
| Naturopathy | American Association of Naturopathic Physicians (AANP) |
| Oral Medicine | American Academy of Oral Medicine (AAOM) |

Table 2. Associations that declined participation

| Specialty | Association | Reasons for Declining |
|---------------------------|--|---|
| Dentistry | American Dental Association (ADA) | Declined, ADA concluded that “this issue does not affect enough dentists to warrant a significant investment of time” |
| Medicine | American Medical Association (AMA) | Failed to respond |
| | American Osteopathic Association (AOA) | Failed to respond |
| Obstetrics and Gynecology | American College of Obstetricians and Gynecologists (ACOG) | Declined, survey not approved for distribution |
| Otolaryngology | American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) | Failed to respond |
| | American Academy of Otolaryngic Allergy (AAOA) | Declined, did not think otolaryngologists are the target market for the survey |
| | American Rhinologic Society (ARS) | Declined, do not send out surveys unless they are requested by a member, unable to identify a member to request survey distribution |
| Wound Care | American Professional Wound Care Association (APWCA) | Failed to respond |
| | Wound Healing Society (WHS) | Failed to respond |

CURRENT AND HISTORIC USE

Summary of background information

- Boric acid is not available as an FDA-approved product.
- Boric acid is not available as an OTC product in the US.
- There is a current United States Pharmacopeia (USP) monograph for boric acid.
- Boric acid is not available in any of the foreign medicine registries searched.

Table 3. Currently approved products – US

No approved products in the US

Table 4. Currently approved products–select non-US countries and regions

No approved products in the selected non-US countries and region

Summary of literature review

- Total number of studies included: 61 studies (26 descriptive, 25 experimental, and 10 observational).
- Most of the studies were from the US (21).
- The most common indication for the use of boric acid in the US was vaginitis followed by vulvovaginal candidiasis. The most common indications from the non-US studies were vulvovaginal candidiasis and otitis media.
- There was a US study that utilized a compounded 600mg capsule for vaginitis. The other US study did not specify the compounded product used for vulvovaginal candidiasis. From the non-US studies, there is a compounded 600mg capsule identified for use in vulvovaginal candidiasis and vaginitis.

Table 5. Types of studies

| Types of Studies | Number of Studies |
|--------------------------------|--------------------------|
| Descriptive ¹⁻²⁶ | 26 |
| Experimental ²⁷⁻⁵¹ | 25 |
| Observational ⁵²⁻⁶¹ | 10 |

Table 6. Number of studies by country

| Country | Number of Studies |
|--|-------------------|
| Brazil ⁵² | 1 |
| Canada ^{1,12,28,50} | 4 |
| China ⁵¹ | 1 |
| France ¹⁵ | 1 |
| Germany ^{8,13,14} | 3 |
| Greece ¹¹ | 1 |
| India ^{32,40,41,46} | 4 |
| Iran ^{27,33,56} | 3 |
| Israel ²⁴ | 1 |
| Italy ^{6,20,31,37} | 4 |
| New Zealand ⁵⁴ | 1 |
| Poland ⁴⁴ | 1 |
| Portugal ²⁹ | 1 |
| South Africa ^{34,35} | 2 |
| Spain ³⁰ | 1 |
| Tanzania ³⁸ | 1 |
| Thailand ⁴³ | 1 |
| Tunisia ⁵³ | 1 |
| Turkey ^{39,45,55} | 3 |
| UK ^{4,7,25,36,47} | 5 |
| US ^{2,3,5,9,10,16-19,21-23,26,42,48,49,57-61} | 21 |
| Total US: 21 | |
| Total non-US Countries: 40 | |

Table 7. Number of studies by combinations

No combination products were nominated

Table 8. Dosage by indication – US

| Indication | Dose | Concentration | Dosage Form | ROA | Duration of Treatment |
|--|----------------|---------------|----------------------|------------|-----------------------|
| Vaginitis ^{17,21,23,57,58,60,61} | 600-1200mg/day | 600mg | Capsule, suppository | Vaginal | 10 days-5 months |
| Vulvovaginal candidiasis ^{18,22,26,48,49,59} | 300-1200mg/day | 600mg | Capsule | Vaginal | 14-19 days |
| | – | 5% | Ointment | Topical | 14 days |
| Trichomonas vaginalis ^{3,5,16} | 600-1200mg/day | 600mg | Capsule, suppository | Vaginal | 2 months-1 18 days |
| Bacterial vaginosis ^{17,42} | 600mg/day | 600mg | Capsule | Vaginal | 21 days |
| Dermatitis ^{9,10} | – | 3% | Ointment, solution | Topical | – |
| Acne ⁹ | – | – | Ointment, solution | Topical | – |
| Acute radiation reaction or sunburn ⁹ | – | – | Ointment, solution | Topical | – |
| After electrodesiccation ⁹ | – | – | Ointment, solution | Topical | – |
| <i>Aspergillus niger</i> infection ² | – | 2.5% | Solution | Ophthalmic | 3 months |
| Aural discharge ¹⁹ | – | – | – | Otic | – |
| Fungal infection ⁹ | – | – | Ointment, solution | Topical | – |
| Moist eczema ⁹ | – | – | Ointment, solution | Topical | – |
| Nonspecific inflammation with edema & vasculature ⁹ | – | – | Ointment, solution | Topical | – |
| Otitis externa ⁹ | – | – | Ointment, solution | Topical | – |

Abbreviations: “–”, not mentioned; ROA, route of administration.

Table 9. Dosage by indication – non-US countries

| Indication | Dose | Concentration | Dosage Form | ROA | Duration of Treatment |
|---|--------------------------------------|---------------|-------------------------|---------|-----------------------|
| Vulvovaginal candidiasis ^{8,11,14,20,25,31,33,40,41} | 600mg/every other day- 1200mg/day | 300-600mg | Capsule, suppository | Vaginal | 7-39 days |
| Otitis media ^{4,12,34-36,38,54} | 12 drops/day | 2% | Powder, solution | Otic | 10 days-3 months |
| Periodontitis ^{28,32,45,46} | 1 mL/week | 0.75% | Gel, solution | Oral | 6 months |
| Otomycosis ^{30,39,43} | – | 3-5% | Solution | Otic | 1-2 weeks |
| Otitis externa ^{27,47} | 8-9 drops/day | 4% | – | Otic | 10-21 days |
| Vaginitis ^{7,13} | 600mg/day | 600mg | Capsule | Vaginal | 14 days |
| Bacterial vaginosis ⁵⁰ | – | 600mg | Cream | Vaginal | 10 days |
| Burning mouth syndrome ³⁷ | – | 5% | Solution | Oral | 8 weeks |
| Contact dermatitis ⁵¹ | – | 3% | Solution | Topical | – |
| Deep wounds, Pseudomonas aeruginosa based skin injuries ¹⁵ | – | – | Solution | Topical | Few days-few weeks |
| Diabetic neuropathy ⁵⁶ | – | 3% | Solution | Topical | 1-4 weeks |
| Exit site infection ²⁴ | 5 drops | 2% | Solution | Topical | – |
| Extra vasation injury ⁵⁵ | – | 3% | Solution | Topical | – |
| Herpes-virus induced infection of the mouth and ears* ⁴⁴ | – | 20% | Ointment | Topical | 2-14 days |
| Necrotizing fasciitis ⁶ | – | 3% | Solution | Topical | – |

| | | | | | |
|--|----------------|-------|----------|------------|------------------|
| Patient reported self-medication for the eye before emergency care ⁵² | – | – | Solution | Ophthalmic | – |
| Trachoma ⁵³ | – | 5% | Ointment | Topical | 60 days |
| Trichomonas vaginalis ¹ | 600-1200mg/day | 600mg | Capsule | Vaginal | 3 weeks-5 months |

Abbreviations: “–”, not mentioned; ROA, route of administration.

Table 10. Compounded products – US

| Indication | Publication Year | Compounding Method | Dosage Form | Final Strength |
|--|------------------|---|-------------|----------------|
| Vaginitis ⁶¹ | 2003 | <ul style="list-style-type: none"> Gelatin capsule with 600mg boric acid | Capsule | 600mg |
| Vulvovaginal candidiasis ⁵⁹ | 2016 | <ul style="list-style-type: none"> “Products were compounded” | – | – |

Abbreviations: “–”, not mentioned.

Table 11. Compounded products – non-US countries

| Indication | Compounding Method | Dosage Form | Final Strength |
|---|--|----------------------|----------------|
| Vulvovaginal candidiasis ^{11,29,31,33} | <ul style="list-style-type: none"> 600 mg gelatin capsule^{29,33}/suppository¹¹ supplied by compounding pharmacy Powder placed into capsule and used as a suppository³¹ | Capsule, suppository | 600mg |
| Chronic periodontitis ^{32,46} | <ul style="list-style-type: none"> Boric acid and zinc oxide dissolved separately in ethanol, and then added to a polymer dispersion (consists of dispersing optimized amount of different gelling agents like carbopol, sodium carboxymethyl cellulose, and methylcellulose (3% w/v) in water). Glycerin 0.5 mL and propylparaben 0.02 mg were added to the dispersion and then mixed. | Gel | 0.75% |
| Bacterial vaginosis ⁵⁰ | <ul style="list-style-type: none"> Boric acid 600 mg compounded in emollient cream | – | – |
| Vaginitis ⁷ | <ul style="list-style-type: none"> Supplied by compounding pharmacy | Capsule | 600mg |

Abbreviations: “–”, not mentioned.

Summary of focus groups/interviews of medical experts and specialty organizations

Two (2) interviews were conducted. Two (2) medical experts, one specializing in dentistry and one in otolaryngology, failed to respond to the interview request.

Table 12. Overview of interviewees

| Interviewee | Level of Training | Specialty | Current Practice Setting | Experience with Boric Acid | Interview Summary Response |
|--------------------|--------------------------|---|---------------------------------|-----------------------------------|---|
| DER_06 | MD | Dermatology Dermatology/Immunology | Independent consultant | Yes | <ul style="list-style-type: none"> • Boric acid is very rarely used. • Does not need office stock. • Unclear indication for office use nowadays • 50 years ago – used for bad contact dermatitis and poison ivy. Was available without a prescription (Borax powder). |
| INF_01 | MD | Infectious Disease Internal Medicine | Academic medical institution | Yes | <ul style="list-style-type: none"> • Used compounded boric acid intravaginally for recurrent urinary tract infection before. • Does not need office stock. • Cannot think of any situation for otic administration. |

Abbreviation: MD, Doctor of Medicine.

Summary of survey results

Table 13. Characteristics of survey respondents [21 people responded to the survey^a]

| Board Certification | DMD/DDS | MD | ND | No Response |
|---|----------------|-----------|-----------|--------------------|
| Dermatology | 0 | 2 | 0 | 0 |
| Fellow of the American Board of Naturopathic Oncology | 0 | 0 | 1 | 0 |
| Naturopathic Doctor | 0 | 0 | 3 | 0 |
| Naturopathic Physician | 0 | 0 | 3 | 0 |
| Oral Medicine | 2 | 0 | 0 | 0 |
| Pain Medicine | 1 | 0 | 0 | 0 |
| Sleep Medicine | 1 | 0 | 0 | 0 |
| No Board Certification | 0 | 0 | 0 | 0 |
| No Response | 0 | 0 | 0 | 13 |

Abbreviations: DMD/DDS, Doctor of Medicine in Dentistry; MD, Doctor of Medicine; ND, Naturopathic Doctor.

^aSome respondents reported more than one terminal clinical degree or board certification.

Table 14. Types of products used, prescribed, or recommended

| Types of Products | Respondents, n (N=9^a) |
|--------------------------|---|
| Compounded | 3 ^b |
| FDA-approved | 0 |
| Over-the-counter | 3 |
| Dietary | 1 |
| Unsure | 2 |
| No response | 0 |

^aOut of 21 respondents, 9 reported using, prescribing, or recommending multiple types of boric acid product.

^bOne (1) respondent used in combination but did not specify the formulation.

Table 15. Compounded use of boric acid in practice^a

| Indication | Strength | Dosing frequency | Dosage Form | ROA | Duration of Treatment | Patient Population |
|---------------------|----------|------------------|-------------|-----------|-----------------------|--------------------|
| Bacterial vaginosis | 600mg | Twice daily | Capsule | Vaginally | 7-14 days | Women |

Abbreviation: ROA, route of administration.

^aOne (1) respondent.

Table 16. Indications for which boric acid is considered a standard therapy

| Indication | Standard Therapy | | |
|---|---------------------|-------------------------|-----------------|
| | Compounded, n (N=3) | Non-compounded, n (N=4) | Unsure, n (N=2) |
| Athlete’s foot | 0 | 1 | 0 |
| Bacterial vaginosis | 1 | 1 | 0 |
| Other ^a | 0 | 1 | 0 |
| “As a wash for eyes, anti-yeast wash for vaginitis” | 0 | 1 | 0 |
| No response | 2 | 0 | 2 |

^aOne (1) respondent replied: “eyes, vagina, msny”

Table 17. Reasons for using a compounded product instead of any FDA-approved product

| Reasons |
|--|
| <ul style="list-style-type: none"> “cost effective” |

Table 18. Change in frequency of compounded boric acid usage over the past 5 years

| | Respondents, n (N=3) |
|--------------------------------|----------------------|
| No–use has remained consistent | 0 |
| Yes–I use it LESS often now | 0 |
| Yes–I use it MORE often now | 1 |
| No response | 2 |

Table 19. Do you stock non-patient specific compounded boric acid in your practice?

| | Respondents, n (N=3) |
|-------------|-----------------------------|
| No | 1 |
| Yes | 0 |
| No response | 2 |

Table 20. Questions related to stocking non-patient specific compounded boric acid

No survey respondents provided this information

CONCLUSION

Boric acid (UNII code: R57ZHV85D4) was nominated for inclusion on the 503B Bulks List for treatment of bacterial vaginosis, candida vulvovaginitis, and external otitis as a 150-600 mg otic capsule to be administered via an insufflator bulb. Boric acid is not available in any of the foreign medicine registries searched.

From the literature review conducted, the most common indication in the US for boric acid was vaginitis followed by vulvovaginal candidiasis. The most common indications from the non-US studies were vulvovaginal candidiasis and otitis media. There was one (1) US study where a compounded 600mg capsule was used to treat for vaginitis. The other US study that utilized a compounded product did not specify the type of product used to treat vulvovaginal candidiasis. From the non-US studies, there is one (1) study that used a compounded 600mg capsule to treat vulvovaginal candidiasis and vaginitis.

From the interviews, both interviewees did not think there was a need for office stock. One interviewee expressed there was an unclear indication for office use while the other interviewee had used compounded boric acid intravaginally for recurrent urinary tract infection. The interviewee could not think of any situation for otic administration.

From the survey responses, nine (9) out of 21 respondents used boric acid. Three (3) respondents reported using compounded boric acid products, with one (1) respondent using compounded 600 mg boric acid capsules for bacterial vaginosis.

APPENDICES

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Appendix 2. Survey instrument

Start of Block: Welcome Page

The University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI), in collaboration with the Food and Drug Administration (FDA), is conducting research regarding the use of certain bulk drug substances nominated for use in compounding by outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act. In particular, we are interested in the current and historic use of these substances in clinical practice. This survey is for **boric acid**. As a medical expert, we appreciate your input regarding the use of this substance in your clinical practice. This information will assist FDA in its development of a list of bulk drug substances that outsourcing facilities can use in compounding under section 503B of the Act. All responses are anonymous.

OMB Control No. 0910-0871

Expiration date: June 30, 2022

The time required to complete this information collection is estimated to average 30 minutes, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. If you have additional questions or concerns about this research study, please email: compounding@rx.umaryland.edu. If you have questions about your rights as a research subject, please contact HRPO at 410-760-5037 or hrpo@umaryland.edu.

End of Block: Welcome Page

Start of Block: Boric acid

Q1. What type(s) of product(s) do you use, prescribe, or recommend for **boric acid**? Please check all that apply.

- Compounded drug product
- FDA-approved drug product
- Over the counter drug product
- Dietary supplement (e.g. vitamin or herbal supplement products sold in retail setting)
- Unsure

Skip To: Q13 If What type(s) of product(s) do you use, prescribe, or recommend for boric acid? Please check all th... != Compounded drug product

Skip To: Q2 If What type(s) of product(s) do you use, prescribe, or recommend for boric acid? Please check all th... = Compounded drug product

Display This Question:

If What type(s) of product(s) do you use, prescribe, or recommend for boric acid? Please check all th... = Compounded drug product

Q2. Please list any conditions or diseases for which you use compounded **boric acid** in your practice. Please include the strength(s), dosing frequency(ies), dosage form(s), route(s) of administration, duration of therapy, and patient population (ex. age, gender, comorbidities, allergies, etc).

| | Strength(s) (please include units) | Dosing frequency(ies) | Dosage form(s) | Route(s) of administration | Duration of therapy | Patient population |
|----------------------------------|---------------------------------------|-----------------------|----------------|----------------------------|---------------------|--------------------|
| Condition 1 (please describe) | | | | | | |
| Condition 2 (please describe) | | | | | | |
| Condition 3 (please describe) | | | | | | |
| Condition 4 (please describe) | | | | | | |
| Condition 5 (please describe) | | | | | | |

Q3. Do you use compounded **boric acid** as a single agent active ingredient, or as one active ingredient in a combination product? Please check all that apply.

- Single
- Combination

Skip To: Q5 If Do you use compounded boric acid as a single agent active ingredient, or as one active ingredient... != Combination

Display This Question:

If Loop current: Do you use compounded boric acid as a single agent active ingredient, or as one active ingredient... = Combination

Q4. Please list all combination products in which you use compounded **boric acid**.

Q5. For which, if any, diseases or conditions do you consider compounded **boric acid** standard therapy?

Q6. Does your specialty describe the use of compounded **boric acid** in medical practice guidelines or other resources?

Q7. Over the past 5 years, has the frequency in which you have used compounded **boric acid** changed?

- Yes - I use it **MORE** often now (briefly describe why) _____
- Yes - I use it **LESS** often now (briefly describe why) _____
- No - use has remained consistent

Q8. Why do you use compounded **boric acid** instead of any FDA-approved drug product?

Q9. Do you stock non-patient-specific compounded **boric acid** in your practice location?

- Yes
- No

Skip To: End of Block If Do you stock non-patient-specific compounded boric acid in your practice location? = No

Display This Question:

If Do you stock non-patient-specific compounded boric acid in your practice location? = Yes

Q10. In what practice location(s) do you stock non-patient-specific compounded **boric acid**? Please check all that apply.

- Physician office
- Outpatient clinic
- Emergency room
- Operating room
- Inpatient ward
- Other (please describe) _____

Q11. How do you obtain your stock of non-patient-specific compounded **boric acid**? Please check all that apply.

- Purchase from a compounding pharmacy
- Purchase from an outsourcing facility
- Compound the product yourself
- Other (please describe) _____

Q12. Why do you keep a stock of non-patient-specific compounded **boric acid**? Please check all that apply.

- Convenience
- Emergencies
- Other (please describe) _____

Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded boric acid? Please check all that apply. = Convenience

Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded boric acid? Please check all that apply. = Emergencies

Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded boric acid? Please check all that apply. = Other (please describe)

Q13. For which, if any, diseases or conditions do you consider **boric acid** standard therapy?

Q14. Does your specialty describe the use of **boric acid** in medical practice guidelines or other resources?

End of Block: Boric acid

Start of Block: Background Information

Q15. What is your terminal clinical degree? Please check all that apply.

- Doctor of Medicine (MD)
- Doctor of Osteopathic Medicine (DO)
- Doctor of Medicine in Dentistry (DMD/DDS)
- Naturopathic Doctor (ND)
- Nurse Practitioner (NP)
- Physician Assistant (PA)
- Other (please describe) _____

Q16. Which of the following Board certification(s) do you hold? Please check all that apply.

- No Board certification
- Allergy and Immunology
- Anesthesiology
- Cardiovascular Disease
- Critical Care Medicine
- Dermatology
- Emergency Medicine
- Endocrinology, Diabetes and Metabolism
- Family Medicine
- Gastroenterology
- Hematology
- Infectious Disease
- Internal Medicine
- Medical Toxicology
- Naturopathic Doctor
- Naturopathic Physician
- Nephrology
- Neurology
- Obstetrics and Gynecology
- Oncology
- Ophthalmology
- Otolaryngology
- Pain Medicine
- Pediatrics
- Psychiatry
- Rheumatology
- Sleep Medicine
- Surgery (please describe) _____
- Urology
- Other (please describe) _____

End of Block: Background Information