



Public Health
England

Protecting and improving the nation's health

Rapid Review Panel

Guidance and Requirements for Applicants

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

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1.0 About the Rapid Review Panel

1.1 What is the rapid review panel?

The Rapid Review Panel (RRP) evaluates products for potential use in the NHS on the basis of submitted scientific evidence to support claims of improved efficiency or efficacy of infection prevention and control (IPC) interventions to reduce healthcare associated infections (HCAIs).

Products are voluntarily submitted for consideration and are evaluated on the basis of the supplied scientific evidence. They are examined against two criteria; Efficacy of the product within the context of the NHS, and Innovation to distinguish the applicant products from those currently within the NHS. These criteria are outlined further in [section 2.3](#).

For products which are in early stages of development, ([Section 1.5](#)) the RRP can also be used to seek scientific advice regarding a product's feasibility and research to support its use in an NHS environment. This Pre-Evaluation process is separate from the full evaluations with the RRP and is available to assist companies in the scientific support of their products. It will not result in an evaluation level. ([Section 1.4](#))

It is important to note that the RRP will only consider the scientific evidence supporting the product's use. The RRP does not consider the commercial aspects, including cost effectiveness, of a product in their evaluations. Further information and a copy of the Terms of Reference can be found on [the RRP webpage](#).

The RRP reserves the right to be critical of, and comment, on the safety or feasibility of a product in its response to applicants. ([Section 2.2.3](#)) It will do so where it deems such comments are appropriate in the context of the NHS. It is in the interests of both the applicants and the panel to ensure products which may be recommended to the NHS supply chain are safe.

1.2 Confidentiality

All information submitted to the RRP is treated as commercial in confidence and is stored securely. Applications will be archived in digital format for a period of 7 years.

The RRP operates under confidentiality arrangements. None of the information submitted to the RRP is disclosed to any third party other than to the extent required by law, by any governmental or other regulatory authority, or by a court or other authority of competent jurisdiction. Where such disclosure is required, as far as it is legally permitted to do so, the RRP will give applicants as much notice as possible of the disclosure. Panel members work impartially and should not be approached by parties who are not involved in the review process to disclose information about the RRP's discussions regarding particular submissions. RRP members openly declare any potential or actual conflicts of interest; conflicts of interest will result in Panel members recusing themselves from the recommendation process.

1.3 Why submit your product for RRP evaluation?

The RRP provides evaluations on the basis of improved efficiency or efficacy over existing available products, innovation, and use. Evaluations by the RRP are used by the NHS Supply Chain, healthcare providers and those acting on behalf of healthcare providers to assist in decision making processes.

All evaluations are published on the [RRP webpage](#) and are shared directly with the NHS Supply Chain and Public Health England. Submissions receiving an E1/E2 are invited to initiate a discussion with the NHS Supply Chain regarding the potential of entering the NHS Supply Chain procurement catalogue. The NHS Supply Chain may require further criteria or evidence which was not submitted during the RRP process; it is the responsibility of successful recommendation E1/E2 applicants to discuss and provide this. The RRP is not responsible for the product entering the NHS Supply Chain procurement catalogue or for the adoption of the product within the NHS.

1.4 Pre-evaluation expert advice (product surgery)

The RRP will also provide scientific advice regarding products which are at an early stage of development ([section 1.5](#)); the product should be in the early stages of technological and applied product research and process research. This advice is intended as constructive feedback in collaboration with applicants and may include:

- Identification of areas for improvement
- Identification of gaps in scientific evidence
- Highlights of any safety concerns
- Highlights of any feasibility concerns
- A sense check of the product ahead of further development and research

The aim of the pre-evaluation advice is to provide an informal platform to improve the likelihood of favourable RRP evaluation when the product has undergone further development and research; ahead of subsequent submission to the panel with supporting scientific evidence. A confidential feedback report will be returned to applicants.

The feedback returned to companies through this process is for advice only and is made in good faith. The advice issued is not intended to be exhaustive, does not represent the RRP's endorsement and does not guarantee a higher rating in the full RRP evaluation. RRP will not accept responsibility for any effects resultant to the company in following this advice. The RRP will not accept repeat applications to the Pre-evaluation process if a previous application has occurred within 1 year.

1.5 Product stage of development

The RRP recommends that applicant products have undergone, as a minimum, technological validity in laboratories where the basic technological components are integrated to assess early feasibility of the product. This will provide the RRP with supporting scientific evidence in order to undergo the full review process (RRP evaluation). Products which are at an earlier phase of development are encouraged to apply to the product surgery. ([Section 1.4](#))

The use of Technology Readiness Levels (TRL) as outlined by “[The TRL Scale as a Research & Innovation Policy Tool, EARTO Recommendations \(Annex 1\)](#)” may be useful for applicants in determining the stage of development of their product.

1.6 Products outside of the RRP’s remit

The RRP will not review antimicrobial therapies for treating infections, therapeutic products or products that do not contribute to improvements in efficiency or efficacy of IPC interventions to reduce HCAs.

1.7 Regulatory approval

The RRP is able to publish evaluations on products or processes prior to them receiving the necessary regulatory approval in the UK. If the necessary UK regulatory approval is not in place at the time of the review, it must be sought, and granted, prior to that product being introduced into the UK healthcare market. Where applicable products for review already have an appropriate CE mark affixed, the submission should state under which directive the CE mark is applied. Where applicable products for review already have marketing authorisation through different means, this directive should also be stated. There will be an additional line on the published statement to illustrate if the product has not yet received regulatory approval

1.8 RRP evaluations

Following review the RRP will make one of the following evaluations for publication:

- E1** Basic research and development, validation and recent in use evaluations/trials have shown that the product is likely to offer benefit(s) in improving infection prevention and control (IPC) interventions to reduce healthcare associated infections (HCAI) within the NHS. The RRP recommends considering the use of this product in the NHS to improve IPC interventions to reduce HCAs
- E2** Basic research and development has been completed and the product may have potential value. The RRP recommends in use evaluations/trials to demonstrate improved efficiency or efficacy in improving infection prevention and control to reduce healthcare associated infections are undertaken within an active NHS clinical setting
- E3** Basic research and development has begun and the product may have value; the product requires head-to-head trials, *in vitro* where applicable, against existing available products to demonstrate improved efficiency or efficacy in improving infection prevention and control interventions to reduce healthcare associated infection
- E4** Potentially useful product but insufficient evidence presented within this submission. Further research and development with the product as intended to be used in the NHS is required to demonstrate improvements in infection prevention and control interventions to reduce healthcare associated infections before it is ready for in use evaluation within the NHS
- E5** Evidence presented does not demonstrate that the product more efficient or efficacious at improving infection prevention and control interventions to reduce healthcare associated infections than other available products currently in use
- E6** Evidence presented does not demonstrate that the product has a contribution to make to improvements in infection prevention and control interventions to reduce healthcare associated infections
- NE** **(No Evaluation):** this product is outside the remit for review or the evidence has been submitted in a way which does not allow for an evaluation by the Rapid Review Panel

Confidential commentary will also be returned to the applicant, providing further detail as to the result of the evaluation.

Evaluation disclaimer: The RRP does not formally review cost-effectiveness or implementation barriers during its evaluation of products; these factors may be considered by the NHS supply chain should the product gain an E1 or E2. It is the responsibility of the applicant to carry out any further required development, including trials, cost-effectiveness assessments or product implementation within the NHS. All statements comparing the efficiency or efficacy of products are in the context of products available for use to the NHS at the date of evaluation.

Included within this evaluation page will be the following **evaluation grid**:

Criteria:	Comments:
1. Efficacy:	
Purpose	
Central principle	
Efficacy within shelf life	
Supporting trials	
Comparative trials	
2. Innovation:	
Improvements over products available to the NHS	
Novelty of product compared to products available to the NHS	

1.8.1 Evaluation publication template



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REFERENCE: Company – Product Name

Date of RRP Evaluation

Evaluation: statement in full.

This section may include:

- *A brief product description*
- *A high-level statement to illustrate the rationale behind the Panel evaluation*
- *The UK regulatory status of the product*

Evaluation grid:

Criteria:	Comments:
1. Efficacy	
Purpose	
Central principle	
Efficacy within shelf life	
Supporting trials	
Comparative trials	
2. Innovation	
Improvements over products available to the NHS	
Novelty of product compared to products available to the NHS	

Evaluation Disclaimer: The RRP does not formally review cost-effectiveness or implementation barriers during its evaluation of products; these factors may be considered in a separate process. It is the responsibility of the applicant to carry out any further required development, including trials, cost-effectiveness assessments or product implementation within the NHS. All statements comparing the efficiency or efficacy of products are in the context of products available for use to the NHS at the date of evaluation.

2.0 RRP Processes

2.1 How are products identified for evaluation?

Manufacturers should self-refer their products for evaluation by the RRP by contacting the RRP secretariat (rrp@phe.gov.uk) and requesting an application form. There is no application fee for the RRP review.

2.1.1 Resubmission to the RRP

The RRP will re-evaluate a product given significant changes to the application. Applicants who choose to resubmit a product for review are required to complete a supplementary document for approval by the RRP before a complete reapplication can be submitted to the secretariat. This document will clearly demonstrate how the confidential comments regarding their previous product application have been considered within the new application, including a summary of any changes to the evidence base to support the product claims. It is within the discretion of the RRP to determine if the changes detailed are significant enough to warrant a re-evaluation.

Applicants should consider the time required for this step when planning to meet their submission deadlines. No evidence will be submitted with the reapplication form, only with the final resubmission. The reapplication form does not require a wet-ink signature and can be sent to rrp@phe.gov.uk. A re-evaluation does not guarantee a higher evaluation score; and could also result in a lower recommendation score.

2.2 On what basis are products evaluated on?

2.2.1 Improved efficacy over existing available products

Applicants will be expected to clearly define the purpose of their product including, where applicable, which micro-organisms the product is effective against. Applicants will be expected to demonstrate that the use of their product will fulfil this purpose through substantiated evidence and that its use will be effective in improving IPC interventions against HCAs.

The central principle or core concept for which the product operates will also be examined by the RRP and so should be reflected in the evidence provided.

The application will need to demonstrate that claims made within the application regarding the product's efficacy are substantiated with scientific evidence. Products should also be shown to retain efficacy for the duration of the products reported shelf life. Claims of a product's use over time and retention of efficacy over time will also need to be substantiated with scientific evidence.

The product will be compared to current options available to the NHS. Therefore, in order to reach a higher RRP rating, the product must also demonstrate through substantiated evidence that its effects will be better than a method available to the NHS which produces the same outcome. This evidence may include improved *in vitro* or *in vivo* activity versus methods

available to the NHS. To achieve this, applicants will be expected to identify their own suitable comparators, and where the product is novel or innovative, identify comparators which fulfil a similar function. These comparators will achieve similar outcomes, and may include similar products with fewer features, for example, the similar outcomes between disinfecting hands with soap and water and alcohol based hand gels.

The RRP prefers evidence from “head-to-head” trials which directly compare products with existing available products, including the most relevant products in current NHS use. Head-to-head contemporaneous testing is best conducted in the same laboratory, using the same methods, under the same conditions by the same personnel. Where no head-to-head trials are available, consideration will be given to indirect comparisons, subject to justification of fully described analysis and comparisons. All comparison trials should be completed by an independent third-party. Reports should include full details on product compositions, testing protocols and results. The RRP reserves the right to be critical of the products selected for comparison during evaluations

2.2.2 Innovation

The remit of the RRP is to evaluate products which claim to improve efficiency or efficacy of IPC interventions to reduce HCAs; applicants are asked to identify the innovations of the product in the context of this primary criterion. Identification of innovation or novelty through the receipt of a patent alone is not sufficient.

When discussing the product and processes involved, applicants should supply robust scientific evidence that identifies the “what” or “how” and “why” of the products innovation which demonstrates how these innovations distinguish them from currently in-use products within the NHS, in the context of efficiency or efficacy.

2.2.3 Additional commentary: product safety

Products should be appropriate to meet the requirements of patient care and safety within NHS settings, and must be safe and feasible in their use within the care setting the product is intended for. All product safety information must be provided, including the product composition where applicable. The submission should include a clear description of the product and how the product is recommended to be used. This should include all protocols and procedures, including any that may have to be adhered to for the product/process to be effective.

Where products require the aid of additional electrical or mechanical equipment, tests that are undertaken with same equipment as will be used in the intended NHS healthcare setting are preferred. In addition, information should be provided in which setting their product is expected to be used in within healthcare and by which personnel. Any limitations pertaining to the product or processes used should be clearly highlighted; this includes any specialised training required for users.

2.3 Efficacy guide questions

For a strong submission, the applicant should be considering the following questions when compiling evidence to demonstrate the efficacy of the product:

- Have product claims been substantiated with basic tests conducted by a third-party?
- Do the tests conducted on the product/process accurately reflect;
 - How and in which setting the product would be used in the NHS?
 - The circumstances which would be encountered in the proposed NHS setting?
- Are there existing available products in the NHS which are used for the same purpose or to achieve the same ends?
 - Has the Company conducted concurrent head-to-head tests with the identified existing available products?
- Has the Company conducted clinical trials in an appropriate healthcare setting in the NHS to demonstrate improvements to IPC?
- Do the tests demonstrate improvements in efficacy in IPC interventions to reduce HCAIs within the NHS?

2.4 Submission and evidence checklists

The focus of the application must be towards demonstrating how the product improves IPC interventions to reduce HCAIs. All product claims should be substantiated with robust scientific evidence.

All applications will be audited by the scientific Secretariat before evaluation by the RRP; products which do not meet the submission requirements and where companies are unable to amend their application in time for submission may be delayed in consideration until the next evaluation meeting.

Applicants should meet all of the requirements of the evidence checklist. Applications which fulfil all requirements of the evidence checklist to a high quality are considered more robust by the RRP in satisfying their criteria. The full checklist to assist with pre-application is available in Appendix 1.

2.4.1 Core checklist:

Products must meet ALL requirements from the core evidence checklist in order to proceed. Any missing items from the core checklist will cause the application to be delayed and may require deferral to the subsequent RRP meeting or withdrawal of the application.

- i. the application and all submitted evidence is for a single product or set of very similar products;
- ii. all sections of the application and appendices are clearly labelled and complete; all submitted evidence is referenced within the text and in the appendices section of the application form.
- iii. the application only provides evidence for the product as it is intended to be used
- iv. the application includes an assessment of the products potential efficiency or effectiveness with a clear potential for improving IPC interventions to reduce HCAs and a description of the product's innovation, quality and use;
- v. a full and detailed listing of product composition must be provided, including all components and formulation ingredients at the concentrations intended to be used;
- vi. quality and safety issues for storage and use of the product should be assessed and provided to cover the use of the product within the healthcare setting;

2.4.2 Evidence checklist:

Applicants should meet all of the requirements of the evidence checklist in order to facilitate a better application. From the RRP's experience; applicants who address all items in both the core and evidence checklists generally achieve a faster evaluation process and often reach higher evaluation scores.

- vii. all submitted product testing evidence includes fully detailed methods and results;
- viii. all appropriate information is provided by the manufacturer to demonstrate risk and safety assessments have been made to EU/UK requirements; submit a Materials Safety Data Sheet (MSDS) if applicable;
- ix. submitted evidence contains the *in vitro* activity of the product; where possible, *in vitro* or *in vivo* evidence submitted should be from peer reviewed publications or have been undertaken by a third-party laboratory;
- x. submitted evidence should contain head-to-head testing to demonstrate improvements in efficiency or efficacy over existing available products within the NHS
- xi. clinical data to support product claims should be provided if available

3.0 Making an Application

3.1 Submissions

3.1.1 Submitting your product for full review

Companies who wish to have their product reviewed by the RRP must complete an application form available from the RRP secretariat (rrp@phe.gov.uk) and indicate that they would like to undergo a full RRP review. Include in the email the name of the company and the product(s) which you intend to submit and a brief descriptor of the product itself and its relation to infection prevention and control. You will be provided with a list of the RRP key dates and deadlines at the time that you request an application pack.

Each submission must only address a single product as it is intended to be used in the NHS. If you wish for more than one product to be considered, applicants must make a separate submission for each. Products that include different formularies or processes for their function (e.g. liquids; sprays or aerosolised products) must submit a separate application for each one.

The RRP has a limit on the number of products it can review during any one meeting and so the number of reviews per session is capped. Applications will be reviewed on a first-come first-served basis and may be moved to subsequent meeting dates at the discretion of the RRP secretariat. Late submissions will be placed on the agenda for the next available meeting. RRP meetings are held quarterly.

Manufacturers should ensure that all relevant information pertinent to the RRP review is disclosed at the time of application. There will be no subsequent opportunity to submit information within the review period unless specifically requested to do so by the RRP. Evidence not referenced within the application and listed in section 3 of the application form will not be considered.

To facilitate review, the information submitted should be as relevant, succinct and informative as possible. Evidence provided should pertain to the product as outlined in its application to the RRP. All sections of the application form must be completed; all sections including appendices must be in English. When including an appendix item, please give context for what it adds to the submission. The application form should contain enough detail to be initially read without referring to the appendices for context.

3.1.2 Submitting your product for pre-evaluation (Product Surgery)

Companies who wish to seek the scientific advice of the RRP regarding the development, scientific research or feasibility of a product in an NHS environment must complete an application form available from the RRP secretariat (rrp@phe.gov.uk) and indicate that they would like to submit the product to the RRP product surgery. As with the full review, please include a brief descriptor of the product itself and its relation to infection prevention and control. The product surgery will occur at the same RRP panel meetings where full product reviews are undertaken, and so you will be provided with a list of the RRP key dates and deadlines to submit your application form.

As with the product reviews, each submission must only address a single product as it is intended to be used in the NHS. If you wish for more than one product to be considered, applicants must make a separate submission for each. Products that include different formularies or processes to function e.g. liquids; sprays or aerosolised products must submit a separate application for each one.

As the RRP has a limit on the number of products it can review during any one meeting, timeliness of advice for products submitted for the product surgery may be impacted during busy periods. Applicants will be given advice in following their application on a first-come first-served basis; applications may be moved to subsequent meeting dates at the discretion of the RRP secretariat. The applicant will be notified in this eventuality. Late submissions will be placed on the agenda for the next available meeting.

3.2 Quality, value and relevance of submitted evidence

All evidence supplied should be assessed by the applicant for the quality, value and relevance that it adds to the application. These aspects will be considered by the RRP as part of their review process.

3.2.1 Quality

The RRP favours use of peer reviewed articles and scientific papers in order to provide evidence to support the application (product). The peer-review process involves an independent expert appraisal of the complete study for validity, value and relevance. Accepted peer-reviewed studies are considered of higher scientific quality and credibility than non-peer-reviewed studies or scientific opinion.

3.2.2 Value

There are several useful frameworks for assessing the value of evidence. The value of evidence should be presented in the context of effectiveness, appropriateness and feasibility of the study design. Conventional 'gold standard' study designs are multi-centre studies or

systematic reviews/meta-analysis involving randomised control trials. These studies incorporate randomisation and comparisons with suitable controls; as such results are less likely to be biased. Lesser standards for scientific studies may remove randomisation or controls, possibly increasing bias. For example, observational studies may have controls, but result in the inclusion of researcher bias.

3.2.3 Relevance

Selected evidence should be clear as to why it has been included. Applicants should consider the relevance of all submitted items, and what it adds to the application. The purpose, the “why” of each discrete piece of submitted evidence should make clear to the RRP as to how the evidence supports the product claims and why it’s being included in the submission.

It is important to consider that the RRP does not formally review cost-effectiveness or implementation barriers during its evaluation of products when assessing the relevance of submitted evidence. The RRP is an expert scientific panel; consumer testimonials may be helpful in marketing material, but are often not relevant in a scientific evaluation.

3.3 Evidence base

Applicants should provide evidence of the *in vitro* activity of the product. Reports submitted as evidence should be from independent, third-party laboratories or peer reviewed publications. There is a preference for testing following EU/UK standards. All laboratory reports submitted as evidence should include full details of product composition, methods and results. Statements concerning the efficiency or effectiveness of the product/process, and its impact in improving IPC interventions to reduce HCAs must be supported by documented scientific evidence (published or other evidence of impact).

Applicants should justify their choice of experimental methodology based on the relevance of that methodology to the particular application(s) proposed and the relevance of the end-point to the improvements in IPC interventions to reduce HCAs. In considering this justification applicants should be mindful of the ‘in-use’ circumstances that may prevail during product storage and use, and include any relevant ‘in use’ evidence.

Evidence supplied using previous versions, iterations or brand names of the current product must provide appropriate documentation and demonstrate that they are *identical* to the application product as intended for use in the NHS; without this information the RRP will exclude this evidence from the review.

All evidence, analyses or modelling provided should be methodologically sound, minimise any bias, be reproducible, have validity and be amenable to external scrutiny.

3.4 Chemical, biological or physical action

The application should clearly describe any chemical, biological or physical action the product uses to be effective at improving IPC interventions to reduce HCAs. Applicants should clearly describe how the product should be used in the healthcare setting, including any additional equipment required for use of the product; the compositions of any components must be provided.

3.5 Product composition

The applicant should clearly describe the composition of the product or provide appropriate information to ensure assessment of quality, risk and safety. All information submitted to the RRP is treated as confidential.

All laboratory evidence should include information on the composition of the product tested including any specific equipment used to deploy or generate any active component. The RRP will only consider evidence for the product as it is intended to be marketed in the UK, together with an explanation for their inclusion.

The product composition has to be the same composition as that which is intended to be used in the UK.

3.6 Published evidence

Please identify and include all relevant studies (published and unpublished) pertaining to your application. If there are a large number of studies, please tabulate information about each study – for example study identifier/reference, study design, comparator(s), and key effectiveness. You are required to give your reasons for excluding any study. Literature with tenuous relevance to the product in the application should be avoided.

3.7 Referencing

The Vancouver system should be used. Each piece of work cited in the text should have a unique number, assigned in the order of citation. If the work is cited more than once, the same citation number should be used. The number should be written in brackets (#) at the end of the statement. When citing one piece of work: Recent research indicates xxxxx (1). Or, when more than one piece of work is cited within the same sentence: Research indicates xxxxx (1-4, 7). When citing information associated with a web site please add the access date in parenthesis.

All referenced material you wish included in the evaluation must be added as an appendix and listed appropriately in sections 2.12 and 3.0 of the application form.

For further information on citing and citation conventions follow:

<http://www.southampton.ac.uk/library/resources/documents/vancouverreferencing.pdf>

The following is an example of order and style to be used:

1. Arrami M, Garner H. A tale of two citations. *Nature* 2008; 451(7177):397-9.
2. Simons NE, Menzies B, Matthews M. *A Short Course in Soil and Rock Slope Engineering*. London: Thomas Telford Publishing; 2001.
3. Public Health England, Rapid Review Panel. *Information and Guidance*.
<https://www.gov.uk/government/groups/rapid-review-panel> (accessed 10 Nov 2014).

3.8 Appendices

The application form should contain sufficient information to allow a basic overview of the product without constant direct referral to the appendices. Provide the context for each appendix item within the text to demonstrate the appendix item has been included. Include any factors that should be taken into consideration when interpreting the evidence.

The appendices should contain the evidence that supports your analysis (especially repetitive or lengthy information) or validates your conclusions. All appendices must be directly relevant to the application and each appendix must be referenced within the body of the application form. Only evidence that is specifically cited in your application should be included in your submission. That evidence and an interpretation of what it shows should be individually referred to in the application.

All appendices must be listed in section 3.0 of the application form. The RRP will disregard any documentation within the appendices that is not referenced within the body of the application form. Where excerpts from the supporting information (i.e. part of the data set) are placed in the body of the report, the complete set of information (i.e. all of the data set) must be included as an appendix.

3.8.1 Labelling appendices

Each separate appendix should be lettered sequentially e.g. Appendix A, Appendix B1, Appendix B2, Appendix C, etc. The order they are presented in is dictated by the order they are mentioned in the text of the application.

The first page of each appendix should contain both the appendix letter and the name of the document **on both the paper and digital version**. The appendix letter should appear at the top right hand corner of each page of the appendix to enable cross-referencing by Panel members. For example:

Appendix A

Bug Clear: Safety Data Sheet

InfoInfoInfoInfoInfoInfoInfoInfoInfoInfoInfoInfoInfoInfoInfoInfoInfoInfoInfo
InfoInfoInfoInfoInfoInfoInfoInfoInfoInfo.....

Appendix B1			
Table 1: Inhibitory Effect of Bug Clear			
Concentration	Time A	Time B	Time C
X%	05:32	08:18	3:52

Each appendix must be referenced within the text of the application form for example:

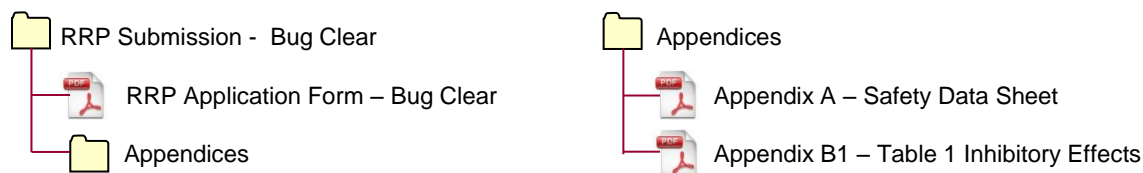
For the manufacturer's materials safety data sheet, see Appendix A

Or

Table 1, Appendix B, shows the inhibitory effect of Bug Clear. Total viable counts were reduced by 10% within the first five minutes. When exposed for 60 minutes total viable counts were reduced by 99.99%.

3.8.2 Electronic files

Digital submission should have a single main level folder with the application form and an optional single appendices folder. All files should be labelled appropriately and in PDF format. Do not use subfolders to file appendices, you will be asked to resubmit if you do this. Only the electronic copy of your full submission will be retained once archived.



3.9 Tables and figures

All tables and figures should be numbered sequentially, and referred to in the text. The information contained in each table or figure must be explained clearly within the supporting text.

3.10 Conditions of review and signatures

Applicants are asked to read, complete and sign the conditions of review and endorsement exclusion on the application form.

‘Wet ink’ signatures are required to validate both the:

- conditions of review; this verifies that the signatory is authorised to submit their product/process to the RRP, the applicants have read and understood the information and guidance, terms and remit of the RRP and that all material relevant to the review has been disclosed to the RRP and that the application is true and complete to the best of their knowledge
- endorsement exclusion; this verifies that the Company shall not use the evaluation as an endorsement or recommendation of the product in marketing materials, and when sharing either the evaluation or marked correspondence, that the information is always shared in full and not quoted separately

Two ‘wet-ink’ signed hard copies plus an electronic copy should be sent to the RRP secretariat to arrive by the deadline provided. The RRP will not review a product without wet-ink signatures to both conditions of review and the endorsement exclusion.

3.11 Use of panel evaluations

You do not have to ask permission to link directly to pages hosted on the RRP's site. We do permit our pages to be loaded into frames on your site; however, the pages must load into the user's entire window. You must not use the PHE logo to link to our site without prior permission.

The use of the RRP name, initials, and any RRP emblems (including PHE logo) which would express or imply any endorsement or sponsorship is strictly prohibited. Applicants must quote in its entirety the RRP's public evaluation, including the evaluation disclaimer. If possible, a direct link to the document on the RRP website should be used.

3.12 Following submission

You will be informed by the secretariat that your application has been received. The secretariat will check your application against the evidence checklist ([section 2.4](#)). Applications that do not contain a completed checklist will be informed; the application may not be forwarded to the panel until the criteria have been complete and an amended application is resubmitted in full. In such event, the secretariat cannot guarantee that amended applications will be reviewed at the upcoming meeting.

3.13 Changes in applicant contact details

To aid expediency the secretariat should be informed of any changes in contact details and/or ownership; it is the applicant's responsibility to provide notifications of change in your contact details and/or ownership.

If there are any questions or clarification required concerning the guidance or application, please email rrp@phe.gov.uk

3.14 How to submit an application

When submitting an application form companies should ensure that:

- ☐ the submission and evidence checklist ([section 2.4](#)) is complete;
- ☐ all of the appendices are clearly labelled (electronic and hard copies);
- ☐ the conditions of review and endorsement exclusion section have been completed and signed in 'wet ink' on both hard copies;
- ☐ all references have been made available (electronic and hard copies) and submitted in duplicate (hard copies);
- ☐ a signed (e-signature or scanned) and labelled electronic copy of the submission in full is sent to rrp@phe.gov.uk;
- ☐ two hard copies of the full submission are sent to the address below ([section 3.15](#));

3.15 Application submission address

2 individually-signed, hard copies of completed application forms with the full submission in **duplicate** should be posted to the address below and an **electronic version of the full submission with labelled appendices** should be emailed to: **rrp@phe.gov.uk**

**James Vaudrey
Rapid Review Panel
Public Health England
Floor 4S, Wellington House
133-155 Waterloo Road
London
SE1 8UG**

Appendix 1: Checklists

Before final submission:

- ☐ the submission and evidence checklist (below) is complete;
- ☐ all of the appendices are clearly labelled (electronic and hard copies);
- ☐ the conditions of review and endorsement exclusion section have been completed and signed in 'wet ink' on both hard copies;
- ☐ all references have been made available (electronic and hard copies) and submitted in duplicate (hard copies);
- ☐ a signed (e-signature or scanned) and labelled electronic copy of the submission in full is sent to rrp@phe.gov.uk;
- ☐ two hard copies of the full submission are sent to the address below (section 3.15); Submission and Evidence Checklist:

Core Requirements:

- ☐ the application and all submitted evidence is for a single product;
- ☐ all sections of the application and appendices are clearly labelled and complete; all submitted evidence is referenced within the text and in the appendices section of the application form.
- ☐ the application only provides evidence for the product as it is intended to be used in the NHS;
- ☐ the application includes an assessment of the products potential efficiency or effectiveness with a clear potential for improving IPC interventions to reduce HCAs and a description of the product's innovation, quality and use;
- ☐ all submitted product testing evidence includes fully detailed methods and results;
- ☐ a complete detailed listing of product composition and concentrations must be provided;

Evidence Requirements:

- ☐ all appropriate information is provided by the manufacturer to demonstrate risk and safety assessments have been made to EU/UK requirements; submit a Materials Safety Data Sheet (MSDS) if applicable;
- ☐ quality and safety issues for storage and use of the product should be assessed and provided to cover the use of the product within the healthcare setting;
- ☐ submitted evidence contains the in vitro activity of the product; where possible, in vitro or in vivo evidence submitted should be from peer reviewed publications or have been undertaken by a third-party laboratory;
- ☐ submitted evidence should contain head-to-head testing to demonstrate improvements in efficiency or efficacy over existing available products within the NHS
- ☐ clinical data to support product claims should be provided if available;