

# An Exploration of the Efficacy of Name-Brand Digestive Relief Medications Versus Non-FDA Approved Alternatives

Focused topic  
... may depend on how "efficacy" is measured.

Research Question: Do non-FDA approved stomach medications perform as well as FDA approved counterparts?

Excellent focused question but may be hard to answer. perhaps best to select a criteria

## Introduction:

Recent studies have shown that there has been an upward trend in consumer purchasing of medication that has not been approved by the Federal Drug Administration (FDA).

Agreed

Statistics show that as of 2007, 38.3% of adults opted to purchase non-conventional drugs, and this number has only increased.<sup>1</sup> It has now become common for consumers, especially

millennials, to spend more money on non-FDA approved, or "alternative", medicine due to a preference for an organic product. In fact, younger generations have started a "Clean Label" movement which favors ingredients that are not "unpronounceable" or "chemical-sounding".<sup>2</sup>

ok...

quot: supported statement!

However, there is a distinct lack of scientific evidence that the use of non-FDA approved drugs has health benefits, nor that using over-the-counter approved medication has deficits. So is it

truly worth it to spend more money on a product with a "clean label"? Do these products work as

well as drugs that have been revered by consumers for years due to their successes? In my

new paragraph needed

experiment, I explored the efficacy of alternative drugs to name-brand ones in order to address

these question.<sup>3</sup> By comparing the pH of .155 molar solutions of HCl before and after adding a

dose of Pepto-Bismol (FDA approved) and Maty's (alternative), their efficacy can be compared.

this is critical.

<sup>1</sup>"The Use of Complementary and Alternative Medicine in the United States," National Center for Complementary and Integrative Health, September 24, 2017, n/a, accessed March 22, 2019, [https://nccih.nih.gov/research/statistics/2007/camsurvey\\_fs1.htm](https://nccih.nih.gov/research/statistics/2007/camsurvey_fs1.htm).

<sup>2</sup>Laura Cassiday, "Clean Label: The next Generation," AOCS, September 2017, n/a, accessed March 22, 2019, <https://www.aocs.org/stay-informed/inform-magazine/featured-articles/clean-label-the-next-generation-september-2017>.

this would be an appropriate time to defend your method.

This needs support... what's your evidence?



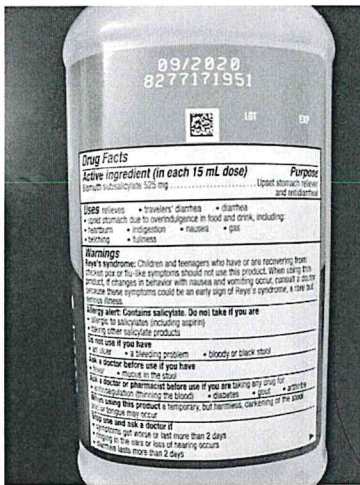
*this is vague - I think you could include your reasons without making it too long.*

**Prediction:**

Based off of my preliminary research and my assessment of the ingredients in each product, I initially predicted that the Maty's organic antacid will not perform as well as Pepto-Bismol chemical based antacid, thus showing that Pepto-Bismol is a better choice for consumers than Maty's.

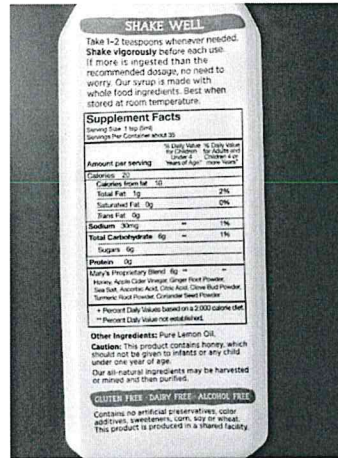
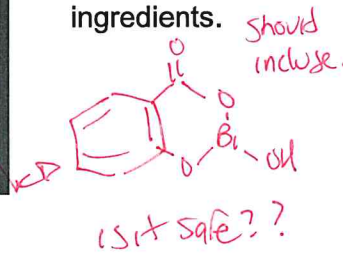
**Pepto Active Ingredients**

**Maty's Key Ingredients (no active ones)**



**- Bismuth subsalicylate**

Pepto is widely known as a remedy for stomach ailments. It is FDA-approved and uses chemical ingredients.



- Apple cider vinegar
  - Citric Acid
  - Lemon
  - Honey
  - Ginger
- Maty's is a natural remedy that is used primarily by those looking for alternative medicines. Each ingredient is organic and easy to pronounce in order to appeal to these consumers.

Given that many of the key ingredients in Maty's are acidic, I found it difficult to see how it could function as an antacid. However, I did find several sources explaining how apple cider vinegar can be used as a remedy for stomach pain caused by bloating. However, there is no scientific evidence for its effectiveness; all of the reports thus far have been anecdotal and not a result of a controlled study.<sup>3</sup> Ginger is known to have soothing properties when it comes to an upset stomach. And upon viewing consumer reviews of Maty's, I saw that 72% of the 60 customer

*needs support.*

*gout.*

*My own research indicates that peptobismol is more of an antibacterial than an antacid.*

<sup>3</sup>"8 Amazing Uses for Apple Cider Vinegar," Gerson Institute, May 10, 2018, accessed March 22, 2019, <https://gerson.org/gerpress/8-amazing-uses-for-apple-cider-vinegar/>.





including public reviews in a scientific review is questionable.

reviews showed a five star rating. This prompted me to ponder whether Maty's truly worked as an antacid, or if these customers were subjected to a placebo effect. *OK!* *good!*

Although the anecdotal evidence from consumer reviews is not classified as a controlled study, they provide a tentative idea of whether or not a product "works" for a consumer. For Pepto Bismol, 78% of 179 reviews were five stars, so clearly customers experienced some sort of relief with this product. [There is scientific support for how the active ingredient, bismuth subsalicylate, combined with the inactive ingredients works to relieve stomach pain. Bismuth has antimicrobial properties, so it helps to kill harmful bacteria in the stomach and the intestinal tract that cause pain. <sup>4</sup> Another ingredient, methylcellulose, is an insoluble fiber, so it helps to clear out the digestive tract and reduce symptoms. However, none of these ingredients stood out to me as having pH-increasing properties, so I was curious to see whether or not it was truly an antacid as it claims to be. *agree!* *well at least a professor talked about it,...*

#### Method:

In order to mimic the conditions inside the human stomach so that the medicines could be assessed accurately, I first had to create a solution that had similar properties to stomach fluid. I determined that .155M solution of HCl at a temperature of 37°C (the approximate temperature of the human body) was ideal because it matched the acidity and temperature of stomach fluid. I then planned to measure the pH of this solution before and after adding the medicines. I then decided to manipulate the variable of time in order to determine if the pH would change progressively or immediately. *source needed* *safety should be assessed prior to dispensing liquids.* *and what is that pH?* *good idea*

There are a ton of good scientific papers & in wikipedia: Bismuth subsalicylate.

<sup>4</sup> Gary Hanington, "Professor Hanington's Speaking of Science: The Science of Pepto," Elko Daily Free Press, November 10, 2018, none, accessed March 22, 2019, [https://elkodaily.com/lifestyles/professor-hanington-s-speaking-of-science-the-science-of-pepto/article\\_0bf238ca-c1ab-50c4-9973-acbb39035a8f.html](https://elkodaily.com/lifestyles/professor-hanington-s-speaking-of-science-the-science-of-pepto/article_0bf238ca-c1ab-50c4-9973-acbb39035a8f.html).



- I. Combine .77 mL of 6M HCl solution to 49.33 mL of water (H<sub>2</sub>O) in a beaker. This will result in a beaker containing 50 mL of .155 M HCl solution. ✓
- II. Measure 10 mL of the HCl solution into a separate beaker. Repeat this twice so that there are two beakers, each containing 10 mL of solution. ✓ Safety issues
- III. Use a pH strip to measure the initial pH of the solution.
- IV. Place beakers on a hot-plate set to 37°C and insert a thermometer into each beaker.
- V. When the temperature of the solution reaches 37°C add 7 mL of Pepto Bismol into one beaker and 7 mL of Maty's into the other beaker. should use 3 sig. figs.
- VI. Stir the solution to combine. ✓
- VII. Use a pH strip to measure the final acidity of the solution after:
  - A. 0 minutes
  - B. 5 minutes
  - C. 10 minutes ✓
  - D. 15 minutes
  - E. And 20 minutesA pH strip is OK, but more precise methods are available.
- VIII. Determine the difference from the initial pH. ✓
- IX. Repeat this process three times. ✓

Analysis:

*Quantitative Data*

Below is a table of the data that was recorded. The initial pH of the .155 M HCl solution was measured to be ~5. ✓





### The Effect of Different Medications on the Acidity of a .155 M HCl Solution Over Time

Time (min)	~pH of Pepto Bismol solution	~pH of Maty's solution
0	6	2.5
5	6	2.5
10	6	2.5
15	6	2.5

*looks dull but it was worth doing - good idea.*

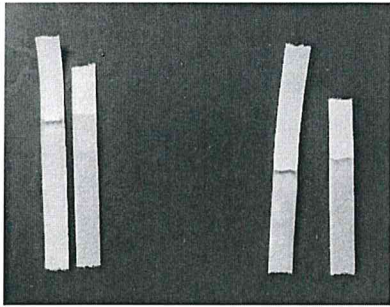
Based on the data, it is clear to see that the variable of time did not influence the change in pH of either solution. This is evident because the pH changed immediately at 0 minutes and then remained constant. In addition, the data shows that, while Pepto Bismol does cause a slight increase in pH, the remaining solution is still relatively acidic. I feel that this would make sense, however, because the medication is not intended to make the contents of the stomach basic because that would cause a disruption in digestion, which could make a consumers' symptoms worse. As predicted, the Maty's solution became more acidic when the medication was added. I predict that this was due to the main ingredient being acidic.

*I don't see a initial pH.*

*do you mean compared to P-B?*

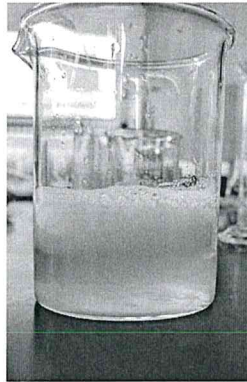


Qualitative Data

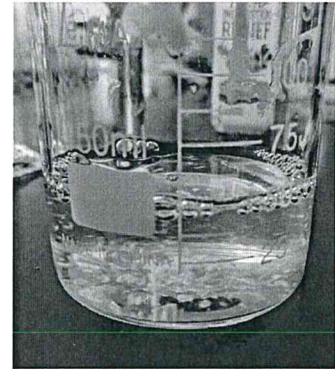


Strips from left to right: Original pH of HCl solution, pH of Maty's solution, original pH of HCl solution, pH of Pepto Bismol solution

Based on the coloration, one can see that the Maty's medicine made the solution more acidic, whereas the Pepto made it slightly more acidic



Above is the resulting solution when additional HCl is added to the Pepto Bismol solution. When HCl is added, the Pepto separates, indicating that there is a basic ingredient in the Pepto. This may explain why the Pepto was able to make the HCl solution less acidic.

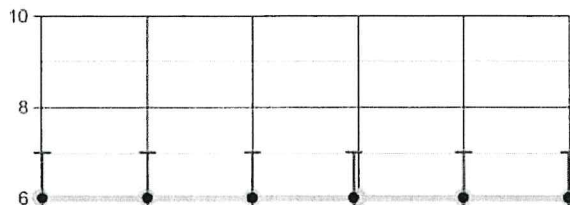


Above is the methylcellulose present in the Pepto Bismol. This formed as soon as the medicine came in contact with the acid and dissolved after a few hours, making the solution heterogeneous.

*I like the study, but it doesn't generate a lot of data.*

Evaluation:

The Change of .155 M HCL Solution Over Time After the Addition of Antacid





quot: support statement

Research has indicated that the accuracy of pH paper is typically within 1 unit of the pH of a solution, meaning that the results from my experiment could be slightly different than what I measured.<sup>5</sup> Below is a graph of the pH's of the solutions indicating possible discrepancies, which would be within ~7% of the accurate pH. ✓

This experiment could be improved if a pH meter was used instead of pH paper because a pH meter gives a more accurate reading, which would thus yield more reliable data and conclusions. In addition, I think it would have been interesting to test more types of medications with varying ingredients. This would provide a more universal conclusion for whether or not non-FDA approved over-the-counter stomach remedies are as effective as their FDA approved counterparts. Lastly, titration could have been used to measure the effectiveness of varying dosages of medicine on decreasing acidity. However, this could be complicated given that the liquids were not homogeneous and were strongly colored. ✓

My findings support my predictions in that Pepto Bismol seemed to be more effective in increasing the pH of the solution, however I was incorrect in my assumption that it would become basic. Upon experimenting and conducting further research, I have concluded that this would be unrealistic because it could endanger the health of the consumer if their stomach fluid became basic. Overall, this experiment helped me learn about how different types of medications work chemically to reduce stomach pain. It also helped me to examine the validity of non-scientific claims about non-FDA approved alternative medicine. ✓

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<sup>5</sup> Philip J. Carlson, "PH Meter Versus PH Paper," Sciencing, March 02, 2019, , accessed April 01, 2019, <https://sciencing.com/ph-meter-versus-ph-paper-5840578.html>.

nice





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## Internal assessment details

### Internal assessment component

Duration: 10 hours Weighting: 20%

- Individual investigation
- This investigation covers assessment objectives 1, 2, 3 and 4.

### Internal assessment criteria

The new assessment model uses five criteria to assess the final report of the individual investigation with the following raw marks and weightings assigned:

Personal engagement 2	Exploration 5	Analysis 4	Evaluation 5	Communication 3	Total 19
2 (8%)	6 (25%)	6 (25%)	6 (25%)	4 (17%)	24 (100%)

Levels of performance are described using multiple indicators per level. In many cases the indicators occur together in a specific level, but not always. Also, not all indicators are always present. This means that a candidate can demonstrate performances that fit into different levels. To accommodate this, the IB assessment models use markbands and advise examiners and teachers to use a **best-fit approach** in deciding the appropriate mark for a particular criterion.

Teachers should read the guidance on using markbands shown above in the section called “Using assessment criteria for internal assessment” before starting to mark. It is also essential to be fully acquainted with the marking of the exemplars in the teacher support material. The precise meaning of the command terms used in the criteria can be found in the glossary of the subject guides.

### Personal engagement

This criterion assesses the extent to which the student engages with the exploration and makes it their own. Personal engagement may be recognized in different attributes and skills. These could include addressing personal interests or showing evidence of independent thinking, creativity or initiative in the designing, implementation or presentation of the investigation.

Mark	Descriptor
0	The student’s report does not reach a standard described by the descriptors below.
1	<p><b>The evidence of personal engagement with the exploration is limited with little independent thinking, initiative or creativity.</b></p> <p>The justification given for choosing the research question and/or the topic under investigation does not demonstrate <b>personal significance, interest or curiosity</b>.</p> <p>There is little evidence of <b>personal input and initiative</b> in the designing, implementation or presentation of the investigation.</p>





2	<p><b>The evidence of personal engagement with the exploration is clear with significant independent thinking, initiative or creativity.</b></p> <p>The justification given for choosing the research question and/or the topic under investigation demonstrates <b>personal significance, interest or curiosity.</b></p> <p>There is evidence of <b>personal input and initiative</b> in the designing, implementation or presentation of the investigation. <i>author is clearly motivated and curious</i></p>
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### Exploration

This criterion assesses the extent to which the student establishes the scientific context for the work, states a clear and focused research question and uses concepts and techniques appropriate to the Diploma Programme level. Where appropriate, this criterion also assesses awareness of safety, environmental, and ethical considerations.

Mark	Descriptor
0	The student's report does not reach a standard described by the descriptors below.
1-2	<p>The topic of the investigation is identified and a research question of some relevance is <b>stated but it is not focused.</b></p> <p>The background information provided for the investigation is <b>superficial</b> or of limited relevance and does not aid the understanding of the context of the investigation.</p> <p>The methodology of the investigation is only appropriate to address the research question to a very limited extent since it takes into consideration few of the significant factors that may influence the relevance, reliability and sufficiency of the collected data.</p> <p>The report shows evidence of limited awareness of the significant safety, ethical or environmental issues that are <b>relevant to the methodology of the investigation*</b>.</p>
3-4	<p>The topic of the investigation is identified and a relevant but not fully focused research question is described.</p> <p>The background information provided for the investigation is mainly appropriate and relevant and aids the understanding of the context of the investigation.</p> <p>The methodology of the investigation is mainly appropriate to address the research question but has limitations since it takes into consideration only some of the significant factors that may influence the relevance, reliability and sufficiency of the collected data.</p> <p>The report shows evidence of some awareness of the significant safety, ethical or environmental issues that are <b>relevant to the methodology of the investigation.*</b></p>
Mark	Descriptor
5-6	<p>The topic of the investigation is identified and a relevant and fully focused research question is clearly described. <i>Topic is clear but a bit too broad since only pt was measured; other</i></p> <p>The background information provided for the investigation is entirely appropriate and relevant and enhances the understanding of the context of the investigation. <i>excellent consideration of FDA vs non FDA medications</i></p> <p>The methodology of the investigation is highly appropriate to address the research question because it takes into consideration all, or nearly all, of the significant factors that may influence the relevance, reliability and sufficiency of the collected data. <i>indicators of efficacy may be superior</i></p> <p>The report shows evidence of full awareness of the significant safety, ethical or environmental issues that are <b>relevant to the methodology of the investigation.*</b></p>

*However no sources to document peptide biosynthesis efficacy were included despite their availability.*

*Ethical and environmental issues covered deeply; safety is not addressed*





## Internal assessment

\* This indicator should only be applied when appropriate to the investigation. See exemplars in TSM. **Analysis**

This criterion assesses the extent to which the student's report provides evidence that the student has selected, recorded, processed and **interpreted** the data in ways that are relevant to the research question and can support a conclusion.

Mark	Descriptor
0	The student's report does not reach a standard described by the descriptors below.
1–2	<p>The report includes <b>insufficient relevant</b> raw data to support a valid conclusion to the research question.</p> <p>Some <b>basic</b> data processing is carried out but is either too <b>inaccurate</b> or too <b>insufficient to lead to a valid</b> conclusion.</p> <p>The report shows evidence of little consideration of the impact of measurement uncertainty on the analysis.</p> <p>The processed data is incorrectly or insufficiently interpreted so that the conclusion is invalid or very incomplete.</p>
3–4	<p>The report includes relevant but incomplete quantitative and qualitative raw data that could support a simple or partially valid conclusion to the research question.</p> <p>Appropriate and sufficient data processing is carried out that could lead to a broadly valid conclusion but there are significant inaccuracies and inconsistencies in the processing.</p> <p>The report shows evidence of some consideration of the impact of measurement uncertainty on the analysis.</p> <p>The processed data is interpreted so that a broadly valid but incomplete or limited conclusion to the research question can be deduced.</p>
5–6	<p>The report includes sufficient relevant quantitative and qualitative raw data that could support a detailed and valid conclusion to the research question.</p> <p>Appropriate and sufficient data processing is carried out with <b>the accuracy</b> required to enable a conclusion to the research question to be drawn that is fully <b>consistent</b> with the experimental data.</p> <p>The report shows evidence of full and appropriate consideration of the impact of measurement uncertainty on the analysis.</p> <p>The processed data is correctly interpreted so that a completely valid and detailed conclusion to the research question can be deduced.</p>

The data produced was very relevant

study only generated 2 numbers.  
 Could do other pH, other temp, other amounts...  
 Amounts could be used to estimate dosage...  
 no data processing... but the study did not require it.  
 conclusion is valid

## Evaluation

This criterion assesses the extent to which the student's report provides evidence of evaluation of the investigation and the results with regard to the research question and the accepted scientific context.

Mark	Descriptor
0	The student's report does not reach a standard described by the descriptors below.



1–2	<p>A conclusion is <b>outlined</b> which is not relevant to the research question or is not supported by the data presented.</p> <p>The conclusion makes superficial comparison to the accepted scientific context.</p> <p>Strengths and weaknesses of the investigation, such as limitations of the data and sources of error, are <b>outlined</b> but are restricted to an <b>account of the practical or procedural issues</b> faced.</p> <p>The student has <b>outlined</b> very few realistic and relevant suggestions for the improvement and extension of the investigation.</p>
3–4	<p>A conclusion is <b>described</b> which is relevant to the research question and supported by the data presented.</p> <p>A conclusion is described which makes some relevant comparison to the accepted scientific context.</p> <p>Strengths and weaknesses of the investigation, such as limitations of the data and sources of error, are <b>described</b> and provide evidence of some awareness of the <b>methodological issues*</b> involved in establishing the conclusion.</p> <p>The student has <b>described</b> some realistic and relevant suggestions for the improvement and extension of the investigation.</p>
5–6	<p>A detailed conclusion is <b>described and justified</b> which is entirely relevant to the research question and fully supported by the data presented.</p> <p>A conclusion is correctly <b>described and justified</b> through relevant comparison to the accepted scientific context. <i>Comparing results to sources would provide context.</i></p> <p>Strengths and weaknesses of the investigation, such as limitations of the data and sources of error, are <b>discussed</b> and provide evidence of a clear understanding of the <b>methodological issues*</b> involved in establishing the conclusion.</p> <p>The student has <b>discussed</b> realistic and relevant suggestions for the improvement and extension of the investigation. <i>The conclusion went beyond simply assessing the pt. Palliative and comfort-based results were also considered.</i></p>

\*See exemplars in TSM for clarification.

### Communication

This criterion assesses whether the investigation is presented and reported in a way that supports effective communication of the focus, process and outcomes.

Mark	Descriptor
0	The student's report does not reach a standard described by the descriptors below.
1–2	<p><b>The presentation of the investigation is unclear, making it difficult to understand the focus, process and outcomes.</b></p> <p>The report is not well structured and is unclear: the necessary information on focus, process and outcomes is missing or is presented in an incoherent or disorganized way.</p> <p>The understanding of the focus, process and outcomes of the investigation is obscured by the presence of inappropriate or irrelevant information.</p> <p>There are many errors in the use of subject specific terminology and conventions*.</p>



3-4	<p><b>The presentation of the investigation is clear. Any errors do not hamper understanding of the focus, process and outcomes.</b></p> <p>The report is well structured and clear: the necessary information on focus, process and outcomes is present and presented in a coherent way.</p> <p>The report is relevant and concise thereby facilitating a ready understanding of the focus, process and outcomes of the investigation.</p> <p>The use of subject specific terminology and conventions is appropriate and correct. Any errors do not hamper understanding.</p>
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\*For example, incorrect/missing labelling of graphs, tables, images; use of units, decimal places. For issues of referencing and citations refer to the "Academic honesty" section.

*Presentation style is engaging. Research in select areas is deep. A defense of the method would have provided a foundation with comparative data.*

## Rationale for practical work

Although the requirements for IA are centred on the investigation, the different types of practical activities that a student may engage in serve other purposes, including:

- illustrating, teaching and reinforcing theoretical concepts
- developing an appreciation of the essential hands-on nature of much scientific work
- developing an appreciation of scientists' use of secondary data from databases
- +developing an appreciation of scientists' use of modelling
- developing an appreciation of the benefits and limitations of scientific methodology.

## Practical scheme of work

The practical scheme of work (PSOW) is the practical course planned by the teacher and acts as a summary of all the investigative activities carried out by a student. Students at SL and HL in the same subject may carry out some of the same investigations.

### Syllabus coverage

The range of practical work carried out should reflect the breadth and depth of the subject syllabus at each level, but it is not necessary to carry out an investigation for every syllabus topic. However, all students must participate in the group 4 project and the IA investigation.

### Planning your practical scheme of work

Teachers are free to formulate their own practical schemes of work by choosing practical activities according to the requirements outlined. Their choices should be based on:

- subjects, levels and options taught
- the needs of their students
- available resources
- teaching styles.





Each scheme must include some complex experiments that make greater conceptual demands on students. A scheme made up entirely of simple experiments, such as ticking boxes or exercises involving filling in tables, will not provide an adequate range of experience for students.

Teachers are encouraged to use the online curriculum centre (OCC) to share ideas about possible practical activities by joining in the discussion forums and adding resources in the subject home pages.

## Flexibility

The practical programme is flexible enough to allow a wide variety of practical activities to be carried out. These could include:

- short labs or projects extending over several weeks
- computer simulations
- using databases for secondary data
- developing and using models
- data-gathering exercises such as questionnaires, user trials and surveys
- data-analysis exercises
- fieldwork.

## Practical work documentation

Details of the practical scheme of work are recorded on *Form 4/PSOW* provided in the *Handbook of procedures*. A copy of the class *4/PSOW* form must be included with any sample set sent for moderation.

## Time allocation for practical work

The recommended teaching times for all Diploma Programme courses are 150 hours at SL and 240 hours at HL. Students at SL are required to spend 40 hours, and students at HL 60 hours, on practical activities (excluding time spent writing up work). These times include 10 hours for the group 4 project and 10 hours for the internal assessment investigation. (Only 2–3 hours of investigative work can be carried out after the deadline for submitting work to the moderator and still be counted in the total number of hours for the practical scheme of work.)







# IB Chemistry: The Internal Assessment

(this is taken directly from the IB chemistry guide)

## Practical work and internal assessment

### General introduction

The internal assessment requirements are the same for biology, chemistry and physics. The internal assessment, worth 20% of the final assessment, consists of one scientific investigation. The individual investigation should cover a topic that is commensurate with the level of the course of study.

Student work is internally assessed by the teacher and externally moderated by the IB. The performance in internal assessment at both SL and HL is marked against common assessment criteria, with a total mark out of 24.

**Note:** Any investigation that is to be used to assess students should be specifically designed to match the assessment criteria.

The internal assessment task will be one scientific investigation taking about 10 hours and the writeup should be about 6 to 12 pages long. Investigations exceeding this length will be penalized in the communication criterion as lacking in conciseness.

The practical investigation, with generic criteria, will allow a wide range of practical activities satisfying the varying needs of biology, chemistry and physics. The investigation addresses many of the learner profile attributes well. See section on “Approaches to the teaching of chemistry” for further links.

The task produced should be complex and commensurate with the level of the course. It should require a purposeful research question and the scientific rationale for it. The marked exemplar material in the teacher support materials will demonstrate that the assessment will be rigorous and of the same standard as the assessment in the previous courses.

Some of the possible tasks include:

- a hands-on laboratory investigation
- using a spreadsheet for analysis and modelling
- extracting data from a database and analysing it graphically
- producing a hybrid of spreadsheet/database work with a traditional hands-on investigation
- using a simulation provided it is interactive and open-ended.

Some tasks may consist of relevant and appropriate qualitative work combined with quantitative work.

The tasks include the traditional hands-on practical investigations as in the previous course. The depth of treatment required for hands-on practical investigations is unchanged from the previous internal assessment and will be shown in detail in the teacher support materials. In addition, detailed assessment of specific aspects of hands-on practical work will be assessed in the written papers as detailed in the relevant topic(s) in the “Syllabus content” section of the guide.

The task will have the same assessment criteria for SL and HL. The five assessment criteria are personal engagement, exploration, analysis, evaluation and communication.

