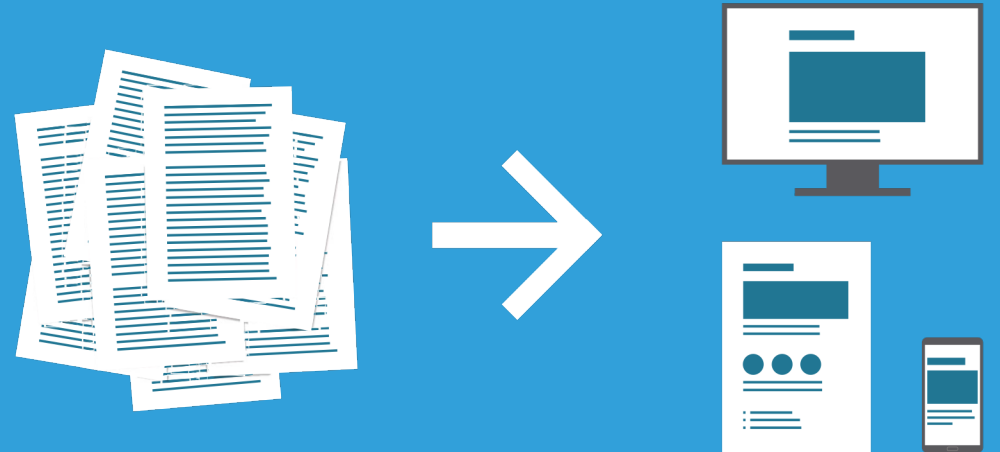


Visual Leaflet®

Making scientific information understandable and usable

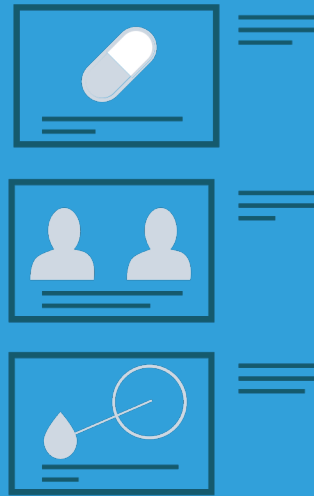


What we do:

We rewrite, order, visualise and animate information:



Herschreven,
geordende teksten.



Gevisualiseerde informatie
en storyboard.



Het eindresultaat gevisualiseerd en
geanimeerd op diverse platformen.

Common situation

- Strong emphasis on text, not on images.
- On paper, not digital
- Structured according to academic tradition, not according to user needs
- Based on academic genre, not based on practical context

No problem for highly educated readers ...

Examples

Boots

PHARMACEUTICALS

Information for the user

Ibuprofen Long Lasting 200 mg Capsules

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription to treat minor conditions. However, you still need to take it carefully to get the best results from it.

- Keep this leaflet, you may need to read it again
- Ask your pharmacist if you need more information or advice

What this medicine is for

This medicine contains ibuprofen which belongs to a group of medicines called non-steroidal anti-inflammatory medicines, which act to relieve pain and reduce swelling. The ibuprofen in the capsule is released slowly over 12 hours. It can be used to relieve headaches, rheumatic and muscular pain, backache, migraine, period pain, dental pain and neuralgia. It can also be used to reduce fever and relieve the symptoms of colds and flu.

Before you take this medicine

This medicine can be taken by adults and children aged 12 years and over. However, some people should not take this medicine or should seek the advice of their pharmacist or doctor first.

Do not take:

- If you have a stomach ulcer, perforation or bleeding of the stomach, or have had one in the past (you may have been sick and it contained blood or dark particles that look like coffee grounds, passed blood in your stools or passed black tarry stools)
- If you have had perforation or a bleeding stomach after taking a non-steroidal anti-inflammatory medicine
- If you are allergic to ibuprofen or any other ingredients in the product, aspirin or other non-steroidal anti-inflammatory medicines (you have ever had asthma, runny nose, itchy skin or swelling of the lips, face or throat after taking these medicines)
- If you are taking aspirin with a daily dose above 75 mg, or other non-steroidal anti-inflammatory medicines
- If you have severe heart, kidney or liver failure
- If you are pregnant

! Talk to your pharmacist or doctor:

- If you have asthma, a history of asthma or other allergic disease, stomach or bowel problems
- If you have other kidney or liver problems (see 'Do not take')
- If you are elderly - you may get more side effects (see back of leaflet)
- If you are taking any other painkillers or receiving regular treatment from your doctor
- If you have had a stroke, or have heart problems, high blood pressure, diabetes, high cholesterol, or you smoke - see 'Risk of heart attack or stroke' below

Other important information

Risk of heart attack or stroke: Ibuprofen may increase the risk if you take large amounts for a long time. The risk is small. Take the lowest amount for the shortest possible time to reduce this risk.

Breastfeeding: You can use this medicine.

Women of childbearing age: If you take this medicine, it may reduce your ability to become pregnant. This effect will be reversed when you stop the medicine.

If you take other medicines

Before you take these capsules, make sure that you tell your pharmacist about ANY other medicines you might be using at the same time, particularly the following:

- Aspirin 75 mg (to prevent heart attacks and strokes) - the protection may be reduced when you take ibuprofen
- Other pain killers
- Medicines to thin your blood (e.g. warfarin)
- Mifepristone (for termination of pregnancy) - do not take ibuprofen if you have taken mifepristone in the last 12 days
- Water tablets (diuretics), medicines to treat high blood pressure, medicines for heart problems
- Corticosteroids, lithium, methotrexate, zidovudine
- Quinolone antibiotics (for infections)
- Medicines for depression
- Ciclosporin or tacrolimus (given after transplant surgery, or for psoriasis or rheumatism)

If you are unsure about interactions with any other medicines, talk to your pharmacist. This includes medicines prescribed by your doctor and medicine you have bought for yourself, including herbal and homeopathic remedies.

APO. LOKATIE-NAAM. STRAATNAAM 18 GEMEENTE

MW. DRs. J.E ACHTERNAAM-ACHTERNAAM, APOTHEKER. TEL. 009 - 123 45 67

01-07-2014 LOKAT V/08-06-1938 GHE00306/2DF

NAAM PATIENT STRAA 62

2x per dag 2 inhalaties

Ter inhalatie

Omschudden voor gebruik

Aanbeveling: na gebruik de mond spoelen.

** benauwdheid (voorkomen) **

1 ST SERETIDE AER 25/250MCG/D

Labels

DCRF-model proefpersoneninformatie – mei 2018

Proefpersoneninformatie

Toelichting voor gebruikers van het Model proefpersoneninformatie

Ook aangeduid als PIF: proefpersoneninformatieformulier

Model voor elk type onderzoek

Deze modelinformatiebrief kan worden gebruikt voor elk type onderzoek. Het model is ontworpen voor zowel interventieonderzoek als observationeel onderzoek. Alle secties van de brief zijn ook voor observationeel onderzoek van toepassing, al valt er daarbij vaak minder te melden (zie de toelichtingen per sectie).

Voorbeelden van interventies: geneesmiddel (wel/niet geregistreerd), medisch hulpmiddel, voedingsproduct, fysiotherapie, medische ingreep/chirurgische techniek, gedragstherapie, psychosociale interventie.

Doel proefpersoneninformatie

Voor deelname van een proefpersoon aan medisch-wetenschappelijk onderzoek is geïnformeerde toestemming nodig. Dit is een proces waar de schriftelijke informatie onderdeel van uitmaakt. Mondelinge informatie en gedachtewisseling en het stellen van vragen horen hier ook bij. Doel van het proces en de schriftelijke informatie is de potentiële proefpersonen op zo'n manier informeren dat zij een weloverwogen keuze kunnen maken om wel of niet mee te doen aan het onderzoek. Het doel van de informatiebrief is niet om de verrichter van het onderzoek in te dekken tegen mogelijke claims of om zoveel mogelijk proefpersonen mee te laten doen aan het onderzoek.

Toelichting typografie:

model vanaf de volgende pagina als volgt invullen voor een specifiek onderzoek:

1. Gewone tekst moet standaard worden gebruikt en mag alleen worden aangepast als deze niet klopt voor het betreffende onderzoek;

2. omschrijving/opties te vervangen door de feitelijke informatie OF de best bij de aard van het onderzoek passende term kiezen

3. Tekst gemarkeerd met VOORBEELDPASSAGE kan naar keuze worden gebruikt. Let op: deze tekst dekt vaak niet de inhoud van de gehele sectie.

4. Voorbeeldtekst in tabelvorm: kopieer/verplaats de gewenste tekst en verwijder daarna de tabel.

5. Zorg dat alle in de opmerking per sectie genoemde aspecten aan de orde komen (als van toepassing)

6. Tot slot, te verwijderen:

- deze pagina (toelichting voor gebruikers)

- bovenste regel van de kopetekst

- de opmerkingen

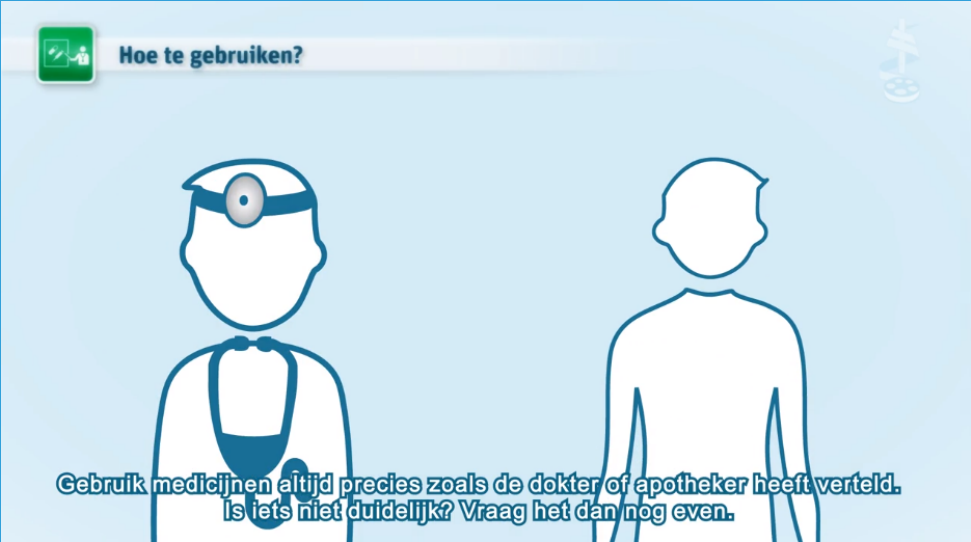
- tekst tussen toelichting en eventueel daaropvolgende tekst

- voorbeeldpassages die niet zijn gebruikt

- teksten voor bijzondere situaties die niet zijn gebruikt

Consent forms

Examples



Package leaflets



Labels



Consent forms

Starting points

Start from the perspective of readers

- What do people need to do with the information?
- Coordinate: start from different layers, starting from main points
- Combine digital and analogue, starting from digital
- Combine text and images, starting from images

Synthon's question:

'How can we prove that Brabio and Copaxone are identical?'

Synthon's question

'How can we prove that Brabio and Copaxone are identical?

Support three actions of *readers*:

- 1. Study the *basics*
- 2. Check the *evidence*
- 3. Make a *decision*

Comparing versions of glatiramer acetate: are they different?

For a patient who needs glatiramer acetate, the studies show that there is no difference between these two medicines.

Only one of the studies indicated a difference, but this difference is not relevant. Both medicines fall well within the safety limits.

Next steps

→ Step 1. Study the basics

Read about what MS is, what medicines are doing and selecting the right medicine.

→ Step 2. Check the evidence

→ Step 3. Make up your mind

A quick overview

Comparing versions of glatiramer acetate: are they different?



Study data and conclusions

Clinical studies

A 9-month, randomised, multicenter, double-blind, active and placebo-controlled Phase 3 study of 794 patients

No difference

An open-label 15-month GTR treatment part

No difference

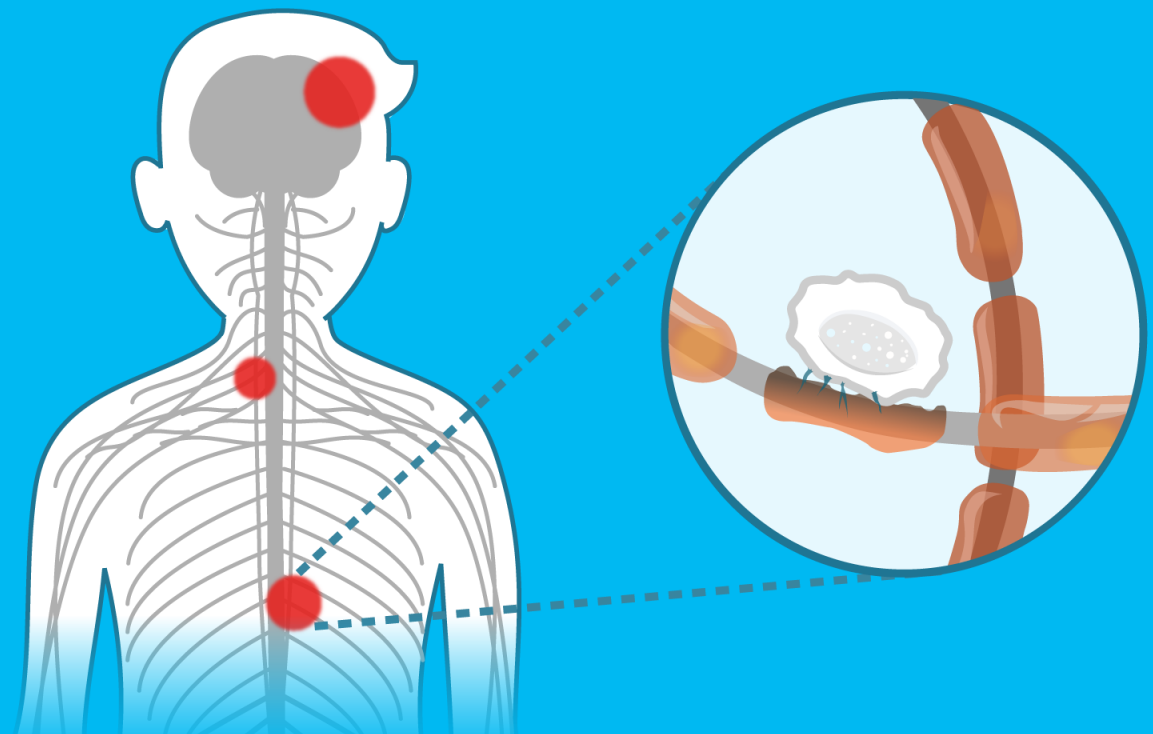
Biometrical studies

Western Blot

No difference

Comparing versions of glatiramer acetate: are they different? - A quick overview

1 What is MS

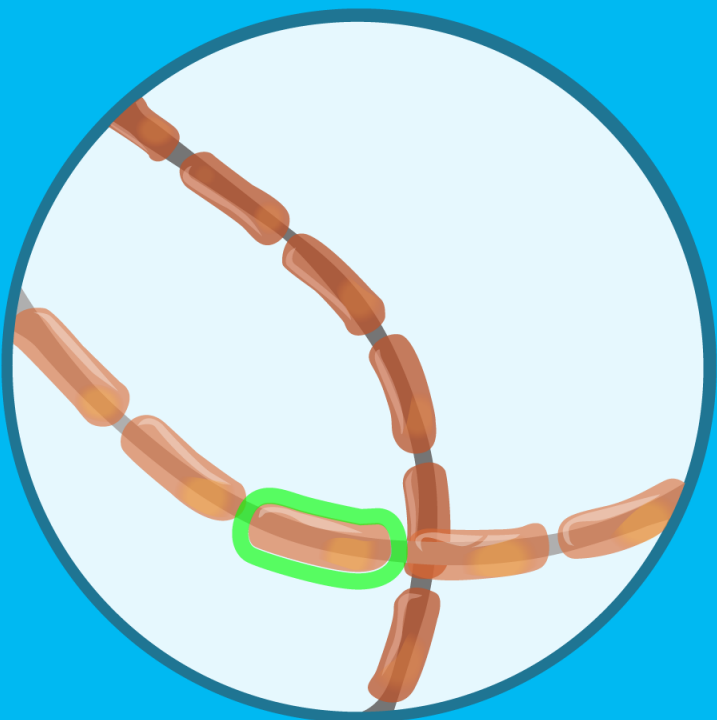


MS are thought to be caused by a defect in the body's immune system, causing inflammation in the brain and spinal cord.

0:23 / 2:34

Comparing versions of glatiramer acetate: are they different? - A quick overview

1 What are medicines doing



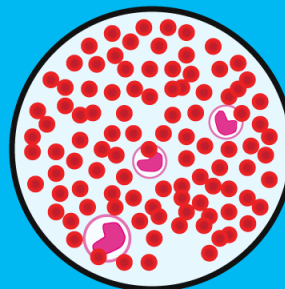
Medicines aim to to reduce the chance of permanent nerve damage.

0:45 / 2:34

5 Are there different kinds of glatiramer acetate?



Clinical
study



Biometrical
study



Chemical
characteristics

There are three main ways to compare mixtures

Comparing versions of glatiramer acetate: are they different? - A quick overview

5 Are there different kinds of glatiramer acetate?

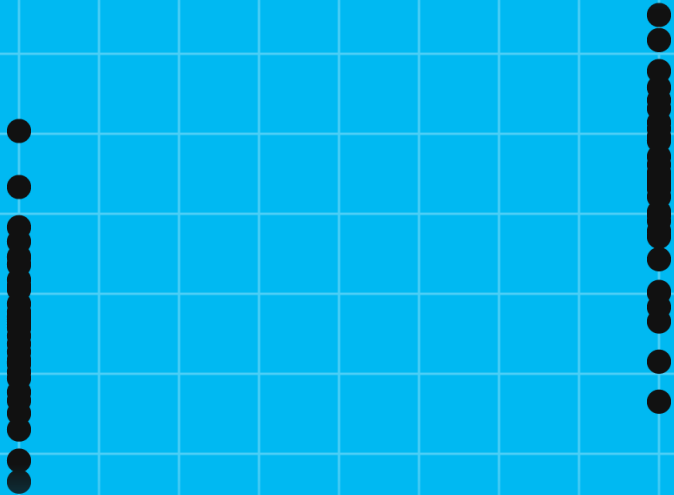
- Western Blot No difference
- Enzyme-linked immunosorbent assay No difference
- Cell Based Assay (CBA) Micro array study No difference
- Experimental Autoimmune Encephalomyelitis No difference
- Experimental Autoimmune Encephalomyelitis PLP model in SJL mice No difference
- Toxicity and safety studies in rat No difference
- Amino Acid Composition No difference
- Peptide mapping/ Proteolytic Digestion Profile No difference
- Chromatographic property after acid digestion No difference

A lot of studies have been done.

Comparing versions of glatiramer acetate: are they different? - A quick overview

5

Are there different kinds of glatiramer acetate?

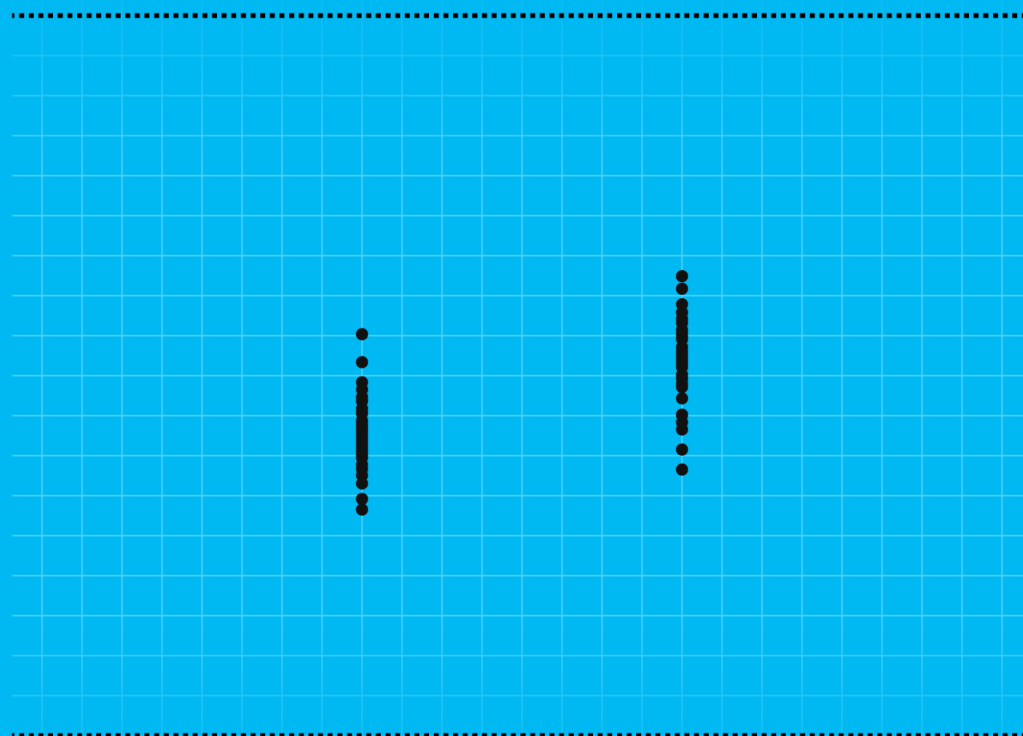


Only one of the studies indicated a difference...

2:08 / 2:34

Comparing versions of glatiramer acetate: are they different? - A quick overview

5 Are there different kinds of glatiramer acetate?



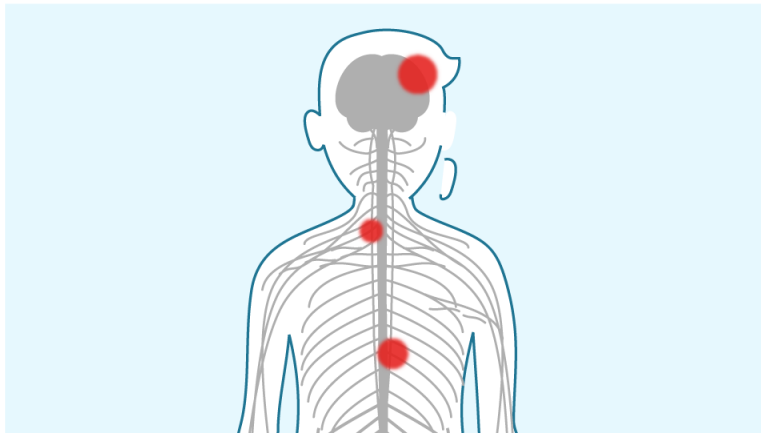
... but this difference is well within the safety limits.

Comparing versions of glatiramer acetate: are they different?

Step 1. Study the basics

What is MS

The symptoms of multiple sclerosis (MS) are thought to be caused by a defect in the body's immune system.



It produces patches of inflammation in the brain and spinal cord. The signals that normally travel through your nerves are interrupted. This reduces your control over many parts of your body.

A quick overview



Read next

[Step 1. Study the basics](#)
→ [What are medicines doing?](#)

Related

→ [The immune system](#)
→ [Overview of available medicines](#)

Comparing versions of glatiramer acetate: are they different?

Step 2. Check the evidence

Are there different kinds of glatiramer acetate?

If every syringe with glatiramer acetate is unique, how can patients be sure that they get what they need? How can we compare two syringes that both contain glatiramer acetate?

It is clear that glatiramer acetate is beneficial for people with multiple sclerosis. But how can doctors compare different medicines that contain glatiramer acetate?

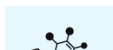
There are three main ways to compare mixtures.



We can compare different versions in a clinical study.



We can compare different versions in biometrical studies.



We can compare the chemical

A quick overview

Check the evidence



Read next

Step 2. Check the evidence

→ [Compare differences](#)

Related

→ [Research methods](#)

→ [Statistical analysis](#)

Neutral Company

Neutral Company https://www.nc.com/

we can compare the chemical characteristics.

[→ Statistical analysis](#)

Each of these three methods has its own methods and types of results.

Below is a table with the results in each of these comparisons: Green = no difference. Orange = difference. Clicking on a table cell reveals the study data and conclusions.

Clinical study

A 9-month, randomised, multicenter, double-blind, active and placebo-controlled Phase 3 study of 794 patients

No difference

followed by an open-label 15-month GTR treatment part

No difference

Biometrical study

Western Blot

No difference

Enzyme-linked immunosorbent assay

No difference

Cell Based Assay (CBA)

No difference

Micro array study

Chemical characteristics

Amino Acid Composition

No difference

Peptide mapping/ Proteolytic Digestion Profile

No difference

Title of the research paper

Difference

Circular Dichroism

Neutral Company

Neutral Company https://www.nc.com/

Neutral Company

Comparing versions of glatiramer acetate: are they different? > Step 2. Check the evidence

Title of the research paper

Contents

Introduction >

> Product Characteristics

> Methods

> Results

> Discussion

> Conclusion

> Supplementary data

Introduction

Nulla vitae elit libero, a pharetra augue. Lorem ipsum dolor sit amet, consectetur adipiscing elit. Praesent commodo cursus magna, vel scelerisque nisl consectetur et. Vivamus sagittis lacus vel augue laoreet rutrum faucibus dolor auctor. Aenean eu leo quam. Pellentesque ornare sem lacinia quam venenatis vestibulum. Morbi leo risus, porta ac consectetur ac, vestibulum at eros.

Vestibulum id ligula porta felis euismod semper. Praesent commodo cursus magna, vel scelerisque nisl consectetur et. Nullam id dolor id nibh ultricies vehicula ut id elit. Etiam porta sem malesuada magna mollis euismod.

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Aenean eu leo quam. Pellentesque ornare sem lacinia quam venenatis

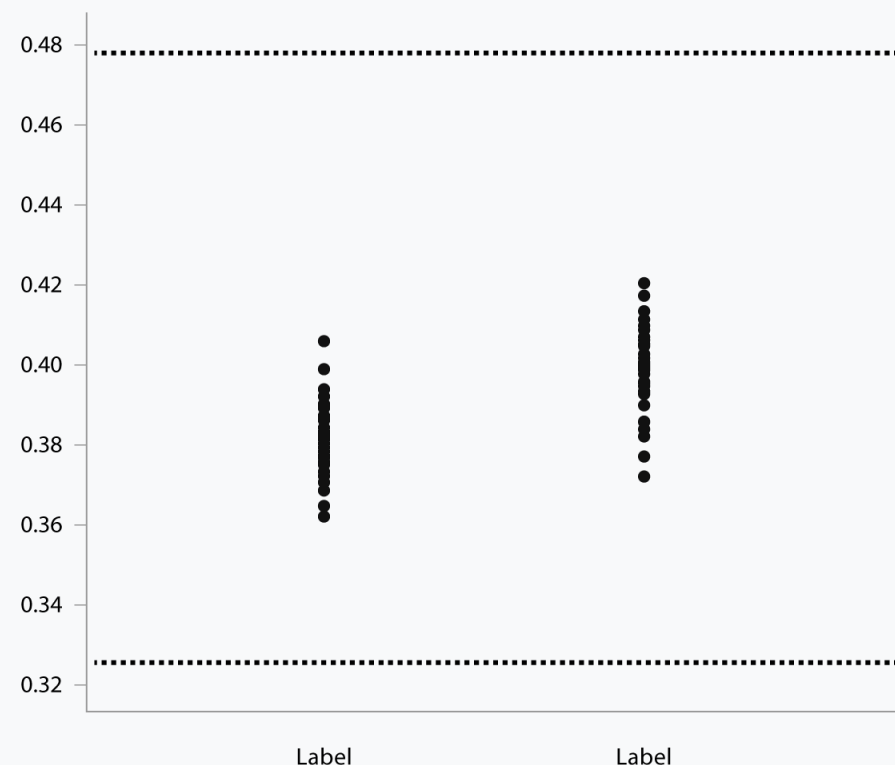
Contents

- > Introduction
- > Product Characteristics
- > Methods
- > Results
 - ✓ Quality Characteristics
 - [Lorem ipsum dolor sit](#)
 - [Amet consectetur](#) Difference
 - [Adipiscing elit sed do](#) Difference
 - [Eiusmod tempor](#)
 - [Incididunt ut labore et](#)
 - [DOLORE](#)
 - [MAGNA](#)
 - [Aliqua Ut Enim](#)
 - > Nonclinical in vitro and in vivo studies
 - > Clinical Studies
- > Discussion
- > Conclusion
- > Supplementary data

vestibulum. Curabitur blandit tempus porttitor. Sed posuere consectetur est at lobortis. Vestibulum id ligula porta felis euismod semper. Maecenas faucibus mollis interdum.

Adipiscing elit sed do

Figure 1: Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua.



What does this mean

Donec id elit non mi porta gravida at eget metus. Cras mattis consectetur purus sit amet fermentum. Nullam quis risus eget urna mollis ornare vel eu leo. Curabitur blandit tempus porttitor. Vivamus sagittis lacus vel augue laoreet rutrum faucibus dolor auctor.

> [Read more](#)

In context

- > [Comparing chemical characteristic](#)
- > [What are relevant differences](#)

Nulla vitae elit libero, a pharetra augue. Lorem ipsum dolor sit amet, consectetur adipiscing elit. Praesent commodo cursus magna, vel

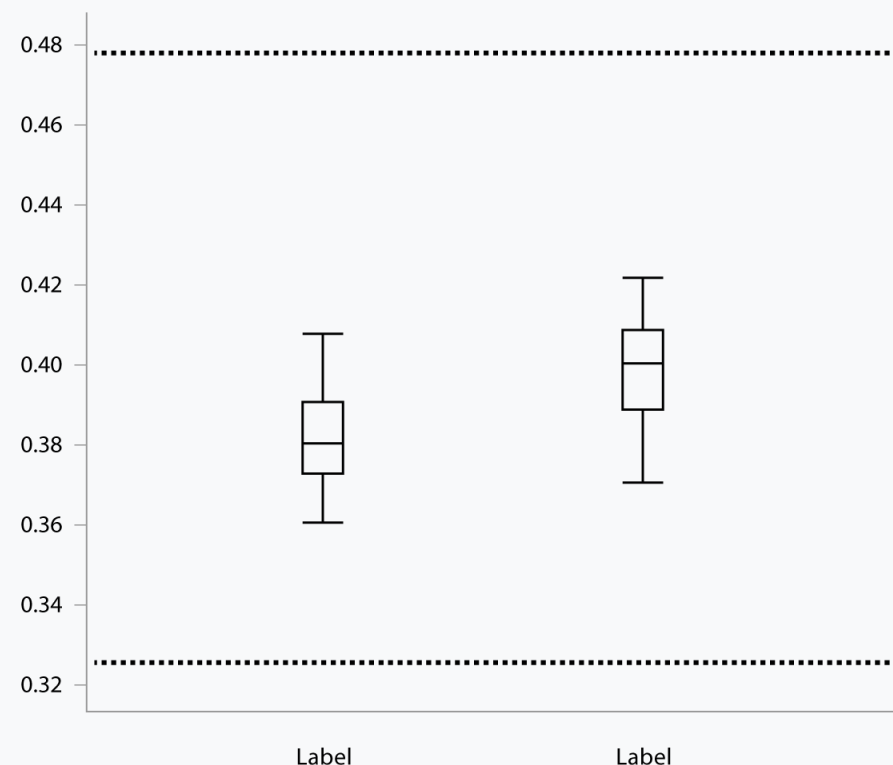
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vestibulum. Curabitur blandit tempus porttitor. Sed posuere consectetur est at lobortis. Vestibulum id ligula porta felis euismod semper. Maecenas faucibus mollis interdum.

Adipiscing elit sed do

Figure 1: Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua.



What does this mean

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> [Read more](#)

In context

- > [Comparing chemical characteristic](#)
- > [What are relevant differences](#)

What do I see



Box plot



Safe margins



Nulla vitae elit libero, a pharetra augue. Lorem ipsum dolor sit amet, consectetur adipiscing elit. Praesent commodo cursus magna, vel