Medicines & Healthcare products Regulatory Agency

British Pharmacopoeia 2026

The most comprehensive collection of authoritative official standards for UK pharmaceutical substances and medicinal products.

July 2025

tso
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This webinar is hosted by TSO – the official publisher of the British Pharmacopoeia.

Welcome and housekeeping

- The webinar is hosted on Zoom
- The webinar will last approximately one hour
- The webinar is being recorded, and all registrants will receive a recording after the webinar
- A copy of the slides will also be available
- Participants will be on mute, and cameras will be disabled throughout the webinar
- Please use the Q&A window for all questions
- Where possible, put the panellist's name against your question so we know who it is for
- Customer survey to complete at the end – Prize Draw to win £100

Webinar agenda

- **British Pharmacopoeia strategy update**
  Presented by BP Editor in Chief, Peter Crowley
- **Introducing the British Pharmacopoeia 2026 edition**
  Presented by Michael Whaley and Rachael Feltham
- **Related substances in the British Pharmacopoeia**
  Presented by Maryna Dmitriieva
- **Live audience Q & A**
  Presented by all
- **Close**

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British Pharmacopoeia strategy update

Peter Crowley, Editor in Chief

Current state of the British Pharmacopoeia

Overview of existing services

Publications

- British Pharmacopoeia
- British Approved Names
- Non-mandatory Guidance and information packs
- National Authority to European Pharmacopoeia

Laboratory Services

- Catalogue of over 850 BP Chemical Reference Substances
- Analytical confirmation of BP monographs
- Regulatory testing
- Enforcement support

Strengths

- Integration with a national regulator
- Involvement with European Pharmacopoeia
- Agency expertise in biologics standardisation and control testing
- National medicines data

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Stakeholder feedback

Direction is led by feedback via queries, surveys and consultations as well as analytics

Users acknowledge the evolution of the BP, which has avoided disruption, with significant improvements over the past 5 years

Clearly a desire for us to build engagement and share more with our users

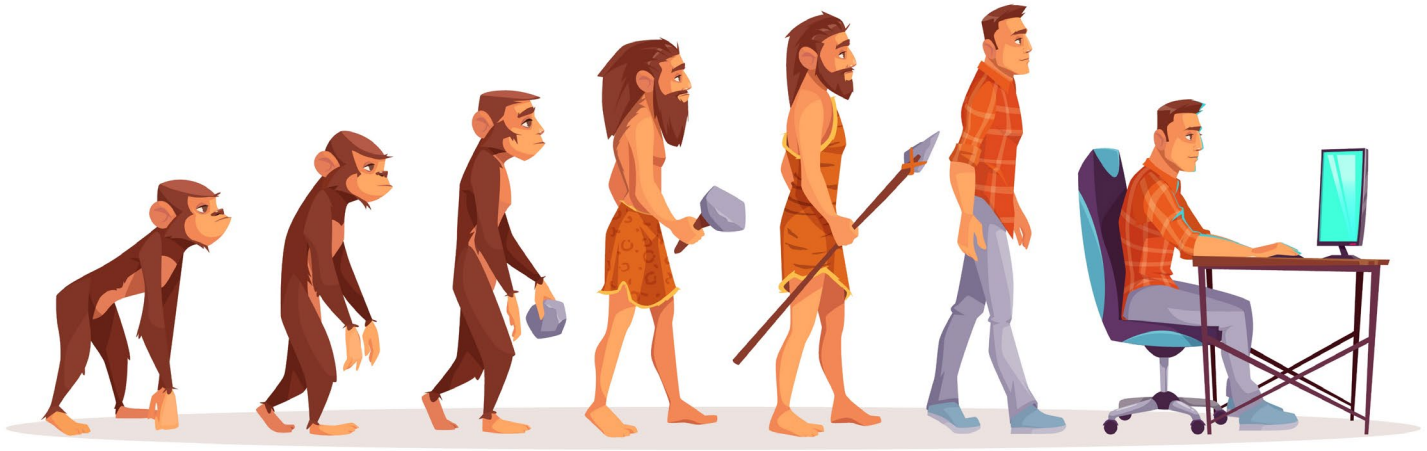
Identifying challenges and opportunities

Internal and External Challenges

Market and Technological Opportunities

Analytical Technologies Phasing out legacy tech and recognising innovations

Digital first era Should the BP continue to be published in print?
Sustainability, cost and ease of use of print vs digital



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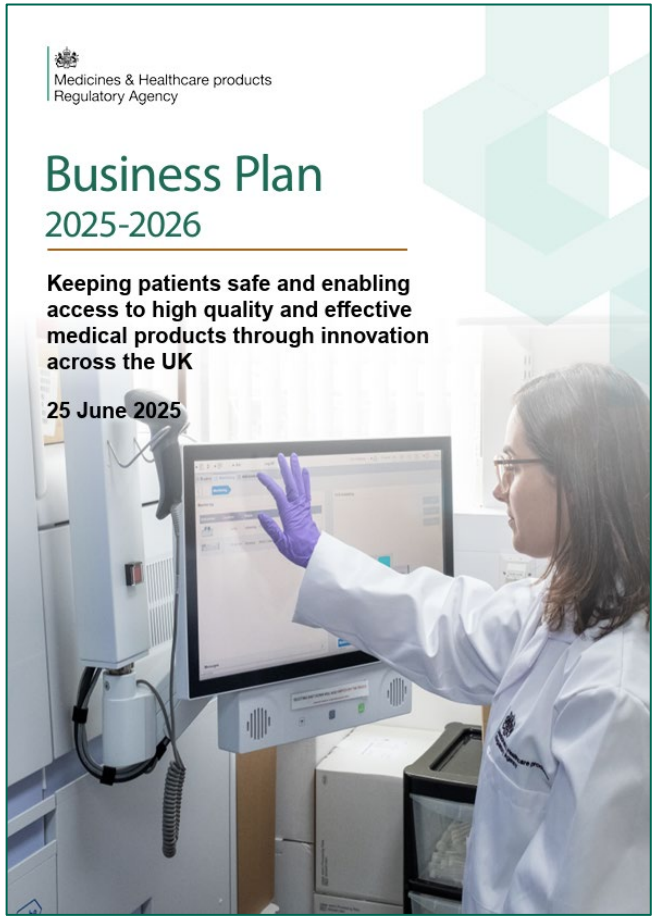
Economic and Political Factors



Key strategic themes

Initial areas of focus

Product Development for Patient Benefit	Monographs for First Generics Review the 2019 BP Biologics strategy Develop and publish public value metrics
Marketing Strategy	Forge alliances exploring advances in technological solutions
Developing Staff	Observers to BP Commission and meetings Modernise membership process
Governance, Performance and Value	
Resilience	Consider alternative content types and formats
Sustainability	Establish a means to measure environmental impact of work

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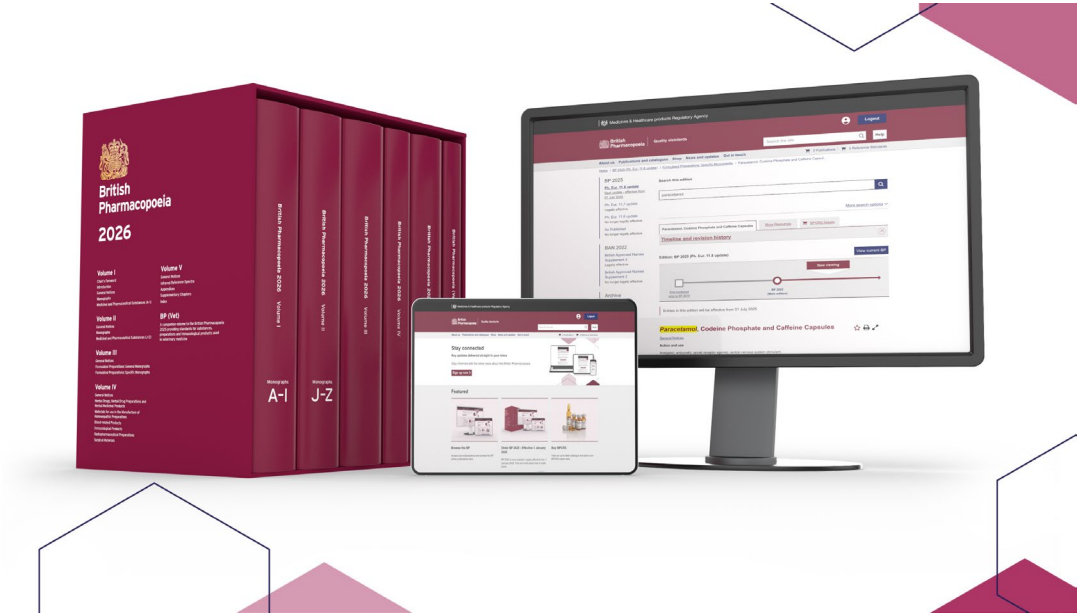
Introducing the British Pharmacopoeia 2026 edition

Michael Whaley and Rachael Feltham

What’s new?

- New product changes for the BP 2026
- Approval of the BP 2026
- New content for the BP 2026
- New features in the monographs

What’s new? (2)



- BP 2026 published on 1 August 2025
- Available to purchase in new ways
  - Single products
  - Build your own discounted two product package
  - Multi-user licence
- All formats contain all BP material including over 1400 monographs for Formulated Preparation
  - benefit from the inclusion of all monographs and guidance from the Ph. Eur. 11th edition and Ph. Eur. supplements up to 11.8.
  - the digital formats have the added benefit of Ph. Eur. 12.1 to 12.3 included as in-year online and download product updates.
- British Approved Names 2026. A new annual online format.

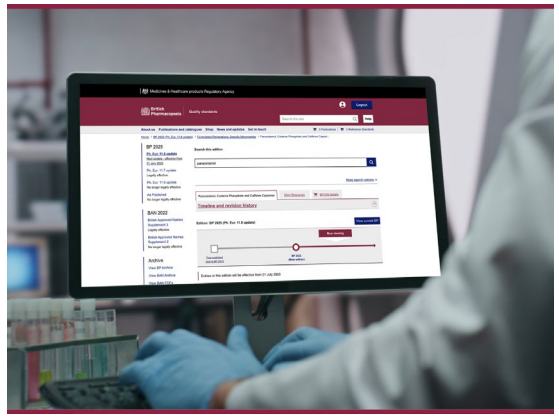
British Pharmacopoeia Commission

At the March 2025 meeting the BPC endorsed:

- the publication of the BP 2026 containing 19 new BP monographs and over 100 revisions
- the publication of the BAN 2026 with 39 new entries

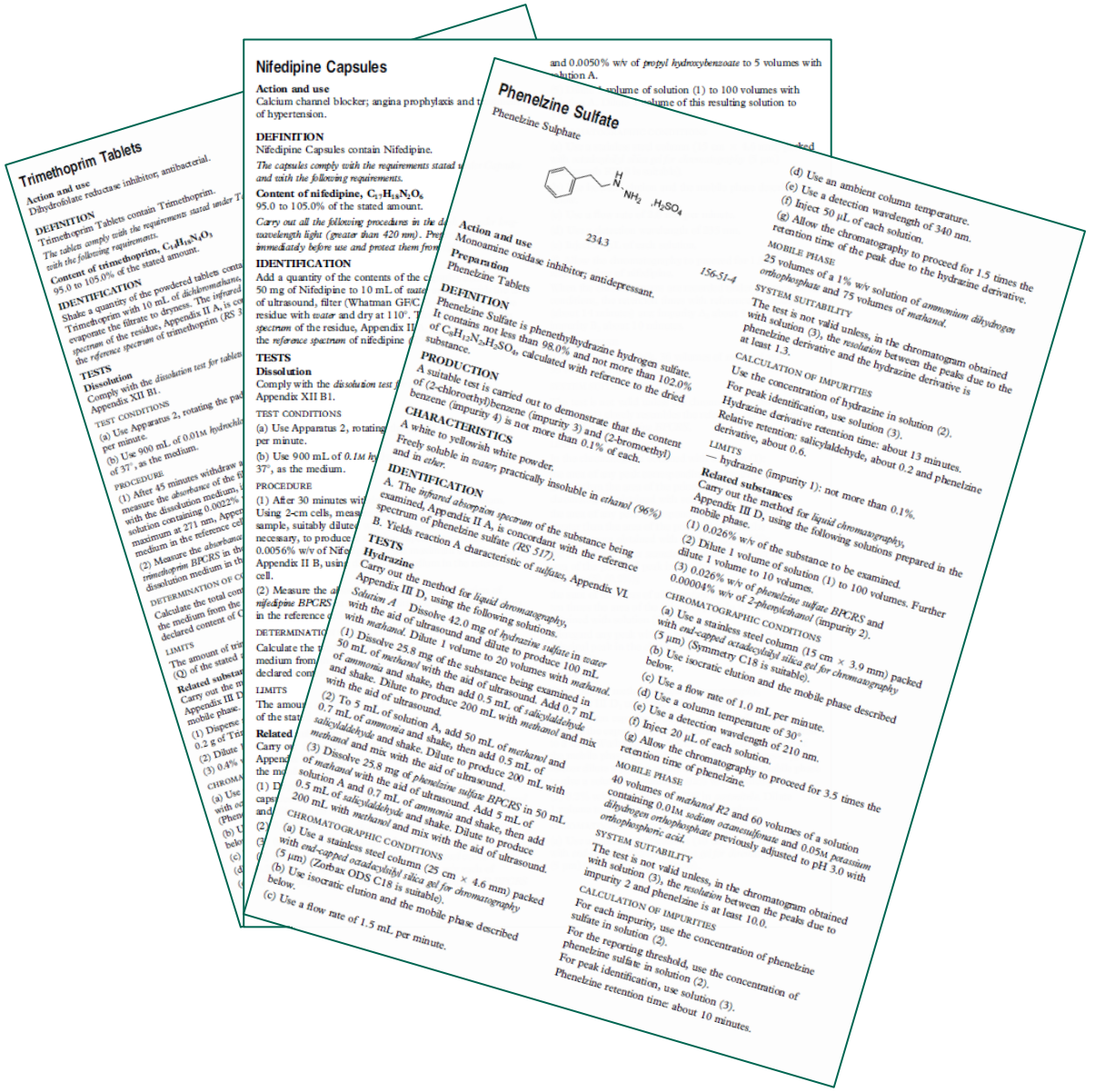
New BP Texts

- Aripiprazole Oral Solution
- Aripiprazole Orodispersible Tablets
- Aripiprazole Tablets
- Diltiazem Cream
- Ibuprofen Injection
- Lansoprazole Oral Suspension
- Latanoprost Eye Drops
- Levetiracetam Granules
- Levetiracetam Infusion
- Levetiracetam Sterile Concentrate
- Levetiracetam Tablets
- Mirabegron Prolonged-release Tablets
- Terbutaline Injection
- Terbutaline Nebuliser Solution
- Tramadol Dispersible Tablets
- Tramadol Orodispersible Tablets
- Tramadol Soluble Tablets
- Trazodone Oral Solution
- Cyperus Rotundus Rhizome



Revised BP Texts

- Over 100 revised texts including
  - Metronidazole Infusion
  - Metronidazole Suppositories
  - Metronidazole Tablets
  - Oxytetracycline Capsules
  - Trimethoprim Tablets
  - Trimethoprim Oral Suspension
  - Nifedipine Capsules
  - Nifedipine Prolonged Release Capsules
  - Nifedipine Prolonged Release Tablets
  - Trazodone Capsules
  - Trazodone Tablets
  - Phenelzine Sulfate
  - Propranolol Tablets
  - Salbutamol Pressurised Inhalation, Suspension
  - Squill

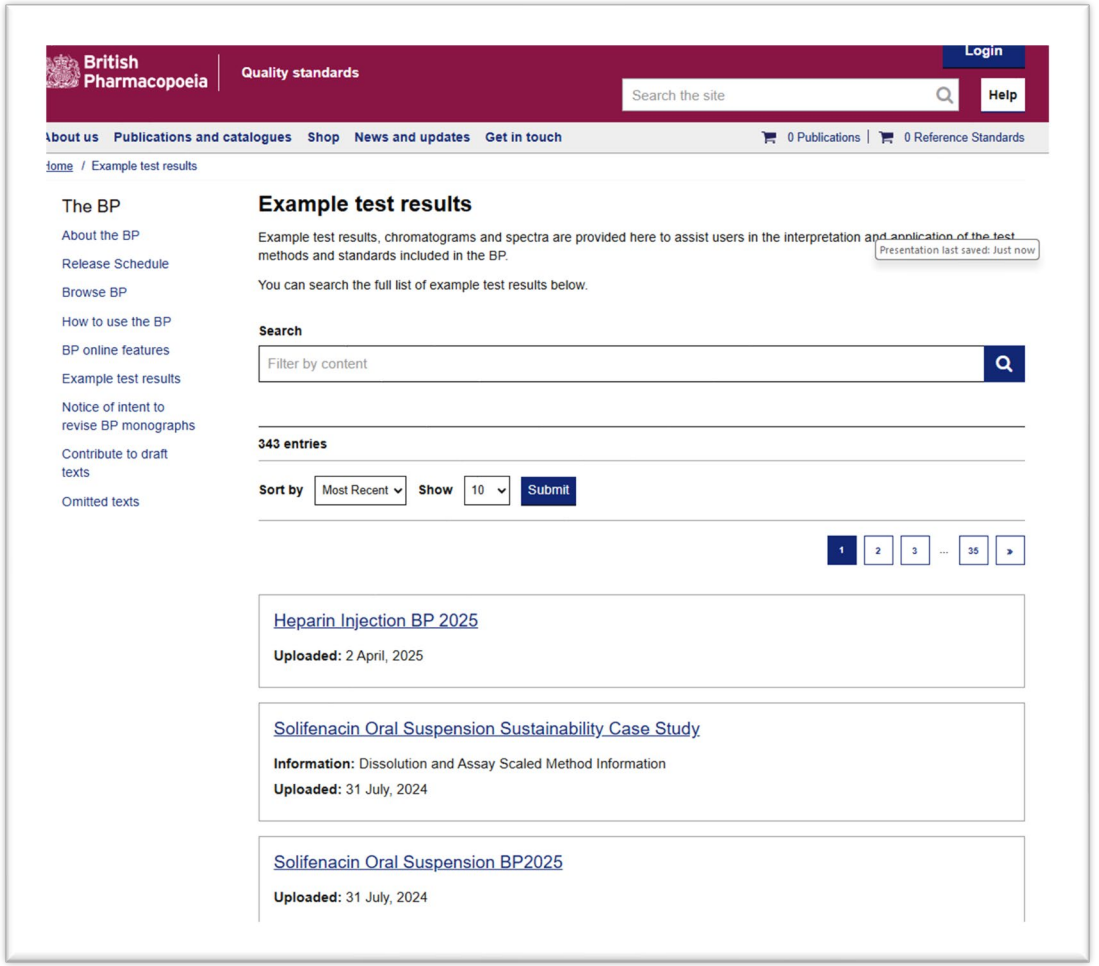


New BPCRS for BP 2026 and beyond

Eleven new BP chemical reference substances are being established this year to support the BP 2026

Guidance and More Resources

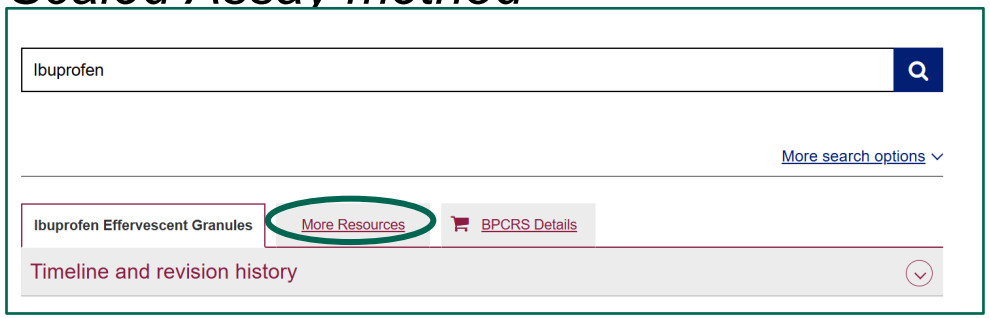
- ATMP Guidance
- AQbD Guidance
- Example test results
- Sustainability Guidance



Ibuprofen monographs – Scaled methods

- Following on from previous BP sustainability work, the BP2026 will have 10 monographs that include resources for scaled methods
- 7 of these monographs are for Ibuprofen products
  - 1 new monograph and 6 revised
  - The monograph family has gone through the development, revision and review process
- The scaled methods utilise the allowed changes from Appendix III Chromatographic Separation Techniques
- Leads to a significant reduction in solvent usage
- BPsustainability@mhra.gov.uk

Scaled Assay method



	Published method	Scaled method
Column length (cm)	25	10
Column I.D. (mm)	4.6	As per published method
Particle size (µm)	10	3
Flow rate (mL/min)	1.5	As per published method
Injection volume (µL)	20	8
Pressure (bar)	108	223
Run time (min)	7	3
Time saved per injection (min)	-	4
Solvent saved per injection (mL)	-	4.5 ~57% reduction

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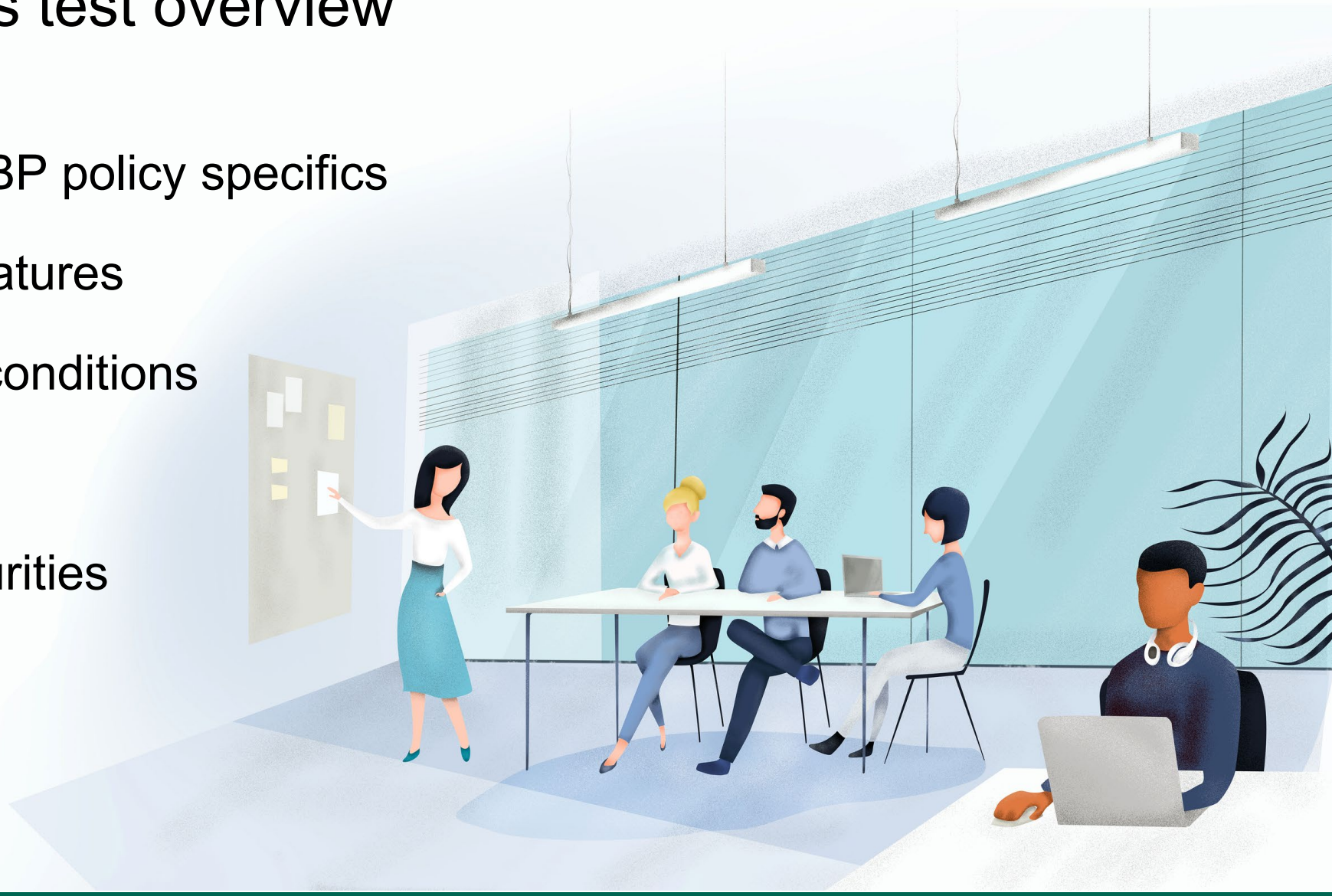
Related substances in the British Pharmacopoeia

Maryna Dmitriieva

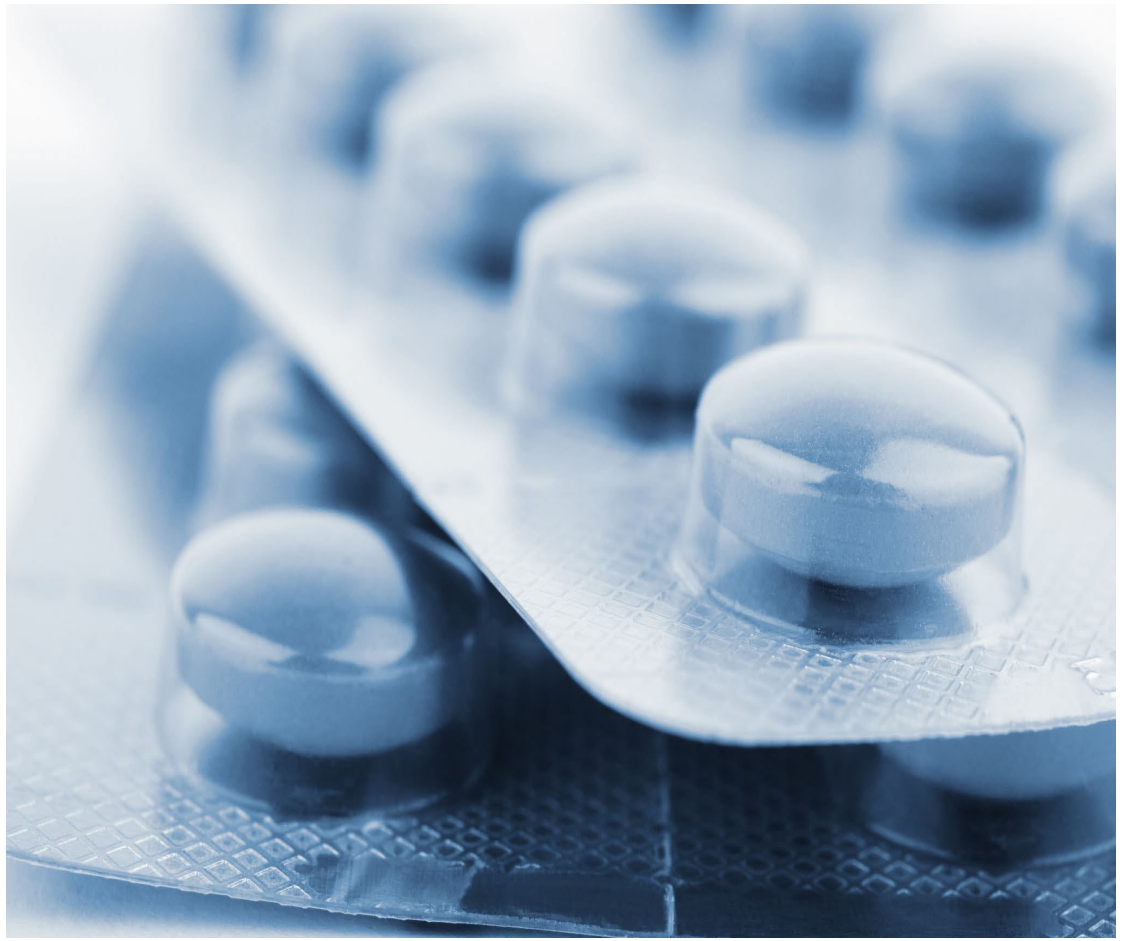
Related substances test overview

- Related substances BP policy specifics
- RS test procedure features
  - Chromatographic conditions
  - System suitability
  - Calculation of impurities
  - Limits
- Transparency



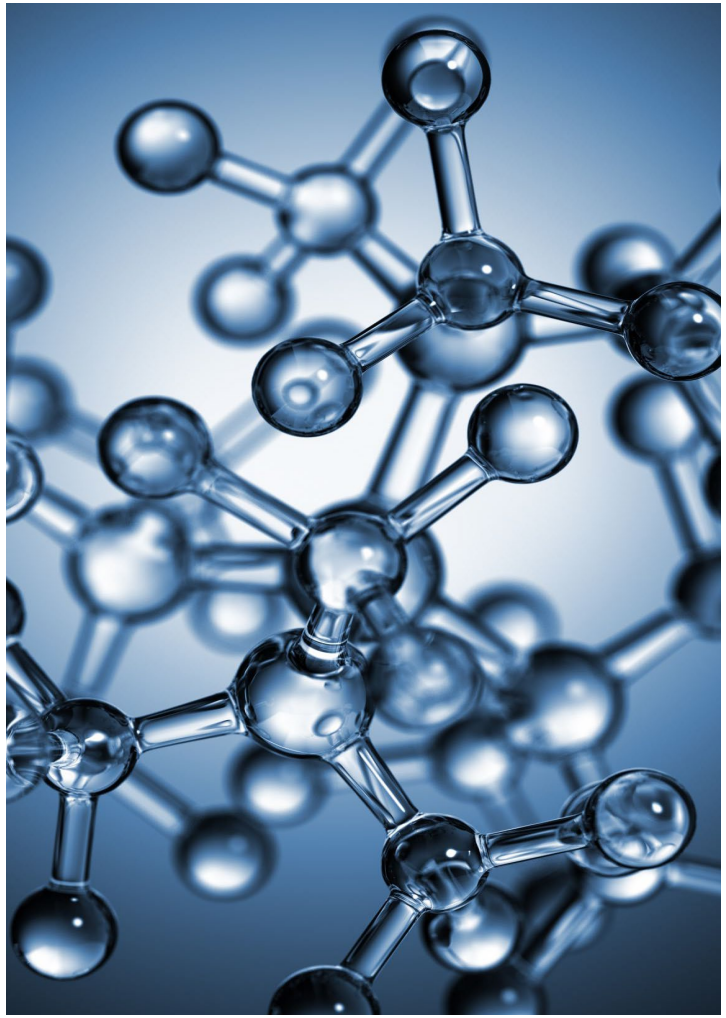
BP policy for Related Substances test

- Designed to provide limits for potential impurities **related** to the drug substance, rather than all possible impurities such as adulterants or contaminants
- The BP approach is to control degradation impurities along with synthetic ones
- BP texts related to the RS test
  - General notice
  - Appendices relevant to the method used, e.g. Appendix III Chromatographic Separation Techniques or Appendix III D. Liquid Chromatography
  - Supplementary chapters , e.g. SC I A. Control of Impurities or SC IV J. Control of Impurities in Substances for Pharmaceutical Use
- BP guidance How to use the BP



Related substances test structure

- **RELATED SUBSTANCES**
  - General instructions
  - Solutions preparation
  - Chromatographic conditions
  - Mobile phase
  - System suitability
  - Calculation of impurities
  - Limits
- **IMPURITIES**



BP Related substances test procedure features (1)

RELATED SUBSTANCES

General instructions

- Method of determination
- Solvents
- Precautions

Solutions preparation

- Final concentration specified – the dilution procedure is the user's responsibility
- Reference material BPCRS and EPCRS

Atorvastatin Tablets

Related substances

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions prepared in solution A.

Solution A Equal volumes of *acetonitrile* and 0.05M *citric acid*, previously adjusted to pH 7.4 with *dilute ammonia R1*.

(1) Shake a quantity of the powdered tablets containing the equivalent of 0.1 g of atorvastatin with 80 mL of solution A, dilute to 100 mL and filter (a 0.45-µm PTFE filter is suitable).
(2) Dilute 1 volume of solution (1) to 100 volumes.
(3) 0.1% w/v of *atorvastatin for peak identification A EPCRS*.
(4) 0.1% w/v of *atorvastatin impurity standard BPCRS*.
(5) Dilute 1 volume of solution (2) to 10 volumes.

BP Related substances test procedure features (2)

CHROMATOGRAPHIC CONDITIONS

- Column – in addition to the sorbent, the brand that was used when the monograph method was established is provided for information
- Details on making adjustments to chromatographic conditions are included in the Appendix III Chromatographic Separation Techniques

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Atorvastatin Tablets

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *end-capped octadecylsilyl silica gel for chromatography* (5 µm) (Kromasil C18 is suitable).

(b) Use gradient elution and the mobile phase described below.

(c) Use the flow rates described below.

(d) Use a column temperature of 30°.

(e) Use a detection wavelength of 244 nm.

(f) Inject 20 µL of each solution.

BP Related substances test procedure features (3)

SYSTEM SUITABILITY

- Standard system suitability requirements for RS procedure, such as system sensitivity and peak symmetry is included to the Appendix III Chromatographic Separation Techniques
- Specific SST requirements are introduced if they differ from the standard requirements

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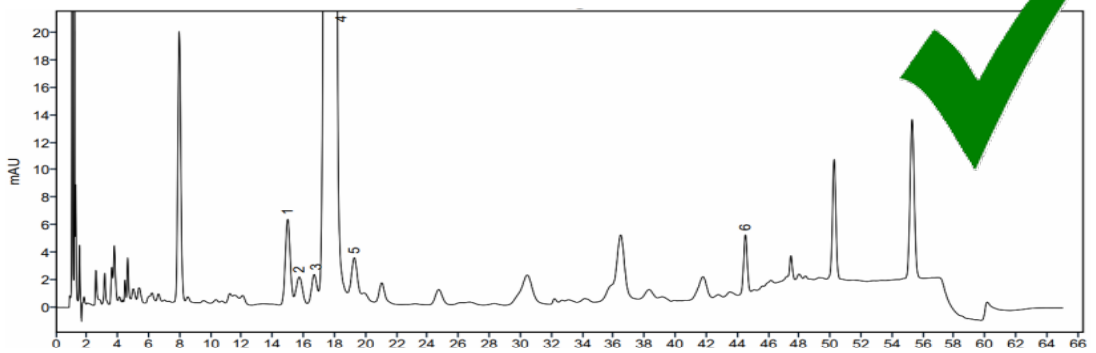
Atorvastatin Tablets

SYSTEM SUITABILITY

The test is not valid unless:

in the chromatogram obtained with solution (3), the *resolution* between the peaks due to atorvastatin and impurity B is at least 1.4;

in the chromatogram obtained with solution (5), the *signal-to-noise ratio* of the peak due to atorvastatin is at least 20.



BP Related substances test procedure features (4)

CALCULATION OF IMPURITIES

- Information for the quantitative limits calculation
- Included in BP monographs from BP 2023
- The terminology used is aligned with ICH guidelines
- The reference solution may be a dilution of the test solution or a reference substance
- Retention time, relative retention are approximate figures
- Correction factor are included if they are outside of the range 0.8 - 1.2

Atorvastatin Tablets

CALCULATION OF IMPURITIES

For each impurity, use the concentration of atorvastatin in solution (2).

For the reporting threshold, use the concentration of atorvastatin in solution (5).

For peak identification, use solutions (3) and (4).

Atorvastatin retention time: about 19 minutes.

Relative retention: impurity A, about 0.85; impurity 1, about 0.9; impurity B, about 0.95; impurity H, about 2.0; impurity 2, about 2.1; impurity 3, about 2.3; impurity 4, about 2.4.

Correction factors: impurity 1, multiply by 1.5; impurities 2 and 3, multiply by 1.9.

BP Related substances test procedure features (5)

LIMITS

- Set up align with relevant ICH guidelines and MHRA assessor advise
- BP guidance on the control of impurities and on calculating limits
  - SC I A. Control of Impurities
  - SC VI A. Pharmacopoeial Calculations

British Pharmacopoeia | Quality standards

Atorvastatin Tablets

LIMITS

— impurities H, 1, 2 and 3: not more than 0.5% of each;

— impurity A: not more than 0.3%;

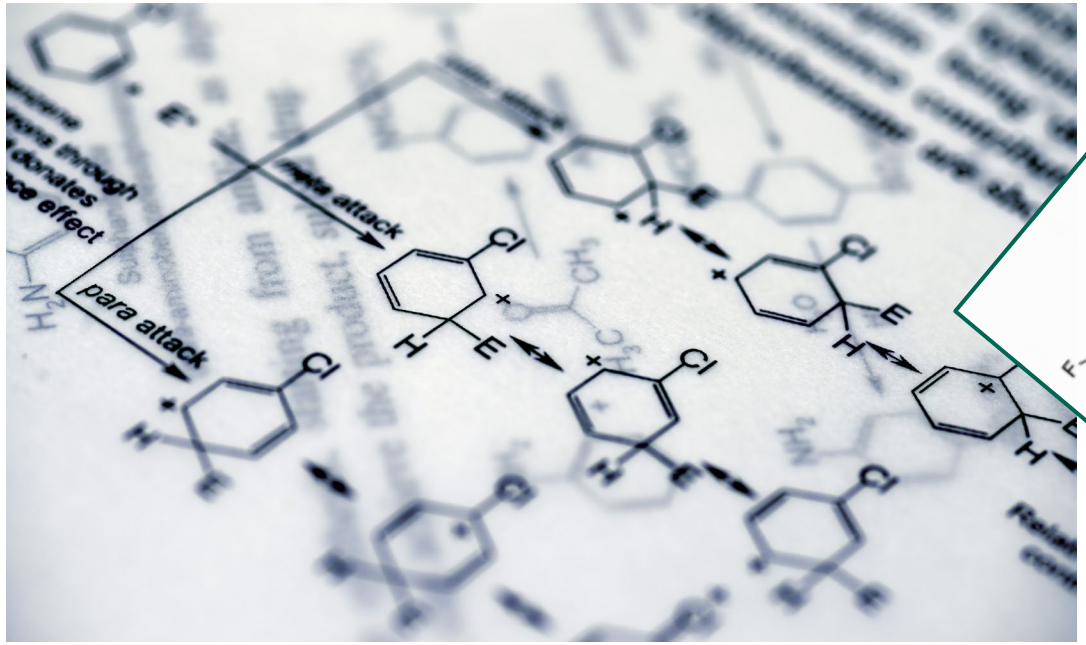
— unspecified impurities: for each impurity, not more than 0.2%;

— total impurities: not more than 2.0%;

— reporting threshold: 0.1%.

Transparency

A statement giving the identities of impurities that are known to be limited by the specifications is being added to appropriate monographs for medicinal substances and formulated

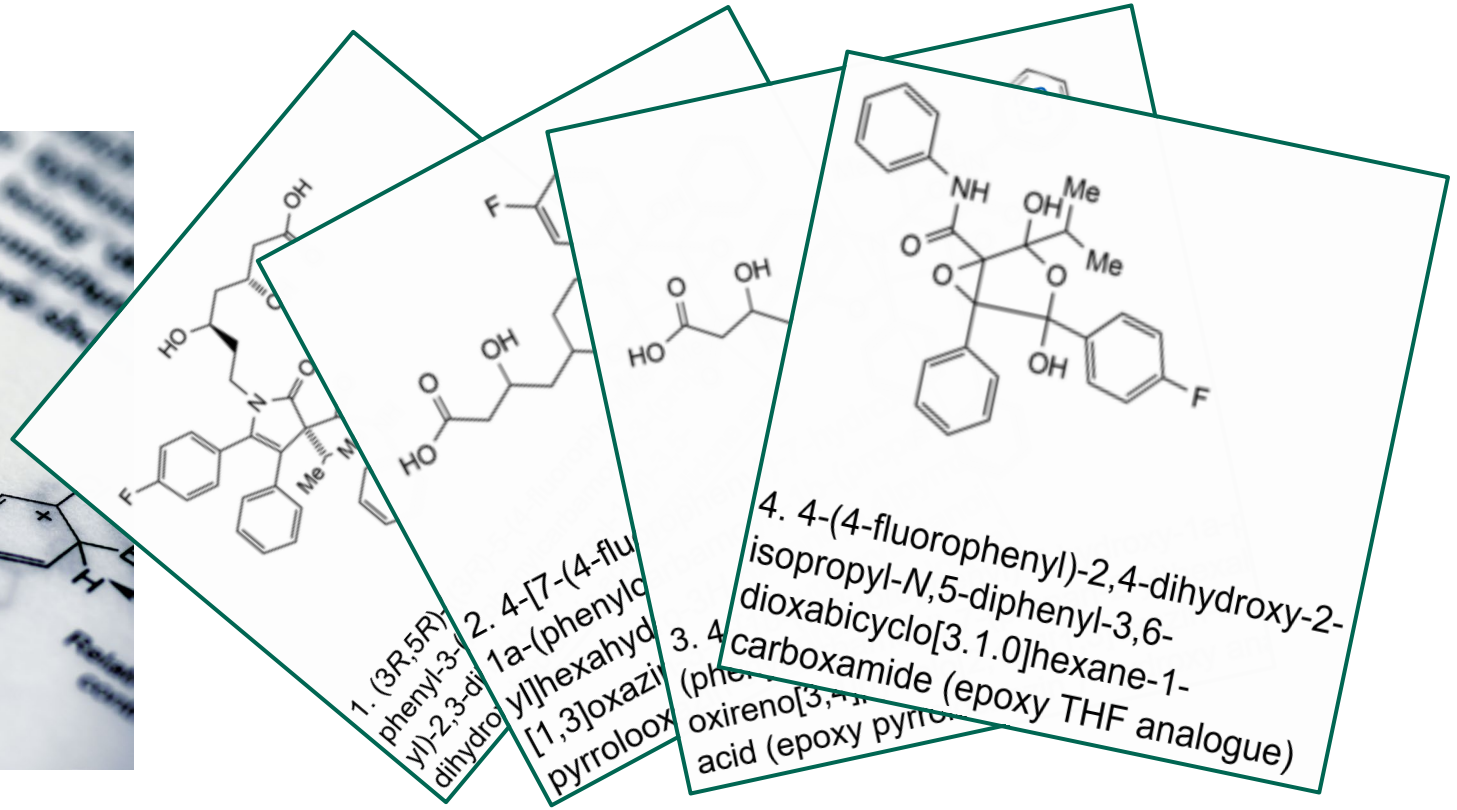


British Pharmacopoeia | Quality standards

Atorvastatin Tablets

IMPURITIES

The impurities limited by the requirements of this monograph include impurities A, B, C, D, F and H listed under Atorvastatin Calcium and:



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Thank you

Questions and answers

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